ETHICAL AND LEGAL ISSUES IN HEALTH CARE

DAVID LEMBERG

Detailed Contents

Preface

In tumultuous times, attending to our health has the potential to contribute substantially to national welfare and well-being, as well as to the welfare and well-being of populations around the world.

Investigating, understanding, and gaining mastery in the areas of ethical and legal issues in healthcare provides all of us, healthcare practitioners, healthcare policy makers, and healthcare consumers, with the necessary tools to develop robust practices of healthcare delivery that will potentiate human flourishing, especially for vulnerable and disadvantaged groups and populations. In this way, exploration and analysis of ethical and legal issues in healthcare, leading to local, national, and global initiatives that make a lasting difference, will assist us in creating and perpetuating an environment in which the human spirit may thrive and prosper.

Toward these ends, *Ethical and Legal Issues in Healthcare* presents, discusses, and analyzes the history of healthcare ethics, key concepts and intellectual traditions, the four principles of biomedical ethics, history of legal systems, tort law and negligence, landmark court decisions and legislation in the context of healthcare ethics, HIPAA, informed consent, patient rights and responsibilities, end-of-life decision making, healthcare issues in contemporary society, and global challenges and the future of healthcare.

Each chapter of *Ethical and Legal Issues in Healthcare* features real-world applications including case studies, discussion questions, "do-it-yourself ethicist" exercises, and "ethics as a doctrine of action" exercises. Overall, *Ethical and Legal Issues in Healthcare* participates directly and dynamically in the process of promoting human flourishing by providing a framework for and contributing to the ongoing growth and development of healthcare students across the spectrum of specialization in nursing, medicine, and the allied health sciences.

Acknowledgments and Dedication

Authoring any book is a journey. This is especially so with a textbook, where one's research and investigations consistently lead one to explore new horizons. Hopefully, the breadth, depth, and richness of the content improves day by day and the final product is an effective compilation of all that has been gained and all that has been learned. I am most grateful for and deeply appreciative of the wonderful support I received from the access services and reference desk personnel and staff at the National University Library. As well, I am very grateful for the expert assistance of the editorial and production staff at Cognella Academic Publishing, who generously shepherded this textbook through all the stages necessary to bring it into being.

Ethical and Legal Issues in Healthcare is dedicated to my wife, who encouraged me and shared her unconditional love and understanding every step of the way.

Author Biography

David Lemberg, M.S., D.C., is Associate Faculty Professor in the Department of Community Health, School of Health and Human Services, National University. He is a Community Member on the Biomedical Ethics Committee of a large medical center in Greater San Diego. Dr. Lemberg received his M.S. in Bioethics from Albany Medical College, having matriculated at the Alden March Bioethics Institute. Previously, he received his D.C. degree from New York Chiropractic College and maintained a private practice in New York City for more than 20 years. Dr. Lemberg was the keynote speaker at The Molecular Convergence Conference in Tulsa, OK, and presented "Science Fiction Becoming Science Fact." He was an invited speaker at the Conference on Communicating Science in Greenville, SC, and presented "Doing Science in a Pluralistic Society." Dr. Lemberg has provided expert commentary for articles in *The New York Times, The Translational Scientist,* and *Popular Science.*

CHAPTER 1

History of Healthcare Ethics

The very first medical ethical principle was likely the well-known phrase, *primum non nocere.* This traditional overarching medical ethical guidance has been transmitted through almost 100 generations, from the time of Hippocrates approximately 2,400 years ago. Of course, Hippocrates was Greek and the words famously attributed to the Hippocratic Oath are in Latin.

Primum non nocere is usually equated with the English phrase, "First, do no harm." The Latin might be more appropriately translated as "First, not to harm," but the sense of the more precise and the more freely translated phrases are fairly identical. For our purposes, considering that Hippocrates's purported message has achieved great fame and acclaim, we need to inquire as to whether "do no harm" or "not to harm" is a sufficient basis upon which to build a system of ethics.

Hippocrates

Hippocrates was born on the island of Cos *circa* 460 B.C.E. and died *circa* 375 B.C.E. He was an exact contemporary of Socrates (c. 470–399 B.C.E.) and Plato (c. 428–347 B.C.E.). Hippocrates died when Aristotle (384–322 B.C.E.) was a child. Hippocrates studied philosophy with Gorgias (the eponymous subject of Plato's dialogue, *Gorgias*) and was lifelong friends with the philosopher Democritus, who participated in developing atomism and taught a materialistic account of the natural world.[1] (Atomism was a materialistic natural philosophy that proposed atoms and the void as the indivisible constituents of the natural world. All material objects were composed of atoms and therefore subject to change.)

FIGURE 1.1 The Parthenon on the Athens Acropolis

Hippocrates was well known in Greek society and is referenced in the Platonic dialogues, *Protagoras* and *Phaedrus*. In the *Protagoras*, Socrates speaks with a young man who is considering studying with Protagoras. Socrates presents the possibility of "going to Hippocrates of Cos, the Asclepiad."[2] Hippocrates is described as a physician. In the *Phaedrus*, Phaedrus tells Socrates, "Hippocrates the Asclepiad says that the nature even of the body can only be understood as a whole,"[3] that is, the functioning of the entire human organism was to be addressed rather than merely the functioning of individual organs.

In the fourth century B.C.E., the new methods and conceptions of medicine promulgated by Hippocrates had great influence on the philosophies of Plato and Aristotle. When Plato was formulating his science of ethics and politics, he modeled it "neither on the mathematical type of knowledge, nor on speculative natural philosophy,"[4] but on medical science. In the *Gorgias*, Plato describes the doctor as one who recognizes sickness because of knowledge of its opposite, health, "and can therefore find ways and means to bring that which is sick back to its normal condition."[5] This method is Plato's model for the philosopher, "who is to do the same for the soul of man and its health."[6] Using medicine as a model, Plato's ethical and political teaching was intended to restore health to the soul of man. Overall, medicine was an essential component of *paideia*, the ancient Greek comprehensive concept encompassing civilization, culture, literature, tradition, and education. *Paideia* represented knowledge of, ability in, and facility with philosophy, poetry, music, mathematics, physics, medicine, rhetoric, gymnastics, and many other disciplines. As a concept, *paideia* implied the original unity of all these aspects and fields of human activity.[7]

The Hippocratic Corpus is a group of approximately seventy treatises written by Hippocrates and his students over many generations. Seven treatises were likely written by Hippocrates himself. These works are characterized by "the closeness and accuracy of his observations, the precision of his descriptions, his freedom from philosophic theory."[8] The "genuine" works of Hippocrates include *The Prognostics*, *Epidemics* (Books I and III), *Ancient Medicine*, and *Aphorisms*. In *Epidemics*, Hippocrates outlined the specific duties and responsibilities of a physician, including referencing the past, diagnosing the present, and foretelling the future. "As to diseases," the *Epidemics* declared, "make a habit of two things—to help, or at least to do no harm."[9] Thus, Hippocrates described the process of obtaining the patient's medical history, evaluating the current clinical circumstances and formulating a diagnosis or diagnoses, and establishing a likely prognosis. The physician's services should benefit the patient or, at worst, not cause harm. We may reasonably conclude that the phrase "first, do no harm" is a well-worn corruption of the *Epidemics* discussion.

The Hippocratic Oath, as we know it, was in fact not written by Hippocrates and possibly not even by members of his school. The oath was written a generation or more after his death[10] and was likely, per Edelstein, a "Pythagorean manifesto,"[11] as it contains various statements conflicting with Hippocratic precepts. As one example, the command to swear by Apollo and Aesculapius is found nowhere else in genuine Hippocratic writings. The followers of Aesculapius were a priesthood not a profession. Edelstein states, "the so-called Oath of Hippocrates is a document uniformly conceived and thoroughly saturated with Pythagorean philosophy." The Pythagorean society or community was founded by Pythagoras (c. 570–c. 490 B.C.E.) in southern Italy in the second half of the sixth century B.C.E. The Pythagoreans had developed a mathematico-metaphysical philosophy, according to which, per Aristotle, "numbers seemed to be the first things in the whole of nature, and the whole heaven to be a musical scale and a number."[12] The Pythagoreans taught not only that Earth was spherical, but also that Earth was not the center of the universe.[13]

BOX 1.1

Hippocratic Oath

I swear by Apollo Physician and Asclepius and Hygieia and Panaceia and all the gods and goddesses, making them my witnesses, that I will fulfill according to my ability and judgment this oath and this covenant:

To hold him who has taught me this art as equal to my parents and to live my life in partnership with him, and if he is in need of money to give him a share of mine, and to regard his offspring as equal to my brothers in male lineage and to teach them this art—if they desire to learn it—without fee and covenant; to give a share of precepts and oral instruction and all the other learning to my sons and to the sons of him who has instructed me and to pupils who have signed the covenant and have taken an oath according to the medical law, but to no one else.

I will apply dietetic measures for the benefit of the sick according to my ability and judgment; I will keep them from harm and injustice.

I will neither give a deadly drug to anybody if asked for it, nor will I make a suggestion to this effect. Similarly, I will not give to a woman an abortive remedy. In purity and holiness I will guard my life and my art.

I will not use the knife, not even on sufferers from stone, but will withdraw in favor of such men as are engaged in this work.

Whatever houses I may visit, I will come for the benefit of the sick, remaining free of all intentional injustice, of all mischief and in particular of sexual relations with both female and male persons, be they free or slaves.

What I may see or hear in the course of the treatment or even outside of the treatment in regard to the life of men, which on no account one must spread abroad, I will keep to myself holding such things shameful to be spoken about.

If I fulfill this oath and do not violate it, may it be granted to me to enjoy life and art, being honored with fame among all men for all time to come; if I transgress it and swear falsely, may the opposite of all this be my lot.

Source: L. Edelstein, "The Hippocratic Oath. Text, Translation and Interpretation." In *Ancient Medicine. Selected Papers of Ludwig Edelstein*, edited by O. Temkin and C. L. Temkin, 6. Baltimore: Johns Hopkins University Press, 1967.

Earth, the planets, and the sun revolved around a central fire or "hearth of the Universe." The school's teachings highlighted the importance of the soul and its right attendance. Overall, the Pythagoreans were "one of the determining influences in the formation of the thought of Plato."[14]

The phrase "do no harm" is not part of the oath, as such. The Edelstein translation compels the swearer to "keep them [the sick] from harm and injustice." Although the actual historical source, if one exists, of "not to harm" is unknown, the implications of the maxim are meaningful and have practical value. *Primum non nocere* and "do no harm" are embedded in iconic medical literature. For example, *Deontologie Medicale*,[15] a noteworthy nineteenth century text on medical

ethics, states, "No physician should ever forget the unbending moral precept: do no harm."[16] If we follow the precepts of Hippocrates himself to make a habit of helping and, at least, not harming, we are able to establish a firm basis for ethical practice, not only in healthcare but in all our activities and interactions with our fellow living beings. More than 1,600 years after the time of Hippocrates, Thomas of Aquino (1225–1274) established similar foundations for moral practice: "This is the first precept of law, that good is to be done and pursued, and evil is to be avoided."[17] Extrapolating from Hippocrates and Thomas, the healthcare practitioner should proceed with caution and exercise her full capacity for judgment, helping to ensure a good outcome or, at least, avoiding harm to the patient under her care. From the perspective of the Pythagoreans, such injustice could relate to "proportion, harmony, or the balance of opposites in the soul and also in the body."[18] Importantly, regardless of the oath's origins, the values inherent in the oath have been considered perennial and timeless ethical standards.

Impact of the Hippocratic Oath on Standards of Care

The Hippocratic philosophy enjoins physicians and all healthcare providers to implement standards of care and assess the proportionality of risks versus benefits. Importantly, harms to the patient may involve more than physical harm. The patient's standing as an individual, deserving of respect, may be harmed by the insistence of a healthcare provider on a particular method of treatment, and the patient's family and community may be harmed in consequence. The requirement for justice may also be located in the Hippocratic philosophy. Helping and not harming extends to all persons in need of care, not only to those who enjoy the good fortune of being able to pay for treatment. Making a habit of helping extends the physician's immediate range of impact beyond the circle of the relatively wealthy and encompasses all socioeconomic classes and levels. In the oath, the student promises to keep the patient from "injustice." Overall, Hippocratic principles may be identified as a primary source of modern healthcare ethics, whose principles embody the following:

- Respect for persons
- Beneficence
- Nonmaleficence (avoiding harm)
- Justice

(Essentially, *respect for persons* represents respect for a person's autonomy, that is, the right of every person as a self-determining individual to make her or his own decisions. *Beneficence* mandates that physicians and all healthcare professionals do good for their patients, that is, provide a benefit and help improve the patient's clinical circumstances. *Nonmaleficence* represents the injunction not to do harm, both in the context of healthcare practice and in the larger context of ethical human relations. *Justice* mandates that all persons should be treated equally, regardless of race, religion, or socioeconomic circumstances. Justice also refers to the fair distribution of scarce resources.)

It is not translocating modern phraseology to describe the medical practice of Hippocrates and his students as holistic. In terms of treating disease, a key problem was "what man is in relation to foods and drinks, and to habits generally, and what will be the effects of each on each individual."[19] Regarding the practice of medicine itself, Hippocrates famously stated, as the opening sentence of his *Aphorisms*, "Life is short, the Art long, opportunity fleeting, experiment treacherous,

judgment difficult."[20] In this first aphorism, Hippocrates embodied moral considerations and the ethical precepts of selflessness, discipline, and right action. Hippocrates recognized the critical importance of effective communication between the physician and the patient. Discussions of the best method of acquainting laypersons with the problems of physicians are found throughout the Hippocratic Corpus. Hippocrates himself wrote, "It is particularly necessary in talking about this art to speak so that laymen can understand."[21] Thus, Hippocrates may be considered the earliest proponent of the ethical principle of respect for persons, developed much later in great detail as the Kantian principle of autonomy.

Hippocrates defined additional first principles of medical ethics, stating a physician should be "prompt to do his whole duty without anxiety, pious without going so far as superstition, conducting himself with propriety in his profession and in all the actions of his life."[22] Thus, more than 2,000 years prior to the birth of Immanuel Kant (1724–1804), Jeremy Bentham (1748–1832), and John Stuart Mill (1806–1873), Hippocrates provided the foundations for formulations of duty-based ethics and utilitarianism, the two cornerstones of modern biomedical ethics.

Scribonius Largus

In addition to the Hippocratic Corpus, early sources of medical humanism and its ethical expression may be found in the writings of Scribonius Largus.[23] His *Compositiones* consists of a compilation of several hundred remedies and medical recipes, supported by an underlying humanistic philosophy of medicine and medical ethics.[24] In *Compositiones*, Scribonius grounds the physician's moral obligations in the special nature of his role in his community and society. The moral imperative and compassion intrinsic to those roles create a humanistic ethic that defines what it is to be a physician.[25]

Compositiones was written between 44 and 48 C.E. In his treatise, Scribonius cites the Hippocratic maxim that declares that, "Medicine is the science of healing, not of harming."[26] His references to the Hippocratic Oath may be the first such citations in any Latin text. Scribonius emphasizes that compassionate healing is the primary end of medicine. Physicians must be virtuous, as patients entrust themselves to their care and depend on their integrity and skill. A physician's self-interest must be subordinated to the interests of his patients. Thus, Scribonius's moral code is virtue-based and duty-based. Virtue-based ethics was propounded by Stoic moral philosophers during the second and first centuries B.C.E. Two of the most influential Stoics were Panaetius of Rhodes (c. 185–110/109 B.C.E.) and his disciple, Poseidonius of Apamaea (c. 135–51 B.C.E.). Marcus Tullius Cicero (106–43 B.C.E.), Roman praetor and consul, attended lectures of Poseidonius at the School of Rhodes in 78 B.C.E. and incorporated Stoic philosophy in *De Officiis* (*On Duty*), Cicero's treatise on morals.

Impact of Scribonius Largus

The Stoic virtues of wisdom, honesty, benevolence, justice, temperance, and courage were also the virtues highlighted and emphasized by Socrates. Virtuous conduct was the practical implementation of Scribonius's medical ethics. Much later, virtue-based ethics provided the foundation for Thomas Percival's *Medical Ethics*,[27] which was incorporated in the American Medical Association's first code of ethics in 1847.

Galen

Subsequent to Hippocrates, the physician who had the greatest impact on the practice of medicine, both from an investigative and a methodological perspective, was Galen (c. 129–c. 200 C.E.). Galen was born in Pergamon, a city in Asia Minor. Galen studied medicine with the foremost teachers of the time at Smyrna, Corinth, and Alexandra. He developed into the outstanding physician of Asia Minor and later moved to Rome at age thirty, where he became physician to the court of the emperor, Marcus Aurelius. Galen was a prolific writer and the author of approximately 600 treatises, of which less than a third exist today.[28] The body of Galen's works established the basis for medical teaching and practice for the succeeding 1,500 years, well into the eighteenth century.[29]

Galen is widely considered the founder of the sciences of anatomy and experimental physiology. Additionally, his medical theory is closely allied with philosophy, as Galen aimed to synthesize the views of Plato and Aristotle and supported the doctrines of Hippocrates. Galen upheld the importance of visible, tangible facts as opposed, for example, to mystical pronouncements, vague beliefs, or mere common sense. A primary purpose, via observation and experiment, was to validate a teleological perspective, that is, the explanation of phenomena by final causes. In other words, the ends of a structure or system dictated its design and mechanism. Galen "adopted a functional approach to the study of living organisms."[30] Structural anatomy could be understood by reference to functions in promoting activities of the whole organism. Per Aristotle, the whole organism is prior to its parts in terms of functional analysis.[31]

Study of the works of Plato and Aristotle provided tools and constructs upon which Galen developed his methods of investigation. Galen had adapted Socratic methods to medical scientific practice.[32] In the *Theaetetus*, Socrates states that he himself practices midwifery.[33] Socrates tells Theaetetus "my concern is not with the body but with the soul … the highest point of my art is the power to prove by every test whether the offspring of a young man's thought is a false phantom or instinct with life and truth."[34] Socrates is elucidating the principles and mechanisms of critical thinking, by which thought, concepts, and explanations are examined for coherence, consistency, validity, and applicability. Ideas or "offspring" are not valid or true merely as a result of being proposed or stated or posted on the Internet. Ideas must be worked through completely, tested and retested in various environments, prior to their attaining acceptance as knowledge, that is, as being accepted as true descriptions of the world.

Extending his metaphor, Socrates suggests to Theaetetus that "we examine your offspring together, and see whether it is a mere wind-egg or has some life in it."[35] A wind-egg, with particular reference to poultry and other birds, is unfertilized. There is no creative force in a wind-egg. Such an inert object has no capability for growth and development or other transformation. Thus, ideas "delivered" into the world may or may not be truthful and valuable. The words themselves are not sufficient and may be no more than "wind." Ideas must be thoroughly tested and examined for "life," with the purpose of assessing them for provisional acceptance into our overall body of knowledge or rejecting them as "false phantoms." Such critical thinking is essential to our ability to understand ourselves, the natural world in which we live, and our appropriate place in the natural world of which we are a part.

In support of the ability to think critically, one of the preferred methods of Socratic discourse was the use of metaphor. Many of us have experience of a family member of friend who consistently appears to think in "pictures" and whose talk is always supported by comparisons,

references, and substitutions of one type of thing for another. In *Poetics,* Aristotle defined metaphor as "the application of an alien name by transference ... or by analogy, that is, proportion."[36] In *Rhetoric,* Aristotle stressed the cognitive function of metaphors and stated that such forms bring about learning.[37] Metaphor not only provides a reference, but also provides a novel description of a thing. Of course, metaphor is a well-known tool in the composition of effective poetry. For example, poet John Keats employs several metaphors in "On First Looking into Chapman's Homer":

> Then felt I like some watcher of the skies
> When a new planet swims into his ken;
> Or like stout Cortez when with eagle eyes
> He star'd at the Pacific—and all his men
> Look'd at each other with a wild surmise—
> Silent, upon a peak in Darien.[38]

"Eagle eyes," "star'd at the Pacific," and "a peak in Darien" are all specific forms of metaphor and the poet uses each to communicate worlds of meaning. Socrates used metaphor as a primary tool for *teaching.*

In a section of Plato's *Republic,* Socrates is discussing with his young friends the nature of justice and injustice. Plato has Socrates tell his rapt audience that the inquiry would be of a serious nature and "would require very good eyes."[39] Socrates proposes the group adopt a method of analysis that he illustrates by use of a metaphor:

> Suppose that a short-sighted person had been asked by someone to read small letters from a distance; and it occurred to someone else that they might be found in another place which was larger and in which the letters were larger—if they were the same and he could read the larger letters first, and then proceed to the lesser—this would have been thought a rare piece of good fortune. ...[40]

Socrates goes on to suggest that the quality of justice is likely to be "larger and more easily discernible" in a discussion of the state. Justice as related to individuals may then be addressed by "proceeding from the greater to the lesser and comparing them." By utilizing a metaphor of comparison of larger letters to smaller letters, Socrates created a powerful method of inquiry into the characteristics of both the natural world and principles of human conduct and the application of those principles, that is, morals and ethics. Thus, seeking out and analyzing the content of comparable scenarios of larger dimensions would facilitate understanding of facts and circumstances with which we are confronted at our own individual, necessarily "small," level. For example, a basic tenet of sociology is that individual behavior may often be best understood in terms of behavior of the group. In physiology, individual biochemical outcomes can only be understood as the result of stochastic (that is, statistically analyzable) interactions of the flows of very large groups of molecules.

In *De placitis Hippocratis et Platonis* (On the doctrines of Hippocrates and Plato), Galen described a compare-and-contrast methodology termed *per similitudinem* (by likenesses).[41] Galen had located this method in both the *Republic* and in Hippocratic surgical works.[42] Galen utilized compare-and-contrast techniques in his investigations of structure and function, employing the logical tools of analysis (proceeding from the effects to causes) and synthesis (proceeding from principles to conclusions). Galen's extensive works included writings on ethics. His main existing

ethical text, *Aff. Pecc. Dig.*,[43] focused on correcting errors of both the rational and nonrational parts of the soul and highlighted the concept of a "higher" good.

Impact of Galen's Work

Galen's "experiential philosophic approach to clinical practice and research"[44] continues to extend across nearly 2,000 years and is applicable to modern medical practice. Following Aristotle's renowned explorations and explanations of nature, Galen's body of work, based on observation and experiment, was systematic and comprehensive. Galen developed principles of scientific investigation and emphasized experience, rationality, and reasoning. As one example of Galen's many breakthroughs (remarkably, in the second century), he demonstrated that arteries contain blood and inferred that blood seeped through communication channels between arteries and veins termed *anastomoses* (now known as capillaries). The actual discovery of capillaries via use of the microscope, by Marcello Malphighi in the mid-1600s, was anticipated by Galen's vital inference fifteen centuries earlier.

Overall, the principles and methods of medical practice, as delineated by Hippocrates and his students and as developed and extended by Galen, provided the de facto basis for all Western medical ethics up to the early 1800s. Codification of Western medical ethics, as such, had not yet been undertaken and, over the centuries, considerations regarding ethical practice could be construed as heuristic, that is, employing an everyday or, colloquially, "seat-of-the-pants" approach, at best.

Ishāq ibn 'Alī al-Ruhāwī

Farther to the East, in the ninth century, the medieval Islamic physician, Ishāq ibn 'Alī al-Ruhāwī, brought out his deontological (duty-based) treatise, *Adab al-tabib*, "Practical Ethics of the Physician."[45] During that century, translations into Arabic were undertaken of the great Greek mathematicians, physicians, astronomers, and philosophers and became available at a rapid rate. These works catalyzed the accelerated development of Arabic science in the ninth to eleventh centuries. For example, by 900 C.E., Galen's medical and philosophical works were known in Arabic and used extensively. In addition, the deontological (duty-based) ethics of the ninth century Arabic world was influenced by the Stoic philosophy as presented in the works of Galen.[46] al-Ruhāwī's text is a comprehensive account of the relations among physicians, nurses, and patients, including moral obligations occurring in the course of medical practice. al-Ruhāwī consistently referenced his numerous sources, including Plato's theories of the soul and Aristotle's *Metaphysics*. al-Ruhāwī cited Hippocrates' *Epidemics* and *On the Embryo* and Galen's *On the Opinions of Hippocrates and Plato* and *On the Treatment of the Healthy*. al-Ruhāwī constantly stressed that the highest type of humanity could be obtained by "the cultivation of Greek rational ethics to attain man's oneness with God."[47] Following these precepts was necessary for the growth and development of moral understanding.

al-Ruhāwī emphasized that psychological care of patients was an appropriate component of medical ethics. He wrote that "The physician must better his relationship to and endure the distress of the patients. He must pay attention to any statement heard from them." These considerations were necessary as the patient's complaints or displays of distress "may be important in the diagnosis of the ailment."[48] Medical ethical dilemmas may arise when a physician is confronted

with patient demands. al-Ruhāwī cited Galen's recommendations in support of a practical ethical approach to such circumstances, stating, "It is essential that the physician not follow the will of the patient unless it benefits him in his improvement."[49] Going further, al-Ruhāwī insisted that the physician employ all means available to aid the patient and preserve health, including the employment of psychology. With respect to supporting the welfare of patients, al-Ruhāwī stated the physician should maintain "silence as to the diagnosis in the case of a patient who would not understand."[50] The physician should "make an effort to have a good rapport with his patient" and "must always have patience and try to understand the ill one."[51]

al-Ruhāwī provided a comprehensive overview of the actions of a physician regarding the patient. He stated, "The method of justice of the physician and its beginning is that it is necessary to be good, training one's self, and taking care of it by employing good morals and actions."[52] The physician should demonstrate courage, generosity, kindness, and justice. Physicians should bestow the benefits of their practice "on all people without distinguishing them as to friend or foe, in agreement or disagreement."[53]

Impact of al-Ruhāwī's Work

Quoting Hippocrates, al-Ruhāwī indicated that the practice of medicine involves three factors, the illness, the patient, and the physician. Healthcare providers and patients must cooperate to combat illness and restore health. Thus, in the ninth century, al-Ruhāwī provided continuity to the philosophies of Socrates, Plato, and Aristotle and the medical ethics of Hippocrates and Galen. "Practical Ethics of the Physician" is the only medieval Arabic work known to have broadly considered the components and applications of medical ethics. As in the works of his Greek predecessors, we can locate in al-Ruhāwī's interdisciplinary treatise the foundations of our modern medical ethical principles of autonomy, beneficence, and justice.

Thomas Percival

However, just as there is a historical gap of more than 600 years between Galen and al-Ruhāwī, an even wider gap of approximately 900 years exists between the ninth century of al-Ruhāwī and the mid-eighteenth century of Thomas Percival (1740–1804). Percival's *Medical Ethics* helped establish rules of conduct and an ethos for physician practice in a period known as the Age of Reason or the Age of Enlightenment. Percival was born in Lancashire, England, and completed his medical studies in Leiden, the Netherlands. He was a scholar in science, literature, and morals and published *Philosophical, Medical, and Experimental Essays* (1776) in addition to *Medical Ethics; or a Code of Institutes and Precepts, Adapted to the Professional Conduct of Physicians and Surgeons* (1803). *Medical Ethics* was comprised of four sections that discussed professional conduct relative to hospitals, professional conduct in private or general practice, and professional duties requiring a knowledge of law. Percival's first rule or regulation referred to care of the patient. His first principle stated physicians should "minister to the sick ... reflecting that the ease, the health, and the lives of those committed to their charge depend on their skill, attention, and fidelity."[54] The physician's deportment should unite "tenderness with steadiness, and condescension with authority, as to inspire the minds of their patients with gratitude, respect, and confidence."[55] Thus, in his first precept, Percival established, in the closing years of the Enlightenment, the biomedical ethical principle of beneficence, that is, helping those who

are unwell. Percival's beneficence may be retrospectively interpreted as thoroughly imbued with a paternalistic spirit, a perspective no longer acceptable in today's healthcare practice. However, up until the late twentieth century, Percival's characterizations of physician–patient interactions were the accepted modes of relationship.

Extending his focus on beneficence, Percival stated that the physician should not fail, when appropriate, "to give to the friends of the patient timely notice of danger, when it really occurs, and even to the patient himself, if absolutely necessary."[56] Again, from the perspective of current healthcare practice, we could consider such notifications as breaching confidentiality. Percival's intent was likely focused on considerations of the patient's welfare and overall well-being. In contrast, Percival emphasized confidentiality regarding the patient's circumstances, stating, "Secrecy and delicacy, when required by peculiar circumstances, should be strictly observed." Confidential interactions with other professionals should be discreet and scrupulous with "regard to fidelity and honour."[57] Thus, Percival established certain boundaries of confidentiality, pointing the way toward the modern healthcare principle of autonomy and current implementations of patient rights. In addition to precepts of professional conduct, Percival described the research and scholarly activity now known as case reporting. Percival wrote, "At the close of every interesting and important case, especially when it hath terminated fatally, a physician should trace back, in calm reflection, all the steps, which he had taken in the treatment of it. This review ... will furnish the most authentic documents, on which individual experience can be formed."[58]

Impact of Percival on Medical Ethics

Percival's *Medical Ethics* provided the basis for the first Code of Ethics adopted by the American Medical Association (AMA) at its initial meeting in 1847.[59] The AMA Code of Ethics[60] was attributed officially to Percival. Article I of the AMA code was titled, "Of the Duties of Physicians to Their Patients, and of the Obligations of Patients to Their Physicians." Article I, Section 1 stated that a physician should be "ever ready to obey the calls of the sick" and quoted extensively from Percival's *Medical Ethics*, Chapter I, Precept I. Secrecy should be "strictly observed" when required by peculiar circumstances. This obligation "extends beyond the period of professional services" (Article I, Section 2). The AMA Code of Ethics followed Percival in providing "timely notice of danger" to friends of the patient. Regarding obligations of patients toward physicians, a patient "should always apply for advice in what may appear to him trivial cases, for the most fatal results often supervene on the slightest accidents" (Article I, Section 3). Further, patients should "faithfully and unreservedly communicate to their physician the supposed cause of their disease" (Article I, Section 4). Regarding physician instructions, Article II, Section 6 of the AMA Code of Ethics stated, "The obedience of a patient to the prescriptions of his physician should be prompt and implicit. He should never permit his own crude opinions as to their fitness, to influence his attention to them." As to the nature of the physician–patient relationship, a patient should, after his recovery, "entertain a just and enduring sense of the value of the services rendered him by his physician" (Article II, Section 10). The remainder of the code presented "The Duties of Physicians to Each Other, and to the Profession at Large" and "The Duties of the Profession to the Public, and of the Obligations of the Public to the Profession."

The two major items on the agenda of the AMA's initial meeting were the establishment of a code of ethics and enumerating the minimum requirements for education and training of medical practitioners. The 1847 AMA Code of Ethics set forth basic obligations of physicians toward their patients regarding the duty to care and respect for confidentiality, but also enshrined

a strongly paternalistic physician–patient relationship. The patient was expected to follow the physician's instructions without question. The patient's obedience was enjoined and the patient's gratitude was expected. It is important to recall that, although such paternalistic proscriptions may appear outmoded and unacceptable today, up until a mere forty years ago the physician's instructions and directions were never questioned by the patient. Essentially, until quite recently, the doctor's word was law. The changes wrought in physician–patient relationships since the mid-1970s were based, first, on the revelations, in the aftermath of World War II, of Nazi medical crimes, and subsequently, the vigorous public response to news of the Willowbrook Hepatitis Experiments and the Tuskegee Syphilis Study. Biomedical ethics was formalized in the wake of shocking revelations regarding two long-term experiments being conducted in an institution for developmentally handicapped children in Staten Island, New York, and a college town in the deep South in Tuskegee, Alabama. These medical experiments came to public attention in the early 1970s. The resulting national demand for corrective action led to the formation of a congressional commission and, ultimately, promulgation of new, high-level ethical standards for biomedical ethical practice.

The Nuremberg Code

Very shortly after Nazi Germany surrendered to the Allies on May 7, 1945, Allied forces began to discover facts on the ground concerning the reported atrocities that had occurred in the concentration camps at Auschwitz, Bergen-Belsen, Treblinka, Dachau, and other locations in Germany and Poland. In addition to discovering the camps and freeing the prisoners, Allied forces learned about the "medical experiments" German physicians had systematically performed during the years of Nazi tyranny. These experiments were of three main types: those studying means of survival for Axis military personnel, those developing and testing drugs and other methods of treatment for injuries and illnesses Axis forces encountered while in action, and those attempting to "study" the "differences" between so-called races, for example, how members of different "races" withstood exposure to various infectious diseases. Other even more heinous experiments aimed at perfecting inexpensive and efficient methods for the mass killings of Jews, Roma, and other populations deemed racially or genetically undesirable by Nazi leaders.

War crimes trials were conducted between October 1945 and October 1946, during which the International Military Tribunal tried twenty-two major war criminals on crimes against humanity. Previously, on December 17, 1942, leaders of the United States, Great Britain, and the Soviet Union had proclaimed the first joint official declaration identifying the mass murder of European Jews and resolving to prosecute those responsible for violence against civilian populations. The Subsequent Nuremberg Proceedings occurred between December 1946 and August 1949, during which ninety-seven convictions were obtained against high-ranking German officials, including physicians, industrialists, and members of the German High Command.

The Nuremberg Doctors Trial opened on December 9, 1946, and focused on experiments with human beings conducted in the Nazi concentration camps. In his opening statement, Brigadier General Telford Taylor, the chief counsel for war crimes, charged the defendants with "murders, tortures, and other atrocities committed in the name of medical science. The victims of these crimes are numbered in the hundreds of thousands. A handful only are still alive … most of these miserable victims were slaughtered outright or died in the course of the tortures

to which they were subjected."[61] General Taylor's opening statement indicated the charges were being brought "in the name of the United States of America." The defendants, many of whom were noted to be trained physicians and distinguished scientists, were being tried by a court of American judges. The twenty-three defendants, all but three of whom were physicians, were accused of torture and murder in the conduct of medical experiments on inmates of the Nazi concentration camps. At issue in the Nuremberg Doctors Trial was an investigation of purported war crimes and crimes against humanity as well as rules that must be observed in the conduct of medical experimentation.[62]

A recurring theme during the course of the trial was the relevance of Hippocratic ethics and the Hippocratic Oath to medical experiments on human subjects. A primary concern focused on whether Hippocratic ethics could provide a sufficient basis for medical research ethics without risk to the human rights of subjects. Regarding the duty of physicians with respect to research, it was noted "the medical Hippocratic attitude prohibits an experiment if the foregone conclusion, probability or a priori reason to believe exists that death or disabling injury of the experimental subject will occur."[63] Testimony at the trial noted that physician-researchers were enjoined by the Hippocratic Oath to have "respect for life and the human rights of his experimental patient."[64] Importantly, however, medical research lies outside the beneficent context of the physician–patient relationship. Hippocratic ethics could not be counted on to provide necessary protections for research subjects. Thus, the key contribution of the Nuremberg Code was to "merge Hippocratic ethics and the protection of human rights into a single code."[65] The code requires physician-investigators to uphold the best interests of research subjects and establishes principles by which research subjects can actively protect themselves.

The Nuremberg Code,[66] formulated in August 1947, is a component of the Doctors Trial final judgment. In the preamble to the code, the judges emphasized they were addressing not only the crimes committed by these specific defendants, but were establishing principles upon which to base all medical research. The judges indicated that "certain basic principles must be observed in order to satisfy moral, ethical, and legal concepts" in the practice of medical experiments upon human beings. The first principle of the Nuremberg Code declared the primacy of voluntary consent of human research subjects:

> 1. The voluntary consent of the human subject is absolutely essential.
>
> This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.
>
> The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.[67]

Never before in the 2,400-year history of recorded medical practice and scholarly activity had specific requirements for informed consent been delineated. The Hippocratic Oath, which had been described in the Doctors Trial as critically guiding the ethical behavior of physicians, does not discuss medical research. Thomas Percival's *Medical Ethics* briefly refers to "new remedies and new methods of chirurgical treatment" and indicates that a physician will frequently find he has a "new region of medical science to explore."[68] Percival recommended keeping a regular journal, but did not discuss the conduct of research as such. Similarly, the various iterations of the AMA Code of Ethics had never referred to the obligations of physicians whenever they employed such "new remedies and new methods" of treatment. In the event, in consequence of the investigation leading up to the Nuremberg Doctors Trial, the AMA House of Delegates adopted a report of the AMA Judicial Council regarding the conduct of medical research. The report, adopted on December 10, 1946, included three rules:

> In order to conform to the ethics of the AMA, three requirements must be satisfied: (1) the voluntary consent of the person on whom the experiment is to be performed must be obtained; (2) the danger of each experiment must be previously investigated by animal experimentation; and (3) the experiment must be performed under proper medical protection and management.[69]

Impact of the Nuremberg Code

We may conjecture that the AMA rules were designed hastily, in part so that the Nuremberg prosecution could point to written regulations regarding the conduct of medical research. However, we may retrospectively assert that the AMA rules were basic at best. The notion of "voluntary consent" was imprecise and failed to define the nature of the investigations and procedures to which the research subject was consenting. "Voluntary consent" did not specify the components of meaningful consent and did not evaluate potential pitfalls regarding subtle means of coercion. Further, this primitive requirement for "voluntary consent" failed to address the potential participation of vulnerable groups such as children, those without sufficient cognitive capacity, and prisoners. Additionally, the requirement for "proper medical protection and management" was amorphous. Various communities and jurisdictions might hold differing notions of the practical meaning of "proper." A standard of care was implicit rather than explicit, and the notion of "proper" was not protected from the possibilities of conflicts of interest and financial or other personal gain on behalf of those conducting the research in question.

Thus, the Nuremberg Doctors Trial judges recognized the immediate need for a universal code of conduct regarding protections for human subjects of medical research. Critically, the first principle of the Nuremberg Code thoroughly defined and elucidated the meaning of voluntary consent of research subjects. The code's first principle emphasized the requirement for legal capacity to give consent. Such consent must be based on sufficient understanding of the subject matter to enable appropriate decision making, that is, decision making in the potential research subject's best interests. The person must be apprised of the nature, purpose, and duration of the experiment and also of potential risks of participation, including inconveniences, hazards, and deleterious effects upon the person's health. Additionally, the code's first principle emphasized the duty and responsibility of those responsible for the conduct of the experiment to ascertain the quality of the consent obtained. In other words, fully informed and freely given consent was the primary requirement of medical research on human subjects.

In effect, the Nuremberg Code declared the primacy of human dignity as against the needs of any research program. Principle 6 declared that the risk to be undertaken by research subjects should never exceed the risk determined by the "humanitarian importance of the problem to be solved by the experiment."[70] Principle 9 declared that, during the course of the experiment, the human subject "should be at liberty to bring the experiment to an end."[71] Thus, the person participating in a medical research experiment should, based on her own discretion, be free to cease such participation at any time. Principle 10 declared that those in charge of the experiment "must be prepared to terminate the experiment at any stage, if ... continuation of the experiment is likely to result in injury, disability, or death to the experimental subject."[72]

Overall, the Nuremberg Code is considered the most important document in the history of medical research ethics. The code made clear what had never been expressly formulated before. The Nuremberg Doctors Trial judges were forthrightly responding to heinous actions perpetrated by physicians and scientists, that is, those who held society's trust and confidence and were enjoined by duties and responsibilities to safeguard and protect the members of society. In the context of an investigation into alleged crimes against humanity, the Nuremberg Doctors Trial judges formulated rules protecting all human research subjects of all medical research experiments. These principles, "based on human subjects' rights to thoroughgoing self-determination,"[73] were subsequently extended by common law judges, in cases such as *Natanson v. Kline,* to encompass the entire practice of medicine.[74]

In 1964, fifteen years after the conclusion of the Subsequent Nuremberg Proceedings, the World Medical Association (WMA) General Assembly adopted the Declaration of Helsinki, a statement of ethical principles for medical research involving human subjects.[75] As of 2013, the Declaration of Helsinki had undergone seven revisions. The 2013 Declaration enumerates these and other principles:

- It is the duty of the physician to promote and safeguard the health, well-being and rights of patients, including those who are involved in medical research.
- Medical research is subject to ethical standards that promote and ensure respect for all human subjects and protect their health and rights.
- While the primary purpose of medical research is to generate new knowledge, this goal can never take precedence over the rights and interests of individual research subjects.
- Medical research involving human subjects may only be conducted if the importance of the objective outweighs the risks and burdens to the research subjects.
- All vulnerable groups and individuals should receive specifically considered protection.
- The research protocol must be submitted for consideration, comment, guidance and approval to the concerned research ethics committee before the study begins.[76]

The Nuremberg Code focuses on the rights and protections of human subjects of medical research. The Nuremberg Doctors Trial judges had recognized that the rules for ethical conduct of medical research needed to be established on a broader foundation than that provided by Hippocratic ethics and concepts of beneficence. The Declaration of Helsinki emphasizes the obligations of physician-researchers to research subjects.[77] Together, the Nuremberg Code and Declaration of Helsinki served as models for U.S. federal regulations. These regulations require both informed consent of research subjects and prior peer review of proposed research protocols, conducted by an institutional review board (IRB) of the research institution or hospital.

Importantly, federal regulations require IRB inclusion of a community representative.[78] Such regulations, in the United States and worldwide, are a direct outcome of the human rights perspective enshrined in the Nuremberg Code that "acknowledges the centrality of informed consent and the right of the subject to withdraw."[79]

But, overall, despite the establishment by the Nuremberg Code of the primacy of the rights of individuals and meaningful protections for human research subjects, medical research continued to be conducted that disregarded those rights and protections. Such violations, both flagrant and subtle, are exemplified by the Willowbrook Hepatitis Experiments and the Tuskegee Syphilis Study.

The Willowbrook Hepatitis Experiments

The hepatitis experiments at the Willowbrook State School in Staten Island, New York, were launched in 1955 and continued for fifteen years. The principal scientist, Saul Krugman, described the purpose of the research in the *New England Journal of Medicine*. The intentions were to

> ... describe the circumstances under which the disease occurred, and the effect of gamma globulin in reducing its occurrence; an attempt to induce 'passive-active immunity' by feeding virus to persons protected by gamma globulin; and excretion of virus during the incubation period of the disease.[80]

The purpose of the research was "an attempt to control the high prevalence of infectious hepatitis in an institution for mentally defective patients."[81]

Thus, the Willowbrook hepatitis study focused on a serious public health problem. Over the course of fifteen years, the researchers did groundbreaking work on the natural history, epidemiology, and prevention of hepatitis. Type A and type B were identified and distinguished. Immunoglobulins were proven effective in preventing hepatitis type B. The first prototype inactivated hepatitis B vaccine was developed. These were all landmark accomplishments. But the research and experimentation were done on a most vulnerable and defenseless population, that is, children with retarded mental development.

From the mid-1950s to the early 1970s, selected new Willowbrook residents were systematically infected with hepatitis virus.[82] The Willowbrook study could be considered a "natural experiment," described by Claude Bernard as a "study of nature."[83] Per Bernard, "only study of nature can give scholars a true perception of science." The work at Willowbrook could be construed as a natural experiment, as hepatitis was endemic in the institution. New residents would likely contract the disease in only a few weeks. Thus, the justification could be offered that deliberately infecting new residents was really no different from what would have happened anyway, and the research protocol allowed for scientific investigation of the disease and identification of possible treatments. However, a natural experiment is appropriately characterized as observational. In terms of healthcare, if no known and effective treatment exists for a disease, then observation of the natural history and course of that disease is ethical and reasonable. But at Willowbrook, specific interventions, that is, deliberate injection of live hepatitis virus, were undertaken, and the ethical support of a natural experiment was no longer applicable.

During the mid-1950s, Krugman was invited to join the Willowbrook staff as a consultant in infectious diseases. Hepatitis affected virtually every child at Willowbrook, as well as many employees. The majority of the residents had severe or profound retardation of mental

development and conditions at the institution were optimal for transmission of hepatitis. Krugman had stated that the occurrence of hepatitis among Willowbrook children was predictable and inevitable. "After one year of careful observation and study," Krugman and his team concluded that a well-designed study would provide new knowledge on the natural history and prevention of hepatitis. Such knowledge might also enable the development of a vaccine. Thus, "the exposure of a small number of newly admitted children to the endemic Willowbrook strain of hepatitis virus" was undertaken based on these goals.[84] Only children whose parents gave consent would be included. Krugman noted several outcomes of the Willowbrook Hepatitis Studies, including (1) identification of two distinct types of hepatitis; (2) demonstration that hepatitis B infection is transmitted by intimate contact and oral as well as non-oral exposure; (3) demonstration that hepatitis B immune globulin was effective for the prevention of type B hepatitis; and (4) development of the first prototype inactivated hepatitis B vaccine.[85] These research outcomes were of fundamental importance and years later, in 1986, Krugman emphasized that the Willowbrook experiments were ethical and justifiable.[86] Nonetheless, the numerous ethical problems inherent in the conduct of research on vulnerable populations created significant controversy.

Krugman and his team stated their activities at Willowbrook were an attempt to control the high prevalence of infectious hepatitis in an institution for persons with cognitive developmental delays.[87] In 1955, the Willowbrook resident population had grown to nearly 4,500 children and was increasing at an approximate rate of one child per day. The researchers had assessed that most children at Willowbrook were exposed to hepatitis virus naturally, in consideration of the circumstances prevailing at the institution. The study's specific intervention was to feed live hepatitis virus to selected new residents. The researchers emphasized that the study group would only include children whose parents gave consent. It is important to note that the Willowbrook research was "conducted under the sponsorship of the Commission on Viral Infections, Armed Forces Epidemiological Board, and was supported in part by the Office of the Surgeon General, Department of the Army."[88]

Hepatitis virus was obtained from bodily fluids of six children with recognized jaundice. Permission was obtained from parents of children aged five to ten who were newly admitted to the institution. On December 6, 1956, eleven children were injected with gamma globulin and, thirty minutes later, "were fed approximately twice the 50% infectivity dose of virus."[89] Five children served as "controls" and only were fed the dose of hepatitis virus. Five months later, on May 7, 1957, ten of the subjects were again fed the equivalent of two grams of infected bodily fluids. Of these ten, seven had previously received gamma globulin and hepatitis virus. Importantly, none of those seven children developed hepatitis with jaundice in response to the "challenge" dose. Also, a new group of fourteen children were fed the same dose of virus suspension. Ten of the new group of children received gamma globulin injections and four served as "controls." In 1958, Krugman and his team reported on the two trials and noted the protective effect of gamma globulin. Prevalence of hepatitis was reduced in the group injected with gamma globulin as compared with "controls" who had only received infected bodily fluids. The researchers also reported on an apparent "alimentary tract phase" in which hepatitis virus is multiplying and excreted during an incubation period with no evidence of signs or symptoms.[90] Thus, the studies had documented the natural history of infectious hepatitis and evaluated a method for the control of the disease in an institutional population. Overall, the Willowbrook hepatitis studies were conducted from 1955 to 1970 and were reported in major journals.

In 1966, Henry K. Beecher described twenty-two examples of human experimentation since World War II, each of which demonstrated various serious ethical problems. Beecher noted that, "Evidence is at hand that many of the patients in the examples to follow never had the risk satisfactorily explained to them and ... hundreds have not known that they were the subjects of an experiment."[91] He stated, "what seem to be breaches of ethical conduct in experimentation are by no means rare, but are almost, one fears, universal." In Example 16, Beecher described a study in which "Artificial induction of hepatitis was carried out in an institution for mentally defective children in which a mild form of hepatitis was endemic."[92] Beecher noted that parents gave consent for these procedures, but "nothing is said regarding what was told them concerning the appreciable hazards involved." Beecher's article represented the pinnacle of twenty years of professional discussion and debate among researchers, clinicians, and philosophers regarding the conduct of research on human subjects. His revelations of research ethics transgressions inspired a public policy process that ultimately resulted in the establishment of federal regulatory bodies and systems of oversight of clinical research.

The Willowbrook studies investigated methods of preventing hepatitis infection, especially in an institutional setting. But the studies involved deliberately infecting children with live hepatitis virus. Willowbrook was closed to new admissions in late 1964. Parents who applied for their children to be admitted received a form letter stating there was no room for new admissions and they were being placed on a waiting list. However, the hepatitis program occupied its own space in Willowbrook and "continued to admit new patients as each new study group began."[93] New form letters were sent, indicating the presence of "a few vacancies in the hepatitis research unit if the parents cared to consider volunteering their child for that."[94]

Regarding prior methods of consent for participation in the Willowbrook hepatitis studies, the National Institute of Health website contains a "Letter to Parents" dated November 15, 1958, and indicates that parents received this letter from researchers in the Willowbrook Study. The letter states the following:

> We are studying the possibility of preventing epidemics of hepatitis on a new principle. Virus is introduced and gamma globulin given later to some, so that either no attack or only a mild attack of hepatitis is expected to follow. This may give the children immunity against this disease for life. We should like to give your child this new form of prevention with the hope that it will afford protection.
>
> Permission form is enclosed for your consideration. If you wish to have your children given the benefit of this new preventive, will you so signify by signing the form.[95]

Krugman and his colleagues published many articles and the nature and conduct of the study were well known. Methods of obtaining informed consent "changed progressively during the course of the studies."[96] Initially, information was provided to parents by letter or a personal interview. Later, a group technique was utilized to obtain consent. Parents were given a tour of the facilities. Group discussions presented the purposes of the research program, potential benefits, and potential hazards. Questions were encouraged. Two weeks later, parents were contacted for their decision by a psychiatric social worker. The researchers emphasized that "From 1956 the protocols were reviewed and sanctioned by various local, state, and federal agencies."[97]

Regardless, the ethics and possible ethical breaches of the Willowbrook research protocols were ongoingly discussed and challenged in the medical literature.

Willowbrook: Controversies and Ethical Outcomes

Controversy persisted in the literature with significant criticism of the Willowbrook hepatitis studies, followed periodically by responses by Krugman and others on his team. Of particular importance was a series of letters submitted to *The Lancet* in 1971. In the April 10, 1971, issue, Dr. Stephen Goldby noted the entire program was unjustifiable, regardless of the therapeutic importance of the results.[98] Goldby discussed the indefensibility of giving "potentially dangerous infected material to children" with or without parental consent. especially when those children had retarded cognitive development. He declared "the question of parental consent was irrelevant." Further, no benefit to the research subjects could conceivably result. Krugman's response was published in the May 8th issue.[99] He stated the studies "clearly demonstrated a 'therapeutic effect' for the children involved." Krugman emphasized the possibility of controlling hepatitis at Willowbrook, with expansion of benefits to the children's families and employees of the institution, as well as to worldwide populations "plagued by an insoluble hepatitis problem for many generations." He listed four justifications for exposing the children who served as research subjects to hepatitis virus: (1) the children were likely to be exposed to identical strains of virus under natural conditions existing at Willowbrook; (2) the children would be admitted to a special unit that was better equipped and better staffed, isolating them from other infectious diseases prevalent in the institution and reducing the risk of exposure to such infections; (3) "they were likely to have a subclinical infection followed by immunity to the particular hepatitis virus"; and (4) only children whose parents provided informed consent would be included in the research.[100]

On June 5, 1971, a letter to *The Lancet* from Dr. M. H. Pappworth questioned the components of valid consent and whether ends justify means.[101] Pappworth referenced the letter to parents seeking admission to Willowbrook. That letter had indicated vacancies in the "hepatitis unit" for children whose parents provided permission for the children's participation in the hepatitis research study. Such consent was invalid owing to "its element of coercion." Referring to Krugman's prior description of the study's method of providing information to parents in a group setting, Pappworth noted such a procedure was "extremely unsatisfactory because even a single enthusiast can sway the diffident." Regarding ends and means and the claim that the experiments on children were justified by subsequent therapeutic effects, Pappworth noted, "Any experiment is ethical or not at its inception." Research experiments do not become ethical owing to the achievement of extending the capabilities of medicine. He emphasized that, "Every human being has the right to be treated with decency." This right "must always supersede every consideration of what may benefit mankind." The claims of society or science do not have priority over the rights of individuals or a physician's obligations to patients.

Hindsight, of course, may provide a skewed perspective, but current ethical considerations are not substantively different from those prevailing in the 1950s. The 1958 "Letter to Parents" informs them that "virus is introduced" and "either no attack or only a mild attack of hepatitis" is to be expected.[102] The content of these statements appears fairly benign, but may be construed as disingenuous and failing to fulfill the spirit of informed consent. For example, it is reasonable to presume that such parents were highly motivated to have their children enrolled at Willowbrook. Parents under the duress of substantial day-to-day cares would likely not think about considerations beyond the reassurances provided in the letter. But "virus is introduced" hides

the fact that children were fed bodily fluids of other children infected with hepatitis. Further, the researchers could never be certain regarding the nature of the outcome for any particular child. "No attack" or a "mild attack" might be statistically likely, but a more serious or even fatal result was always possible. Additionally, the letter appealed directly to the desire of parents to care for their child. What parent would not choose to opt for "the benefit of this new preventive"? It may be reasonably asserted that the researchers overstated their case and implied a benefit without fully discussing the corresponding risks.

Thus, numerous profound ethical problems inhered to the Willowbrook hepatitis study design. First, the study population consisted of children, an intrinsically vulnerable group. Further, these specific children were even more vulnerable as a consequence of their mental developmental disabilities. Parents were not fully informed of the risks to which their children would be exposed and, in some cases, there was undue inducement for consent. Willowbrook children were deliberately infected with live hepatitis virus. Additionally, there were no compelling reasons to study hepatitis in children prior to studying the disease in adults.

Krugman's justifications may be refuted point by point. The likelihood of the children's natural exposure to hepatitis infection is materially different from intentionally feeding a child live hepatitis virus. An adult could conceivably consent to participating in such a research protocol, but the Willowbrook research was conducted on a specifically vulnerable subset of children, who as a group were inherently vulnerable in the context of medical research. Regarding the special unit in which the research was conducted, the implication was that protection would be provided from certain infectious diseases while simultaneously intentionally infecting the child with hepatitis. Again, a child, and specifically these children, would not be able to appropriately assess the risks and benefits and assent to their parents' informed choice. Further, the endemic prevalence of hepatitis at Willowbrook could have been combatted by thoroughly cleaning the institution's various buildings and implementing systematic practices of sanitation and antisepsis. Such measures would likely have provided real, measurable benefits to the entire Willowbrook population, both residents and employees. There would have been no need to study the natural history of hepatitis at Willowbrook in the first instance. The claim of the likelihood of a subclinical infection followed by immunity to the specific hepatitis strain is rebutted by the oft-described mild clinical presentation of the hepatitis infections endemic at Willowbrook. Immunity would not have been needed if the institution itself had not been a breeding ground for infection. Finally, although parental consent was obtained, the appropriateness of such consent is arguable from numerous perspectives. It is not apparent that parental consent could have been characterized as fully informed, at any stage of the Willowbrook consent processes. For a period in the mid-1960s, after the institution had closed to new admissions, parental consent was obtained in circumstances that may be reasonably deemed as coercive.

Finally, there is the overarching consideration of whether parental consent is ever appropriate for a child's participation in medical research. It may be fairly questioned whether children under age ten, as a reasonable boundary, should ever be subjects of experimental research. Such children, no matter how intelligent or self-aware, may be universally assessed as incapable of determining the essential characteristics and consequences of medical research. It may be argued that these considerations hold even when there is a likelihood of benefit to the child. Parents may not fairly evaluate such risks and benefits, as the child's own perspectives and value systems cannot be fully known. In contrast, if the benefit might be great and the child's circumstances were dire, parental consent could be assessed as being appropriately in the child's best interest.

The parents would be acting, essentially, as the child's surrogate, as the child does not have the capacity required to make such a choice. Otherwise, however, and in all cases of research deemed to be undertaken for the acquisition of scientific knowledge or the good of society as a whole, participation of a child under age ten in medical research should be closely questioned. The vulnerability of children should be dispositive. A child over age ten could "assent" to participation as a research subject and the parents would provide formal consent. Although their cognitive capabilities are still developing and their value systems are far from a state of maturity, respect may be granted for such a child's capacity for decision making and self-governance.

Thus, overall, the justifications provided by Krugman and his team regarding their considerations and the processes involved in obtaining parental informed consent were not then, and are not now, sufficient to sanction the inclusion of children in an experimental research study. As these specific children were the most vulnerable of an inherently vulnerable population, parental consent was that much more unacceptable as validation for the conduct of such research. The primary responsibility of parents, and of society as a whole, in this context, is to protect the welfare of children and provide a safe and secure environment in which they can thrive, grow, and develop. By placing children at risk for indeterminate and unknowable harms, the Willowbrook Hepatitis Studies abrogated the most basic standard of care.

The Tuskegee Syphilis Study

In 1932, the U.S. Public Health Service launched a study of untreated syphilis in Macon County, Alabama, as one of several investigations whose ultimate objective was the control of venereal disease. Macon County had been selected as the region of interest owing to a prior demonstration of the high prevalence (35 percent) of syphilis in the county. Ultimately, the study became a forty-year project and followed the effects of untreated syphilis in 399 black men. These men had received no therapy. A group of 201 men who were assessed to be free of syphilis comprised the control group.[103]

After four decades of local activity on the part of the Tuskegee Institute, the institute's affiliated hospital, and hundreds of physicians in Macon County,[104] as well as ongoing supervision by the federal government, the study was brought to the attention of the public by, essentially, one newspaper article. On July 26, 1972, a *New York Times* article, "Syphilis Victims in U.S. Study Went Untreated for 40 Years," described the Tuskegee Study, begun "in 1932 with about 600 black men, mostly poor and uneducated."[105] An Associated Press article, published on the same day, stated that approximately 200 men in the syphilis group received no treatment at all, even after penicillin had been discovered to be a cure for syphilis and had become widely available. The article noted "a definite moral problem existed when the study was undertaken."[106] The public outcry and response was swift, leading to the formation of the Department of Health, Education, and Welfare (DHEW) Tuskegee Syphilis Study Ad Hoc Advisory Panel on August 28, 1972. The panel's purpose was to "investigate the circumstances surrounding the Tuskegee, Alabama, study of untreated syphilis in the male Negro initiated by the United States Public Health Service in 1932."[107] The panel's functions were to determine whether the Tuskegee Syphilis Study was justified in 1932 and whether the study should have been continued after penicillin became generally available. Further, the panel was to recommend whether the study should be continued or terminated. The panel was to assess whether existing policies protecting the rights

of patients participating in health research supported or conducted by the DHEW were sufficient and to recommend policy improvements if needed.[108]

The panel's Initial Recommendation on October 25, 1972, discussed the second charge to the panel regarding continuation or termination of the study. The panel stated that no convincing evidence had been presented "that participants in the study were adequately informed about the nature of the experiment, either at its inception or subsequently."[109] The Initial Recommendation noted that from the onset of the study, the United States Public Health Service "maintained a continuous policy of withholding treatment for syphilis from the infected subjects." The panel noted the existence of common medical knowledge, prior to the start of the study, that "untreated syphilitic infection produces disability and premature mortality." Further, since the late 1940s, treatment with penicillin for syphilis in all stages of the disease had been recommended by numerous medical authorities. As approximately 125 of the research subjects, including 50 of the controls, were still alive, the panel recommended immediate termination of the Study of Untreated Syphilis in Black Males in Macon County, Alabama, known as the Tuskegee Syphilis Study.[110] The Initial Recommendation stated the research subjects were to be given "the care now required to treat any disabilities resulting from their participation." The Public Health Service was to immediately inform all surviving research subjects "of the nature of their participation in the study and the desire of the Public Health Service to assess their current health status."[111]

Subsequently, the *Detroit Free Press* published an extensive investigative journalism report on November 5, 1972.[112] The article noted that, in 1932, treatment for syphilis had been available for at least fifteen years and some states (including Alabama) had laws requiring infected persons to get treatment. The initial group of research subjects were recruited in response to a notice that had been read in church asking men to get treated for "bad blood." Over time, continued participation in the study was obtained by the provision of "free medicines" (typically iron tonic and aspirin), free hot meals, transportation to and from examinations, and "burial insurance." Although by 1945 it had been tentatively suggested that penicillin appeared to be effective against latent syphilis, even in 1950 justifications continued to be provided that "it behooves the medical profession to know for sure what happens if the disease is not treated."[113] The outcomes of lack of care were stark. A 1952 report indicated that autopsies on ninety-two research subjects showed that twenty-eight of the men with syphilis had died as a direct result of the disease.

The Final Report of the Tuskegee Syphilis Study Ad Hoc Advisory Panel, on April 24, 1973, focused on whether the study was justified in 1932.[114] The report provided historical background, including a discussion of the Cooperative Clinical Studies in the Treatment of Syphilis (1928–1942).[115] In 1932, these studies reported that treatment resulted in a satisfactory clinical outcome in 35 percent of patients with untreated latent syphilis. Results of a retrospective study of 473 untreated syphilis patients, conducted in Oslo, Norway, were published in 1929. The Oslo study provided clinical data that, for the first time, suggested the probability of "spontaneous cure, continued latency, or serious or fatal outcome."[116] Overall, in 1932, much was still unknown regarding the natural history and epidemiology of late and latent syphilis.

The Final Report noted there was no protocol documenting the original intent of the Tuskegee Syphilis Study and no evidence had been identified that "a written protocol ever existed for this study."[117] Various theories regarding the purpose included a study of the natural history of syphilis, a short-term study of the "incidence and clinical course of late latent syphilis in the Negro male," and a study that would "provide valuable data for a syphilis control program for a rural impoverished community."[118] The Final Report reiterated there was no evidence that

informed consent had been obtained. Such consent should have included knowledge of the risk of human life and information regarding possible infection of friends and relatives. Numerous errors in the performance of the study were described. The "untreated" group in fact was a group of treated and untreated subjects, as many of the study participants received "arsenical injections" or other treatment, but "not necessarily in doses considered curative for syphilis." Patient file data suggested that control subjects who became syphilitic were transferred to the "untreated" group. There was no evidence that standardization of evaluative procedures existed at any time. Thus, the validity and reliability of the study was inherently compromised. The "true scientific merits of a longitudinal study of this nature"[119] were open to question. Importantly, the panel stated the "results are disproportionately meager compared with known risks to human subjects involved."[120]

Regarding whether the study should have been continued when penicillin became generally available, the panel noted that, in 1932, "treatment of syphilis in all stages was being provided through the use of a variety of chemotherapeutic agents."[121] Thus, as of 1932, in the United States treatment was being recommended for all stages of syphilis. The therapeutic benefits of penicillin were clinically documented by the early 1950s. In 1953, the USPHS Center for Disease Control reported "treatment of syphilitic mothers in all stages of infection with penicillin." Additionally, it was "known as early as 1932 that 85 percent of patients treated in late latent syphilis would enjoy prolonged maintenance of good health and freedom from disease as opposed to 35 percent if left untreated."[122] But rather than receiving effective treatment for a known condition, in some cases Tuskegee Syphilis Study research subjects were actively denied such treatment. According to the director of the regional Public Health Service in Hot Springs, Arkansas, the patients in the study "received no treatment on our recommendations."[123] Further, a number of study participants were called to army duty during 1941 and 1942, but the local draft board agreed to exclude those draftees from receiving treatment for syphilis. The Final Report noted a "crucial absence of evidence that patients were given a 'choice' of continuing in the study once penicillin became readily available." The report highlighted "the magnitude of encroachment on the human lives and well-being of the participants in this study."[124] The scientific merits of the study were "vastly overshadowed by the violation of basic ethical principles pertaining to human dignity and human life."[125] The Tuskegee Syphilis Study Ad Hoc Advisory Panel concluded that, in retrospect, the study was ethically unjustified in 1932. A short-term research project might have been appropriate. But a longitudinal study conducted over a duration of years was determined to be scientifically unsound, with meager benefits compared with the known risks to the human subjects.

Thus, the Tuskegee Syphilis Study was severely ethically compromised at its inception. The research subjects represented a vulnerable group, as their literacy rate and cultural status were low. Further, in the early 1930s, their status as black males increased their vulnerability in terms of the conduct of medical research. These men were never provided the consideration of informed consent. On the contrary, they believed they were being treated for "bad blood." The men thought they were participating in a public health demonstration similar to one that had been previously conducted in Tuskegee. They were never told they were participants in a research study. Further, the study's purpose of performing autopsies on the research subjects upon their demise was hidden from the men.[126] The lack of respect for human dignity was systematic and pervasive. It may be reasonably stated that the men were deceived as to the nature of the study, the likelihood that autopsies would be performed upon their demise, and coerced into

continued participation. Withholding treatment, even the relatively ineffective treatments of the 1930s and early 1940s, violated the most basic standards of physician conduct. As the benefits of treatment were generally known at the time the study began, investigating untreated syphilis could be reasonably construed as actively harming the research subjects by acts of omission.

Impact of the Tuskegee Syphilis Study

In the aftermath of the 1960s Civil Rights Movement, the revelations regarding the Tuskegee Syphilis Study were especially outrageous. The Ad Hoc Advisory Panel was empowered four weeks after the appearance of the Associated Press article in *The New York Times* and across the country. A US$1.8 billion class action lawsuit was filed,[127] alleging the study had violated rights guaranteed by several constitutional amendments. In early 1973, hearings on human experimentation and the Tuskegee Syphilis Study were held by the U.S. Senate Subcommittee on Health, chaired by Senator Ted Kennedy. *Pollard v. United States* was settled in 1974 and the Tuskegee study participants and their families were awarded US$10 million. In 1974, the National Research Act was signed into law on July 12, 1974. Title II established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The commission was empaneled to "conduct a comprehensive investigation and study to identify the basic ethical principles which should underlie the conduct of biomedical and behavioral research involving human subjects"[128] and develop guidelines for the conduct of such research in accordance with these principles. The commission was to consider the following:

1. The boundaries between biomedical research involving human subjects and the routine practice of medicine
2. The role of assessing risk-benefit criteria in determining the appropriateness of research involving human subjects
3. Guidelines for the selection of human subjects for participation in biomedical research
4. The nature and definition of informed consent in various research protocols
5. Mechanisms for evaluating and monitoring the performance of Institutional Review Boards and appropriate enforcement mechanisms for implementing their decisions[129]

The commission was to identify requirements for informed consent for participation of children, the institutionalized mentally infirm, and prisoners in biomedical research. The commission would investigate such research conducted or supported under programs administered by DHEW regarding the nature of the consent obtained from such persons. Considerations encompassed "the adequacy of the information given them respecting the nature and purpose of the research, procedures to be used, risks and discomforts, anticipated benefits from the research, ... and the competence and the freedom of such persons to make a choice for or against involvement in such research."[130]

Institutional Review Boards were established in Section 474 of the Public Health Service Act (Institutional Review Boards: Ethics Guidance Program).[131] Section 474 (a) required that "each entity which applies for a grant or contract under this Act for any project or program which involves the conduct of biomedical or behavioral research involving human subjects" submit assurances that it has established an Institutional Review Board to review proposed research involving human subjects "in order to protect the rights of the human subjects of such research."[132]

Origins of Healthcare Ethics: Summary

Looking back, although the Hippocratic Oath has been revered for more than two thousand years, the oath's context perpetuates a paternalistic mode of relationship between the physician and the patient. Paternalism, as such, involves making decisions for another that the decision maker believes are in that person's best interest. In healthcare, paternalism involves making choices for patients who are capable of making their own choices. The paternalistic mode of patient–physician interactions directly impinges upon, and essentially abrogates, the patient's right of autonomy. In various translations, the oath essentially declares that physicians will utilize regimens that benefit patients, according to the physician's ability and judgment, and the physician will do no harm or injustice to her patients. In one translation, the Hippocratic Oath states, "I will use treatment to help the sick according to my ability and judgment, but never with view to injury and wrong-doing."[133] In another translation, the Hippocratic Oath states, "I will follow that system of regimen that, according to my ability and judgment, I consider for the benefit of my patients, and abstain from whatever is deleterious and mischievous."[134] But the Hippocratic Oath's declarations do not consider the possibility that the patient has a right to choose, even if that choice did not produce the most good for the patient. The physician knew what was best, and patients were expected to submit to the physician's judgment. The AMA Code of Ethics, adopted in 1847 and revised in 1903, 1912, and 1947, similarly failed to specifically address patient rights. Principles of Medical Ethics had been issued by the AMA since the early 1900s. A major change, intended to distinguish between medical etiquette and medical ethics, appeared in the 1957 revision. Section 1 of the AMA Principles of Medical Ethics (1957) stated, "The principal objective of the medical profession is to render service to humanity with full respect for the dignity of man."[135] Section 9 enjoined physicians to respect the confidentiality of patients and Section 10 highlighted the responsibilities of physicians not only to individual patients but also to society. But none of the sections discusses patient rights, patient protections, or concepts of justice. It may be reasonably asserted that, with all best intentions, the broad ethical chasms inherent in medical codes of conduct dating to the time of Hippocrates unwittingly facilitated opportunities for violations of the rights of patients and human subjects of medical research, as demonstrated in the Willowbrook Hepatitis Study and the Tuskegee Syphilis Study. It became the responsibility of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research to attempt to correct these critical oversights and provide a framework that would foster ethical conduct and establish protections for human subjects in the practice of medical research.

The Belmont Report

The primary deliverable of the investigations and studies of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research was *The Belmont Report: Ethical Principles and Guidelines for Protection of Human Subjects of Biomedical and Behavioral Research*, submitted to President Jimmy Carter and Secretary Joseph A. Califano, Jr., Department of Health, Education, and Welfare, on September 30, 1978.[136] In his letter to President Carter, Kenneth J. Ryan, Chairman of the Commission, referenced the commission's mandate under Public Law 93-348:

> The identification of basic ethical principles that should underlie the conduct of research involving human subjects, and the development of guidelines to assure that such principles are followed.[137]

The *Belmont Report* did not make specific proposals but recommended the report be "adopted in its entirety as a statement of departmental policy on the conduct of research involving human subjects."[138] The principles enumerated in the report "will guide resolution of ethical problems arising from research involving human subjects."[139]

The *Belmont Report* established three basic ethical principles that would guide the conduct of such research: *respect for persons, beneficence,* and *justice.* Additionally, the report established boundaries between medical practice and biomedical research. Medical practice was characterized as interventions designed solely to enhance the well-being of an individual patient that have a reasonable chance of success. Research was characterized as an activity designed to test a hypothesis, enable conclusions to be drawn, and develop or contribute to generalizable knowledge. Research methods are usually described in a formal protocol that delineates the objectives and procedures designed to attain those objectives. Research and practice may be conducted together "when research is designed to evaluate the safety and efficacy of a therapy." The report emphasized, "the general rule is that if there is any element of research in an activity, that activity should undergo review for the protection of human subjects."[140]

The ethical principle of *respect for persons* mandates that "individuals should be treated as autonomous agents" and "persons with diminished autonomy are entitled to protection."[141] Autonomous persons are capable of making their own choices and taking actions on their own behalf. In the context of medical research, withholding information shows lack of respect for the autonomy of research subjects. Such withholding would materially impair the person's capability of making a free and informed judgment or choice. Correspondingly, respect for persons requires protections for those who have not developed full capacity for self-determination, such as children, or those whose capacity has been impaired by "illness, mental disability, or circumstances that severely restrict liberty."[142] Surrogate decision makers may be identified who will uphold the rights of those who lack sufficient capacity and the choice to participate in medical research must be free of all coercive influence.

The ethical principle of *beneficence* mandates respect for a person's decisions. Patients and research subjects should be protected from harm and efforts made to secure their well-being. The *Belmont Report* indicated that, more than merely doing good, beneficence represented an obligation. In the context of medical practice and research, beneficence sets forth the requirement to maximize benefits and minimize possible harms.

The ethical principle of *justice* represented new considerations regarding the practice of medicine and the conduct of medical research. Regarding medical research, justice refers to the balance between those who bear the burdens of such research and those who receive its benefits. For example, it would be unjust if research subjects consisted primarily of those from lower socioeconomic classes and other disadvantaged groups, while the benefits of research, such as access to new medications, were primarily available to wealthier members of society. Rather, justice requires equal distributions of burdens and benefits. In terms of medical practice and medical services, the ethical principle of justice mandates equitable distribution of those services. Thus, we may assess it is unjust when, as is most commonly the case, residents of "inner city" neighborhoods in major urban metropolitan regions do not have ready access to teaching

hospitals and other healthcare delivery centers. It is unjust when pharmaceuticals are priced at thousands of dollars a month, or even more than US$100,000 per year, and are affordable by only a very few. Overall, the ethical principle of justice extended the physician's responsibilities beyond interactions with individuals to proactively include comprehensive relationships with and duties toward society.

Practical applications of the *Belmont Report* included implementation of informed consent protocols. Requirements for appropriate and valid informed consent are based on respect for persons, and include provision of necessary information, assessment of comprehension, and voluntary agreement to participation, free of coercion and undue influence. Formal, systematic assessments of risks and benefits were required, representing application of beneficence. The principle of justice led to "moral requirements that there be fair procedures and outcomes in the selection of research subjects."[143] The burdens and benefits of research must be fairly distributed across all segments of society. Further, certain classes of potential subjects, such as prisoners or those institutionalized based on cognitive infirmities, should be included as research subjects only on certain conditions. Other vulnerable populations, including children and the economically disadvantaged, deserve special protections in the conduct of medical research.

American Nurses Association Code of Ethics

Professional nursing is defined as "the protection, promotion, and optimization of health and abilities, prevention of illness and injury, alleviation of suffering through the diagnosis and treatment of human response, and advocacy in the care of individuals, families, communities, and populations."[144] Nurses in all specialties and at all levels of healthcare organizational involvement encounter biomedical ethical issues and challenges on a daily basis. For example, a 2010 study reported that more than 60 percent of nurses surveyed identified patient rights, autonomy, and informed consent as issues encountered on a daily or frequent basis.[145] Additional frequently encountered ethical issues were breaches of patient confidentiality or right to privacy, advanced care planning, surrogate decision making, and end-of-life decision making.[146]

As with all professional healthcare providers, a code of ethics provides a framework for ethical assessment, analysis, and decision making. The first formal code of ethics for nurses was adopted in 1950.[147] Previously, in 1926, the American Nurses Association (ANA) had published a suggested Code of Ethics, intended to solicit feedback and criticism from its members.[148] The purpose of the proposed code was to "create a sensitiveness to ethical situations and to formulate general principles."[149] The 1960 ANA Code for Professional Nurses specified 17 provisions, the first of which noted the "fundamental responsibility ... to conserve life, to alleviate suffering, and to promote health."[150] In 1968, the code's provisions were reduced to ten and the new code included brief interpretations intended as aids in applying the provision.[151] The 1968 ANA Code for Professional Nurses emphasized the nurse's duty-based obligation to "respect the dignity of man, unrestricted by considerations of nationality, race, creed, color, or status" and to "safeguard the individual's right to privacy."[152] The 2001 ANA Code of Ethics was described as ethical guidelines or statements "intended to guide practice, research, and education for the discipline of nursing."[153]

Code of Ethics for Nurses with Interpretive Statements, the most recent update, was published by the ANA in 2015.[154] The 2015 code contains nine provisions and "addresses individual as

well as collective nursing intentions and actions; it requires each nurse to demonstrate ethical competence in professional life."[155] For example, Provision 1 states, "The nurse practices with compassion and respect for the inherent dignity, worth, and unique attributes of every person."[156] In emphasizing respect for human dignity, Provision 1 affirms the patient's right to self-determination. Provision 3 states, "The nurse promotes, advocates for, and protects the rights, health, and safety of the patient."[157] Provision 3 upholds patient rights of privacy and confidentiality and stresses protection of human subjects in medical research. Provision 8 states, "The nurse collaborates with other health professionals and the public to protect human rights, promote health diplomacy, and reduce health disparities."[158] Provision 8 declares that health is a universal right[159] and describes nurses' obligations to "advance health and human rights and reduce disparities."[160] Additional provisions delineate the duties of nurses to address ethical concerns in the healthcare environment and implement principles of social justice in nursing and health policy.[161] Overall, the ANA *Code of Ethics for Nurses with Interpretive Statements* emphasizes action and calls nurses to actively meet "the most important moral challenges of the 21st century."[162]

CONCLUSION

At present, in the early decades of the twenty-first century, it seems that medical moral and ethical dilemmas have persisted and increased. Mechanisms and efficacy for obtaining informed consent, both in terms of medical practice and research, continue to be critically evaluated. Requirements for informed consent have been questioned and even attacked. The integrity of the medical profession as a whole is no longer taken for granted, as it is often unclear whether medicine is a healing profession or a business. The frequency of opioid prescription practices and widespread opioid abuse and addiction represent failures to fulfill beneficence. The persistence of health disparities, such as the markedly unequal prevalences of diabetes and cardiovascular disease among members of certain racial and ethnic minorities, represents society's overall failure to broadly implement biomedical ethical principles. The staggeringly high costs of healthcare in the United States, approximately two times the per capita expenditures in many other developed nations, perpetuate inequities in access to affordable care and unfairly distribute the burdens of ill health and disease. In Chapter 2 we will further explore key concepts and intellectual traditions of the principles of biomedical ethics and in Chapters 3 and 4 we will explore the application of these principles to contemporary issues in healthcare.

DISCUSSION QUESTIONS

1. Discuss the application of Galen's "experiential philosophic approach" to your own clinical healthcare practice. Describe how you might achieve a greater certainty of knowledge within your discipline. Discuss the steps you might take to achieve a greater precision of language with respect to your internal process, your interactions with colleagues, and your interactions with patients.
2. In Plato's dialogue *The Phaedrus,* Socrates learns that, according to Hippocrates, "the nature even of the body can only be understood as a whole."[163] Discuss the implications of this assertion for modern healthcare practice. Describe the types of treatment methods

that might be derived from these considerations. How might the concept of holism ("wholism") be extended beyond the realm of healthcare?

3. From the perspective of the healthcare provider–patient relationship, describe the similarities and differences between healthcare delivery in ancient Greece and Rome (the time of Hippocrates, the Pythagoreans, and Galen) and healthcare delivery in the early twenty-first century. Discuss modes of interaction in the time of the ancients that would be appropriate and applicable to patient–physician relationships today.

DO-IT-YOURSELF ETHICIST

1. The medieval Islamic physician al-Ruhāwī asserted that his colleagues should demonstrate courage, generosity, kindness, and justice. Describe specific circumstances in which you have demonstrated each of these virtues in your healthcare practice (or in your field of employment if you are not currently engaged in work in the healthcare field).
2. Both the Willowbrook Hepatitis Experiments and the Tuskegee Syphilis Study involved serious violations of the rights of members of vulnerable populations. At present, you are a member of your organization's institutional review board (IRB). The IRB has received proposals for research similar to the programs conducted at Willowbrook and in Macon County, Alabama. Describe your recommendations for revision of the proposed research projects including appropriate methods of obtaining informed consent and the incorporation of specific protections for potentially vulnerable research subjects.
3. In Precept XXVIII of his preeminent work, *Medical Ethics*, Thomas Percival enjoins the physician to engage in the regular practice of case review and case reporting.[164] As the leader of your institution's healthcare quality team, describe to your colleagues the process of case review and case reporting. Discuss the benefits of these activities for the patient, the healthcare practitioner, and the healthcare organization. Present a sample case report based on a recent interesting and instructive case.

REAL-WORLD APPLICATIONS— ETHICS AS A DOCTRINE OF ACTION

You have volunteered to give an in-house presentation titled "The Hippocratic Oath in the Twenty-first century." As part of your talk you will discuss the oath's injunction "to impart precept."[165]

- Describe the rules, principles, knowledge, and skills encompassed by the term *precept* as it applies to the field of healthcare.
- Discuss the ethical obligations of a teacher imparting these precepts.
- Discuss the oath's command to "keep pure and holy both my life and my art."[166]
- Describe the meanings and implications of the phrase *pure and holy* as it applies to healthcare practice.
- Discuss practical examples that demonstrate a healthcare practitioner's adherence to the injunction to "keep pure and holy both my life and my art."

REFERENCES

[1]D. W. Richards, "Hippocrates of Ostia," *JAMA* 204, no. 12 (1968): 1049–1056.

[2]B. Jowett, *The Dialogues of Plato*, 3rd ed., vol. I (Oxford, UK: Clarendon Press, 1892), 131.

[3]Ibid, 479.

[4]W. Jaeger, *The Ideals of Greek Culture*, vol. III, *The Conflict of Cultural Ideals in the Age of Plato*, trans. Gilbert Highet (New York, Oxford University Press, 1944), 21.

[5]Ibid.

[6]Ibid. 21–22.

[7]W. Jaeger, *Paideia: The Ideals of Greek Culture*, vol. I, *Archaic Greece and the Mind of Athens*, 3rd English ed., trans. Gilbert Highet (New York, Oxford University Press, 1946), v.

[8]Richards, "Hippocrates of Ostia," 1050.

[9]W. H. S. Jones, trans., *Epidemics I*, vol. I, *Hippocrates* (Cambridge, MA, Harvard University Press, 1957), 165.

[10]Richards, "Hippocrates of Ostia," 1051.

[11]L. Edelstein, "The Hippocratic Oath. Text, Translation and Interpretation," *Bulletin of the History of Medicine*, suppl. 1 (1943).

[12]Aristotle, *Metaphysics*, 985, b 31-986, a 3.

[13]F. Copleston, *A History of Philosophy*, vol. I (New York Doubleday, 1946), 36–37.

[14]Ibid., 37.

[15]M. Simon, *Deontologie Medicale* (Paris, J. B. Bailliere, 1845), 269.

[16]A. R. Jonsen, "Do No Harm," *Annals of Internal Medicine* 88 (1978): 827–832.

[17]Thomas of Aquino, *Summa Theologica, First Part of the Second Part (Treatise on Law)*, Question 94, Article 2., trans. Fathers of the English Dominican Province (Cincinnati, OH: Benziger Bros., 1947).

[18]E. L. Minar, "Reviewed Work(s): The Hippocratic Oath: Text, Translation and Interpretation by Ludwig Edelstein," *American Journal of Philology* 66, no. 1 (1945): 105–108.

[19]W. H. S. Jones, trans., "Ancient Medicine," in *Hippocrates*, vol. I (Cambridge, MA, Harvard University Press, 1957), 54–55.

[20]W. H. S. Jones, trans., "Aphorisms," in *Hippocrates*, vol. IV, Loeb Classical Library 150 (Cambridge, MA, Harvard University Press, 1959), 99.

[21]W. Jaeger, "The Ideals of Greek Culture," 13.

[22]"Hippocrates, 1966," *JAMA* 194, no. 12 (1965): 149–150.

[23]L. Edelstein, "The Professional Ethics of Greek Physicians," in *Ancient Medicine. Selected Papers of Ludwig Edelstein*, eds. O. Temkin and C. L. Temkin (Baltimore, Johns Hopkins University Press, 1967), 319–348.

[24]J. S. Hamilton, "Scribonius Largus on the medical profession," *Bulletin of the History of Medicine* 60, no. 2 (1986): 209–216.

[25]E. D. Pellegrino and A. A. Pellegrino, "Humanism and Ethics on Roman Medicine. Translation and Commentary on a Text of Scribonius Largus," *Literature and Medicine* 7 (1988): 22–38.

[26]Ibid., 26.

[27]T. Percival, "Medical Ethics: Or, a Code of Institutes and Precepts, Adapted to the Professional Conduct of Physicians and Surgeons," in *The Works, Literary, Moral, and Medical, of Thomas Percival, M.D.* vol. II (London: Cruttwell, 1807).

[28]R. F. Kotrc and K. R. Walters, "A Bibliography of the Galenic Corpus." *Transactions and Studies of the College of Physicians of Philadelphia* 1, no. 4 (1979): 256–304.

[29]A. Pasipoularides, "Galen, Father of Systematic Medicine. An Essay on the Evolution of Modern Medicine and Cardiology," *International Journal of Cardiology* 172, no. 1 (2014): 47–58.

[30]M. Schiefsky, "Galen's Teleology and Functional Explanations," in *Oxford Studies in Ancient Philosophy*, ed. D Sedley, vol. 33 (New York, Oxford University Press, 2007), 369–400.

[31]*De partibus animalium* [On the Parts of Animals], II, 1–2.

[32]Pasipoularides, "Galen, Father of Systematic Medicine."

[33]F. M. Cornford, *Plato's Theory of Knowledge. The Theaetetus* and *The Sophist* (New York, Dover Publications, 2003), *Theaetetus*, line 149.

[34]Ibid., *Theaetetus*, lines 150B–150C.

[35]Ibid., *Theaetetus*, line 151E.

[36]Aristotle, *Poetics*, 1457b9–16 and 20–22.

[37]Aristotle, *Rhetoric*, III.10, 1410b14f.

[38]J. Keats, "On First Looking into Chapman's Homer," in *The Complete Poetical Works and Letters of John Keats, ed.* H. E. Scudder (Boston, Houghton, Mifflin, 1899), 9.

[39]B. Jowett, *The Republic of Plato*, 3rd ed. (London: Oxford, 1888), II: 368.

[40]Ibid.

[41]C. Galen, *De placitis Hippocratis and Platonis*, Book 9, chap. 2, *Galeni Opera Omnia*, ed. C. G. Kuhn, vol. V (Leipzig: Prostat in officina libraria Car. Cnoblochii, 1825), 720.

[42]R. French, *William Harvey's Natural Philosophy* (Reissue) (Cambridge, UK, Cambridge University Press, 2006).

[43]C. Galen, "*Affections and Errors of the Soul* (*De propriorum animi cuiuslibet affectuum et peccatorum dignotione et curatione*)" in *Corpus Medicorum Graecorum* (*CMG*), ed. W. de Boer, Vol. 4, 1.1 (Leipzig: Teubner, 1937).

[44]Pasipoularides, "Galen, Father of Systematic Medicine," 55.

[45]M. Levey, "Medical Ethics of Medieval Islam with Special Reference to Al-Ruhāwī's "Practical Ethics of the Physician," *Transactions of the American Philosophical Society* 57, no. 3 (1967): 1–100.

[46]Ibid., 7.

[47]Ibid., 9.

[48]Ibid., 10.

[49]Ibid., 11.

[50]Ibid., 13.

[51]Ibid.

[52]Ibid.

[53]Ibid.

[54]Percival, "Medical Ethics," chap. I, Precept I.

[55]Ibid.

[56]Percival, "Medical Ethics," chap. II, Precept III.

[57]Percival, "Medical Ethics," chap. II, Precept I.

[58]Percival, "Medical Ethics," chap. I, Precept XXVIII.

[59]"Editorial: Thomas Percival (1740–1804). Codifier of Medical Ethics," *JAMA* 194, no. 12 (1965): 151–152.

[60]Code of Ethics of the American Medical Association, adopted May 1847 (Philadelphia: Turner Hamilton, 1871).

[61]*International Military Tribunal: Trials of War Criminals before the Nuremberg Military Tribunals Under Control Council Law No. 10*, vol. I (Washington, DC: U.S. Government Printing Office, 1946–1949). https://www.loc.gov/rr/frd/Military_Law/pdf/NT_war-criminals_Vol-I.pdf.

[62]Ibid.

[63]L. Alexander, "Ethics of Human Experimentation," *Psychiatric Journal of the University of Ottawa* 1 (1976): 40–46.

[64]*Records of the United States Nuernberg War Crimes Trials. United States of America v. Karl Brandt et al. (Case I)*. November 21, 1946–August 20, 1947 (Washington, DC: National Archives and Records Service. General Services Administration, 1974) (Microfilm Publications No. M887).

[65]E. Shuster, "Fifty Years Later. The Significance of the Nuremberg Code," *New England Journal of Medicine* 337, no. 20 (1997): 1436–1440.

[66]"The Nuremberg Code," in *Doctors of Infamy: The Story of the Nazi Medical Crimes*, eds. A. Mitscherlich and F. Mielke (New York: Schuman, 1949), xxiii–xxv. Also, the Nuremberg Code may be located online on the National Institutes of Health website, https://history.nih.gov/research/downloads/nuremberg.pdf.

[67]Ibid.

[68]Percival, "Medical Ethics," 378, 388.

[69]"Supplementary Report of the Judicial Council," Proceedings of the House of Delegates Annual Meeting, December, 9–11, 1946. *JAMA* 132 (1946): 1090.

[70]"The Nuremberg Code."

[71]Ibid.

[72]Ibid.

[73]J. Katz, "The Nuremberg Code and the Nuremberg Trial," *JAMA* 276, no. 20 (1996): 1662–1666.

[74]*Natanson v. Kline*, 350 P.2d 1093, 186 Kan. 393 (1960), 354 P.2d 670, 187 Kan. 186 (1960).

[75]World Medical Association Declaration of Helsinki, 1964, https://www.aix-scientifics.com/en/_helsinki64.html.

[76]"Special Communication. World Medical Association Declaration of Helsinki," *JAMA* 310, no. 20 (2013): 2191–2194.

[77]Ibid.

[78]National Institutes of Health, 45 CFR 46 §46.107 (Code of Federal Regulations; Public Welfare, Department of Health and Human Services; Protection of Research Subjects; IRB Membership) (Revised January 15, 2009), https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/.

[79]Shuster, "Fifty Years Later," 1440.

[80]R. Ward, S. Krugman, J. P. Giles et al., "Infectious Hepatitis. Studies of Its Natural History and Prevention," *New England Journal of Medicine* 258 (1958): 407–416.

[81]Ibid.

[82]D. J. Rothman, "Were Tuskegee & Willowbrook 'Studies in Nature'?" *Hastings Center Report* 12, no. 2 (1982): 5–7.

[83]C. Bernard, *An Introduction to the Study of Experimental Medicine* [1865] (New York, Dover Publications, 1957).

[84]S. Krugman, "The Willowbrook Hepatitis Studies Revisited. Ethical Aspects," *Infectious Diseases* 8, no. 1 (1986): 157–162.

[85]Ibid., 161.

[86]Ibid., 157.

[87]Ward et al., "Infectious Hepatitis," 407.

[88]Ibid.

[89]Ibid., 414.

[90]Ibid., 416.

[91]H. K. Beecher, "Ethics and Clinical Research," *New England Journal of Medicine* 274 (1966): 1354–1360.

[92]Ibid., 1358.

[93]Medical Tribune Staff Report, "Studies with children backed on medical, ethical grounds," *Medical Tribune and Medical News*, February 20, 1967.

[94]P. Ramsey, *The Patient as Person* (New Haven, CT: Yale University Press, 1970), Judgment on Willowbrook, note 8.

[95]National Institutes of Health, Office of Science Education, https://science.education.nih.gov/supplements/webversions/bioethics/guide/pdf/Master_5-4.pdf.

[96]Krugman, "Willowbrook Hepatitis Studies Revisited," 159.

[97]Ibid., 160.

[98]S. Goldby, "Experiments at the Willowbrook State School," *The Lancet* 297, no. 7702 (1971): 749.

[99]S. Krugman, "Experiments at the Willowbrook State School," *The Lancet* 297, no. 7706 (1971): 966–967.

[100]Ibid., 967.

[101]M. H. Pappworth, "The Willowbrook Experiments," *The Lancet* 297, no. 7710 (1971): 1181.

[102]National Institutes of Health, Office of Science Education.

[103]Final Report of the Tuskegee Syphilis Study Ad Hoc Advisory Panel. Report on Charge I. Washington, DC: U.S. Department of Health, Education and Welfare, April 24, 1973.

[104]Rothman, "Tuskegee and Willowbrook," 5.

[105]J. Heller, "Syphilis Victims in U.S. Study Went Untreated for 40 Years," *New York Times*, July 26, 1972.

[106]Associated Press, "Syphilis' Side Effects Studied," *Freeport Journal Standard* (Freeport, IL), July 26, 1972.

[107]Final Report of the Tuskegee Syphilis Study, Charter, August 28, 1972.

[108]Ibid.

[109]Ibid., Initial Recommendation of the Tuskegee Syphilis Study Ad Hoc Advisory Panel, October 25, 1972.

[110]Ibid.

[111]Ibid.

[112]D. Katz, "Why 430 Blacks with Syphilis Went Uncured for 40 Years," *Detroit Free Press*, November 5, 1972.

[113]Ibid.

[114]Final Report of the Tuskegee Syphilis Study.

[115]J. E. Moore, "Latent Syphilis Cooperative Clinical Studies in the Treatment of Syphilis." Reprint No. 45. *Venereal Disease Information* XIII, nos. 8–12 (1932); XIV, no. 1 (1933), 1–56.

[116]Final Report of the Tuskegee Syphilis Study.

[117]Ibid.

[118]Ibid.

[119]Ibid.

[120]Ibid.

[121]Ibid.

[122]Ibid.

[123]O. C. Wenger, "Untreated Syphilis in Negro Male," Hot Springs Seminar, 9/18/1950. Tuskegee Files, Center for Disease Control, Atlanta, GA.

[124]Final Report of the Tuskegee Syphilis Study.

[125]Ibid.

[126]A. M. Brandt, "Racism and Research. The Case of the Tuskegee Syphilis Study," *Hastings Center Report* 8, no. 6 (1978): 21–29.

[127]*Pollard v. United States*, Civil Action No. 4126-N; M.D. Ala. 1972.

[128]Public Law 93-348, Public Health Service Act (July 12, 1974). SEC. 202. (a) (1) (A), https://history.nih.gov/research/downloads/PL93-348.pdf.

[129]Ibid., SEC. 202. (a) (1) (B).

[130]Ibid., SEC. 202. (a) (2).

[131]Ibid., SEC. 474. (a).

[132]Ibid.

[133]W. H. S. Jones, trans., "The Oath," in Hippocrates, vol. I (Cambridge, MA, Harvard University Press, 1957), 299.

[134]F. Adams, trans. *The Genuine Works of Hippocrates*, vol. II (London: The Sydenham Society, 1849), 780.

[135]AMA Principles of Medical Ethics, June 1957, https://www.ama-assn.org/sites/default/files/media-browser/public/ethics/1957_principles_0.pdf.

[136]National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research: *The Belmont Report. Ethical Principles and Guidelines for the Protection of Human Subjects of Research*. DHEW Publication No. (OS) 78-0012. Washington, D.C., Government Printing Office, 1978, 4, https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/.

[137]Ibid., September 30, 1978 letter to President Carter.

[138]Ibid.

[139]Ibid., 2.

[140]Ibid., 4.

[141]Ibid.

[142]Ibid., 5.

[143]Ibid., 18.

[144]American Nurses Association, *Nursing's Social Policy Statement: The Essence of the Profession* (Silver Spring, MD: American Nurses Association, 2010), 10.

[145]C. M. Ulrich, C. Taylor, K. Soeken et al., "Everyday Ethics: Ethical Issues and Stress in Nursing Practice," *Journal of Advanced Nursing* 66, no. 11 (2010): 2510–2519, doi:10.3912/OJIN.Vol20No02Man04, referencing M. Fowler, "Nursing Ethics," in *Ethical Dilemmas and Nursing Practice*, 4th ed., eds. A. J. Davis, M. A. Arosker, J. A. Liaschenko et al. (New York: Pearson, 1997).

[146]Ibid., 2513.

[147]B. Epstein, and M. Turner "The Nursing Code of Ethics: Its Value, Its History," *Journal of Issues in Nursing* 20, no. 2 (2015): online manuscript 4; M. Fowler, "The Evolution of the Code for Nurses," *California Nurse* 81, no. 5 (1985): 5.

[148]"A Suggested Code: A Code of Ethics Presented for the Consideration of the American Nurses' Association," *American Journal of Nursing* 26, no. 8 (1926): 599–601.

[149]Ibid., 599.

[150]"American Nurses Association: The Code for Professional Nurses," *American Journal of Nursing* 60, no. 9 (1960): 1287.

[151]Epstein and Turner, "The Nursing Code of Ethics."

[152]American Nurses Association. Code for Nurses. *American Journal of Nursing* 68, no. 12 (1968): 2581–2585.

[153]C. L. Milton, "The American Nurses Association Code of Ethics: A Reflection on the Ethics of Respect and Human Dignity with Nurse as Expert," *Nursing Science Quarterly* 16, no. 4 (2003): 301–304.

[154]American Nurses Association, *Code of Ethics for Nurses with Interpretive Statements* (Silver Spring, MD: American Nurses Association, 2015).

[155]Ibid., viii.

[156]Ibid., 1.

[157]Ibid., 9.

[158]Ibid., 31.

[159]Ibid.

[160]Ibid., 32.

[161]Ibid., pp. 36–37.

[162]Ibid., 40.

[163]B. Jowett, *The Dialogues of Plato*, 479.

[164]Percival, "Medical Ethics," chap. I, Precept XXVIII.

[165]Jones, "The Oath," 299.

[166]Ibid.

Figure Credit

Fig. 1.1: Copyright © 2010 Depositphotos/AndreySt.

CHAPTER 2

Key Concepts and Intellectual Traditions

Virtue is that which makes its possessor good, and his work likewise[1]

— Thomas of Aquino, *Summa Theologica*

Overview: The Bioethical Enterprise

In the context of healthcare and overall medical practice, bioethics refers to the application of ethical analysis to medical decision making. The field of bioethics is quite new, having been conceived and launched in the early 1970s. The term *bioethics* is itself a neologism, a new word spontaneously invented to characterize the melding of several disciplines. The goal of bioethics is to stimulate new inquiry, exploration, and development of methods for solving critical problems confronting humanity in general and medical practice in particular.

In the 1990s the origins of the new word were vigorously investigated. Ultimately, in 2008, a 1927 German-language article was identified with a title that incorporated the term *Bio-Ethik*.[2] *Bio-ethik* may be reasonably translated as *bioethics*, and the title of the article by Fritz Jahr has been translated as "Bio-Ethics: A Review of the Ethical Relationships of Humans to Animals and Plants."[3] Jahr, a Protestant pastor, educator, and philosopher, stated that bio-ethik was "the assumption of moral duties not only towards humans but to all living beings as well."[4] Jahr established a "bioethical imperative," extending Immanuel Kant's categorical imperative (see below). Jahr's bioethical imperative guided ethical responsibilities in the life sciences to encompass all forms of life. Jahr's imperative has been translated as "Respect every living being on principle as a goal in itself and treat it, if possible, as such!"[5] Thus, Jahr envisioned a global ethics that encompassed our relations and interactions with each other and with all forms of life. Such modes of relationship with the natural world had already been featured in Henry David Thoreau's *Journal*[6] and *Walden*,[7] which prefigured the seminal discussions of environmental conservation in *The Sand County Almanac* by Aldo Leopold.[8]

A more recent origin of the term *bioethics* is attributed to Van Rensselaer Potter, a research oncologist and Associate Director of the McArdle Laboratory for Cancer Research at the University of Wisconsin–Madison. Over the course of his long and distinguished career, Potter served as President of the American Society for Cell Biology (1964) and President of the American Association for Cancer Research (1974), and was a Fellow of the American Association for the Advancement of Science. Potter proposed the term *bioethics* in 1970 in his article, "Bioethics, the Science of Survival."[9]

In his 1970 article, Potter declared that solutions to the numerous and increasing problems confronting society, that is, humanity, required the application of ethical values to biological facts. As ethics may be understood as the study of human values, Potter stated, "all ethics implies action according to moral standards."[10] He proposed the term *bioethics* to describe ethical action in the biological sphere. Activity in the new, broad field of bioethics would enable solutions to diverse urgent problems including environmental conservation, urban living, population pressure, international relations, and aging societies. Bioethics would address sustainable interactions between humanity and the land and humanity and wildlife. "Bio" was to be understood as expanding the boundaries of traditional biological sciences to include the humanities and social sciences, "with an emphasis on philosophy."[11] The overall intention of bioethics was to facilitate survival of "the fragile web of life" and provide a "bridge to the future."[12] The future of life on Earth, including the future of humanity, could not be taken for granted. Bioethics would help policy makers, communities, and individuals learn "how to use knowledge for social good."[13] In "Bioethics, the Science of Survival," Potter created a new word, described a new field, and proposed far-reaching calls to action to stimulate positive engagement with each other and the natural world of which we are a part.

But Potter was not alone in his considerations of necessary solutions to complex problems. In October 1971, a press release from Georgetown University announced a Kennedy Foundation grant to establish the Kennedy Institute for the Study of Human Reproduction and Bioethics.[14] The press release stated the institute will be "unique in its purpose of combining ethics and science" and will "pioneer in the development of a new field of joint research which the Institute's founders have named *bioethics*." Andre E. Hellegers, the director of the new institute, stated the bioethics program "will bring expertise to the new and growing ethical problems in medicine today."[15] Apparently, the institute's founders "did not realize that they were using the same word" that Potter had already coined to identify a new field with identical characteristics.[16]

Regardless, by the mid-1970s, the term *bioethics*, ultimately derived from the concepts and content of Jahr's *bio-ethik* and Potter's *bioethics*, was in widespread public use. The new field was characterized as a discipline in a 1973 article.[17] In 1974, "bioethics" was adopted as a subject heading by the Library of Congress.[18] It is critically important to emphasize that *bioethics* as such is a broad field of investigation, study, and endeavor, and that *biomedical ethics* is a subdivision or subset of the overall discipline of bioethics. Bioethics, as originally conceived, is a holistic endeavor. Human activity has consequences for our families, neighbors, coworkers, and every other living organism that shares our web of life. Bioethics, as a field, has been described as a force for change. The cardinal principles identified in the Belmont Report, that is, respect for persons, beneficence, and justice, can be explored and extrapolated "almost without end to yield robust ethical and moral frameworks."[19] These frameworks are applicable not only to modern healthcare problems but also to the numerous global crises facing us today. In terms of biomedicine, bioethics is applicable to solving the problems posed by genetic technology, activities of

global pharmaceutical corporations, and the business of healthcare. Use of bioethical analysis will assist in providing equitable solutions to healthcare delivery in the United States and the fair distribution of scarce resources. From a global perspective, bioethics is widely applicable in the identification of solutions to problems involving environmental conservation, climate change, species extinction, population pressure, mass migration, global poverty, and global public health.

Ethics itself is a doctrine of action, involving elucidating the distinctions between right and wrong. Thus, at all levels of society, bioethics can provide effective analysis from the multiple perspectives of human values and biological science. These analyses will then enable the identification of ethical, just, and workable solutions required for the survival, not only of the human species, but of all life on our planet. The starting points are awareness and education. Biomedical or healthcare ethics, as a subset of bioethics, can take the lead in the process of reorienting and revitalizing healthcare itself. The four principles of biomedical ethics[20] (that is, the three principles identified in the Belmont Report plus the principle of nonmaleficence) provide a foundation for analysis of specific problems encountered in the healthcare provider–patient relationship and development of ethical solutions to those problems. More generally, biomedical or healthcare ethics is applicable to the analysis of policy issues involving healthcare delivery, equitable resource allocation, and the appropriateness of genetic and other medical technologies. All of these issues and problems are immediate and the need for workable solutions is urgent. The four principles of biomedical ethics provide an open-ended resource, essentially a comprehensive toolbox, from which to begin meaningful work on these many and varied issues confronting individual well-being, human relationships, and global welfare.

Autonomy

The modern concept of *autonomy* is derived from the philosophy of Immanuel Kant (1724–1804), the great philosopher from Königsberg in East Prussia. Kant had received his doctorate in 1755 and served as a *Privatdozent* (lecturer) until 1770, when he was appointed professor of logic and metaphysics at the University of Königsberg.[21] Kant's canonical works include the *Critique of Pure Reason*, the *Critique of Practical Reason*, the *Critique of Judgment*, and the *Metaphysics of Morals*. A large component of Kant's philosophical work was directed toward an exploration of morals and an investigation of the sources of our practical ethical principles. In *Fundamental Principles of the Metaphysic of Morals*, Kant stated his purpose was "nothing more than the investigation and establishment of *the supreme principle of morality*."[22] Kant described the concept of a *good will*, that is, "a good which is always good in itself, by virtue of its intrinsic value, and not simply in relation to the production of some end."[23] To expand on the concept of *good*, Kant turned to a consideration of duty, the preeminent component of moral consciousness. A good will is one that acts for the sake of duty. Actions performed for the sake of duty are those that have moral worth. It is still required to understand what is meant by *duty*, and Kant states, "Duty is the necessity of acting from respect for the law."[24] And, by law, Kant means the *moral law*.

Thus, all actions undertaken for a purpose other than duty are not moral actions as such. They may be good actions, but they are not necessarily good in themselves and are associated with the accomplishment of some other goal or end. A person's action to buy a car is not a moral action. The choice to live in an urban versus a rural location may be a good option for some families. In contrast, living in a rural setting versus a city may be a good choice for other families.

These good choices are useful and valuable for the persons involved and are likely intended to promote their good. But these are not moral choices in that they are not undertaken from respect for the law, that is, the moral law. But what exactly is the moral law?

Kant understood the essential characteristic of law as such, that is, the moral law, to be universality. Just as physical laws such as gravity or Newton's laws of motion are universal laws, everywhere applicable, so is the moral law. As humans, we are capable of acting to fulfill all kinds of purposes. Kant used the term *maxim* to describe these subjective principles of volition. For example, a New Yorker's fashion sense, or maxim, may be completely different from that of a Parisian. One family may prefer to live in a two-story home in a rural county, whereas another family may prefer a single-level floor plan in the city. None of these principles for subjective action, or maxims, are universal. Rather, they represent the unique choices of a person, family, or group. These choices and actions are circumstantial and likely subject to change. They are not universal, not applicable to all persons at all times.

In contrast, the moral law pertains to all of us. Kant proposed that the moral law derives from practical reason and takes the form of an imperative, that is, a command that *ought* to be fulfilled. Kant presented two formulations of what he termed the *categorical imperative*, the imperative that commanded actions "not as means to any end, but as good in themselves."[25] The categorical imperative, therefore, "declares an action to be necessary in itself without reference to any purpose, that is, without any other end."[26] Kant's categorical imperative commanded that our maxims or principles of volition, those purposes upon which we base our subjective choices and actions, should conform to or align with the universal moral law. Thus, Kant stated the categorical imperative was to *"Act only on that maxim whereby you can at the same time will that it should become a universal law."*[27] Two paragraphs later (in *Fundamental Principles of the Metaphysic of Morals*) Kant also expressed the categorical imperative ("imperative of duty") as *"Act as if the maxim of your action were to become by your will a Universal Law of Nature."*[28]

The categorical imperative directs one to act only on those principles that, if you could make them so, should become universal laws. As a counterexample, Kant described a person who is forced by circumstances to borrow money. The person knows he will not be able to repay the loan, but understands no one will lend him what he needs unless he promises repayment at a specific date. The person comprehends that such a false promise would be inconsistent with duty, but he goes ahead anyway. The maxim of the person's action could be expressed as, "When I think of myself in want of money, I will borrow money and promise to repay it, although I know that I never can do so."[29] If such a maxim became a universal law, all practices of borrowing and lending would cease, as no lender would have any trust in the guarantees of the borrower. Our entire system of commerce and banking, and therefore our economy, would collapse. Thus, the borrower's maxim is not categorical.

As well, Kant described a prosperous person who observes others contending with "great wretchedness." The person understands he could help these others, but thinks, "What concern is it of mine?" He justifies his attitude by the belief that people are as happy as they can make themselves. The person in prosperity considers, "I will take nothing from him nor even envy him, only I do not wish to contribute anything to his welfare or to his assistance in distress."[30] If the prosperous person's maxim, that is, the lack of concern and unwillingness to contribute to the welfare of another, became a universal law, then a society could no longer claim it was based on ideals of fairness and equality of opportunity. Such a society would likely devolve, as the English philosopher Thomas Hobbes stated in *Leviathan*, into the condition of a "war of all

against all" (*bellum omnium contra omnes*).[31] A rational person would not wish such conflict to be universal, and thus a rational person, upon reflection and consideration, would choose to act on behalf of others. The prosperous person, upon comparing his selfish instinct with the rule of the categorical imperative, might choose a course of action in line with the moral law. In this case, the categorical imperative would lead to action very similar to the command in Luke 6:31—"And as ye would that men should do to you, do ye also to them likewise."[32] Or, as Rabbi Hillel said to the man who asked the rabbi to teach him the entire Torah while the man was standing on one foot, "That which is despicable to you, do not do to your neighbor, this is the whole Torah, and the rest is commentary."[33] It is likely that every person, when applying rational thought, would desire that these two commands, both later characterized as the Golden Rule, would, per Kant's categorical imperative, become universal law.

Kant also stated the categorical imperative as, *"So act as to treat humanity, whether in your own person or in that of any other, always in every case as an end, never as means only."*[34] In this formulation, Kant was pointing to an understanding that a person's "rational nature exists as an end in itself."[35] Thus, for example, when we hire a contractor to repair the tiles on the roof of our house, or when we place an order with a waiter at a restaurant, those persons are serving as means to fulfill our ends. In the case of the contractor, our ends include the safety of our family and the structural integrity of our home. In the second case, our ends include the satisfaction of hunger and the enjoyment of a dinner served at a venue other than our own kitchen. We use the contractor and waiter as means to accomplish these ends, but we also appropriately interact with them as human beings, not as robots. We may demonstrate our respect for them as persons with rational natures, that is, as ends in themselves, by politeness and courtesy. For example, we may express gratitude for their service and may even inquire as to their welfare and that of their families. In other words, we indicate by our words and deeds that we recognize and honor their existence as individuals who possess their own interests, purposes, and goals. We demonstrate our recognition and understanding that they are also rational beings, ends in themselves, and not merely tools to serve our own interests.

Acting so that the maxim, or principle, of your actions could be applied by all others necessitates our consideration of the welfare and well-being of those others. The categorical imperative mandates our consideration of the existence and nature of our rights as individuals and, by extension, the consideration of those same rights held by others. Per the categorical imperative, we not only have rights but also responsibilities. We are responsible for the outcomes of our actions, in that we need to carefully ascertain the likely outcomes if all others acted as we did. Thus, overall, implicit in Kant's several formulations of the categorical imperative is respect for persons. We treat others as ends in themselves, not merely as means. Persons are ends in themselves based on their capability for independent thought, that is, based on their rational nature. This rational nature enables a person to conceive her or his own sets of goals, purposes, and desires, that is, the person's capability for self-determination. This autonomy of the will, this capability for choosing based on the rational nature of human beings, is "the supreme principle of morality"[36] and the "sole principle of all moral laws, and of all duties which conform to them."[37]

Our self-respect, our respect for our own rational nature, compels our rational respect for others. Our respect for others embodies our respect for their capabilities of self-determination, that is, their autonomy. It may also be concluded, based on a slightly different analysis, that respect for persons itself derives from autonomy of the will. That autonomy is the principle upon which the categorical imperative is based. Thus, respect for persons, honoring their autonomy

as self-determining individuals, is the basis, or ground, for all ethical codes of action in the arena of human relations.

The principle of beneficence had been the ground of Hippocratic thought and the Hippocratic Oath in regard to the physician–patient relationship. In *Epidemics*, Hippocrates had declared, "As to diseases, make a habit of two things—to help, or at least to do no harm."[38] Much later, in 1847, the American Medical Association adopted its first Code of Ethics, which stated in Article I, Section I, that physicians should be "ever ready to obey the calls of the sick.[39]

However, more recently, it began to be recognized that the intention to do good, to help the patient, was insufficient to protect patient rights. As modern biomedical ethical codes began to be considered, developed, and evaluated in the aftermath of World War II, it was reasonable that the principle of autonomy, and the resultant concept of respect for persons, attained predominance. Previously the rights of patients, that is, their rights as individuals, had been considered minimally, primarily in regard to confidentiality. Beneficence, in the absence of patient understanding, consent, and active participation in medical decision making, did not protect patients from the potential harms of medical research and the harms of medical paternalism, harms resulting from the attitude of physicians that they knew best how to support and assist their patients' interests.

Thus, respect for persons was required as a principle upon which to ground biomedical ethics, that is, ethical decision making and ethical actions in the arena of biomedical practice. In 1947, the first principle of the Nuremberg Code stated, "The voluntary consent of the human subject is absolutely essential."[40] In 1979, the *Belmont Report's* discussion of respect for persons highlighted that "individuals should be treated as autonomous agents."[41] Subsequently, textbooks such as *Principles of Biomedical Ethics*[42] emphasized the importance of autonomy and the principle of respect for persons continued to gain prominence.

At present, the biomedical ethical principle of autonomy is primarily manifested in the requirement for informed consent. The Nuremberg Code had specified the content of sufficient informed consent in great detail.[43] Informed consent requires that the patient be "adequately instructed about the ratio of risk and benefit involved in the procedure as compared to alternative procedures or no treatment at all."[44] The U.S. Government Code of Federal Regulations states that a patient or the patient's representative "has the right to make informed decisions regarding his or her care."[45] The Joint Commission defines informed consent as the following:

> Agreement or permission accompanied by full notice about the care, treatment, or service that is the subject of the consent. A patient must be apprised of the nature, risks, and alternatives of a medical procedure or treatment before the physician or other health care professional begins any such course. After receiving this information, the patient then either consents to or refuses such a procedure or treatment.[46]

The principle of autonomy mandates a person's right to make her own decisions regarding medical treatment and the ability to direct her own medical care. Autonomy implies the right to refuse treatment, even if such refusal would likely result in great harm or even loss of life. For example, based on the biomedical ethical principle of autonomy, a person may establish a do-not-resuscitate (DNR) order, instructing emergency responders and other medical personnel not to attempt to restart the person's heart in the event he or she is discovered unconscious and without a pulse. A person with end-stage kidney disease, requiring dialysis treatment several times per week, may ultimately decide that her quality of life is unacceptable and choose to

terminate such treatment, even though that choice will certainly end her life. A person who has witnessed the sufferings of a parent or friend with Alzheimer's disease may write an advance directive specifying treatment he does not wish to receive in the case of a defined interval of loss of decision-making capacity. Such instructions might include the cessation of all efforts to give him food and water, which would likely result in a peaceful demise[47] within approximately fourteen days. This right of autonomy, this right of personal decision making, may be located in Kant's conception of personal freedom. Paraphrasing, Kant indicated that for a person to think of herself as free was to think of herself as able to act according to self-legislated principles.[48] Thus, overall, in terms of healthcare, persons who are ill continue to conceive of themselves as free and are able to make autonomous choices. Regarding the benefits and harms of such autonomous choices, the Hippocratic Oath "did not consider the possibility that the patient might have a right to choose even if that choice did not produce the most good for the patient."[49]

As a corollary, significant ethical problems result from asserting patient autonomy as a *positive right*, that is, the right to insist that certain services be provided. For example, in today's medical practice, it is common for patients to insist that they be prescribed specific medications. Owing to the advent of direct-to-consumer (DTC) advertising in 1997,[50] people learn of the purported benefits of certain medications in the context of glossy, colorful magazine ads and highly produced, fanciful television ads populated by attractive models, actors, and spokespeople. Potential side effects and other harms are either buried in small print or hurried through in barely intelligible, muffled tones at the end of the commercial. Of course, as consumers, we are as susceptible to being swayed by a pharmaceutical commercial as by ads for cars, trucks, perfumes, and breakfast cereal. DTC advertising has successfully positioned pharmaceuticals and medical devices as attractive commodities. (The baleful implication is that the patient is a customer and medical practice is nothing more than a commercial transaction.) Thus, a patient may demand a prescription for Abilify because he feels depressed, unaware that Abilify (aripiprazole) is an atypical antipsychotic medication whose primary indications are schizophrenia and bipolar disorder, and whose use may be associated with serious adverse effects.[51]

Another assertion of the presumed positive right to require fulfillment of self-determined choices occurs regularly in hospitals during treatment of patients who may be at the end of life. For example, an eighty-year-old woman is discovered unconscious at her home and rushed to the hospital. The critical care team determines the patient has suffered a large cerebral hemorrhage. The patient stabilizes but remains unconscious. Her son and daughter meet with the attending physician responsible for their mother's care and insist the hospital "do everything" to keep their mother alive. "Do everything," as an open-ended command, could encompass any type of medication, insertion of a feeding tube, long-term maintenance of a ventilator, and repeated attempts at cardiopulmonary resuscitation. "Do everything" could even include drilling a burr hole to remove hemorrhagic fluid from around the brain. Hospital medical staff, ethics committees, and administrators must evaluate these cases and assess appropriate, ethical courses of action on a regular basis, sometimes weekly or almost daily, depending on the size of the institution.

The emergence of patient advocacy groups represents another manifestation of the positive right to choose. Advocacy groups demand recognition of the issues, problems, and circumstances related to a specific disease or disorder. These special interest groups even insist on the right to specific treatment. They lobby Congress, the National Institute of Health, and pharmaceutical corporations to encourage research and the development of solutions that will assist loved ones afflicted with the particular condition.

These examples notwithstanding, the assertion of a positive right is not supported. For example, in *Jackson v. City of Joliet*, the U.S. Court of Appeals for the 7th Circuit asserted, "the Constitution is a charter of negative rather than positive liberties."[52] The existence of a positive right imposes obligations on the part of another, that is, a positive right requires that a person be provided with something.[53] However, the principle of autonomy, based on the human capability for rational thought, asserts the right of *self-determination*. The choices I make are my choices, freely chosen by me (assuming, of course, the absence of undue influence exerted by others). As a consequence of my self-determined choices, I will take appropriate actions on my own behalf toward fulfillment of the content of those choices. In no way does my choice require the participation of another, that is, my choice does not mandate any specific action on the part of another individual, group, or agency.

Thus, the principle of autonomy is not concerned with rights as such, as many view them in modern society. The self-determination embodied in autonomy is not appropriately associated with self-fulfillment, self-expression, or any other notion of personal uniqueness commonly cherished in the late twentieth and early twenty-first centuries. Kant does not equate autonomy "with any distinctive form of personal independence or self-expression."[54] Autonomy, specifically, manifests our duty to fulfill the moral law as expressed by Kant's categorical imperative. If a person acts so as "to treat humanity, whether in your own person or in that of any other, always in every case as an end, never as means only," then one's actions are moral actions.

Kant's Three Problems

As an extremely interesting sidebar to our discussion of autonomy, it is well worth noting that the great philosopher Immanuel Kant was able to postulate freedom, immortality, and the existence of God based on the moral law. Through the ages, these concepts had comprised the three primary problems in the study of metaphysics. For Kant, metaphysics was defined as knowledge after which reason strived "independently of all experience."[55] Kant was exploring the "possibility or impossibility of metaphysics in general."[56] Having described and defined the categorical imperative, that is, the moral law, Kant determined that freedom, immortality, and the existence of God were required as its basis.

Freedom

As we have seen, Kant had long investigated, in *Fundamental Principles of the Metaphysic of Morals* and other works, the possibility and content of a *supreme principle of morality*. He had established the categorical imperative, in several formulations, as this supreme principle, that is, the moral law. The moral law is categorical in that it is specific and universal, rather than hypothetical and contingent upon circumstances. The moral law is an imperative in that it imposes an obligation on the rational person for fulfillment. In other words, the moral law *ought* to be fulfilled.

Thus, as an imperative, the existence of the moral law implies that rational persons have a choice. We are not machines or computers, programmed to follow sets of instructions. "Ought" implies we should adhere to the moral law, but we may choose not to. If we were so designed that we would always follow the prescriptions of a moral law, then there would be no need for a moral law as such. Things would just be the way they are. Everyone would automatically follow built-in rules for conduct, and there would be no need to search for the sources of morality. In fact, the notion of "morality" would not even arise, as there would be no alternatives available in terms of human actions. Actions would always follow the built-in code, whatever that was.

If we are not free, then there is no need for rational thought. If we are not free, then there is no need for a moral law, because there is no possibility for choice. Therefore, if we can assert the existence of a moral law, such a law must be based on the possibility of freedom. Rationality itself requires the possibility of freedom. Practical reason, that is, the will of a rational being, "must regard itself as free, that is, the will of such a being cannot be a will of its own except under the idea of freedom."[57] *Freedom,* therefore, is a condition or postulate of the moral law.

However, per Kant, freedom cannot be proved. The world we live in, the world of experience, is based on natural law and ruled by causality. Effects are determined by causes, and freedom is not a component of such deterministic phenomena. In contrast, rational thought is independent and self-generated. Rational thought occurs outside the world of sense, that is, rational thought occurs in an *intelligible* world. The idea of freedom, therefore, operates or is located in this intelligible, suprasensible world, and we can posit that freedom makes possible the existence of the moral law.

Immortality

Kant also postulates immortality as a condition of practical reason. He states, "The moral law is the sole determining principle of a pure will."[58] In other words, all our rational actions are based on the categorical imperative. (Of course, many actions may be contingent, based on circumstances, and follow our whims, desires, or other preferences of the moment.) Kant asserts that the *summum bonum* (the highest or supreme good) is the "whole object of pure practical reason."[59] By taking actions directed toward accomplishing the *summum bonum,* we are acting to fulfill the moral law. We could say that as we do good in the world, we're not only helping ourselves, our families, and members of our communities to fulfill our ends, but we're also caring for other living creatures and our shared environment. Overall, as we do good, we're following the commands of the categorical imperative. But how do we specify the *summum bonum?* What are the components of the supreme good and how do we recognize them?

Kant clarifies that the *summum bonum* is the *perfect* or *whole* good, whereas *supreme* is "that condition which is itself unconditioned."[60] The *supreme* good is the highest good, dependent on no other good for its qualities of goodness. Kant indicates that *virtue* is "worthiness to be happy,"[61] that is, happiness in the sense of being on the path to attaining the *summum bonum.* A person's acts are virtuous in that they contribute to his overall such worthiness. Thus, virtue is the supreme good. But rational beings also need and deserve happiness. Therefore, the perfect and whole good, "as the object of the desires of rational finite beings,"[62] also requires happiness. Happiness itself is not supreme, as a person may derive happiness from many actions and things that do not necessarily contribute to virtue. For example, purchasing a new motorcycle or light truck may make us happy, but does not add to our overall worthiness, that is, the purchase does not assist us on our path to the perfect good. Kant affirms that happiness may be pleasant to one who is happy, but "is not of itself absolutely and in all respects good, but always presupposes morally right behavior as its condition."[63] The happiness we are considering with respect to the *summum bonum,* the perfect or whole good, is always happiness that is based on morally right behavior, actions based on the categorical imperative.

Thus, the moral law commands us to act so that the principle of our action could become a universal law, and to treat other persons as ends in themselves and not merely as means to our ends. Our object, as we follow the moral law, is promotion of the *summum bonum,* which includes both virtue and happiness. Importantly, we are not commanded to pursue virtue because

it causes happiness. Rather, we are commanded to pursue virtue that causes happiness.[64] Happiness is not the end of our actions. The union of virtue and happiness, the *summum bonum,* is that end. But Kant poses the critical question, "How is the *summum bonum* practically possible?"[65] Upon reflection, we understand that attainment of the perfect good is not possible in the physical world. The natural world, the world of experience, is a realm of constant change. The design of the world may be perfect, but the components of the world are not. For example, the physical elements of the world are in a continual state of breakdown, renewal, and ultimate decay. Further, not all persons are contributing to the *summum bonum,* and the objective good that we accomplish may be compromised by the actions of another. Considering these limitations and obstacles, attainment of the perfect good may only be possible in the suprasensible world.

Kant indicates that the supreme condition of the *summum bonum* is "the perfect accordance of the mind with the moral law."[66] But he declares that no rational being of the sensible world is capable of such perfect accord. Therefore, the perfect good can only be attained by infinite progress toward that goal. Such unending progress "is only possible on the supposition of an endless duration of the existence and personality of the same rational being (which is called the immortality of the soul)."[67] Thus, if we posit the existence of the moral law as the principle of rational thought, as we must as the condition of coherent human activity and human relations, then a condition of the moral law itself is immortality of the soul. This immortality, per Kant, is "a postulate of pure practical reason."[68] We cannot demonstrate immortality of the soul, we cannot prove it, but it is an inseparable result of the possibility of the moral law. To deny immortality would be to deny the moral law itself.[69] In Kant's philosophical system, the moral law requires both freedom and immortality.

Kant's third postulate is the condition for a synthetic relationship between virtue and happiness, that is, a relationship of combination or mutual contribution. This relationship is not analytic in that neither one can be derived from an analysis of the other. For example, in the world of experience, a person may achieve a state of happiness (however temporarily) by going to an amusing movie or observing the graceful flight of a flock of swallows. But these experiences do not increase her virtue, as such. Conversely, a person may satisfy a promise to take his young children to the park for the afternoon, and thus fulfill a moral duty that is necessarily virtuous. But he may feel this is a hardship, as what he really wanted to do was to relax at home and watch the football game. Performing the virtuous act may have diminished his overall happiness, in a way. Therefore, virtue and happiness are concepts independent of each other and their relationship is one of synthesis. Each may contribute to the other. Also, the relationship between happiness and virtue must be *a priori,* that is, the relationship is prior to and does not depend on experience. What, then, is the basis for this relationship?

The Existence of God

To investigate and answer this question, Kant describes happiness as "the condition of a rational being in the world with whom *everything goes according to his wish and will.*"[70] Happiness, therefore, depends on harmony of the entirety of physical nature with a person's whole end. But, as we all experience every day, such harmony does not exist. We are not the cause of the existence of the world and do not have control over natural events. Therefore, as the moral law mandates the pursuit of the *summum bonum,* and as there is a necessary connection between virtue and happiness, prior to all experience, we may postulate "the existence of a cause of all nature, distinct from nature itself, and containing the principle of this connection, namely, of the

exact harmony of happiness with morality."[71] This supreme cause is identified by Kant as God, the Supreme Being. As we have seen, it is our moral duty to promote the *summum bonum*. It is thus necessary to presuppose the possibility of the perfect good. But the perfect good depends on connections and relationships that cannot be established in the natural world, the world of experience. Therefore, per Kant, "it is morally necessary to assume the existence of God."[72] (As Anselm of Canterbury famously argued in the eleventh century, this assumption might simply mean acknowledging the existence of a being or of a reality that is greater than any other being or reality that one can imagine.) Kant acknowledges that this conjecture is a matter of faith, as the assumption is based on pure reason rather than facts that we have obtained from experience.

Overall, Kant states that the moral law is founded on autonomy of the will. The postulates of freedom, immortality, and the existence of God are practical, necessary suppositions. These postulates, which Kant terms "postulates of pure practical reason in general,"[73] do not represent facts of our existence and are not themselves susceptible of proof in the world in which we live. The postulates are obtained by the activities of reason and provide support for our functioning as moral beings. Importantly, in our specific context, the biomedical ethical principle of autonomy derives from freedom, which Kant has demonstrated is a postulate of the moral law.

Autonomy and Healthcare Delivery

In the modern healthcare setting, the biomedical ethical principle of autonomy is manifested by respect for persons, that is, acknowledging the right of the patient as an autonomous individual to make her own decisions. What patients require of healthcare providers is their knowledge and expertise regarding physiology and pathology, ability to accurately assess a clinical scenario and arrive at an appropriate diagnosis, and skill in recommending presumably effective methods of treatment. But, per the freedom of the individual implicit in the Kantian categorical imperative, the patient retains the right to choose whether to proceed with recommended treatment. Thus, the biomedical ethical principle of autonomy redefines the interaction between doctor and patient as a *partnership*, a coequal relationship in which both parties are attempting to identify appropriate solutions to the patient's health-related problems. Respect for persons creates a relationship in which each partner honors the other, recognizes and respects the other's value and contribution, and acts to implement mutually agreed upon actions intended to achieve optimal results. It may readily be observed that the principle of autonomy is applicable not only in the field of healthcare, but in all human interactions, relationships, and endeavors.

Duty-Based Ethics

Duty-based ethics or *deontological ethics* evaluates the moral goodness of an action based on the characteristics of the action itself. *Deontology* derives from the Greek words *δέον* (duty; obligation) and *λόγος* (ground; principle of order or knowledge). Duty-based or deontological ethics may be traced back to Kant's formulations of the categorical imperative, such as "Act as if the maxim of your action were to become by your will a Universal Law of Nature."[74] As discussed above, the categorical imperative upholds the moral law and implements respect for persons. The categorical imperative is a command that *ought* to be fulfilled. It is a *duty*.

From the deontological perspective, an action is right or wrong *in itself*, rather than based on an assessment of the consequences of the action (as in *utilitarianism*). Morally right actions have priority over actions that merely produce a good outcome. An *action* may be defined as the production of a change in the state of affairs.[75] *Right*, of course, is much more difficult to

define and great philosophers have been attempting to do so for more than 2,500 years. Without begging the question, it may be fairly stated that we have an intrinsic understanding of *rightness*. For example, it is right to fulfill our promises, to redress wrongs we have done, and to return equivalent value for services provided by others.[76] These actions are duties of *perfect obligation*.[77] In contrast, certain actions such as telling a falsehood or stealing are morally forbidden. What is required is for us to reflect on the characteristics of our possible actions in terms of rightness and wrongness. We are much more likely to do our duty by engaging in such reflection, rather than acting without thinking.

Thus, we have to recognize the inherent rightness of an action as distinct from the consequences of that action. However, importantly, upon consideration we may discern that it is right to promote the general welfare. In this way, deontological ethics and utilitarian ethics overlap. These ethical frameworks are not mutually exclusive. As we reflect, we may come to understand that right actions, undertaken owing to their rightness, necessarily result in an increase in the general welfare, that is, the good. The right and the good are inseparable. Therefore, as students of ethics, we are not served by a simplistic opposition of deontology and utilitarianism. Rather, an ethics based on achieving the greatest good provides a counterpoint to an ethics based on duty.

Beneficence

Regarding the origins of the concept of *beneficence*, the great philosopher David Hume (1711–1776) listed the epithet *beneficent* as an example of the possible high attainments of human nature.[78] Hume indicated that "by doing good only, can a man truly enjoy the advantages of being eminent."[79] Thus, by doing good, that is, by fulfilling the requirements of the principle of beneficence, healthcare providers also attain respect and uphold the codes and standards of their professions. Going farther, Hume declared that "no qualities are more entitled to the general good will and approbation of mankind than beneficence and humanity, ... and a generous concern for our kind and species."[80] Beneficence, or taking action resulting in good, is associated with generosity and concern for the welfare of others. Such generosity and concern are essential characteristics of all healthcare providers and are formalized in the biomedical ethical principle of beneficence.

The Ethical Mandate

The mandate for beneficence may be further located in *utilitarianism*, an approach to moral evaluation and moral decision making applicable to ethical conduct and the fields of political and social action. The precursors of utilitarianism date to the writings of the ancient Greek philosopher Epicurus (341–270 B.C.E.),[81] who taught that humans by nature seek to attain pleasure and avoid pain. In the modern era, utilitarianism was most extensively developed by Jeremy Bentham (1748–1832) and John Stuart Mill (1806–1873). Bentham was a lawyer, but rather than practicing law, he devoted himself to the study of legislation[82] and became a well-known political and social reformer. Bentham's writings are voluminous. In 1776 he published *Fragment on Government*, whose preface contains the first formulation of his most famous aphorism, "It is the greatest happiness of the greatest number that is the measure of right and wrong."[83] Bentham described this formula as a fundamental axiom that serves as grounds for reformation. Of note, the phrase "the greatest happiness of the greatest number" is found in

the Introduction to *Treatise of Crimes and Punishments* (1764) by Caesar-Bonesana, Marquis de Beccaria (1738–1794).[84] Prior to both Beccaria and Bentham, Francis Hutcheson had stated, "In comparing the moral qualities of actions ... that action is best, which procures the greatest happiness for the greatest number."[85] Bentham was also influenced by the French Enlightenment philosopher Claude-Adrien Helvetius (1715–1771), a "pioneer in utilitarian moral theory and in its application to the reform of society."[86] And, contemporaneously, Hume had declared that "public utility is the sole origin of justice."[87] A very interesting sidebar is that Karl Marx famously asserted (paraphrasing) that "Hume was primarily concerned with understanding the world, whereas Bentham was primarily concerned with changing it."[88]

Utilitarianism

Utilitarianism implements what Bentham described as the *principle of utility*, "that principle which approves or disapproves of every action whatsoever, according to the tendency which it appears to have to augment or diminish the happiness of the party whose interest is in question."[89] Thus, increase or decrease of happiness was the criterion by which the utility of an action was to be assessed. Bentham defined *utility* as that property in any object that "tends to produce benefit, advantage, pleasure, good, or happiness" or prevents "mischief, pain, evil, or unhappiness to the party whose interest is considered."[90] He noted that advantage, pleasure, good, or happiness "come to the same thing," that is, these assessments are synonymous or identical. Actions, whether taken by or directed toward individuals, communities, or governments, should be based on utilitarian considerations of achieving the greatest good for the greatest number. Bentham was developing a moral system based on these concepts of utility, a system that could establish the moral character of human actions. He asserted the following in Chapter 1 of *An Introduction to the Principles of Morals and Legislation*:

> Nature has placed mankind under the governance of two sovereign masters, *pain* and *pleasure*. It is for them alone to point out what we ought to do, as well as to determine what we shall do. On the one hand, the standard of right and wrong, on the other the chain of causes and effects, are fastened to their throne.[91]

Pleasure and pain were not merely physical and mental sensations. These indicators, whether assessed by prior experience or calculated as likely occurrences, provided the basis for moral evaluation and ethical action. Proposed actions on any scale, undertaken by the individual, community, or government, were right or wrong based on the pleasure or pain that would be produced. Accomplishing the greatest good was the primary moral and ethical concern. Essentially, Bentham was stating that our entire moral system was based on seeking pleasure and avoiding pain. Kant's moral law, the categorical imperative and its obligations, was not the primary reference point in Bentham's system of conduct. The utility of an action determined its moral value. Bentham described the principle of utility as

> that principle which states the greatest happiness of all those whose interest is in question, as being the right and proper, and only right and proper and universally desirable end of human action.[92]

In evaluating the moral rightness of an action, that is, whether such action would be ethical, the only criterion in utilitarianism is whether it would contribute to the greatest happiness of the person or people concerned. Overall, an action would conform to the principle of utility

when "its tendency to augment the happiness of the community is greater than any it has to diminish it."[93] Thus, the utilitarian framework substantially contributes to the foundation of the biomedical ethical principle of beneficence. Health is a benefit and a key contributor to a person's overall happiness. Healthcare providers contribute to the greatest happiness by assisting persons to achieve improved levels of health. Evaluation of the risks and benefits of proposed treatment fulfills the utilitarian requirement for assessing the tendency of an action to augment or diminish happiness. Bentham includes benevolence, that is, goodness or kindness, in his list of "several simple pleasures of which human nature is susceptible."[94] The pleasures of benevolence "are the pleasures resulting from the view of any pleasures supposed to be possessed by the beings who may be the objects of benevolence."[95] Thus, by increasing the patient's *pleasure*, the good he obtains via increased health and well-being, the healthcare provider's own happiness is increased. From the utilitarian perspective, healthcare practice, adhering to the principle of beneficence, increases the greatest happiness of the greatest number.

The writings of the British philosopher John Stuart Mill include *On Liberty, Utilitarianism,* and *Principles of Political Economy.* In *Utilitarianism,* first published in book form in 1863, Mill states a primary concern:

> From the dawn of philosophy the question concerning the *summum bonum,* or, what is the same thing, concerning the foundation of morality, has been accounted the main problem in speculative thought. ...[96]

Mill, too, as did Bentham, located that foundation in the *greatest happiness principle.* Mill stated that "actions are right in proportion as they tend to promote happiness, wrong as they tend to produce the reverse of happiness."[97] Regarding the ends of human actions, that is, the ultimate purpose of those actions, Mill stated that "pleasure and freedom from pain are the only things desirable as ends."[98] The greatest happiness encompassed quality as well as quantity, and represented the range of human experience, not merely physical sensations of pleasure. Mill emphasized the pleasures of the intellect, feelings, and imagination, as well as moral sentiments. The standard for utility was not the greatest happiness of the individual agent, the one who was taking action, but the overall greatest amount of happiness. Right actions make other people happier and provide benefit for the world in general. The ultimate end is an existence "as rich as possible in enjoyments, both in point of quantity and quality." This ultimate end "is necessarily also the standard of morality,"[99] defined as the rules and precepts for human conduct.

Utilitarian and deontological (duty-based) ethical systems are often contrasted as competing schools of thought. But the obligations of the categorical imperative mandate us to consider the welfare of others as the rule of our actions. Our duty is to ensure that our actions are good actions. We should only take actions whose *maxim,* or principle, could become universal, that is, one that could be legitimately followed by all other persons. Moral actions necessarily accomplish not only our good, but the good of humankind. Therefore, it may be reasonably concluded that Kant's categorical imperative, *"Act only on that maxim whereby you can at the same time will that it should become a universal law,"*[100] results in actions that create the greatest good for the greatest number. Similarly, utilitarianism imposes a *duty* on all persons to act in accordance with the principle of utility. We are obliged, in the utilitarian system, to follow the greatest happiness principle, that is, to promote the greatest good. Thus, Kantian ethics and utilitarianism have different premises and differing orientations. But each consists of considerable elements of the other, as is reasonable considering that both systems are concerned with ultimate foundations

of morality. Both systems are directed at maximizing individual human flourishing and the welfare of humanity as a whole. In this way, Kantian ethics and utilitarianism provide the foundations for the biomedical ethical principle of beneficence.

Overall, the principle of beneficence, the responsibility to do good, to provide benefit to the patient, has been a cornerstone of biomedical ethics for more than 2,400 years. A basic question central to *operationalizing* the principle of beneficence, that is, putting beneficence into action, involves what is actually meant by *good*. Interestingly, exploring the notion of *the good* itself has been ongoing for approximately the same 2,400 years.

Internal Standard of the Good

The great philosopher Plato, in his dramatizations of the life and thought of his renowned teacher Socrates, helps us to better understand the nature of the good. For example, in the *Philebus*, Plato presents a conversation among Socrates, Philebus, and Protarchus regarding whether wisdom or pleasure is more desirable and advantageous of all things. Socrates frames this inquiry as regarding "some state and disposition of the soul which has the property of making all men happy."[101] In other words, Socrates and his friends are investigating the characteristics and the nature of the good. Socrates proposes the possibility of a third state, better than either wisdom or pleasure, in which the good may be located. During the course of a long discussion, Socrates asks Protarchus whether he would choose to have a life of all wisdom devoid of pleasure, or all pleasure devoid of wisdom. Protarchus answers in the negative to both these scenarios and agrees that the perfect and entirely good cannot be either wisdom or pleasure. Socrates concurs and informs Protarchus that "we should seek the good, not in the unmixed life but in the mixed."[102] Socrates suggests that by mingling elements of each class which have the most truth, the union would "suffice to give us the loveliest of lives."[103] He then proposes that mixtures of the highest value, those universally beloved by all, possess, in addition to truth, the properties of beauty and symmetry. Thus, beauty, symmetry, and truth "taken together we may regard as the single cause of the mixture, and the mixture as being good by reason of the infusion of them."[104] Socrates then applies these qualities of the good to a final analysis of pleasure and wisdom, and concludes that "in measure, and the mean, and the suitable, and the like, the eternal nature has been found."[105] In other words, all things tending to the good are those that are balanced and moderate, seemly and fitting, and do not partake of any extreme.

FIGURE 2.1 Plato and Aristotle in a detail from Raphael's *The School of Athens*

In the *Theaetetus*, Plato presents an inquiry into the nature of knowledge, and Socrates tells his friends that people should strive to become righteous, just, and wise.

FIGURE 2.2 Statue of Socrates at the modern Academy of Athens

In the *Protagoras,* Plato presents a disputation between Socrates and Protagoras, the preeminent Sophist and teacher of virtue. Two primary topics of the wide-ranging conversation are whether virtue is one or many things and whether virtue can be taught. Throughout Plato's *Dialogues,* Socrates has identified virtue with knowledge. Further, personal qualities or characteristics such as courage, temperance, justice, and wisdom are not disparate entities, but comprise a unity. Taken individually, each element is a virtue in itself. But each element contains qualities of the other. For example, justice contains elements of temperance or even-handedness, and courage contains elements of wisdom or the application of the right action to the right circumstance. Overall, virtue is not any of these qualities in isolation, but the unification of these qualities in "knowledge of what is truly good for man and of the means to attain that good."[106]

In the *Protagoras,* Socrates brings to the attention of his listeners the famous aphorism, "Hard is it to be good," which he attributes to Pittacus, a philosopher of Lacedaemon (Sparta). Socrates explains that this saying does not mean that it is difficult to be good, but rather that it is difficult to become good. As an example of becoming good, Socrates asks, "And what sort of well-doing makes a man a good physician? Clearly, the knowledge of the art of healing the sick."[107] Overall, the good is obtained by the pursuit of virtue, by ongoingly engaging in actions of courage, temperance, justice, wisdom, and other virtuous activities. Of great benefit is the possibility that virtue can be taught, and the attainment of virtue is therefore potentially available to all. At the conclusion of the *Protagoras,* Socrates summarizes his attempt "to prove that all things are knowledge, including justice, and temperance, and courage—which tends to show that virtue can certainly be taught."[108]

Aristotle begins the *Nicomachean Ethics* with an inquiry into the nature of the good. He asserts that "Every art and every scientific inquiry, and similarly every action and purpose, may be said to aim at some good. Hence the good has been well defined as that at which all things aim."[109] As there are various activities in which people engage, including the arts and sciences, the ends of these activities are also various. As examples, Aristotle states that health is the end of medicine and wealth is the end of domestic economy. Overall, we have intermediate goals that are subordinate to other, more far-reaching goals. Those goals or ends may in turn be subordinate to other, higher-level goals. But what is the good, that is, the value, worth, or purpose, of these activities? Aristotle asserts the good is "that for the sake of which all else is done."[110] For example, we go to college to further our education, learn more about the world,

and prepare for a career. We work to earn income to provide shelter, food, and clothing for our families and ourselves. We do these things so that we and our families may grow, develop, and fulfill our particular purposes and functions as unique human beings. Regarding the final end of these purposes and functions, Aristotle concludes,

> If it is true in the sphere of action there is an end which we wish for its own sake, and for the sake of which we wish everything else, ... it is clear that this will be the good or the supreme good.[111]

Happiness is this supreme good. We desire honor, wisdom, and pleasure for themselves but also as a means to happiness, as we judge that by the result of achieving these goods we will be happy. We always choose happiness for itself and never as a means to anything else. Thus, for Aristotle, happiness (*eudaimonia*) was the goal or end of all human activity. (The Greek word εὐδαιμονία is variously translated as happiness or flourishing.) Happiness is self-sufficient and "that which, taken by itself, makes life desirable, and wholly free from want."[112] Happiness is the ultimate end of all action. We achieve happiness by fulfilling our functions as human beings in the context of a complete life, performed in accordance with virtue. The happy person is engaged in virtuous action and constantly and consistently pursues her activities in accord with justice, courage, temperance, and wisdom. Aristotle asserts that "happiness is an activity of soul in accordance with complete or perfect virtue,"[113] thus uniting the supreme good with a moral foundation and the methods for achieving that good.

Much later, in 1725, Frances Hutcheson (1694–1746) stated in *An Inquiry into the Original of Our Ideas of Beauty and Virtue* that "in equal degrees of happiness, expected to proceed from the action, the virtue is in proportion to the number of persons to whom the happiness shall extend."[114] Thus, happiness is the good, and the more people who benefit from an action, the greater the virtue of that action. Hutcheson finds the origins of moral ideas, a moral sense of excellence, "in every appearance, or evidence of benevolence."[115] More than 2,000 years previously, Aristotle's writings on ethics included an examination of the characteristics of ἀρετή (arête), which means *excellence* or *virtue*. Per Hutcheson, excellence is associated with benevolence, and thus excellence is another characteristic of the good.

Approximately twenty-five years after Hutcheson's *Inquiry*, Hume wrote, in his *Enquiry Concerning the Principles of Morals* (1751), that epithets such as *humane, merciful,* and *beneficent* "are known in all languages, and universally express the highest merit, which human nature is capable of attaining."[116] Hume was discussing benevolent feelings or sentiments (affections) and indicated these are universally approved and engage the goodwill of humankind. He states that the qualities of beneficence and humanity are entitled to this general goodwill and approbation. When a beneficent, humane woman or man is praised, such praise insists on "the happiness and satisfaction, derived to society from his [or her] intercourse [interaction] and good offices."[117] Thus, beneficence is associated with the ultimate outcome of happiness, which derives from the *good offices* or useful activities of the person being praised. Praise, in general, is implied in the descriptor *useful*. In assessing questions of morality, Hume states "this circumstance of public utility is ever principally in view."[118] The impact of an action on society as a whole is a predominant consideration in an assessment of rightness or wrongness. Beneficence inheres in actions directed toward achieving the good. Hume makes this very clear:

> If usefulness, therefore, be a source of moral sentiment, and if this usefulness be not always considered with a reference to self, it follows that everything which contributes to the happiness of society recommends itself directly to our approbation and goodwill. Here is a principle which accounts in great part for the origin of morality.[119]

Usefulness, not only to an individual but more broadly to society, is a foundational component of morality. Right actions, therefore, are useful actions and promote happiness, that is, the overall good of society.

In the context of healthcare, when people are healthy and well they are able to pursue their own good and the good of their families and communities. Thus, the goal of healthcare services is to help patients achieve optimal functioning with respect to their own physiology. The best health that a person can achieve is the measure of success, in contrast to "perfect health." Healthcare services help a person maximize her or his own health, from the perspective of the person's own baseline. By helping patients (persons) achieve their own optimum levels of health and, therefore, optimum capability for meaningful activity, healthcare practitioners provide substantial utility to society. In this way, the beneficent activities of healthcare professionals contribute directly to increasing the happiness of patients and indirectly to increasing the happiness of society. The achievement of the good, whose nature has been proposed and investigated by the great philosophers from Plato and Aristotle through Hume and Kant, is accomplished in part via useful activities of healthcare professionals in fulfillment of the biomedical ethical principle of beneficence.

Nonmaleficence

The biomedical ethical principle of *nonmaleficence*, that is, the injunction not to do harm, is not merely the obverse of beneficence, the biomedical ethical injunction to help the patient. It is useful to recall that ethics overall, and biomedical ethics in particular, evaluates the following:

- Values relating to human conduct
- Rightness or wrongness of actions
- Goodness or badness of the motives and ends of such actions

These ethical considerations assist in the assessment of potential instances of violations of the biomedical ethical principle of nonmaleficence.

Persons as patients may be harmed in numerous ways. Per the declaration of Hippocrates "to help, or at least to do no harm,"[120] nonmaleficence implies that physical and physiological harm should not be incurred by the patient as a result of a medical procedure or treatment. Unnecessary procedures should not be performed. Also, the burdens of treatment, that is, side effects of medication, side effects of procedures, and reduced quality of life, should be avoided at best and minimized at worst. Nonmaleficence is relative in that harms accompany many medical treatments. For example, chemotherapy and radiation therapy, two predominant methods for treating cancer, involve substantial harms, including significant disturbances to the patient's gastrointestinal system and severe depression of the patient's immune system.

Lower limb amputation, possibly required in late-stage, uncontrolled diabetes, results in permanent disfigurement and impairment. Medications to control high blood pressure have a range of side effects, including swelling of the legs, dizziness, difficulty breathing, and sexual dysfunction (in men). Harms of medical treatment may be acceptable if they are assessed to be less significant than the benefit of that treatment. As an example, lower limb amputation in diabetes may be an acceptable cost of staying alive. Therefore, overall, nonmaleficence refers to avoidable harms and intentional harms.

Justice

The biomedical ethical principle of *justice* necessitates that all patients should be treated equally, regardless of race, ethnicity, age, socioeconomic status, or insurance status. Justice mandates equal access to healthcare, which implies that affordable care is available to all. Justice in the healthcare field is primarily focused on *distributive justice*, that is, appropriate use of resources and equity in distribution of scarce resources. Justice in healthcare also extends to participants in medical research and considers who ought to receive the benefits of such research and who ought to bear its burdens. For example, when pharmaceutical research is conducted in a developing nation such as Uganda or Mozambique, a primary concern involves standards of care.

Utilizing a local standard of care that does not conform to the standard of care in the sponsoring country (most often, the United States) "results in a double standard in research."[121] Justice would require that the highest standard of care, that is, the most stringent standard in a comparison between the two countries, should be applied to offshore medical research. Otherwise, those in the sponsoring country (with annual incomes much greater than the annual incomes of those in the country hosting the research, many of whom earn in the range of US$2 per day) would derive health benefits from research conducted on those with reduced protections from the harm of that research. Such an imbalance of benefits and harms contravenes the biomedical ethical principle of justice.

Additionally, per the *Belmont Report*, medical research "should not unduly involve persons from groups unlikely to be among the beneficiaries of subsequent applications of the research."[122] For example, medical research subjects are often comprised of homeless persons and others who are economically disadvantaged.[123] It is reasonable to assert that these research subjects would likely not be able to afford the pharmaceutical products developed on the basis of research enabled by their participation. Justice would require equitable distribution of such pharmaceuticals, including programs to underwrite the costs of providing medications to indigent populations.

The biomedical ethical principle of justice, specifically, distributive justice, requires societies to develop solutions to fair allocation of scarce healthcare resources. In the United States, as a heterogeneous society with common interests, we could locate the requirement for distributive justice in the Declaration of Independence. This foundational document stated that all men (all persons) are created equal and have unalienable rights including life, liberty, and the pursuit of happiness. Unalienable rights are those that cannot be denied or taken away. But one's right to pursue happiness and one's right to life, even one's right to liberty, are constrained by a lack of optimal health. A member of society who is not healthy is less able, possibly substantially

less able, to pursue her life plan (happiness) compared with one who enjoys peak health. One's right to life is necessarily curtailed by the morbidity and mortality associated with acute and chronic disease. A member of society does not have the right to be free of disease, of course, but the human rights enshrined in the Declaration of Independence entail equality of opportunity to address problems of ill health. The biomedical ethical requirement for distributive justice mandates implementation of laws and public policies to make healthcare services available to all.

Distributive justice in healthcare involves equality of access and equality of affordability. For example, many cancer drugs cost patients more than US$100,000 per year.[124] As such pharmaceuticals are only affordable by the wealthy, access to these medications is necessarily unequal across all segments of society. Often, the costs are paid by third parties such as private insurance companies and Medicare. But payments for highly priced services are passed on to all consumers in the form of increased insurance premiums and higher deductibles and out-of-pocket payments. Increasing costs of health insurance make it unaffordable to increasing numbers of individuals and families. Thus, highly priced medications (as examples of the high costs of many healthcare services) result in ever-increasing inequalities of access to healthcare.

Extending beyond the considerations of those participating in the delivery of healthcare services, the ongoing question to society as a whole in the arena of social justice involves the fair distribution of scarce resources to meet competing healthcare needs. We have a moral necessity to devise solutions to these problems, as healthcare "protects an individual's fair share of the normal range of opportunities (or plans of life) that reasonable people would choose in a given society."[125] Provision of all services to all people is not possible, as time, human capital, supplies, and financial support are limited. Therefore, a sufficiently fair method for distribution of a nation's healthcare resources is required. Two complementary solutions to achieving such equitable distribution involve universal access to appropriate healthcare and defining an acceptable minimum of healthcare services that would be available to all in the universal system.

Since the 1970s, the public health community has generally recognized that universal healthcare coverage is a fundamental goal.[126] Almost every nation in the developed world, including countries in Western Europe, Canada, Australia, New Zealand, Argentina, and South Korea, have implemented some form of universal healthcare.[127] (The United States is a notable exception to this list.) In 2005, the World Health Organization (WHO) formulated an integrated definition of universal healthcare. World Health Assembly Resolution 58.33 states that universal coverage "is defined as access to key promotive, preventive, curative and rehabilitative health interventions for all at an affordable cost, thereby achieving equity in access."[128] Thus, ideally, every person should have equal access to specific healthcare services.

Many attempts have been made to locate the requirement of equality of access to healthcare in a purported right to healthcare. But the existence of such a right is problematic. If person A has a right to X, that is, a good, service, or intangible construct such as liberty, then A is entitled to X. X is due to her or him. But valid rights claims, in this example a person's right to X, may be backed by coercion or sanctions.[129] In other words, the right to X may be supported by force of law. However, the right to healthcare, if such a right existed, would entail ongoing provision of healthcare services, unless the right was narrowed by definition of a specific set of services to which people would be entitled. The right to healthcare would be distinct from well-recognized rights such as the right to life, liberty, and the pursuit of happiness.

These latter rights are open-ended. There are no limitations on how much life or liberty a person may enjoy, except in cases in which a person's expression of life or liberty infringes on the life or liberty of another.

Utilitarianism, that is, the assessment of rightness or wrongness of actions based on the consequences of those actions, would probably not provide support for a right to healthcare. For example, it is not clear that the greatest good for the greatest number would be served by providing healthcare services to all. Many members of society who would receive those services may not contribute meaningfully to the welfare of society as a whole. From a utilitarian perspective, the greatest good might be served by providing healthcare services to a specific group or class of high-functioning persons. Although counterarguments might exist, it is reasonable to conclude that utilitarianism does not provide a secure foundation for a right to healthcare.

In contrast, duty-based ethics, derived from considerations of Kant's categorical imperative, might support a right to healthcare, in that we as a society could will that access to healthcare be universal. But, again, unlimited access to healthcare services is not possible under conditions of scarce resources, and we would therefore conclude that as access to healthcare for all would need to be constrained, such access is no longer categorical and can no longer be considered a right as such.

Further, the right to healthcare would be a new right, and it is notoriously difficult to identify sufficient justification for new rights. Recognizing the importance of not creating rights out of thin air, so to speak, the writers of the U.S. Constitution made the process of amending that founding document extremely arduous, requiring that a proposed amendment be ratified by three-quarters of the state legislatures. The U.S. Supreme Court has used the notion of *substantive due process* to expand the definition of rights and protect rights and freedoms not specifically identified in the Constitution. The right to privacy, established in the landmark decision *Griswold v. Connecticut,* is an example of a right derived from the First, Fourth, and Ninth Amendments. But the use of substantive due process to provide justification for new rights was and remains controversial.[130]

Summary

In terms of real-world applications, attention to the *social determinants of health* necessarily involves application of biomedical ethical principles. As discussed in Chapter 4, the social determinants of health include safe and affordable housing, access to education, availability of healthy foods, and availability of local emergency healthcare services.[131] WHO has stated that the healthcare system itself is a social determinant of health.[132] By directing more of society's resources toward achieving equity in healthcare accessibility and affordability, national governments and international governing bodies can utilize the biomedical ethical principles of autonomy (respect for persons), beneficence, and justice (distributive justice) to achieve improved health status and well-being across all socioeconomic sectors. Specific WHO recommendations include (1) placing health and health equity at the center of urban governance and planning; (2) building healthcare systems based on "principles of equity, disease prevention, and health promotion"; and (3) fairly allocating government resources "for action on the social determinants of health."[133]

BOX 2.1

Case Study: Unrepresented Patient at the End of Life

Mabel McKenzie, a seventy-four-year-old resident of a skilled nursing facility, was admitted to a local healthcare center with acute brain dysfunction (acute metabolic encephalopathy), diabetes mellitus type 2, and dehydration. Previously, McKenzie had suffered an acute cerebrovascular accident (stroke) with resultant functional quadriplegia. At present, she was not improving with medical treatment. Her neurological prognosis was poor in that she had severe cognitive impairment and she did not respond to verbal cues. Examinations by a hospitalist and a neurologist concurred that McKenzie had no capacity for medical decision making. Several attending physicians assessed that she had poor functional status, her prognosis was poor, and comfort care (easing troubling symptoms without escalating the current level of treatment) was appropriate. No advance directive was on file and McKenzie had no known relatives or close friends. A consultation with the hospital Biomedical Ethics Committee was requested as she was an unrepresented patient (a patient who lacks capacity for medical decision making and for whom no family members or close friends have been identified).[134]

Ethical Analysis

1. From the perspectives of the biomedical ethical principles of autonomy and beneficence, if McKenzie's preferences and desires regarding medical treatment are unknown, what courses of action might be recommended by the Biomedical Ethics Committee?
2. From the perspective of the biomedical ethical principle of justice, identify and discuss two public policy measures that would help to improve the health status of individuals such as McKenzie and possibly prevent clinical deterioration.
3. Regarding clinical management of this case and from the perspective of the biomedical ethical principle of nonmaleficence, compare and contrast comfort care versus interventional treatment such as surgery.

KEY TERMS

Social Determinants of Health

The social determinants of health (SDOH) are responsible for inequities in health, that is, the differences in health seen within and among individuals, families, communities, and countries. SDOH are the "circumstances in which people grow, live, work, and age."[135] SDOH include access to the basic material circumstances necessary for health such as general sanitary living conditions, clean water, adequate nutrition and housing, education, and local emergency/health services.[136]

DISCUSSION QUESTIONS

1. Per Van Rensselaer Potter, discuss how a broader conception of bioethics provides a "bridge to the future."[137] Discuss the components and characteristics of this "future" and the public policy measures that will be required to achieve such a future.
2. In *Fundamental Principles of the Metaphysic of Morals,* Kant stated, "Duty is the necessity of acting from respect for the law."[138] Discuss the obligations encompassed by Kant's conception of *duty* from the perspective of an individual member of society and from the perspective of a healthcare provider in relation to her patients. Discuss Kant's conception of the *law.* What is the source of the *law?* How are laws such as federal and state laws derived from the *law?*
3. Compare and contrast an ethical system based on evaluating the utility of one's actions (utilitarianism) versus an ethical system based on respect for persons (one's duty to others in consideration of their rational nature; deontology). Discuss common themes in both systems. Describe areas of disagreement between these systems. Describe a situation in which ethical analyses using these systems lead to conflicting conclusions and describe your method of achieving a meaningful resolution.

DO-IT-YOURSELF ETHICIST

1. You have been invited to give a guest lecture on healthcare ethics to an undergraduate class at a local college. Your primary theme is the interplay among the four biomedical ethical principles of autonomy, beneficence, nonmaleficence, and justice. In preparing your talk, describe how each principle may be derived from the others. Choose one of the principles, and discuss the potential impact on healthcare practice if that principle were consistently violated. Discuss how the four principles comprise a working unit and present a case study that features application of all of the principles.
2. As a healthcare professional, your regular activities include writing feature articles for national newspapers. One of your primary areas of interest is a more general application of the four principles of biomedical ethics. Write a 750-word op-ed article discussing how these four principles may be successfully applied to other areas of human endeavor, including political action. Discuss examples of legislation that would be consistent with the four principles of biomedical ethics and examples of contemporary legislation that fail to implement these principles.
3. As a recognized expert in the field of healthcare ethics, you have been invited to testify before the U.S. Senate Committee on Health, Education, Labor, and Pensions. The committee is considering new comprehensive healthcare legislation and has requested your input on the ethical basis of a right to healthcare. Prepare a brief set of remarks (750 words) supporting and denying support to the existence of such a right. Include a discussion of the mandate for distributive justice in a democratic society. How will your overall conclusions support construction of healthcare legislation that will benefit all socioeconomic groups and segments of the population?

REAL-WORLD APPLICATIONS—ETHICS AS A DOCTRINE OF ACTION

As part of your healthcare organization's annual Humanities Week activities, you have been invited to write and direct a short play on the contribution of philosophy to healthcare practice. Your theme is a timeless conference on healthcare ethics whose participants include Socrates, Aristotle, Hume, Kant, Bentham, and Mill. These great philosophers are panelists in a roundtable discussion of the state of healthcare in the early twenty-first century. Compose a short (seven to ten pages) play in which each great philosopher addresses the primary roundtable topic, interacts with his colleagues, and proposes remedies from his particular perspective for the deficiencies and shortcomings of modern healthcare delivery systems.

REFERENCES

[1]Thomas of Aquino, *Summa Theologica, First Part of the Second Part*, Question 55, Article 3, quoting Aristotle, *Nicomachean Ethics*, Book 2, chap. 6, trans. Fathers of the English Dominican Province (Cincinnati, OH: Benziger Bros., 1947).

[2]H.-M. Sass, "Fritz Jahr's 1927 Concept of Bioethics," *Kennedy Institute of Ethics Journal* 17, no. 4 (2008): 279–295.

[3]F. Jahr, "Bio-Ethik: Eine Umschau über die ethischen Beziehungen des Menschen zu Tier und Pflanze," *Kosmos: Handweiser für Naturfreunde* 24, no. 1 (1927): 2–4.

[4]Sass, "Fritz Jahr's 1927 Concept of Bioethics," 281.

[5]Ibid.

[6]D. Searls, ed., *The Journal of Henry David Thoreau, 1837–1861* (New York: New York Review of Books Classics, 2009).

[7]H. D. Thoreau, *Walden; or, Life in the Woods* (Boston: Ticknor and Fields, 1854).

[8]A. Leopold, *A Sand County Almanac* (New York, Ballantine Books, 1986).

[9]V. R. Potter, "Bioethics, the Science of Survival," *Perspectives in Biology and Medicine* 14, no. 1 (1970): 127–153.

[10]Ibid., 127.

[11]Ibid.

[12]Ibid., 128.

[13]Ibid., 152.

[14]"News from Georgetown University: Kennedy Foundation Gives $1,350,000 to Establish Institute for Bioethics at Georgetown University," Georgetown University, Washington, DC, October 2, 1971, https://repository.library.georgetown.edu/bitstream/handle/10822/761732/kennedy_foundation_kennedy_institute_of_ethics_press_release_1971.pdf.

[15]Ibid.

[16]W. T. Reich, "The Word 'Bioethics': Its Birth and the Legacies of Those Who Shaped It," *Kennedy Institute of Ethics Journal* 4, no. 4 (1994): 319–335.

[17]D. Callahan, "Bioethics as a Discipline," *Hastings Center Studies* 1, no. 1 (1973): 66–73.

[18]Reich, "The Word 'Bioethics,'" 330.

[19]D. Lemberg, "Bioethics as a Force for Change—Health Care Policy, Financial Systems, and Environmental Conservation," Albany Medical College, *BIOETHICS TODAY*, April 30, 2012, http://www.amc.edu/bioethicsblog/post.cfm/bioethics-as-a-force-for-change-health-care-policy-financial-systems-and-environmental-conservation.

[20]T. L. Beauchamp and J. F. Childress, *Principles of Biomedical Ethics*, 7th ed. (New York: Oxford University Press, 2012).

[21]F. Copleston, *A History of Philosophy*, vol. VI (New York: Doubleday, 1960), 181.

[22]Immanuel Kant, "Fundamental Principles of the Metaphysic of Morals," in *Kant's Critique of Practical Reason and Other Works on the Theory of Ethics*, ed. T. K. Abbott, 6th ed. (London: Longmans, Green, and Co., 1909), 7.

[23]Copleston, *A History of Philosophy*, vol. VI, 315.

[24]Kant, "Fundamental Principles of the Metaphysic of Morals," 16.

[25]Copleston, *A History of Philosophy*, vol. VI, 323.

[26]Kant, "Fundamental Principles of the Metaphysic of Morals,"32.

[27]Ibid., 38.

[28]Ibid., 39.

[29]Ibid., 40.

[30]Ibid., 41.

[31]T. Hobbes, *Leviathan*, part I, chap. 13, 1651 ed. (Oxford, UK: Clarendon Press, 1909).

[32]King James Version, *The Scofield Study Bible* (New York, Oxford University Press, 2003), 1342.

[33]*Babylonian Talmud*, Shabbat 31a.

[34]Kant, "Fundamental Principles," 47.

[35]Ibid.

[36]Ibid., 59.

[37]Immanuel Kant, "Critical Examination of Practical Reason," in *Kant's Critique of Practical Reason and Other Works on the Theory of Ethics*, ed. T. K. Abbott, 6th ed. (London: Longmans, Green, and Co., 1909), 122.

[38]W. H. S. Jones, trans., *Epidemics I*, vol. I, *Hippocrates* (Cambridge, MA, Harvard University Press, 1957), 165.

[39]Code of Ethics of the American Medical Association, adopted May 1847 (Philadelphia: Turner Hamilton, 1871).

[40]"The Nuremberg Code," in *Doctors of Infamy: The Story of the Nazi Medical Crimes*, eds. A. Mitscherlich and F. Mielke (New York: Schuman, 1949), xxiii–xxv. Also, the Nuremberg Code may be located online on the National Institutes of Health website, https://history.nih.gov/research/downloads/nuremberg.pdf.

[41]*The Belmont Report* (Washington, DC: Department of Health, Education, and Welfare, 1979), 4, https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/.

[42]T. L. Beauchamp and J. F. Childress, *Principles of Biomedical Ethics*, 7th ed. (New York: Oxford University Press, 2012).

[43]"The Nuremberg Code."

[44]M. D. Kirby, "Informed Consent: What Does It Mean?" *Journal of Medical Ethics* 9, no. 2 (1983): 69–75.

[45]42 C.F.R. 482.13(b)(2), https://www.gpo.gov/fdsys/pkg/CFR-2010-title42-vol5/pdf/CFR-2010-title42-vol5-sec482-13.pdf.

[46]Glossary, in *Comprehensive Accreditation Manual* (Oakbrook Terrace, IL: Joint Commission, 2016), https://www.jointcommission.org/assets/1/23/Quick_Safety_Issue_Twenty-One_February_2016.pdf.

[47]S. Jacobs, "Death by Voluntary Dehydration. What the Caregivers Say." *New England Journal of Medicine* 349, no. 4 (2003): 325–326.

[48]Immanuel Kant, *Critique of Practical Reason* (*Kritik der praktischen Vernunft*) (1788), 5:29.

[49]R. M. Veatch, *The Basics of Bioethics*, 3rd ed. (New York: Taylor & Francis, 2012), 57.

[50]*Report to Congressional Requesters. Prescription Drugs. FDA Oversight of Direct-to-Consumer Advertising Has Limitations* (Washington, DC: U.S. General Accounting Office, 2002), 2, http://www.gao.gov/new.items/d03177.pdf.

[51]K. Selfani, F. L. Soland, S. Chouinard, et al., "Movement Disorders Induced by the 'Atypical' Antipsychotic Aripiprazole," *Neurologist* 22, no. 1 (2017): 24–28.

[52]*Jackson v. City of Joliet*, 715 F. 2d 1200, *certiorari* denied, 465 U.S. 1049 (1984).

[53]D. P. Currie, "Positive and Negative Constitutional Rights," *University of Chicago Law Review* 53, no. 3 (1986): 864–890.

[54]O. O'Neill, *Autonomy and Trust in Bioethics* (New York: Cambridge University Press, 2002), 83.

[55]N. K. Smith, *Immanuel Kant's Critique of Pure Reason* (London: Macmillan, 1929), preface, 9.

[56]Ibid.

[57]Kant, "Fundamental Principles of the Metaphysic of Morals," 67.

[58]Kant, "Critical Examination of Practical Reason," 204.

[59]Ibid.

[60]Ibid., 206.

[61]Ibid.

[62]Ibid.

[63]Ibid., 206–207.

[64]Copleston, *A History of Philosophy*, vol. VI, 338.

[65]Kant, "Critical Examination of Practical Reason," 208.

[66]Ibid., 218.

[67]Ibid., 218–219.

[68]Ibid., 218.

[69]Copleston, *A History of Philosophy*, vol. VI, 338.

[70]Kant, "Critical Examination of Practical Reason," 221.

[71]Ibid.

[72]Ibid., 222.

[73]Ibid., 229.

[74]Kant, "Fundamental Principles of the Metaphysic of Morals," 39.

[75]W. E. Ross, *The Right and the Good* (New York: Oxford University Press, 1930/2002), 42.

[76]Ibid.

[77]John Stuart Mill, "Utilitarianism," in *The Works of John Stuart Mill*, vol. III (London: George Routledge & Sons, 1895), 94.

[78]L. A. Selby-Bigge, ed., *An Enquiry Concerning the Human Understanding, and an Enquiry Concerning the Principles of Morals by David Hume*, reprinted from the posthumous edition of 1777 (Oxford, Clarendon Press, 1894), 222.

[79]Ibid., 177.

[80]Ibid., 178.

[81]F. Copleston, *A History of Philosophy*, vol. VIII (New York Doubleday, 1966), 8.

[82]W. L. Davidson, *Political Thought in England. The Utilitarians from Bentham to J.S. Mill* (London: Williams and Norgate, 1915).

[83]F. C. Montague, ed., *A Fragment on Government by Jeremy Bentham* (Oxford, UK: Clarendon Press, 1891), 93.

[84]Ibid., 26–27.

[85]F. Hutcheson, *An Inquiry into the Original of Our Ideas of Beauty and Virtue*, 4th ed. (London: Midwinter, Bettesworth, Hitch et al., 1738), 210–211.

[86]Copleston, *A History of Philosophy*, vol. VIII, 4.

[87]Hume, *An Enquiry Concerning the Human Understanding, and an Enquiry Concerning the Principles of Morals*, 183.

[88]Copleston, *A History of Philosophy*, vol. VIII, 3.

[89]J. Bentham, *An Introduction to the Principles of Morals and Legislation*, reprint of "A New Edition, corrected by the Author," published in 1823 (Oxford, UK: Clarendon Press, 1907), 2.

[90]Ibid.

[91]Ibid., 1.

[92]Ibid.

[93]Ibid., 3.

[94]Ibid., 33.

[95]Ibid., 36.

[96]Mill, "Utilitarianism," 1.

[97]Ibid., 13

[98]Ibid.

[99]Ibid., 22

[100]Kant, "Fundamental Principles of the Metaphysic of Morals," 38.

[101]B. Jowett, *The Dialogues of Plato*, vol. IV, 3rd ed. (Oxford, UK, Clarendon Press, 1892), 582.

[102]Ibid., 644.

[103]Ibid., 645.

[104]Ibid., 649.

[105]Ibid., 650.

[106]F. Copleston, *A History of Philosophy*, vol. I (New York Doubleday, 1946), 219.

[107]Jowett, *Dialogues of Plato*, vol. I, 207.

[108]Ibid., 226.

[109]J. E. C. Welldon, trans., *The Nicomachean Ethics of Aristotle* (London: MacMillan and Co., 1920), 75.

[110]Ibid., 87.

[111]Ibid., 76.

[112]Ibid., 88.

[113]Ibid., 104.

[114]Hutcheson, *An Inquiry into the Original of Our Ideas*, 210.

[115]Ibid., 297.

[116]Hume, *An Enquiry Concerning the Human Understanding*, 222.

[117]Ibid., 224.

[118]Ibid., 226.

[119]Ibid., 265.

[120]Jones, *Epidemics I*.

[121]P. Lurie and S. M. Wolfe, "Unethical Trials of Interventions to Reduce Perinatal Transmission of the HIV Virus in Developing Countries," *New England Journal of Medicine* 337, no. 12 (1997): 853–855.

[122]*The Belmont Report*, 10.

[123]T. L. Beauchamp, B. Jennings, E. D. Kinney et al., "Pharmaceutical Research Involving the Homeless," *Journal of Medicine and Philosophy* 27, no. 5 (2002): 547–564.

[124]K. Thomas, "The Complex Math Behind Spiraling Prescription Drug Prices," *New York Times*, April 27, 2016.

[125]N. Daniels, "Justice, Health, and Health Care," in *Medicine and Social Justice*, eds. R. Rhodes M. P. Battin, and A. Silvers (New York: Oxford University Press, 2002), 7.

[126]G. Backman, P. Hunt, R. Khosla et al., "Health Systems and the Right to Health. An Assessment of 194 Countries," *The Lancet* 372, no. 9655 (2008): 2047–2085.

[127]D. Stuckler, A. B. Feigl, and S. Basu et al., *The Political Economy of Universal Health Coverage. First Symposium on Health Systems Research*, November 16–19, 2010, Montreux Switzerland, http://www.pacifichealthsummit.org/downloads/UHC/the%20political%20economy%20of%20uhc.PDF.

[128]World Health Organization (WHO). Sustainable Health Financing, Universal Coverage and Social Health Insurance. World Health

Assembly Resolution 58.33 (2005), http://www.who.int/health_financing/documents/cov-wharesolution5833/en/.

[129]A. E. Buchanan, "The Right to a Decent Minimum of Health Care," *Philosophy and Public Affairs* 13, no. 1 (1984): 55–78.

[130]D. O. Conkle, "Three Theories of Substantive Due Process," *North Carolina Law Review* 85, no. 1 (2006): 63, http://www.repository.law.indiana.edu/cgi/viewcontent.cgi?article=1166&context=facpub.

[131]Health People 2020, Social Determinants of Health, https://www.healthypeople.gov/2020/topics-objectives/topic/social-determinants-of-health.

[132]World Health Organization Commission on the Social Determinants of Health, *Closing the Gap in a Generation. Health Equity Through Action on the Social Determinants of Health* (WHO: Geneva, Switzerland, 2008), 8, http://apps.who.int/iris/bitstream/10665/43943/1/9789241563703_eng.pdf.

[133]Ibid., 202–204.

[134]T. M. Pope, "Making Medical Decisions for Patients without Surrogates," *New England Journal of Medicine* 369 (2013): 1976–1978.

[135]WHO Commission on the Social Determinants of Health, *Closing the Gap in a Generation*, iii.

[136]Health People 2020, Social Determinants of Health, https://www.healthypeople.gov/2020/topics-objectives/topic/social-determinants-of-health

[137]Potter, "Bioethics, the Science of Survival," 128.

[138]Kant, "Fundamental Principles of the Metaphysic of Morals," 16.

Figure Credits

Fig. 2.1: Source: https://commons.wikimedia.org/wiki/File:Sanzio_01_Plato_Aristotle.jpg

CHAPTER 3

The Four Principles of Biomedical Ethics

AUTONOMY AND NONMALEFICENCE

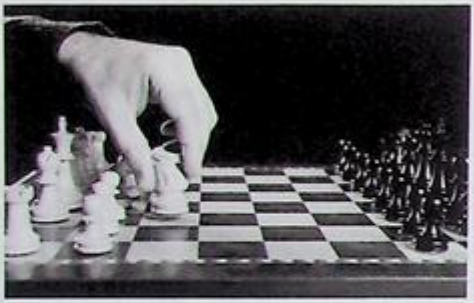
As described in Chapters 1 and 2, revelations regarding the failure of medical researchers to adequately protect their human subjects from harm, or worse, led in the United States, in 1974, to legislation establishing the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. In turn, the commission's primary deliverable, the *Belmont Report*, was submitted to President Jimmy Carter on September 30, 1978. The report identified three basic ethical principles that would guide the conduct of such research: respect for persons, beneficence, and justice. Contemporaneously, the textbook *Principles of Biomedical Ethics*,[1] published in 1979, highlighted four moral principles that were central to biomedical practice and the relationship between the healthcare professional and the patient: respect for autonomy, nonmaleficence, beneficence, and justice. Regardless of particular naming conventions and the order of discussion, these four principles of biomedical ethics provide the foundation for healthcare ethical practice.

AUTONOMY

The biomedical ethical principle of *autonomy* represents respect for persons. As discussed in Chapter 2, respect for a person implies respect for that person's intrinsic capacity for making her own decisions. Such respect is demonstrated by not attempting to coerce, influence unduly, or undermine the person's decision-making process. Respect for persons is respect for that person's ability to choose freely as an independent member of a family, community, or society.

In terms of medical practice, autonomy inheres in a person's right to agree or disagree with the implementation of a recommended test, procedure, or course of treatment. Autonomy, in essence, implies the person's right to direct the process of his own medical care. Autonomy does not mandate that a person's requests must be fulfilled, but that the person has the right to choose freely. The principle of autonomy as manifested in medical practice continues to evolve and includes

FIGURE 3.1 Autonomy as self-determination



informed consent, the right to refuse treatment, the ability to state one's preferences regarding end-of-life circumstances in an advance directive, identifying a surrogate decision maker to implement those preferences, and establishing do-not-resuscitate (DNR) orders.

In biomedical ethics, respect for persons refers to a person's capability for rational thought and self-determination. The patient's implied right to make an informed choice regarding treatment relates to the choice to accept or reject proposed treatment. Also, respect for persons implies that patients have the right to enumerate in advance treatments they do not want performed, in the case in which they are no longer capable of stating their wishes and preferences. But the biomedical ethical principle of autonomy does not mandate that specific requests for treatment be fulfilled. Such requests may be construed as self-determined, but they represent instances of what may be termed *individual autonomy*.[2] These choices (in these instances, the patient's wants), do not require fulfillment by the family physician or the hospital medical team. Obtaining medical services is not identical to obtaining a new automobile or a new pair of shoes. Healthcare providers have a professional obligation to uphold the *best interests standard*,[3] that is, to only provide those services that will be of benefit to the patient. If a patient's or family's request for services is deemed to be not in the patient's best interest, then there is no obligation to provide those services.

Importantly, the biomedical ethical principle of autonomy points to the need for a physician–patient *partnership*, a relationship in which each party honors and respects the contributions of the other. In such a partnership, as opposed to a paternalistic interaction, the physician (or other healthcare provider) demonstrates respect by engaging the patient in an exploration of the clinical circumstances and available treatment options. Rather than proceeding on a paternalistic path and telling the patient how things are going to go and what needs to be done, the physician addresses the patient's concerns, discusses the risks and benefits of proposed treatment, and provides sufficient information for the patient to make an informed choice.

Although such a physician–patient partnership is not truly one of equals, in that the physician or healthcare provider has extensive knowledge, is an expert in her specialty, and holds a position of accepted authority, the relationship is appropriately understood as one of *equality*, with each party contributing to the decision-making process. It is the physician's responsibility to involve and authentically interact with the patient, offering guidance and assistance. In the end, the patient's well-considered choice should prevail. Ultimately, individuals "must be allowed to decide their own destiny,"[4] in terms of accepting or rejecting proposed treatment.

Early History of Informed Consent

Informed consent is a direct manifestation of a person's right of self-determination and describes the process by which a patient agrees to implementation of proposed treatment. Informed consent must be freely given and fully informed, based on the provision of sufficient information to support a reasoned choice. For example, a patient is not fully informed if the physician does not provide all relevant information or does not explain the procedure or treatment adequately. A patient is not fully informed if the risks have not been explained sufficiently or if there has been any element of inducement or coercion. Also, it is not possible to obtain informed consent in cases in which the patient does not have capacity, that is, does not have the cognitive capability to formulate a decision.

The process of obtaining informed consent is a relatively new transaction in the physician-patient relationship. As discussed in Chapter 1, a doctrine of informed consent with respect to participation in medical research was first delineated and mandated in the Nuremberg Code in 1947.[5] The Nuremberg Code was formulated in the aftermath of World War II and written in response to the revelations of crimes against humanity disclosed in the Nuremberg Doctors Trial. The defendants were accused of torture and murder in the conduct of medical experiments on prisoners in the Nazi concentration camps. The facts made known at the trial necessitated the development of a code that would establish principles upon which to base all medical research and therefore protect human rights.[6] As the Nuremberg Doctors Trial proceeded, it became clear to the judges that a requirement for voluntary consent of human research subjects was paramount. Thus, as discussed in Chapter 1, the first principle of the Nuremberg Code declared that the voluntary consent of the human subject is absolutely essential.[7]

This strong and stringent requirement for voluntary consent was enshrined in the Nuremberg Code to protect human subjects participating in medical research. But persons as patients seeking medical treatment were not protected by a similar requirement. The informed consent of patients to the recommendations of their physicians had never been considered until the mid-twentieth century, approximately a decade after the promulgation of the Nuremberg Code. To the contrary, over the course of approximately 2,400 years of recorded medical practice, the primary mode of physician–patient interaction was one in which the physician's assessment of what was best for the patient dictated the course of action. This paternalistic framework may be considered to derive from the Hippocratic Oath, by which the swearer asserts, "I will use treatment to help the sick according to my ability and judgment, but never with a view to injury and wrong-doing."[8] In another translation, the Hippocratic Oath states, "I will follow that system of regimen which, according to my ability and judgment, I consider for the benefit of my patients, and abstain from whatever is deleterious and mischievous."[9] Thus, historically, the patient herself had not been included in the medical decision-making process, beyond the legal requirement of consenting to the treatment proposed (in other words, permitting treatment to proceed). Her desires and preferences and her perspective on how the proposed treatment would contribute to her quality of life had never been a consideration. Importantly, the benefits and risks of the proposed treatment were evaluated only by the physician, whose analysis was then presented to the patient in the form of a statement of what was going to be done. Patients themselves did not have an opportunity to formulate their own assessments of the risks and benefits and apply that understanding to their own circumstances. A patient's consent or authorization to proceed with recommended treatment merely represented assent to the recommendation and would not have

been based on specific information provided to assist in decision making. Historically, consent to treatment was not *informed* consent.

In the United States, cases involving questions of consent to treatment initially focused on "simple" consent. Legally, simple consent protects patients against the imposition of unwanted medical interventions, which could be determined to constitute assault and battery. An *assault* is an act that causes a person to anticipate an immediate harmful or offensive contact. The act of assault causes the apprehension in the victim of imminent harm. The defendant in a civil action is subject to liability for *simple battery* when he intentionally touches the body of the plaintiff (intentionally causes bodily contact) in a way not authorized by the plaintiff or justified by her apparent wishes, and the contact is either harmful or against the plaintiff's will.[10] For example, in *Marchbanks v. Borum,*[11] the Court of Appeals of the state of Mississippi declared, "One commits a battery by the very touching of another person without his consent." In *Mims v. Boland,* the Court of Appeals of Georgia stated, "A physician who undertakes to treat another without express or implied consent of the patient is guilty of at least a technical battery." [12]

In *Mohr v. Williams,*[13] an early case (1905) focusing on patient consent to treatment, the plaintiff had agreed to undergo surgery on her right ear. But while the patient was anesthetized and unconscious, the defendant, a specialist in ear disorders, found the left ear to be in more serious condition and operated instead on the left ear. The plaintiff claimed the surgery had seriously impaired her sense of hearing and brought an action to recover damages. In *Mohr,* the Supreme Court of Minnesota stated the defendant could have explained to the plaintiff the risks, dangers, and probable advantages of the operation and "given her the opportunity to be the final arbiter as to whether or not she would take her chances with the operation, or living without it."[14] The *Mohr* opinion quoted a contemporary torts treatise:

> Such is the natural right of the individual, which the law recognizes as a legal right. Consent, therefore, of an individual, must be either expressly or impliedly given before a surgeon may have the right to operate.[15]

Mohr noted that in all other trades and professions "contracts are entered into by the mutual agreement of the interested parties."[16] The same rule should be applied to interactions between physicians and patients. The patient should be able to weigh the dangers and risks and consent to medical treatment, if she chooses, thereby entering into a contract authorizing the physician to proceed.

Mohr noted that surgery by a physician upon the body of a patient "is wrongful and unlawful where performed without the express or implied consent of the patient."[17] The *Mohr* court quoted the opinion in *Pratt v. Davis,*[18] noting the following:

> The free citizen's first and greatest right, which underlies all others—the right to the inviolability of his person; in other words the right to himself—is the subject of universal acquiescence, and this right necessarily forbids a physician or surgeon ... to violate, without permission, the bodily integrity of his patient ... and operating upon him without his consent or knowledge.[19]

Overall, in 1905, *Mohr v. Williams* identified consent to treatment as a component of the right of self-determination. Per *Mohr,* the elements of consent include due deliberation, that is, the opportunity to consider the risks and benefits and apply that understanding to one's own situation. As the patient and physician effectively enter into a contract, their relationship is

necessarily one of equal participants. An operation performed without the patient's consent is wrongful and unlawful. Thus, *Mohr v. Williams* helped establish the precedents supporting the legal decisions of the later twentieth century regarding informed consent.

The consequences of medical paternalism were considered further in 1914, in the landmark case of *Schloendorff v. Society of New York Hospital.*[20] *Schloendorff* concerned a plaintiff who had been admitted to a hospital complaining of effects of an unknown stomach disorder. The plaintiff testified that she consented to an examination under anesthesia to determine the nature of a lump in her abdomen, but she would not permit surgery. However, under anesthesia, a mass was removed that was later determined to be a fibroid tumor. Subsequently, gangrene developed in the plaintiff's left arm and "some of her fingers had to be amputated."[21] The plaintiff asserted that removal of the tumor was done without her consent or knowledge. Her statement was contradicted by the house physician, visiting surgeon, and several attendant nurses. In his discussion of the ramifications of the case, Justice Benjamin Cardozo wrote the following:

> Every human being of adult years and sound mind has the right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault, for which he is liable in damages. This is true except in cases of emergency where the patient is unconscious and where it is necessary to operate before consent can be obtained.[22]

Schloendorff and Justice Cardozo's forthright phraseology have been cited extensively since the decision was rendered. *Schloendorff* categorically affirmed every person's right of self-determination and applied that right to the circumstances of patients considering medical treatment. Patient consent is required prior to administration of any treatment and medical decision making, ultimately, represents the choice of the patient. As a sidebar, from the perspective of tort law, a physician who performs treatment without having obtained patient consent commits an assault. Thus, the biomedical ethical principle of autonomy is based firmly on *Schloendorff.* In the context of medical treatment, manifesting the principle of autonomy and the right of self-determination would be enhanced by the patient's review of information provided by the physician regarding proposed treatment. But legal requirements for physicians to disclose details concerning treatment, that is, a duty to disclose, did not emerge until the 1950s.

In 1957, in *Salgo v. Leland Stanford Jr. University Board of Trustees et al.,*[23] the plaintiff had been experiencing low back pain with cramping in his legs upon walking. His physician diagnosed a probable occlusion of the abdominal aorta and the plaintiff was advised he had a serious circulatory disturbance. The plaintiff underwent aortography (injection of contrast material into the aorta, followed by radiographic imaging), but testified he had not been informed that aortography was to be performed. The physicians in the case contradicted that assertion, but admitted that the details of the procedure and the possible risks had not been explained to the patient. In the event, when the plaintiff awoke the morning after the procedure he discovered that his lower legs were paralyzed. The condition was permanent. He brought a malpractice action to recover damages.

In *Salgo,* the Court of Appeals of California held that a physician's duty to disclose information included "any facts which are necessary to form the basis of an intelligent consent by the patient to the proposed treatment."[24] Further, "the physician may not minimize the known dangers of a procedure or operation in order to induce his patient's consent."[25] The *Salgo* court emphasized "full disclosure of facts necessary to an informed consent."[26] These holdings represented the

introduction of new elements into the law.[27] A patient's mere consent to treatment was no longer sufficient. Consent needed to be based on the presentation of facts relevant to the proposed treatment, potentially including benefits, risks, consequences, and alternatives. In other words, consent needed to be *informed*.

It may be reasonably concluded from the *Salgo* opinion that uninformed consent is not true consent. But the *Salgo* court was also concerned that a physician might provide too much information regarding risks and alarm a patient, causing the patient to refuse to undergo treatment that actually posed minimal risk. Risk to the patient might even be increased owing to the physiological results of apprehension caused by physician disclosures. Further, the *Salgo* court stated that physicians must employ discretion in discussing elements of risk, based on a patient's mental and emotional condition, although such discretion must be consistent with the requirement for informed consent. By stating "in discussing the element of risk a certain amount of discretion must be employed,"[28] the *Salgo* court inadvertently perpetuated a practice of paternalism. A determination of how much information to disclose would be based on the physician's assessment of the patient's mental and emotional status, rather than on the patient's declaration of the kinds of information she wished to receive.

In 1960, the decision in *Natanson v. Kline*[29] extended the *Salgo* discussion regarding the physician's duty to disclose. The plaintiff had brought a malpractice action to recover for injuries resulting from radiation therapy with radioactive cobalt. Her "entire chest, skin, cartilage and bone were completely destroyed in those areas"[30] that had undergone radiation therapy. In *Natanson*, the Supreme Court of Kansas noted that "Anglo-American law starts with the premise of thorough-going self determination."[31] As such, a patient may, if she is of sound mind, "expressly prohibit the performance of life-saving surgery, or other medical treatment."[32] A physician may believe that treatment is necessary, but she may not substitute her own judgment for that of the patient "by any form of artifice or deception."[33] But, as in *Salgo*, the *Natanson* court noted that a physician's obligation to disclose information regarding treatment "is limited to those disclosures which a reasonable medical practitioner would make under the same or similar circumstances."[34] A physician would utilize medical judgment in determining how best to fulfill her obligation to her patient. *Natanson* required disclosure "sufficient to assure an informed consent" and indicated physician choices would be appropriate if the physician "was motivated only by the patient's best therapeutic interests and he proceeded as competent medical men would have done in a similar situation."[35] Although emphasizing patient rights and the importance of informed consent, *Natanson* relied on medical standards of practice and physician judgment to determine the content of physician disclosure. The *Natanson* court did not consider that patient preferences and requirements regarding disclosure of information were necessary to make an informed choice.

Importantly, regarding the evolution of legal doctrine on informed consent, *Natanson* may be considered to have shifted the ground of liability in consent cases from battery to negligence. The plaintiff had sought damages for injuries resulting from alleged acts of negligence, including failure to warn her that treatment "involved great risk of bodily injury or death."[36] *Natanson* noted that negligence may be defined as a "violation of the duty to use due and proper care."[37] The *Natanson* court stated the following:

> The fundamental distinction between assault and battery on the one hand, and negligence such as would constitute malpractice, on the other, is that the former is intentional and the latter unintentional.[38]

In *Natanson,* the patient consented to treatment but alleged "the nature and consequences of the risks of the treatment were not properly explained to her."[39] Thus, the question before the court was "whether the physician has obtained the informed consent of the patient to render the treatment administered."[40] In considering the nature and content of an appropriate informed consent conversation between patient and physician, the *Natanson* court asked the following:

> What is the extent of a physician's duty to confide in his patient where the physician suggests or recommends a particular method of treatment? What duty is there upon him to explain the nature and probable consequences of that treatment to the patient? To what extent should he disclose the existence and nature of the risks inherent in the treatment?[41]

As noted above, *Natanson* indicated that the responses to these inquiries would be based, in a specific case, on the disclosures a reasonable medical practitioner would make. *Natanson* discussed imposing liability for malpractice "if the treatment were administered without such explanation where explanation could reasonably be made" and stated that obligating such disclosures and explanations to a patient by a physician would not present "any insurmountable obstacles."[42] Thus, per *Natanson,* failure to obtain adequate informed consent could be grounds for a liability action based on negligence.

In an opinion denying a rehearing, the Supreme Court of Kansas noted that a physician has a legal obligation to make a reasonable disclosure to her patient regarding the risks and hazards of proposed treatment.[43] The *Natanson* court noted that "negligence is an essential element of malpractice" and "a causal relation must be established by the patient, between the negligent act of the physician and the injury of the patient."[44] Overall, the *Natanson* court opined that the evidence was sufficient and would authorize a jury to infer that had the plaintiff been properly informed, she would not have undergone the cobalt irradiation treatments.[45]

Salgo and many other cases involving patient consent to treatment and allegations of assault and battery, and cases such as *Natanson* and others involving negligence, relied on a *medical standard of disclosure,* which itself is an implementation of the *medical standard of care.* The medical standard of care is the specific procedure or medical conduct, that is, the custom or practice, that a relevant medical community considered to be acceptable at the time of an alleged battery or negligence.[46] But medical standards are fluid in that they may vary with the locality as well as the particular medical specialty. Further, there are "virtually thousands of standards of care pertaining to health care services in the United States today."[47] Regarding the medical standard of disclosure, if custom requires no disclosure, then a physician has no duty to reveal information to a patient, no matter how critical that information might be. For example, in 1980, in *Wooley v. Henderson,* the Supreme Judicial Court of Maine stated that "the scope of a physician's duty to disclose is measured by those communications a reasonable medical practitioner in that branch of medicine would make under the same or similar circumstances."[48] Even later, in 2004, in *Hamilton v. Bares,* the Supreme Court of Nebraska held that "Informed consent shall mean consent to a procedure based on information which would ordinarily be provided to the patient under like circumstances by health care providers engaged in a similar practice in the locality or in similar localities."[49] Thus, the medical standard of disclosure only minimally addressed the patient's right of self-determination. Patient consent to treatment was necessary, but it was the physician's prerogative to determine the content of information presented to the patient to obtain consent.

The medical standard of disclosure was rejected by the District of Columbia Court of Appeals in *Canterbury v. Spence* in 1972.[50] In *Canterbury*, the plaintiff had been evaluated by a neurosurgeon owing to a complaint of severe pain between the shoulder blades. The plaintiff underwent a myelogram (injection of radiographic contrast material into the spinal canal) that revealed a filling defect (indicating a yet-to-be identified space-occupying lesion) at the level of the fourth thoracic vertebra. The plaintiff, nineteen years old at the time, was told a laminectomy (removal of the posterior arch of the vertebra) was necessary. The plaintiff's mother was phoned and she asked the surgeon if the recommended surgery was serious. He replied, "not any more than any other operation."[51] The plaintiff's mother expressed her consent to the surgery. After the operation, the plaintiff noticed he could not move his legs and was having trouble breathing. He underwent a second surgery that restored some control of his leg muscles. But problems persisted and the plaintiff filed suit in 1963 alleging, among other things, failure of the surgeon to inform him of the risks involved.

In *Canterbury*, the District of Columbia Court of Appeals found that testimony by the plaintiff and his mother that the surgeon "did not reveal the risk of paralysis from the laminectomy made out a prima facie case of violation of the physician's duty to disclose."[52] Importantly, during the trial the surgeon had testified that paralysis may be anticipated "somewhere in the nature of one percent" of the laminectomies performed and termed this risk "a very slight possibility."[53] The surgeon stated that communicating that risk to the patient was not good medical practice as "it might deter patients from undergoing needed surgery and might produce adverse psychological reactions which could preclude the success of the operation."[54] The *Canterbury* court vigorously rebutted this assertion.

Canterbury noted that similar suits charging failure of a physician to disclose adequately the risks and alternatives of proposed treatment have been adjudicated over the past fifty years. But there has been disagreement among the courts regarding interpretation of such requirements and their adequate application. *Canterbury* referenced *Schloendorff* and stated, "True consent to what happens to one's self is the informed exercise of a choice, and that entails an opportunity to evaluate knowledgeably the options available and the risks attendant upon each."[55] In effect, the *Canterbury* court was specifically emphasizing the requirement that consent represents an *informed* choice. Such informed consent must be based on receipt of sufficient information so that a patient is able to think through, assess, and compare and contrast the risks, benefits, and other characteristics of proposed treatment to those of alternatives, as well as to the potential outcomes of no treatment. As *Canterbury* stated, "The physician is under an obligation to communicate specific information to the patient when the exigencies of reasonable care call for it. ... Just as plainly, due care normally demands that the physician warn the patient of any risks to his well-being which contemplated therapy may involve."[56]

Thus, the surgeon in *Canterbury* had not fulfilled his duty to disclose the approximate 1 percent risk of paralysis after laminectomy. The surgeon's assessment of the relevance of the risk or the potential harms to his patient that might have ensued upon disclosure of that risk were not appropriate considerations. The *Canterbury* court opined the following:

> It is the prerogative of the patient, not the physician, to determine for himself the direction in which his interests seem to lie. To enable the patient to chart his course understandably, some familiarity with the therapeutic alternatives and their hazards becomes essential. A reasonable revelation in these respects is not only a necessity

> but, as we see it, is as much a matter of the physician's duty. ... It is, too, a duty to impart information which the patient has every right to expect.[57]

The *Canterbury* court highlighted and clearly described the consequences and ramifications of the "change in doctrinal emphasis"[58] that its opinion mandated. Regarding the duty to disclose, *Canterbury* stated "The majority of courts dealing with the problem have made the duty depend on whether it was the custom of physicians practicing in the community to make the particular disclosure to the patient."[59] Thus, prior to *Canterbury,* the medical standard of disclosure was the basis for deciding suits alleging failure to obtain consent and attendant battery. (As *Canterbury* noted, "It is the settled rule that therapy not authorized by the patient may amount to a tort—a common law battery—by the physician."[60]) However, the *Canterbury* court firmly disputed the appropriateness of the medical standard:

> To bind the disclosure obligation to medical usage is to arrogate the decision on revelation to the physician alone. Respect for the patient's right of self-determination on particular therapy demands a standard set by law for physicians rather than one which physicians may or may not impose upon themselves.[61]

Patients have the right to determine for themselves whether proposed treatments are appropriate and fulfillment of that right required a legal standard, as against standards set by medical communities that varied by locale or might even be subject to opinion.

Regarding the scope of disclosure the physician is legally obliged to make, *Canterbury* stated "the patient's right of self-decision shapes the boundaries of the duty to reveal."[62] The patient requires sufficient information to make an intelligent choice, that is, information material to the decision, and "the law must itself set the standard for adequate disclosure."[63] The topics requiring communication of information, that is, those topics material to a patient's decision-making process, are "the inherent and potential hazards of the proposed treatment, the alternatives to that treatment, if any, and the results likely if the patient remains untreated."[64] Thus, the *Canterbury* court outlined precisely the requirements for disclosure of information material to informed consent of a patient. But a physician cannot be reasonably required to disclose and discuss *all* the details of treatment, *all* of the possible risks, and *all* of the potential alternatives. Rather, the scope of the standard of disclosure "remains objective with due regard for the patient's informational needs and with suitable leeway for the physician's situation."[65] Information regarding risk is thus material when a *reasonable person* "would be likely to attach significance to the risk or cluster of risks in deciding whether or not to forego the proposed therapy."[66]

A potential disability may dramatically outweigh the potential benefit of therapy and a very small risk of death or other serious consequences may be significant to a reasonable person. The *Canterbury* court emphasized, "There is no bright line separating the significant from the insignificant; the answer in any case must abide a rule of reason."[67] Two exceptions to the duty to disclose involve circumstances in which (1) the patient is unconscious or otherwise incapable of consenting and harm from a failure to treat outweighs any possible harms of treatment or (2) when disclosure of risk poses so substantial a threat to the well-being of the patient, that is, the knowledge itself would harm the patient, that such disclosure is contraindicated. Regarding the latter circumstance, per *Canterbury,* "disclosure to a close relative with a view to securing consent to the proposed treatment may be the only alternative open to the physician."[68] Also, regarding the second exception, if legal action were to result from allegations of a physician's

failure to disclose material information, the materiality of that information and the risk of disclosure would be questions for a jury. In the issues determined by *Canterbury,* the court stated it became the jury's responsibility "to decide whether that peril [of paralysis] was of sufficient magnitude to bring the disclosure duty into play."[69] In the event, there was no emergency to interfere with disclosure of information and there was no evidence that the plaintiff's emotional condition was such as to justify concealing the risk of paralysis. The jury, not the defendant, was "the final arbiter of whether nondisclosure was reasonable under the circumstances."[70]

Effectively, *Canterbury* replaced the medical standard of disclosure with the reasonable person standard. *Canterbury* explicitly rejected prior case law that had measured the scope of disclosure in terms of "good medical practice"[71] or professional standards, that is, medical custom in the community.[72] *Canterbury* noted that, "Any definition of scope in terms purely of a professional standard is at odds with the patient's prerogative to decide on projected therapy himself."[73] The D.C. Circuit Court established that information provided to a patient should include a discussion of the risks of the proposed treatment, available alternatives, and likely outcomes if the patient chose not to proceed with treatment. In 1972, twenty-five years after the Nuremberg Code declarations, *Canterbury v. Spence* extended the requirement for informed consent to medical practice as a whole.

Numerous subsequent cases have supported the reasonable person standard or the *materiality standard of disclosure.* For example, in 1998, in *Sgro v. Ross,* the Superior Court of New Jersey referenced the trial court's instructions to the jury that medical information or risk of a medical procedure is material when a reasonable patient "would be likely to attach significance to it in deciding whether or not to submit to the treatment."[74] In 2007, in *Acuna v. Turkish,*[75] the Supreme Court of New Jersey held that physicians have a duty to explain all material medical information and risks of a procedure. The *Acuna* court stated the following:

> It is now settled that a physician has a legal duty to disclose to the patient all medical information that a reasonably prudent patient would find material before deciding whether to undergo a medical procedure. ... The standard focuses on what a reasonable patient needs to know—that is, what a reasonable patient would likely find significant given the risks—to make an informed decision in foregoing or assenting to a medical procedure. ... Generally, the physician is required to inform the patient of the available medical options, the risks associated with those options, and the nature of the intended procedure.[76]

In 2012, in *Felton v. Lovett,*[77] the Supreme Court of Texas stated that "A reasonable health care provider must disclose the risks that would influence a reasonable patient in deciding whether to undergo treatment." However, overall, courts are divided between applying medical versus reasonable person standards of disclosure. A little more than half the states appear to adopt a medical standard of disclosure as opposed to a reasonable person or materiality standard.[78] Many states are under command of a statute in this regard.

Subsequent to *Canterbury,* decisions such as *Gates v. Jensen,*[79] in 1979, supplemented or restated the legal doctrine of informed consent. In *Gates,* the Supreme Court of Washington declared that

> the patient has a right to know the material facts concerning the condition of his or her body, and any risks presented by that condition, so that an informed choice may be made regarding the course which the patient's medical care will take.[80]

Thus, a patient's right to be sufficiently informed regarding proposed medical treatment has been established in case law since the early 1970s. Later formulations of biomedical ethical principles located the right to informed consent in the principle of autonomy, that is, respect for the patient's capability for self-determination.

It has, however, been very difficult to fulfill the ideal of informed consent.[81] The model of a detailed physician–patient interaction in which potential benefits, potential harms, alternatives, and consequences of inaction are discussed sufficiently to enable the patient to freely choose or reject proposed treatment is rarely accomplished in practice. Rather, obtaining informed consent may be considered to have devolved, in many circumstances, to a mechanism in which a patient is presented with a document by a physician's assistant or even the office manager, instructed to read the papers in front of her, asked if she has any questions, and requested to sign the consent form so that treatment may proceed. Such a ritual fails, by any reasonable measure, to fulfill the spirit and intent of requirements for informed consent.

It may be, in fact, that informed consent can never be fully achieved in a medical, or more generally, a healthcare context. It is not possible to disclose all the details of a procedure. For example, if surgery is contemplated, a recitation of the major and minor stages could last for a quarter of an hour or more. A discussion of potential risks is constrained by the uncertainties of the consequences of any intervention in the functioning of a complex system such as the human body. Similarly, it is not reasonable to present all the alternatives to proposed treatment. No healthcare provider is likely to have such a long list readily at hand. Thus, institutionalized endeavors to present a comprehensive account of proposed treatment, which also serves to attempt to minimize the legal risks of the healthcare organization itself, result in all-too-lengthy informed consent documents, which are difficult to comprehend by a nonprofessional layperson at the best of times. Even professional persons, when they themselves are patients, may find it difficult to sufficiently understand the documents they are blithely requested to sign.

It is likely that most people, no matter how intelligent, well-read, and knowledgeable, find themselves, when in the role of a patient, somewhat or substantially bereft of the ability to think clearly, with significant loss of the ability to follow a complex chain of reasoning. Facts that only an hour ago had been readily accessible are now lost in a mental fog. Owing to one's illness, which has been sufficiently concerning to cause one to spend time and money to seek professional advice, the primary goal is to identify a solution to the problem. The possibility of treatment and relief is foremost. If the physician or other healthcare provider seems worthy of trust, then her recommendations are readily agreed to. The patient's need to be restored to good health predominates and his self-determining capability becomes submerged in this quest.

These considerations do not imply that informed consent has been proved to be irrelevant, or that achieving meaningful informed consent is impractical or unattainable in the real world of illness, disease, injury, and other healthcare problems. Rather, the vulnerability of people as patients compels our affirmation of respect for persons. Vulnerable persons require especial concern and consideration. In the context of informed consent, such respect is manifested by

honoring the patient's trust. By establishing that the patient has "control over the amount of information they choose to receive, by offering easy access to specific information,"[82] the patient's trust will be reinforced. Further, it should be clearly established that the patient's consent is revocable at any time. A patient who is secure in the belief that he is not being deceived in any way and who knows he is free to change his mind, that is, to rescind his consent, will likely have the experience that his consent was fully informed and freely given.

Numerous studies have demonstrated that physicians rarely fulfill even minimal standards of disclosure during the process of obtaining a patient's informed consent.[83] The piling on of details of the intended treatment and lengthy enumerations of potential harms, beyond those most probable and concerning, do not authentically assist a patient in making a self-determined choice. What is required is fulfilling the principle of the patient's right to choose and providing information that the patient deems *sufficient* for her to make a considered choice. Such a process takes a certain amount of time, but this duration may be optimized by clear communication on the part of the healthcare provider. A commitment to the concept of a partnership with the patient will cause the physician to provide sufficient information to facilitate that patient's choice. Certain patients may request more details than others. But if the patient has the experience that the physician is willing to provide additional information and that the process is not being rushed, then the patient is likely to feel that he or she has been respected as an individual and her or his right to choose has been fulfilled. In such demonstrations of partnership and trust, the actual time needed to satisfy the requirement for informed consent is minimized. Such a process appropriately matches the needs of the individual patient rather than being merely a mechanistic ritual devoid of meaning.

Introduction to End-of-Life Decision Making

As we have seen, a person's capability for self-determination may be employed in medical decision making when the person finds herself in the role of a patient. This capability is especially relevant in circumstances that may assessed as potentially denoting the end of life. A common example concerns a person with a chronic illness who has been informed the prognosis is terminal, that is, death is expected within a short period of time, usually within six months or less. Such a patient, especially if he is experiencing significant daily pain, may choose to request discontinuation of active treatment interventions.

Other end-of-life scenarios involve patients who are incapable of making decisions on their own behalf. For example, a person is discovered in her kitchen or bedroom, lying on the floor unconscious and without a pulse. Or the highway patrol identifies an unconscious accident victim who has apparently suffered a traumatic head injury. Or a person with early Alzheimer's disease deteriorates clinically to the point at which she no longer has the *cognitive capacity* for decision making. In these situations there is a need to identify a substitute decision maker who will, in effect, speak for the patient. Overall, decision making in potential end-of-life circumstances is concerned with fulfillment of the biomedical ethical principle of respect for persons and the patient's right of autonomy.

The specific applications of the principles and concepts presented in this general overview are rarely straightforward. In the case of a terminally ill patient, conflicts regarding appropriate courses of action commonly arise among the patient, the patient's family, and the care team. For

example, a patient may clearly state he does not wish his life to be prolonged and instructs the care team to withdraw artificial sources of nutrition and hydration, such as a feeding tube or intravenous apparatus. But the care team, including the attending physician, is reluctant to take such actions, as they agree the patient might have several months of life remaining and construe this possibility as meaningful and worthwhile. Or, before these requests can be carried out, the patient becomes confused and unable to follow a chain of reasoning. His children, who have finally arrived from out of town, assert themselves and emphatically insist that no changes be made to the treatment protocol. Moreover, they demand that everything be done to preserve their parent's life.

In another common scenario, a chronically ill person presents to the emergency department of a local medical center, undergoes thoracic or abdominal surgery, rapidly deteriorates, and loses cognitive capacity. It is determined that the patient was homeless and the hospital is unable to locate family members or friends who could provide information regarding the patient's preferences in terms of medical decision making. Such a patient is considered *unrepresented,* and the care team, in consultation with the hospital biomedical ethics committee, will proceed on the basis of the best interests of the patient. The specific nature of those best interests needs to be determined on a case-by-case basis.

Medical decision making in potentially end-of-life situations is inherently final and therefore ethically complex. Questions and concerns arise regarding respect, that is, the patient's right of self-determination, and how to fulfill that right if the patient is cognitively unable to make such decisions. Ethical questions also concern the best methods of helping the patient (beneficence), avoiding harm to the patient by not choosing treatments that will be hurtful or otherwise not contribute to his welfare and well-being (nonmaleficence), and the best use of scarce resources (justice). In terms of autonomy, questions always center on the patient's preferences and desires regarding treatment. The U.S. Supreme Court effectively affirmed the principle of patient autonomy in 1914. In *Schloendorff v. Society of New York Hospital,* Justice Benjamin Cardozo wrote, "Every human being of adult years and sound mind has a right to determine what shall be done with his own body."[84] This landmark ruling enshrined the right of individuals to make their own decisions regarding medical treatment. More than half a century later, owing to further improvements in public health, the advent of more effective pharmaceuticals, and the development of life-sustaining technologies, it became increasingly possible to keep patients alive who might otherwise have expired. But a significant proportion of these individuals were no longer capable of making medical decisions on their own or had suffered substantial compromise to these capabilities. The "sound mind" criterion in *Schloendorff* became a limiting factor and further ethical analysis and legal support were needed to clarify the principle of autonomy in cases in which the patient was not of "sound mind."

In contrast to end-of-life circumstances, people who are reasonably healthy do not require feeding tubes, ventilators, and intravenous lines to sustain life over prolonged periods. Thus, by their very nature, decisions to undergo or forgo knee replacement surgery or surgery for carpal tunnel syndrome are distinct from medical care choices directly related to one's demise. But what if serious complications ensue during the course of such an elective surgery and the patient emerges with substantially impaired cognitive capacity? For example, consider the consequences if the patient suffered cardiac arrest during surgery and the blood supply to his brain was interrupted for more than four minutes. In such an extreme circumstance the patient could very well have sustained extensive, possibly permanent, damage to his cerebral cortex. It

is conceivable that the patient would now require daily supervision and assistance with basic activities of daily living for the rest of his life. The person would no longer be able to interact meaningfully with loved ones and friends. The abilities to function as an independent individual and fulfill one's roles and responsibilities in one's family, at work, and in society would be lost, likely forever. It is conceivable, too, that the patient would not choose, if he had the ability to choose, to live such a life. This scenario, even though the patient might be in his or her thirties, forties, or fifties, is analogous to the end-of-life circumstances of a much older patient with terminal cancer or advanced dementia.

Constructing an *advance directive* may provide substantial assistance in solving complex ethical problems in the context of end-of-life decision making. An advance directive is a legal document in which a person specifies her wishes, desires, and preferences regarding medical treatment in circumstances in which the individual does not have sufficient cognitive capacity to make her own choices. An advance directive formalizes one's preferences at a time during which one is of sound mind, thus satisfying the requirement specified in *Schloendorff*. The legal basis for adhering to a competent person's desires regarding medical treatment was established in 1990 in *Cruzan v. Director, Missouri Department of Health*.[85] Referencing the due process clause of the Fourteenth Amendment, the U.S. Supreme Court stated, "a competent person has a constitutionally protected liberty interest in refusing unwanted medical treatment." In his dissenting opinion, Justice Harry Blackmun went further, stating, "It is unrealistic to say that the preservation of life is an absolute, without regard to the quality of life. ... It is appropriate to consider the quality of life in making decisions about the extraordinary medical treatment."[86]

Thus, competent persons, that is, persons with the cognitive capacity to support medical decision making, have the constitutionally protected right to choose or refuse specific treatment. Implementing a person's preferences becomes problematic when the person is currently incapable of making necessary decisions, and their prior wishes have not been formalized in an advance directive or other similar document. An advance directive provides assistance to persons who wish to protect their interests and the implied welfare of their families in the case of dire medical circumstances.

Introduction to Assessing Capacity

An assessment of a patient's capacity to make medical decisions is necessary when that capacity is called into question. For example, a patient may be nonresponsive, his statements may be unintelligible, his choices may be inconsistent or strongly at variance with previously indicated preferences, or he may be otherwise incoherent. In such circumstances, it is necessary to establish whether that patient has the capacity, at present, to make medical decisions on his own behalf. Of note, *competence* is a legal construct. In most jurisdictions, only a court can determine whether a person is *legally incompetent*.[87]

Decision-making capacity, that is, the capacity to consent to treatment, has been defined as "an individual's ability to understand the significant benefits, risks, and alternatives to proposed health care and to make and communicate a healthcare decision."[88] In practice, decision-making capacity is widely considered to have three or four components:[89]

1. The ability to understand the risks and benefits of proposed treatment
2. The ability to apply that understanding to the patient's own circumstances
3. The ability to express a preference and communicate that choice, either verbally or in writing
4. Consistency of that choice with the patient's previously expressed beliefs, values, and preferences regarding quality of life

As an example of an application of the fourth component, consider a seventy-eight-year-old patient who is currently insisting that her feeding tube be withdrawn and declaring she wants to be let alone and allowed to die. But two floor nurses recall the patient's recent statements regarding how much she's looking forward to celebrating her twin granddaughters' tenth birthday two months from the present. The care team appropriately assesses the patient's current demands as inconsistent with her known preferences and concludes that, at present, the patient fails to meet the capacity threshold required for medical decision making. Of course, if the patient persisted in her demands, a consultation with the hospital ethics committee would be held and formal capacity assessments would likely be requested.

An assessment of capacity to consent to treatment based on the above criteria is necessarily qualitative. A patient's capacity for medical decision making may be variable and is appropriately considered, in certain circumstances, a moving target. For example, a patient may demonstrate sufficient capacity on a certain day and time and fail to demonstrate sufficient capacity on a follow-up assessment. Intense pain may interfere with a patient's ability to adequately comprehend a discussion of risks and benefits of treatment. In an already compromised state, intense pain may further deteriorate a patient's cognitive abilities. Later on, after a dose of pain medication has taken effect, the patient may be capable of following and participating in a detailed conversation. On the other hand, pain medications may cause a certain degree of loss of capacity. Thus, assessment of capacity is necessarily heuristic, that is, experiential (rule of thumb). Capacity assessments may be revisited, as necessary, depending on improvement or worsening of the patient's clinical status.

Importantly, "any physician who is aware of the relevant criteria should be able to assess a patient's competence."[90] Quantitative assessments such as the Mini-Mental Status Examination[91] and the MacArthur Competence Assessment Tool[92] may be employed, if needed, to provide support for the robustness of the assessment. Capacity evaluations by two independent observers, most typically the attending physician and a member of the psychiatry department, assist the recommendations of the hospital ethics committee and the treatment choices of medical staff.

The requirement for evaluation of capacity is supported by various state legislatures. For example, regarding capacity to give informed consent for medical treatment, Section 1890(c) of the Probate Code of the state of California states that no court order in relation to a petition for appointment of a conservator may be granted

> unless supported by a declaration, filed at or before the hearing on the request, executed by a licensed physician, or a licensed psychologist within the scope of his or her licensure, and stating that the proposed conservatee or the conservatee, as the case may be, lacks the capacity to give an informed consent for any form of medical treatment and the reasons therefore.[93]

Of course, in the event of a determination of lack of capacity, the appropriate courses of action will be undertaken by the care team in consultation with the patient's surrogate medical decision maker (if one has been identified) and the patient's family members. End-of-life decision making fully employs and is fully dependent on the four biomedical ethical principles of autonomy, beneficence, nonmaleficence, and justice.

NONMALEFICENCE

As noted in Chapter 2, nonmaleficence refers to avoidable harms and intentional harms. Importantly, and of great concern, is the assessment that approximately 30 percent of U.S. healthcare expenditures are wasted on nonbeneficial treatment and unnecessary diagnostic testing.[94] Unnecessary treatments, including medications, therapies, and surgeries, are always harmful in that a patient's physiology is being altered without an accompanying benefit. The toxicity of medication is generally considered an acceptable harm, as the harm is anticipated to be outweighed by a benefit. When there is no possibility of an attainable benefit, as when medication is unnecessary, then treatment is only harmful. Superfluous diagnostic tests such as unnecessary laboratory and imaging studies are especially problematic, not only in that they are associated with unneeded worry and stress, but they may falsely indicate the presence of a disease. False positives lead to additional testing and possibly treatment, all of which would be considered unnecessary. A false positive diagnosis of breast cancer, for example, may impact an entire family and lead to years of unneeded tests and treatment, psychological harm, and wasted resources.

Harms deriving from healthcare treatment are often related to quality of care issues. In 2001, the Institute of Medicine (IOM) published *Crossing the Quality Chasm*,[95] a white paper highlighting and promoting efforts to improve the quality of healthcare delivery in the U.S. *Crossing the Quality Chasm* focused on six areas for improvement. Fulfilling these core needs was predicted to result in healthcare that was safe, effective, patient-centered, timely, efficient, and equitable. Effective care, for example, would provide services based on scientific knowledge to those who would benefit, and avoid providing treatment to patients not likely to benefit. Safe care would avoid injuries to patients from care that was intended to be beneficial.

Crossing the Quality Chasm continues to be an essential guideline for improving the performance of the U.S. healthcare system, but implementation of the IOM's recommendations has been sporadic and severe problems persist. For example, a 2011 article reported that adverse events occur in one-third of hospital admissions, even in institutions that had launched advanced quality control programs.[96] The annual cost of harmful medical errors, that is, those resulting from improper medical management, was US$17.1 billion in 2008.[97] Also, in 2008, regarding annual deaths due to medical error, the U.S. Department of Health and Human Services Office of Inspector General (OIG) determined there were 180,000 such deaths per year among Medicare beneficiaries alone.[98] Overall, in 2013 it was estimated that medical error was the third largest cause of death in the United States,[99] with an incidence ranging from 210,000 to 400,000 deaths per year associated with medical errors among hospital patients.[100] As well, in 2014 it was estimated that at least one in twenty adults in the United States (approximately 12 million persons) are affected by diagnostic errors each year.[101] Of these diagnostic errors, approximately one-half have the potential to lead to severe harm.[102]

BOX 3.1

Case Study: Family Members Rejecting Advance Directive Specifications

After being discovered unconscious at home, Joe Smith, an eighty-two-year-old male, had been brought by ambulance to the emergency department at a local medical center. Following two days in the intensive care unit, Smith regained consciousness and was transferred to a rehabilitation unit. It had been determined that he had suffered a hemorrhagic stroke (intracerebral hemorrhage) with resultant severe disability. But after four weeks of inpatient therapy, Smith was not yet able to walk or stand. He could not respond to commands and his attempts at speech were garbled. He continued to require round-the-clock assistance with self-care and fulfilling his nutritional needs.

Smith's wife had passed away a year ago and his two adult children lived 3,000 miles away. He had completed an advance directive several years ago, which was on file with his primary care physician and included in his hospital medical record. His advance directive specified that he was not to be resuscitated or intubated, and that if he had lost the capacity for medical decision making and then not regained such capacity within thirty days, he wished to no longer receive food and water and be allowed to expire in the natural course of events. Smith's advance directive had listed his wife as surrogate decision maker (agent to make healthcare decisions for him if he became incapable of making his own decisions), and he had not updated this provision after his wife's death.

Consistent with the HIPAA Privacy Rule (discussed in Chapter 10) and acting in the best interests of the patient, the hospital notified Smith's adult children, William Smith and Mary Jones, of their father's health status. During a care conference with the medical team, both children asserted that their father would no longer wish to adhere to his previously stated preferences regarding medical treatment and would desire to continue living. They requested that the medical team "do everything" to keep their father alive.

Ethical Analysis

1. From the perspective of the biomedical ethical principle of autonomy, discuss whether the medical team is required to uphold Smith's desires as described in his advance directive.
2. List two possible responses by the medical team to Smith's children's request to "do everything" to keep him alive. Discuss ethical considerations in support of each.
3. Describe a possible compromise that could be proposed to William Smith and Mary Jones that would honor the spirit of their father's stated wishes and preferences.

In 2006, the IOM noted that in hospitals, errors are common during the entire medication-use process: "procuring the drug, prescribing, dispensing, administering, and monitoring the patient's response."[103] The IOM estimated there were at least 1.5 million preventable adverse drug events

(ADEs) each year in the United States, including ADEs associated with hospitals, long-term care facilities, and ambulatory care.[104] The estimated costs of these errors in hospitals alone (representing approximately one-third of the preventable ADEs) was US$3.3 billion in 2006.[105]

In 2012, the OIG reported that hospital incident reporting systems capture only 14 percent of patient harms experienced by Medicare beneficiaries.[106] A follow-up investigation by OIG noted that hospitals reported only 1 percent of patient harm events to state notification systems.[107] Accurate reporting requires a commitment to recording and measurement of medical errors, followed by systemwide protocols to improve patient safety. A total systems approach and culture of safety includes the following:

- Creation of centralized and coordinated oversight of patient safety
- Creation of a common set of safety metrics that reflect meaningful outcomes
- Addressing safety across the entire continuum of patient care[108]

But as of 2016, there was no comprehensive nationwide system for recording the various types of medical errors that occur in hospitals, other healthcare institutions such as skilled nursing facilities, and private physician practices.[109]

Health Disparities

The harms to patients described above may be considered harms of commission, that is, harms caused by specific actions. In addition, the structure of the U.S. healthcare system has resulted in significant harms of omission. Prior to the advent of the Patient Protection and Affordable Care Act (ACA) in 2010, 48.3 million people under age sixty-five did not have health insurance in 2010, representing approximately 16 percent of the population.[110] Thus, in 2010, one in six Americans was uninsured, the majority of whom were women and children. In 2015, the number of Americans under age sixty-five without health insurance had improved to 28.4 million, representing approximately 9 percent of the population. The ACA had enabled approximately 20 million Americans to obtain health insurance, many for the first time, but as of 2018 more efforts were needed to extend coverage to the substantial numbers of Americans remaining uninsured.

The issue of health insurance coverage is related to more general concerns regarding healthcare access, availability, and affordability. For example, it is reasonable to conclude that those living in major metropolitan areas have access to healthcare services. Large cities such as New York City, Philadelphia, Chicago, Los Angeles, and San Francisco each have numerous healthcare institutions, many of which are renowned teaching hospitals. But mere access is insufficient to obtain needed healthcare if treatment itself is unaffordable, Further, access itself is relative.

For persons living in inner city districts such as Watts, a Los Angeles neighborhood of approximately 40,000 (2010 census), a trip to a hospital may require an hour or more on unreliable public transportation. The availability of primary care physicians (PCPs) is substantially lower in Texas, Nevada, New Mexico, Mississippi, Georgia, and Arkansas, where the number of PCPs per 100,000 population ranges between 26.5 (Mississippi) and 36.4 (Arkansas). According to the Centers for Disease Control and Prevention, the U.S. national average in 2012 was 46.1.[111]

Thus, in a specific locality, healthcare services may be available in principle. But driving 100 miles one-way (in a rural community) or traveling on a bus/train combination for an hour or more one-way (in a large city) cannot be reasonably considered as actual access. Availability and accessibility are themselves constrained by affordability. For families with annual incomes below the poverty line (US$24,600 for a family of four in 2017[112]), requirements for food and shelter may consume financial resources with nothing remaining for healthcare. Healthcare may not be affordable even for middle-income households. According to the Pew Research Center, in 2014 an annual income of between US$48,300 and US$145,000 placed a family of four in the "middle income" bracket.[113] But the 2016 Milliman Medical Index indicates that the cost of healthcare for a typical American family of four was US$25,826, if that family was covered by an employer-sponsored health insurance plan.[114] The annual employee healthcare cost was US$11,033. Thus, for typical middle income families at the lower end of the earnings bracket, out-of-pocket healthcare costs likely represent almost 25 percent of their annual income. For families not sufficiently fortunate to have employer-sponsored coverage, annual healthcare costs may be in the range of 50 percent of annual earnings. In such circumstances, which affect many American families, use of healthcare services may be postponed as long as possible or even avoided altogether.

The existence of *health disparities* represents another harm of omission and may be reasonably assessed as failure of the U.S. healthcare system to uphold the biomedical ethical principle of nonmaleficence. Health disparities were originally described in the 1985 Report of the Secretary's [Department of Health and Human Services] Task Force on Black and Minority Health.[115] The report documented significant disparities in the distribution of disease and mortality among blacks and other minority groups in the United States compared with whites.

The National Institutes of Health defines health disparities as "gaps in the quality of health and health care that mirror differences in socioeconomic status, racial and ethnic background, and education level."[116] Health disparities have many causes, including lack of accessibility to healthcare, increased risk of disease from genetic or familial factors, and increased risk of disease from occupational exposure. Health disparities denote disproportionate prevalence and incidence of acute and chronic diseases, such as diabetes, hypertension, asthma, hepatitis C, and HIV/AIDS, among racial, ethnic, and socioeconomic population subgroups. For example, prevalence rates of hypertension among adults aged greater than eighteen years were 28.6 percent among whites, 41.3 percent among blacks, and 27.7 percent among Hispanics. The prevalence of hypertension was 32.8 percent in those with family income at or below the federal poverty threshold (FPT) and 27.6 percent in those with family income five times the FPT. Asthma prevalence rates between 2001 and 2010 were 7.9 percent among whites, 10.8 percent among American Indians/Alaska natives, 10.5 percent among blacks, and 15.9 percent among those of Puerto Rican lineage. Diabetes prevalence rates in 2010 were 6.8 percent among whites, 11.3 percent among blacks, and 11.5 percent among Hispanics. The prevalence of diabetes was 10.6 percent in those with family income at or below the federal FPT and 7.6 percent in those with middle-level family income (two to four times the FPT). Using level of education as the measure of health disparities, diabetes prevalence was 11.6 percent among those achieving a level less than high school, 8.5 percent among those with high school or equivalent, and 5.8 percent among those with a college degree or higher. Between 2008 and 2010, the estimated rates of HIV infection diagnoses per 100,000 population in adults aged greater than eighteen

years were 9.1 among whites, 13.5 among American Indians/Alaska natives, 84.0 among blacks, and 30.9 among Hispanics.[117]

Thus, the prevalence of serious chronic diseases is markedly unequal among various racial/ethnic population subgroups. Hypertension and diabetes prevalences, utilizing family income as the criterion of distribution, and diabetes prevalences, utilizing educational level as the criterion of distribution, are markedly unequal. As would be expected, health disparities impact life expectancy at both ends of the spectrum. For example, in 2014, African Americans on average live 75.6 years, whereas life expectancy for whites is 79 years. In 2013, infant mortality in the United States per 1,000 live births was 5.96 overall and 11.11 for infants born to non-Hispanic black mothers.[118] Although the persistence of health disparities is not solely attributable to unequal access and distribution of healthcare services, many more public policy solutions need to be identified and implemented to uphold the biomedical ethical principle of nonmaleficence.

Biotechnology, Genome Engineering, and CRISPR-Cas9

Biotechnology is the application of techniques and methods initially derived from the field of molecular biology for use in medicine and industry. Following development of the polymerase chain reaction (PCR) technique in the early 1980s and the invention of DNA and protein sequencers and synthesizers in the mid-1980s and early 1990s, it became possible to manipulate the genetic material of microorganisms to produce antibiotics, artificial hormones, and other pharmaceuticals for more effective treatment of various diseases. Examples include Enbrel (etanercept), first synthesized in the 1990s, for treatment of rheumatoid arthritis; Rituxan (rituximab), introduced in 1997, for treatment of non-Hodgkin's lymphoma; and Humulin (human-like insulin), first marketed in 1982, for treatment of diabetes.

Etanercept is a novel protein, manufactured via recombinant DNA techniques, that inhibits activity of tumor necrosis factor, a protein (inflammatory cytokine) that initiates and perpetuates inflammatory processes in autoimmune diseases such as rheumatoid arthritis. Rituximab is a monoclonal antibody developed to bind to CD20, a protein located on the surface of mature B-type white blood cells (B lymphocytes). Rituximab's significant antitumor activity stimulated the development of numerous monoclonal antibody cancer treatments.

Humulin was the first recombinant pharmaceutical approved for use in the United States. Recombinant biomolecules are created by inserting DNA sequences from one species into the DNA of a host species, most often bacteria or yeast. The novel host species gene is capable of encoding a protein derived from the foreign genetic information introduced by the recombinant DNA process. In 1978, the first recombinant DNA human insulin was obtained from genetically modified bacteria (*Escherichia coli*). At present, recombinant human insulin is manufactured predominantly using *E. coli* and the yeast *Saccharomyces cerevisiae*.[119]

Molecular biology tools such as recombinant DNA techniques have led to the development of important new medicines of use to many people. But "biotechnology" implicitly involves the creation of novel organisms that contain genetic sequences not found in nature. Agricultural techniques that selectively breed plant and animal species optimized for hardiness, size, or color only utilize the inherent DNA structure of those species. Those historical methods differ qualitatively and quantitatively from molecular biology techniques that create, essentially, new

life forms with artificial genomes. As they did not occur via evolutionary processes, the impact of such organisms on ecological systems is entirely unknown. For example, statements that genetically modified organisms (GMOs) do not harm the environment are entirely meaningless, as the complex interactions among countless species cannot be calculated, regardless of the available computing power.

Complex systems are highly sensitive to small perturbations, as Dr. Ian Malcom, the mathematician in *Jurassic Park*, famously proclaimed. In describing what was then known as chaos theory, Malcom tells his listeners about the "butterfly effect." "A butterfly can flap its wings in Peking," Malcolm says, "and in Central Park you get rain instead of sunshine." Thus, the long-term effects of artificial transfers of genetic material are unpredictable. These effects may range from benign to devastatingly dangerous. Therefore, policy makers must answer the difficult question of whether we should take such chances. Public policy needs to address the "goodness or badness of possible outcomes, the handling of uncertainty and incompleteness in data."[120]

The explosion of research activity since approximately 2010 utilizing the *CRISPR-Cas9* biomolecular system for genetic engineering is especially significant. CRISPRs (clustered regularly interspersed palindromic repeats) were initially described in 1987 in the genome of *E. coli*.[121] It was determined in 2005 that these short repeated sequences of DNA base pairs separated genetic sequences that were originally derived from viruses and plasmids (small circular double-stranded DNA molecules).[122] Shortly thereafter, researchers found that *cas* (CRISPR-associated) genes encoded proteins that cleave DNA strands.[123] It was proposed that CRISPR-Cas was an adaptive immune system developed by bacteria over evolutionary time to protect against viral invaders.[124] The CRISPR sequences contained a genetic memory signature of prior viral infections and the bacterium would then be able to fight off subsequent identical viral intrusions.

Researchers then had the insight that the CRISPR-Cas system could be used to make DNA strand breaks at specific sites in plant and animal cells of interest, with the possibility that custom gene sequences could be introduced at those precise breaks. Studies published in 2013 demonstrated that CRISPR-Cas9 was an efficient tool to edit the genomes of human cells.[125] The CRISPR-Cas9 tool was fast and easy to use compared with prior methods of genetic manipulation. Within a few years, CRISPR-Cas9 had been used to modify the genomes of fruit flies, salamanders, mice, rats, and monkeys, as well as the genomes of rice, wheat, and sorghum. The technology has enabled one-step generation of mouse models of human disease[126] that yield knowledge of those disease processes and facilitate pharmacological studies.

CRISPR-Cas9 research may be of great benefit in furthering understanding of genetic mechanisms and gene-protein interactions in health and disease. But CRISPR-Cas9 technology is capable of permanently altering the genetic code of any organism.[127] Within, effectively, a moment, we can now artificially change living systems that have evolved and been perfected over millions of years. Tinkering with a genetic code is not the same as optimizing the architectural design of a skyscraper or enhancing automobile engine design. A car, truck, or office building does not dynamically interact with living organisms in its environment, other than adding carbon monoxide and other air and water pollutants to the overall ecosystem. But altering the genetic code of any organism, whether bacterium, yeast, plant, or animal, will necessarily lead to unforeseen consequences that may be minimal in some cases and catastrophic in others.

Cognitive Capacity

Cognitive capacity refers to a person's capability for medical decision making. Such capability may be impacted by loss or compromise of higher cortical functions owing to dementia, cardiovascular accident, or traumatic brain injury. Cognitive capacity is assessed by evaluating whether the patient is able to (1) understand the risks and benefits of proposed treatment; (2) apply that assessment to his own situation; (3) express a preference and communicate that choice; and (4) make a reasoned decision consistent with his beliefs and values.

Informed Consent

- Per *Hamilton v. Bares*, "Informed consent shall mean consent to a procedure based on information which would ordinarily be provided to the patient under like circumstances by health care providers engaged in a similar practice in the locality or in similar localities."[133]
- Per *Acuna v. Turkish*, "A physician has a legal duty to disclose to the patient all medical information that a reasonably prudent patient would find material before deciding whether to undergo a medical procedure. ... Generally, the physician is required to inform the patient of the available medical options, the risks associated with those options, and the nature of the intended procedure."[134]
- Per *Canterbury v. Spence*, "True consent to what happens to one's self is the informed exercise of a choice, and that entails an opportunity to evaluate knowledgeably the options available and the risks attendant upon each."[135] The topics material to a patient's decision-making process and requiring disclosure are "the inherent and potential hazards of the proposed treatment, the alternatives to that treatment, if any, and the results likely if the patient remains untreated."[136]

Medical Standard of Care

Regarding standards of care in general, in 1903 Justice Oliver Wendell Holmes stated in *Texas & Pacific Railway Co. v. Behymer* that "What usually is done may be evidence of what ought to be done, but what ought to be done is fixed by a standard of reasonable prudence, whether it usually is complied with or not."[137] The medical standard of care is the specific procedure or medical conduct, that is, the custom or practice, that a relevant medical community considers to be acceptable.[138] For example, in 1995, in *McCourt v. Abernathy*, the Supreme Court of South Carolina stated "the degree of skill and care that a physician must use in diagnosing a condition is that which would be exercised by competent practitioners in the defendant doctor's field of medicine. ... [A physician undertakes] to meet the standard of skill possessed generally by others practicing in his field under similar circumstances."[139]

Medical Standard of Disclosure

The *Canterbury v. Spence* opinion noted that a majority of courts had made the medical duty to disclose "depend on whether it was the custom of physicians practicing in the community to make the particular disclosure to the patient."[140] *Wooley v. Henderson* noted that "The scope of a physician's duty to disclose is measured by those communications a reasonable medical practitioner in that branch of medicine would make under the same or similar circumstances."[141]

Negligence
Negligence is the "failure to exercise the standard of care that a reasonably prudent person would have exercised in a similar situation."[142] As well, negligence is the doing of what a reasonable and prudent person would not do, or the failure to do what such a person would do, under particular circumstances.[143] Per *Natanson v. Kline*, negligence may be defined as a "violation of the duty to use due and proper care."[144] The *Natanson* court noted that "negligence is an essential element of malpractice" and "a causal relation must be established by the patient, between the negligent act of the physician and the injury of the patient."[145]

Reasonable Person Standard of Disclosure
Per *Canterbury v. Spence*, a "risk is thus material when a reasonable person, in what the physician knows or should know to be the patient's position, would be likely to attach significance to the risk or cluster of risks in deciding whether or not to forego the proposed therapy."[146]

NONMALEFICENCE: KEY TERMS

Biotechnology
Biotechnology utilizes cellular and biomolecular processes to develop new technologies that may be applied to macro-level problems such as the treatment of disease and remediation of industrial waste. Biotechnology methods include cloning, stem cell manipulation, gene therapy, and modification of the genetic code.

Genetic Modification
So-called genetically modified organisms (GMOs) have been available for years and include genetically modified soy, corn, alfalfa, and canola. More recently, utilizing biomolecular editing systems such as CRISPR-Cas9, it has become possible to directly and easily (relatively) manipulate the genetic code of any organism or microorganism. The explosion of research involving CRISPR-Cas9 has led to the development of fairly simple techniques for making precise alterations in DNA sequences. The consequences are, in a word, inconceivable.

Health Disparities
Health disparities are defined by the National Institutes of Health as "gaps in the quality of health and health care that mirror differences in socioeconomic status, racial and ethnic background, and education level."[147] Health disparities are associated with inequalities in access to healthcare, affordability of healthcare, and outcomes of healthcare services. Health disparities are associated with inequalities in the incidence and prevalence of infectious, chronic, and environmental diseases.

AUTONOMY: DISCUSSION QUESTIONS

1. Discuss the application of the biomedical ethical principle of autonomy to medical decision making. Provide an example of a patient's assertion of her right of self-determination. Provide an example of ethical conflict owing to the rights of a patient as an autonomous agent.
2. Does the biomedical ethical principle of autonomy include the right of a patient (or the patient's family) to demand treatment? Why or why not? Provide an example of such a demand and discuss the application of the biomedical ethical principle of autonomy to that situation. How would such a demand for healthcare services be resolved?
3. Healthcare providers in the United States practice under substantial time pressures. Given this background, how might it be realistically possible to obtain meaningful informed consent? Describe some mechanisms by which healthcare providers can be assured that the patient was actually meaningfully informed regarding recommended treatment.

4A. Discuss the value that the doctrine of informed consent brings to the doctor-patient relationship.

4B. Discuss how the practice of medicine would change in the absence of the requirement for informed consent.

4C. How would patients be benefited or harmed? How would society be benefited or harmed?

5. What public policy measures would you recommend or implement to help ensure that patients are (1) aware of their rights and the physician's obligation to provide informed consent, (2) knowledgeable regarding the requirements for sufficient informed consent, and (3) better able to comprehend what is being communicated in the doctor-patient encounter?

NONMALEFICENCE: DISCUSSION QUESTIONS

1. Many medical treatments involve short-term harms. Some involve long-term harms. As an exact calculation of risks and benefits cannot be obtained for any particular patient, how do you, the healthcare provider, provide a meaningful assessment of risks and benefits to your patient? Or, taking the perspective of the patient, how would you prefer to have the information provided for greatest understanding?
2. Given the biomedical ethical mandate to do good and not to harm, how do clinicians measure the good they've done or whether they've done good at all? Is such measurement a responsibility of the clinician? Why or why not?
3. As of 2016, there were more than 250,000 deaths per year in the United States due to medical errors.[148] Such errors, fatal or otherwise, represent clear violations of the biomedical ethical principle of nonmaleficence. What might be the drivers of many of these errors? What institutional policies and public policies are needed to reduce the overall incidence of medical errors?

AUTONOMY: DO-IT-YOURSELF ETHICIST

1. Analyze the development of the doctrine of informed consent from *Mohr* and *Pratt* in 1905 through *Schloendorff* in 1914, *Salgo* in 1957, and *Canterbury* in 1972. Apply your analysis to current implementations of informed consent.
   - How does today's healthcare environment differ from healthcare delivery one hundred and fifty years ago? List at least three such differences.
   - How do these differences impact informed consent conversations?
   - Discuss three policy initiatives your healthcare organization could undertake to establish robust informed consent procedures.
2. As an individual healthcare provider, what can you do to ensure effective informed consent, given time constraints, increasing specialization, continuing implementation of new medical technologies, and other challenges in today's healthcare environment?
   - Discuss a solution focusing on time constraints.
   - Discuss a solution focusing on increasing specialization.
   - Discuss a solution focusing on a challenge posed by the use of medical technologies or another factor interfering with obtaining informed consent.
3. Compare informed consent with your activities as a consumer. About what do you wish to be informed when you make a purchase decision? How do consumer rights differ from patient rights? Are patients, in fact, consumers? How does the analogy of patient-as-consumer enhance or diminish the patient–physician interaction and relationship?

NONMALEFICENCE: DO-IT-YOURSELF ETHICIST

1. You have been invited to present a thirty-minute talk on the biomedical ethical principle of nonmaleficence at an upcoming monthly meeting of the local chapter of your professional society. You choose *primum non nocere* as the theme of your presentation. Prepare an outline of your talk, addressing challenges to effective patient-provider communication, problems posed by the advent of new medical technologies, and the impact of current healthcare system designs on effective decision making.
2. Imagine yourself as a new patient at your healthcare institution. Identify the personnel, processes, and protocols you encounter from the moment you enter the facility until the time you leave and walk back to your car, hail a cab, or take public transportation to return home. Experience in your imaginary encounter what works and what does not work. Using your own responses to the process, identify bottlenecks to delivery of effective care and sources of possible confusion, mix-up, or actual error. Make a list of recommendations to upgrade patient management, reduce medical errors, and improve treatment outcomes and patient satisfaction.

AUTONOMY: REAL-WORLD APPLICATIONS—ETHICS AS A DOCTRINE OF ACTION

1. The informed consent process, a demonstration of patient autonomy, requires active participation by the patient. How can you, the healthcare provider, encourage and elicit such active participation? How can you inform yourself of a specific patient's requirements for sufficient information? How can you train yourself to communicate more effectively utilizing terminology and phraseology that patients can understand?
2. From the perspective of informed consent, considering that the patient is at an ongoing disadvantage as he is unwell and seeking assistance, and has various concerns of varying levels of significance related to his health and well-being, it may be difficult to achieve optimal patient education in the initial healthcare encounter. Therefore, as an individual healthcare provider and member of a healthcare institution, discuss your recommendations for enhancing healthcare education in your community. How will your policy proposals address the diversity of languages spoken by members of your community? How will your policy proposals address the specific healthcare needs of your community, especially with respect to health disparities? How will your institution's community activities impact future patient–physician interactions and the informed consent process?
3. Write an article for your healthcare institution's monthly newsletter describing how informed consent procedures improve healthcare delivery and improve patient outcomes. Support your discussion by referencing content from three articles in the peer-reviewed literature.

NONMALEFICENCE: REAL-WORLD APPLICATIONS—ETHICS AS A DOCTRINE OF ACTION

As discussed in Chapter 2, bioethics originally described ethical action in the biological sphere. Thus, the biomedical ethical principle of nonmaleficence can be appropriately extended to encompass prevention or redress of harms to mammals, birds, fish, plants, and other living organisms. The biomedical ethical principle of nonmaleficence informs us that the welfare of humans is not our only concern.

1. Discuss actions you can take within your organization or institution to more broadly apply the biomedical ethical principle of nonmaleficence. How will you assess the outcomes of these actions?
2. Discuss actions you can take within your community to more broadly apply the biomedical ethical principle of nonmaleficence. How will you assess the outcomes of these actions?
3. From a broad perspective of the biomedical ethical principle of nonmaleficence and the information presented thus far in this textbook, discuss the appropriateness or inappropriateness of using animals as subjects in the conduct of biomedical research. What revisions to federal policies, if any, might you recommend as a result of your reflections?

REFERENCES

[1]T. L. Beauchamp and J. F. Childress, *Principles of Biomedical Ethics*, 1st ed. (New York: Oxford University Press, 1979).

[2]O. O'Neill, *Autonomy and Trust in Bioethics* (New York: Cambridge University Press, 2002), 29.

[3]R. Dresser and P. J. Whitehouse, "The Incompetent Patient on the Slippery Slope," *Hasting Center Report* 24, no. 4 (1994): 6–12.

[4]H. T. Engelhardt, "Case Studies in Bioethics: A Demand to Die," *Hastings Center Report* 5, no. 3 (1975): 10.

[5]"The Nuremberg Code," in *Doctors of Infamy: The Story of the Nazi Medical Crimes*, eds. A. Mitscherlich and F. Mielke (New York: Schuman, 1949), xxiii–xxv. Also, the Nuremberg Code may be located online on the National Institutes of Health website, https://history.nih.gov/research/downloads/nuremberg.pdf.

[6]E. Shuster, "Fifty Years Later. The Significance of the Nuremberg Code," *New England Journal of Medicine* 337, no. 20 (1997): 1436–1440.

[7]Mitscherlich and Mielke, *Doctors of Infamy*, xxiii–xxv.

[8]W. H. S. Jones, trans., "The Oath," in Hippocrates, vol. I (Cambridge, MA, Harvard University Press, 1957), 299.

[9]F. Adams, trans., *The Genuine Works of Hippocrates*, vol. II (London: The Sydenham Society, 1849), 780.

[10]D. D. Dobbs, P. T. Hayden, and E. M. Bublick, *Hornbook on Torts*, 2nd ed. (St. Paul, MN: West Academic, 2016), 60–61.

[11]*Marchbanks v. Borum*, 806 So.2d 278 (Miss. Ct. App. 2001).

[12]*Mims v. Boland*, 110 Ga. App. 477, 138 S.E.2d 902 (1964) at 481.

[13]*Mohr v. Williams*, 95 Minn. 261, 104 N.W.12 (1905).

[14]Ibid., at 261.

[15]Ibid., at 268.

[16]Ibid.

[17]Ibid., at 262.

[18]*Pratt v. Davis*, 118 Ill. App. 161 (1905); 37 *Chicago Legal News* 213.

[19]*Mohr v. Williams*, at 268.

[20]*Schloendorff v. Society of New York Hospital*, 211 N.Y. 125, 105 N.E. 92, 93 (1914).

[21]Ibid., at 128.

[22]Ibid., at 129–130.

[23]*Salgo v. Leland Stanford Jr. University Board of Trustees et al.*, 317 P.2d 170, 154 Cal.App.2d 560 (1957).

[24]Ibid., at 578.

[25]Ibid.

[26]Ibid.

[27]R. R. Faden and T. L. Beauchamp, *A History and Theory of Informed Consent* (New York: Oxford University Press, 1986), 126.

[28]*Salgo v. Leland Stanford Jr. University Board of Trustees*, at 578.

[29]*Natanson v. Kline*, 186 Kan. 393 (1960), 350 P.2d 1093.

[30]Ibid., at 397.

[31]Ibid., at 406.

[32]Ibid., at 406–407.

[33]Ibid., at 407.

[34]Ibid., at 409.

[35]Ibid., at 409–410.

[36]Ibid., at 400.

[37]Ibid., at 399.

[38]Ibid., at 402.

[39]Ibid.

[40]Ibid.

[41]Ibid., at 403.

[42]Ibid., at 410.

[43]*Natanson v. Kline*, 187 Kan. 186 (1960), 354 P.2d 670 at 189.

[44]Ibid., at 190.

[45]Ibid., at 191.

[46]Dobbs et al., *Hornbook on Torts*, 503.

[47]E. D. Kinney, "The Brave New World of Medical Standards of Care," *Journal of Law, Medicine, and Ethics* 29 no. 3/4 (2001): 323–334.

[48]*Wooley v. Henderson*, 418 A.2d 1123 (Me. 1980) at 1131.

[49]*Hamilton v. Bares*, 267 Neb. 816, 678 N.W.2d 74 (2004) at 79.

[50]*Canterbury v. Spence*, 464 F.2d 772 (D.C. Cir. 1972).

[51]Ibid., at 777.

[52]Ibid., at 779.

[53]Ibid., at 778.

[54]Ibid.

[55]Ibid., at 780.

[56]Ibid., at 781.

[57]Ibid., at 781–782.

[58]Ibid., at 782.

[59]Ibid., at 783.

[60]Ibid.

[61]Ibid., at 784.

[62]Ibid., at 786.

[63]Ibid., at 787.

[64]Ibid., at 787–788.

[65]Ibid., at 787.

[66]Ibid.

[67]Ibid., at 788.

[68]Ibid., at 789.

[69]Ibid., at 794.

[70]Ibid.

[71]*Shetter v. Rochelle*, 2 Ariz. App. 358, 409 P.2d 74, 86 (1965), modified, 2 Ariz. App. 607, 411 P.2d 45 (1966).

[72]*Williams v. Menehan*, 191 Kan. 6, 379 P.2d 292, 294 (1963); *Govin v. Hunter*, 374 P.2d 421, 424 (Wyo.1962).

[73]*Canterbury v. Spence*, at 786.

[74]*Sgro v. Ross*, 766 A.2d 1147 (1998), 337 N.J. Super. 220.

[75]*Acuna v. Turkish*, 192 N.J. 399, 930 A.2d 416 (2007).

[76]Ibid., at 425.

[77]*Felton v. Lovett*, 388 S.W. 3d 656 (Tex. 2012).

[78]Dobbs et al., *Hornbook on Torts*, 516.

[79]*Gates v. Jensen*, 595 P.2d 919, 92 Wash. 2d 246 (1979).

[80]Ibid., at 250.

[81]D. E. Hall, A.V. Prochazka, and A. S. Fink, "Informed Consent for Clinical Treatment," *Canadian Medical Association Journal* 184, no. 5 (2012): 533–540.

[82]O. O'Neill, "Some Limits of Informed Consent," *Journal of Medical Ethics* 29 (2003): 4–7.

[83]Hall et al., "Informed Consent," 536.

[84]*Schloendorff v. Society of New York Hospital*, 211 N.Y. 125, 105 N.E. 92, 93 (1914).

[85]*Cruzan v. Director, Missouri Department of Health*, 497 U.S. 261, 110 S.Ct. 2841 (1990).

[86]Ibid.

[87]J. W. Berg, P. S. Appelbaum, and T. Grisso, "Constructing Competence: Formulating Standards of Legal Competence to Make Medical Decisions," *Rutgers Law Review* 48, no. 2 (1996): 345–396.

[88]Uniform Health-Care Decisions Act. The National Conference of Commissioners on Uniform State Laws, Uniform Law Commission, 1993, Section 1(3), http://www.uniformlaws.org/shared/docs/health%20care%20decisions/uhcda_final_93.pdf.

[89]A. E. Buchanan and D. W. Brock, *Deciding for Others: The Ethics of Surrogate Decision Making* (New York: Cambridge University Press, 1989), 18–29; P. S. Appelbaum, "Assessment of Patients' Competence to Consent to Treatment," *New England Journal of Medicine* 357, no. 18 (2007): 1834–1840.

[90]Appelbaum, "Assessment of Patients' Competence to Consent to Treatment," 1837.

[91]V. Raymont, W. Bingley, A. Buchanan et al., "Prevalence of Mental Incapacity in Medical Inpatients and Associated Risk Factors: Cross-Sectional Study," *Lancet* 364, no. 9443 (2004): 1421–1427.

[92]T. Grisso and P. S. Appelbaum, *MacArthur Competence Assessment Tool for Treatment (MacCAT-T)* (Sarasota, FL, Professional Resource Press, 1998).

[93]2016 California Code, Probate Code, Division 4, Part 3, Chapter 4: Legal Capacity of Conservatee, Article 2: Capacity to Give Informed Consent for Medical Treatment, https://leginfo.legislature.ca.gov/faces/codes_displayText.xhtml?lawCode=PROB&division=4.&title=&part=3.&chapter=4.&article=2.

[94]H. Brody, "Medicine's Ethical Responsibility for Health Care Reform: The Top Five List," *New England Journal of Medicine* 362, no. 4 (2010): 283–285.

[95]Institute of Medicine, *Crossing the Quality Chasm: A New Health System for the 21st Century* (Washington, DC: National Academy Press, 2001), http://www.nationalacademies.org/hmd/~/media/Files/Report%20Files/2001/Crossing-the-Quality-Chasm/Quality%20Chasm%202001%20%20report%20brief.pdf.

[96]D. C. Classen, R. Resar, F. Griffin et al., "'Global Trigger Tool' Shows That Adverse Events in Hospitals May Be Ten Times Greater than Previously Measured," *Health Affairs* 30, no. 4 (2011): 581–589.

[97]J. van den Bos, K. Rustagi, T. Gray et al., "The $17.1 Billion Problem: The Annual Cost of Measurable Medical Errors," *Health Affairs* 30, no. 4 (2011): 596–603.

[98]U.S. Department of Health and Human Services (HHS), Office of the Inspector General, *Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries* (Washington, DC: HHS, 2010), http://oig.hhs.gov/oei/reports/oei-06-09-00090.pdf.

[99]M. A. Makary and M. Daniel, "Medical Error. The Third Leading Cause of Death in the US," *BMJ* 353 (2016): i2139, http://www.bmj.com/content/353/bmj.i2139.full.

[100]J. T. James, "A New, Evidence-Based Estimate of Patient Harms Associated with Hospital Care," *Journal of Patient Safety* 9, no. 3 (2013): 122–128.

[101]H. Singh, A. N. Meyer, and E. J. Thomas, "The Frequency of Diagnostic Errors in Outpatient Care: Estimations from Three Large Observational Studies Involving US Adult Populations," *BMJ Quality and Safety* 23, no. 9 (2014): 727–731.

[102]H. Singh, T. D. Giardina, A. N. Meyer et al. "Types and Origins of Diagnostic Errors in Primary Care Settings," *JAMA Internal Medicine* 173, no. 6 (2013): 418–425.

[103]P. Aspden, J. Wolcott, L. Bootman, eds., *Preventing Medication Errors* (Washington, DC: National Academies Press, 2006).

[104]Ibid., 5.

[105]Ibid.

[106]D. R. Levinson, *Hospital Incident Reporting Systems Do Not Capture Most Patient Harm* (Washington, DC: U.S. Department of Health and Human Services, Office of Inspector General, 2012), https://oig.hhs.gov/oei/reports/oei-06-09-00091.pdf.

[107]S. Wright, *Memorandum Report. Few Adverse Events in Hospitals Were Reported to State Adverse Event Reporting Systems*, (Washington, DC: U.S. Department of Health and Human Services, Office of Inspector General, 2012), https://oig.hhs.gov/oei/reports/oei-06-09-00092.pdf.

[108]National Patient Safety Foundation (NPSF), *Free from Harm: Accelerating Patient Safety Improvement Fifteen Years After to Err Is Human* (Boston: NPSF, 2015), http://www.ihi.org/resources/Pages/Publications/Free-from-Harm-Accelerating-Patient-Safety-Improvement.aspx.

[109]J. Abbasi, "Headline-Grabbing Study Brings Attention Back to Medical Errors," *JAMA* 316, no. 7 (2016): 698–700.

[110]Centers for Disease Control and Prevention (CDC), "Long-term trends in health insurance coverage. Estimates from the National Health Insurance Survey, 1968–2015" (Atlanta, GA: CDC), https://www.cdc.gov/nchs/data/nhis/earlyrelease/trendshealthinsurance1968_2015.pdf.

[111]Centers for Disease Control and Prevention (CDC), "State Variability in Supply of Office-based Primary Care Providers: United States, 2012" (Atlanta, GA: CDC), https://www.cdc.gov/nchs/products/databriefs/db151.htm.

[112]U.S. Department of Health and Human Services (HHS), "HHS Poverty Guidelines for 2017" (Washington, DC: HHS, 2017), https://aspe.hhs.gov/poverty-guidelines.

[113]Pew Research Center, *The American Middle Class is Losing Ground* (Washington, DC: Pew Research Center, 2015), http://www.pewsocialtrends.org/2015/12/09/the-american-middle-class-is-losing-ground/.

[114]2016 Milliman Medical Index, http://www.milliman.com/mmi/.

[115]M. M. Heckler, *Report of the Secretary's Task Force on Black and Minority Health*, vol. 1, Executive Summary (Washington, DC: U.S. Department of Health and Human Services, 1985).

[116]National Institute of Allergy and Infectious Diseases, *Minority Health*, https://www.niaid.nih.gov/research/minority-health.

[117]Centers for Disease Control and Prevention, "CDC Health Disparities and Inequalities Report, United States, 2013," *Morbidity and Mortality Weekly Report* 62, no. 3 suppl. (November 22, 2013), https://www.cdc.gov/mmwr/pdf/other/su6203.pdf.

[118]National Center for Health Statistics, *Health, United States, 2015, with Special Feature on Racial and Ethnic Health Disparities* (Hyattsville, MD: National Center for Health Statistics, 2016), https://www.cdc.gov/nchs/data/hus/hus15.pdf.

[119]N. A. Baeshen, M. N. Baeshen, A. Sheikh et al., "Cell Factories for Insulin Production," *Microbial Cell Factories* 13 (2014): 141, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4203937/.

[120]P. B. Thompson, "The GMO Quandary and What It Means for Social Philosophy," *Social Philosophy Today* 30 (2014): 7–27.

[121]Y. Ishino, H. Shinagawa, K. Makino et al., "Nucleotide sequence of the iap gene, responsible for alkaline phosphatase isozyme conversion in *Escherichia coli*, and identification of the gene product," *Journal of Bacteriology* 169, no. 12 (1987): 5429–5433.

[122]A. Bolotin, B. Quinquis, A. Sorokin et al., "Clustered Regularly Interspaced Short Palindrome Repeats (Crisprs) Have Spacers of Extrachromosomal Origin," *Microbiology* 151, pt. 8 (2005): 2551–2561; F. J. M. Mojica, C. Díez-Villaseñor, J. Garcia-Martínez et al., "Intervening Sequences of Regularly Spaced Prokaryotic Repeats Derive from Foreign Genetic Elements," *Journal of Molecular Evolution* 60, no. 2 (2005): 174–182.

[123]C. Pourcel, G. Salvignol, and G. Vergnaud, "CRISPR Elements in *Yersinia pestis* acquire New Repeats by Preferential Uptake of Bacteriophage DNA, and Provide Additional Tools for Evolutionary Studies. *Microbiology* 151, pt. 3 (2005): 653–663.

[124]K. S. Makarova, N. V. Grishin, S. A. Shabalina et al., "A Putative RNA-Interference-Based Immune System in Prokaryotes: Computational Analysis of the Predicted Enzymatic Machinery, Functional Analogies with Eukaryotic RNAi, and Hypothetical Mechanisms of Action," *Biology Direct* 1 (2006): 7, https://biologydirect.biomedcentral.com/articles/10.1186/1745-6150-1-7.

[125]L. Cong, F. A. Ran, D. Cox et al., "Multiplex Genome Engineering Using CRISPR/Cas Systems," *Science* 339, no. 6121 (2013): 819–823; M. Jinek, A. East, A. Cheng et al., "RNA-Programmed Genome Editing in Human Cells," *eLife* 2 (2013): e00471, doi:10.7554/eLife.00471; P. Mali, L. Yang, K. M. Esvelt et al., "RNA-Guided Human Genome Engineering via Cas9," *Science* 339, no. 6121 (2013): 823–826.

[126]W. Wang, H. Yang, C. S. Shivalila et al., "One-Step Generation of Mice Carrying Mutations in multiple genes by CRISPR/Cas-Mediated Genome Engineering," *Cell* 153, no. 4 (2013): 910–918.

[127]J. A. Doudna and E. Charpentier, "The New Frontier of Genome Engineering with CRISPR-Cas9," *Science* 346, no. 6213 (2014): 1077, http://science.sciencemag.org/content/346/6213/1258096.

[128]L. Kass, "The New Biology: What Price Relieving Man's Estate?" *Science* 174, no. 4011 (1971): 779–788.

[129]H. Jonas, "Technology and Responsibility: Reflections on the New Tasks of Ethics," in *Philosophical Essays: From Ancient Creed to Technological Man*, ed. H. Jonas (Chicago: University of Chicago Press, 1980).

[130]B. A. Garner, ed., *Black's Law Dictionary*, 10th ed. (St. Paul, MN: West, 2014), 182.

[131]*Marchbanks v. Borum*, at 28.

[132]*Mims v. Boland*, at 481.

[133]*Hamilton v. Bares*, 49.

[134]*Acuna v. Turkish.*

[135]*Canterbury v. Spence*, at 780.

[136]Ibid., at 787–788.

[137]*Texas & Pacific Railway Co. v. Behymer*, 189 U.S. 468 (1903).

[138]Dobbs et al., *Hornbook on Torts*, 503.

[139]*McCourt v. Abernathy*, 457 S.E.2d 603, 607 (S.C. 1995).

[140]*Canterbury v. Spence*, at 783.

[141]*Wooley v. Henderson*, at 1131.

[142]Garner, *Black's Law Dictionary*, 1196.

[143]Ibid.

[144]*Natanson v. Kline*, at 399.

[145]Ibid., at 190.

[146]*Canterbury v. Spence*, at 787, quoting J. R. Waltz, "Scheuneman: Informed Consent to Therapy," *Northwestern University Law Review* 64 (1970): 628–640.

[147]Heckler, *Report on Black and Minority Health.*

[148]M. A. Makary and M. Daniel, "Medical Error: Third Leading Cause of Death in the U.S.," *BMJ* 353 (2016): i2139, doi:10.1136/bmj.i21399, http://www.bmj.com/content/353/bmj.i2139.

Figure Credit

Fig. 3.1: Copyright © 2010 Depositphotos/Elenathewise.

CHAPTER 4

The Four Principles of Biomedical Ethics

BENEFICENCE AND JUSTICE

BENEFICENCE

Since the time of Hippocrates and his school, physicians have been commanded by the Hippocratic Oath to help the sick.[1] Millennia later, the first American Medical Association Code of Ethics, in 1847, enjoined physicians to be "ever ready to obey the calls of the sick."[2] It may seem that this duty is obvious, that a physician's primary responsibility is the welfare of her patient, but doing good in the context of the physician–patient relationship is often contentious.

Objective versus Subjective Beneficence

One of the first considerations regarding the biomedical ethical principle of beneficence is how to assess the intended good and from whose perspective that good should be evaluated. For example, a family physician may recommend statins for a patient who is overweight and who has a high serum cholesterol level. Following the recommendations of national guidelines, the physician believes statin use will provide an important benefit for the patient in terms of preventing or ameliorating cardiovascular disease. In contrast, the patient has informed herself about the numerous side effects of taking statins such as atorvastatin (Lipitor) or simvastatin (Zocor). She decides that the potential risks of taking such drugs outweigh the possible benefits. The patient chooses not to follow her doctor's recommendation and instead begins to implement a heart-healthy diet. Thus, in this scenario, the physician's and the patient's assessments of benefit were in conflict.

Similarly, the evaluation of benefit may be subjective as well as objective. Consider the patient with chronic low back pain whose primary care physician has prescribed opioid medication. Suppose that with medication such as Norco or Percocet, the patient's pain level reduces from 7 to 3 on a 10-point visual analog scale and he is better able to perform activities of daily living. These benefits are objective in that they are measurable and represent improvement in the patient's quality of life. From the physician's point of view, he has fulfilled the principle of

beneficence in that treatment has helped the patient. But after a while, the patient notices he continues to need opioid medication to feel and function better. In other words, he notices his improvement is not sustainable without medication. Additionally, the opioid side effects have become intolerable. In essence, from his subjective perspective, the patient feels his good is no longer being served by remaining on this medication. If the physician attempts to insist that opioid use is appropriate, based on the objective benefits, then his and the patient's assessment of beneficence do not match.

Overall, in the early twenty-first century, it is no longer appropriate for the healthcare provider to impose his or her standard of beneficence. It is essential that the healthcare provider and the patient establish common ground for the good they both wish to obtain. Each patient, that is, each individual, possesses an internal standard of the good that relates to health and well-being. Each individual, more or less precisely, can apply the notion of thriving to their own lives. In these regards, the biomedical ethical principle of beneficence requires healthcare providers to assist patients in achieving the patients' good.

Quality-Adjusted Life Years

Quality of life has become a standard indicator of the effectiveness of healthcare treatment. Many frameworks for specifying the components of quality of life have been proposed and supported, including the four categories of physical status and functional abilities, psychological status and well-being, social interactions, and economic status and related factors.[3] The major domains of quality assessment include physical and occupational function, psychological function, and interactions with family and community. *Quality* may suggest that quality of life is a *soft* criterion in that it attempts to measure psychological states, feelings, and other personal assessments regarding the patient's circumstances, in contrast to historical *hard* statistical endpoints such as serum glucose levels, blood pressure readings, and white blood cell counts. But, since the 1970s, quality-of-life measures have been developed that are appropriately quantifiable, the best example of which is the quality-adjusted life year (QALY). The QALY encompasses the two basic dimensions of treatment, that is, the effect of treatment on length of life and on quality of life. Thus, QALYs encapsulate mortality (length of life), morbidity (quality of life; the impact of the disease or disorder on overall health), utility (the relative importance of these states), and prognosis (length of time in the state of diminished health). By collapsing these outcomes regarding quantity and quality of life into a single measure, QALYs represent an equivalent length of life (compared with one year of full health)[4] and the measure is a valuation of health benefit.[5] Applications of QALYs include individual, physician, and third-party decision making; societal audits, that is, evaluation of ongoing healthcare programs and activities; and societal resource analysis, that is, priority setting across proposed healthcare programs and program changes.

QALYs represent patient preferences for alternative health states.[6] QALY scores range from 1.0, representing optimum functioning or full health, to 0, representing death. These preferences are determined by various research methods. In the *time trade-off method*, subjects are asked to choose between living for a shorter length of time with perfect health and living longer with a well-defined decreased state of health.[7] The comparison reflects the subject's assessment of the quality of life associated with the diminished state of health. For example, a QALY score of

0.50 means that a full year of life with a specific health-related loss of function has the same value, from the individual's perspective, as six months of life at full health. A full year with the disability equates to a half-year at full health. The quality ratings represent the relative desirability of various health states and conditions. In other words, a quality-adjusted life year represents the equivalent of a completely well year of life, that is, twelve months of life free of any symptoms or functional limitations related to health.[8] The preference continuum represented by QALY scores enables rank-ordering of the overall outcomes of specific treatments and of public policy measures. For example, hypothetical treatment A provides 0.1 QALY representing a full year of life at reduced functioning that was equivalent to 10 percent of a full year of life, or approximately five weeks, in which one was completely well. Hypothetical treatment B provides 0.4 QALY representing a full year of life at reduced functioning that was equivalent to 40 percent of a full year of life, or approximately twenty-one weeks, in which one was completely well. Presuming both treatments were directed at the same condition, almost 100 percent of patients would choose treatment B with 0.4 QALY. (Considerations regarding side effects are built-in to the QALY measurement.)

Although "quantifying quality" may be counterintuitive, measures such as QALY are necessary to make effective comparisons among various treatment options. The entire purpose of statistical constructs such as QALYs is to facilitate treatment decision making by healthcare providers and patients and enable public policy makers to most effectively manage scarce healthcare resources. The intent of public policy is to use available resources to produce the greatest benefit for the greatest number of people.[9] Such a policy framework, of course, is a direct implementation of the *summum bonum* of utilitarianism (as discussed in Chapter 2), the mandate to produce the greatest good for the greatest number.

The earliest discussion of the importance of including quality of life considerations in assessing treatment effectiveness is generally attributed to Klarman and his coworkers in 1968.[10] Klarman and colleagues analyzed the costs and outcomes of treating chronic kidney disease and compared hemodialysis, in which an artificial kidney machine removes impurities from a patient's blood, and kidney transplantation. They determined that allowances could be made for certain differences in lifestyle among patients who had undergone kidney transplantation and those on dialysis. For example, patients who had received a kidney transplant had greater vitality, were able to avoid the restrictive regimen of a several-times-per week dialysis schedule, and were able to travel freely without the need for special arrangements to maintain routine dialysis. Klarman and colleagues stated this overall quality-of-life differential could be quantified as a proportion of each year of life gained. As a rule-of-thumb, they set the quality of life adjustment at one-quarter of a life-year. Overall, compared with no treatment, survivorship tables showed that dialysis provided a gain of nine years of life and kidney transplantation a gain of seventeen years. With the adjustment for quality of life, transplantation patients gained 20.5 life-years. Additionally, the overall cost per life-year gained, in 1968 U.S. dollars, was US$2,200, compared with a mean of US$7,900 for patients on dialysis.[11]

Although the 0.25 weighting used by Klarman and colleagues was essentially arbitrary, the method was novel and introduced use of quality-of-life adjustments into the analysis of treatment outcomes. The subsequent introduction and descriptions of the biopsychosocial model of medicine,[12] in which psychological and social factors were included with physiological phenomena in the analysis of medical (including psychiatric) conditions, supported the requirement for revamping understanding of treatment outcomes.

Since 1968, QALYs have evolved into the standard method of comparing the effectiveness of different healthcare interventions.[13] As a measure of health improvement, QALYs help guide healthcare resource allocation decisions.[14] Healthcare policy makers had come to realize that all life-years gained via various treatments were not identical. For example, three years spent in a coma could not be appropriately assessed as equivalent to three years spent with a moderate cognitive disorder or three years spent with the requirement of a cane for ambulation. Thus, outcomes needed to be assessed not only in terms of survivorship, that is, years of life gained, but also in terms of the *quality* of those years.

Quality-of-life measures were required that captured these variations. QALYs fulfilled this requirement, expressing in a single index the effects of treatment or a public health program on both the quantity and quality of life. The essential characteristic of the QALY method is the ability to assign weights, that is, quality adjustments, to various health states. The QALY essentially *standardizes* diverse patients' experiences of their overall quality of life, incorporating estimates of the impact of symptom complexes, physical activity, social activity, sleep, and the ability to work. The standardization provided by QALYs enables direct comparisons among treatments as diverse as in vitro fertilization, a drug rehabilitation program, and surgery for chronic low back pain. As a standardized representation, QALYs may be manipulated arithmetically and used to generate ratios and comparisons. It may be fairly stated that this method of analysis parallels clinical judgment.[15] Thus, QALY measurements may be utilized in clinical decision making,[16] as an outcome in clinical trials, in evaluating public health proposals, and in assessing the impact of new medical devices and technologies.

QALY measurements may be used as a key indicator in *cost-effectiveness analysis* (CEA). CEA assesses the ratio between the amount of benefit provided by a treatment compared with the cost and provides assistance in healthcare public policy decision making. For example, the Panel on Cost Effectiveness in Health and Medicine[17] established recommendations for the use of CEAs in pharmacoeconomics research, including incorporation of QALYs in such analysis. From the perspective of healthcare economics, CEAs address the question, "What is the most inexpensive way to achieve a given outcome?" When QALYs are used as the outcome measure in CEA, the method is called *cost-utility analysis* (CUA). In assessing the benefits of treatment interventions, utility expresses the contrast or trade-off between quantity and quality of life. For example, treatment A may prolong life, but with a likely impairment or loss of function. Treatment B might retain that function, but at the cost of reduced longevity, that is, a shorter life. The utility of treatment, for a specific person, represents a comparison of these alternatives. Utility is a numeric index of preference for a specific outcome. CUA evaluates the cost per QALY. In the absence of such analyses, it is reasonable to question the basis upon which resources are allocated in general and upon which healthcare practitioners are making their treatment choices in particular. The primary considerations should focus on whether there is sufficient evidence of benefit to justify care. Once benefits are established, they can be incorporated in cost-benefit and cost-utility analyses to assess the best use of scarce resources.

By providing the ability to make treatment comparisons, not only with respect to specific diseases but across a range of diseases, CEA and CUA assist in the creation of public policy frameworks that provide maximum net increases in health and well-being for society as a whole. QALYs may also be applied in clinical decision making at the level of the physician-patient relationship. But many ethical issues need to be considered in any application of QALYs.

The question of who is deciding, that is, who are the sources of the data used to calculate QALYs, is of primary importance.

Typically, QALY assessments are calculated from responses to surveys conducted on members of the general public, most of whom are unlikely to have experienced all of the health states they are requested to value.[18] This method is justified on the basis that QALYs are often used for population-wide decisions, that is, public policy applied at the federal and state levels. But in clinical decision making for a specific individual, QALY measures derived from actual patients might be more appropriate. Also, QALYs inherently provide greater weight to acute versus chronic conditions and to younger as against elderly patients. For example, consider a ten-year-old boy who has suffered a severe fracture of his leg. Using standard treatment methods, the outcome is poor for regaining full function. A lifetime of at least moderate functional impairment is likely. But suppose a novel treatment exists that employs the boy's own stem cells to facilitate optimal bone healing and restoration of nearly full function. This treatment has a QALY valuation of 0.9. Next, consider a seventy-year-old man who has suffered a mild stroke and requires three months of yoga therapy to regain moderate function in his left leg. The QALY valuation here is 0.3, as only a modest gain in function is obtainable.

If healthcare resources are scarce, as they are, and if resource allocation was the primary consideration in decision making, treatment of the ten-year-old would always be favored based on QALYs. But although the *absolute* benefit obtainable by the seventy-year-old is much less than that obtainable by the ten-year-old, the subjective benefit for the former may be equally as significant. The older patient's assessment of the obtainable quality of life may be much greater than that of the general population from whom the QALY valuations were derived. From an associated perspective, it may be reasonably asserted that QALY measures underestimate the significance of functional impairment (across all categories) as compared with life expectancy.[19] Optimally, the individual meaning of quality of life should be incorporated into decision making utilizing QALYs.

CEA and CUA are also problematic from the perspective of justice. The specific domain of distributive justice references the fair, equitable use of scarce resources. CEAs and CUAs enable policy makers to rank-order healthcare initiatives and choose programs that (1) maximize QALYs obtainable by a specific budget or (2) achieve a certain number of QALYs at a minimum expense.[20] Ethical support for these policies is provided by the utilitarian principle of the greatest good for the greatest number. But justice requires that minority groups be considered in any distribution of commonly held resources.

The conventional QALY model implies that an intervention's value is proportional to the patient's capacity to benefit.[21] Those with more treatable conditions or greater potentials for health are favored. A too-narrow focus on maximizing QALYs overlooks (or ignores) potential healthcare benefits for those for whom the quality differential is necessarily smaller. If, as a society, we believe that everyone has an equal right to healthcare resources, then our great challenge in this area is to devise more equitable methods for distributing those resources. QALYs are a key, but should not be the only, component of such systems.

Fairness, too, needs to be taken into account. For example, QALYs could be weighted to account for public values concerning distributive justice. It is noteworthy that a primary obstacle to the appropriate implementation of QALYs is that decision makers do not necessarily understand them.[22] Over time, quality-based measures have proliferated, including quality-adjusted cost of care.[23] Research priorities for future use of QALYs include case studies on the applications

of QALYs at various levels in the healthcare system, case studies in a range of decision-making settings, and qualitative research concerning community views on issues of distribution of healthcare resources.[24]

The first public policy application of QALYs was in Oregon. In 1989 the Oregon state legislature passed the Oregon Basic Health Services Act. Senate Bill 27 (1989) "extended Medicaid coverage to Oregonians with income below the poverty level and guaranteed a set of benefits based on a prioritized list of health services."[25] Senate Bill 27 created a Health Services Commission charged with ranking medical services from the most important to the least important. The state of Oregon was attempting to address the increasing need for healthcare services among its poorest citizens while simultaneously addressing the rising costs of such services. Then as now, in the early twenty-first century, healthcare costs were consuming an inordinately large segment of state and federal budgets.

To determine the priority of healthcare services, the Oregon Health Services Commission (OHSC) conducted forty-seven community meetings across the state, which were attended, overall, by more than 1,000 people. Thirteen community values emerged and were grouped by the commission into three attributes: value to society, value to individuals at risk of needing healthcare services, and services essential to basic healthcare.[26] In addition, the commission held twelve public hearings in various locations. Seniors, persons with disabilities, consumers of mental health services, and low-income Oregonians provided testimony regarding the types of healthcare services they wanted covered. The commission then conducted telephone surveys with 1,000 randomly selected Oregonians to evaluate quality-of-life problems and estimate the degree to which each problem would reduce quality of life.[27] Problems such as moderate mobility limitation, major social activity limitation, and trouble learning, remembering, or thinking clearly were rank-ordered using the results of the survey. The OHSC applied these data to calculate QALYs and prioritized 808 medical procedures on this basis. Ultimately, 587 procedures would be paid by the state and services ranking below the cutoff would not be funded.[28]

The Oregon plan was rejected by the federal government, whose waiver was needed as Medicaid was a federally funded program. Two concerns that drew the most criticism were that the Oregon plan would not provide coverage for life support and treatment for very low-birth-weight infants and would not provide active medical treatment for patients with end-stage AIDS. In prioritizing healthcare services, the OHSC had considered that life support for infants born weighing less than 500 grams and at less than twenty-three weeks gestation was ranked 708 in the priority list because such newborns have an estimated probability of survival of 0.00.[29] Evidence had shown that active treatment of end-stage AIDS has no effect on quality of life. However, comfort care would be provided for these patients, as such care was near the top of the list. In the event, the Oregon legislature revised the proposed Medicaid program and the plan was approved by the incoming Clinton administration in March 1993. The *Los Angeles Times* stated Oregon would be permitted "to proceed with the nation's first-ever explicit attempt to ration medical services."[30]

Importantly, by utilizing QALYs to prioritize healthcare services, the Oregon plan developed a nondiscriminatory approach that focused on changes in quality of life anticipated with the use of a specific treatment. The net benefit was *person-neutral*, as the calculated QALY would apply to all patients, regardless of their current health status or disability state. Also, as QALYs are *procedure-neutral*, Oregon was able to prioritize diverse healthcare services, enabling direct comparisons of perceived value/utility on the basis of a standardized measure. Overall, the

Oregon process was a "sophisticated effort to incorporate quality-of-life measurement into resource allocation policy."[31] In effect, Oregon's early use of QALYs to determine the best use of available Medicaid funds was a practical implementation of the biomedical ethical principle of beneficence. Thus, beyond recognizing the moral value of doing good, it is also important to learn how to be able to actually *do* good in a world of limited resources.

Patient Protection and Affordable Care Act

The Patient Protection and Affordable Care Act of 2010 (ACA)[32] has been described as "the most important health care legislation since the 1965 law that created Medicare and Medicaid."[33] A primary purpose of the ACA was to promote and enhance the health and well-being of all Americans. Toward this end, the ACA was designed to address major problems in the U.S. healthcare delivery system, including access to care and other healthcare disparities and inequities. The major components of the legislation focused on prevention, health promotion, and primary care.

For example, the ACA provided improved access to clinical preventive services such as screening for cancer, HIV infection, depression, alcohol misuse, and an annual wellness examination. As well, the ACA established the Community Prevention Services Task Force (CPSTF), to be convened by the Director of the Centers for Disease Control and Prevention.[34] The CPSTF would develop recommendations for delivering population-based community preventive services and impacting "the social, economic, and physical environments that can have broad effects on the health and disease of populations and health disparities."[35] The first CPSTF Annual Report to Congress was delivered in 2011.[36] Goals of the CPSTF included increasing longevity, reducing the burden of chronic illnesses, reducing the likelihood of becoming ill, enhancing national security, preparing communities for emergencies, and empowering individuals, families, schools, communities, and employers.[37] The CPSTF 2014–2015 Annual Report to Congress addressed numerous topic areas including adolescent health, asthma control, cardiovascular disease prevention and control, diabetes prevention and control, disparities in health status, HIV/AIDS prevention, improving mental health, worksite health promotion, and violence prevention.[38] The report noted the CPSTF had completed new reviews regarding comprehensive tobacco control programs, combined diet and physical activity promotion programs to prevent type 2 diabetes, and supplemental academic programs for K-12 students to promote health equity. Updates to existing reviews included those focusing on behavioral interventions directed toward obesity prevention and control, population-based interventions for early detection of oral and pharyngeal cancers, enhanced school-based physical education programs, and community-based interventions for increasing age-appropriate vaccinations.[39]

Regarding health insurance coverage, the ACA required that insurers offer the same plans at the same prices to everyone, regardless of medical history. Section 2704 prohibited preexisting condition exclusions or other discrimination based on health status.[40] To counter the potential for costly losses to health insurance companies resulting from the elimination of preexisting condition restrictions, Section 5000A of the ACA specified an individual mandate, requiring that applicable individuals shall maintain minimum essential health insurance coverage for each month beginning after 2013.[41] The ACA's individual mandate ensured broad diversity of persons in healthcare insurance pools, thus providing substantial revenues to insurers without

corresponding expenditures on behalf of essentially healthy sectors of covered individuals. To enhance compliance, Section 5000A imposed penalties for individuals who failed to meet coverage requirements. Minimum essential coverage included health insurance obtained via Medicare, Medicaid, CHIP, veterans' healthcare programs, employer-sponsored plans, and plans in the individual market within a state.[42] The ACA established minimum standards for health insurance policies and instituted a federal subsidy for persons with lower incomes. For those with the lowest incomes, the subsidy was 100 percent and effectively represented an expansion of Medicaid.[43]

The ACA instituted a preventive services provision applicable to those enrolled in employer-sponsored plans or individual health insurance policies created after March 23, 2010. Preventive services were available at no cost and included blood pressure, diabetes, and cholesterol screenings, well-baby and well-child visits from birth to age twenty-one, vaccinations, and counseling.[44] As well, the ACA established the Patient-Centered Outcomes Research Institute "to assist patients, clinicians, purchasers, and policy-makers in making informed health decisions [based on] research findings with respect to the relative health outcomes, clinical effectiveness, and appropriateness" of medical treatments and services.[45]

The ACA created the National Prevention, Health Promotion and Public Health Council to provide leadership at the federal level "with respect to prevention, wellness and health promotion practices, the public health system, and integrative health care in the United States."[46] Further, Subtitle B described programs to increase access to clinical preventive services, including grants for the establishment of school-based health centers (Section 4101), removal of barriers to preventive services in Medicare (Section 4104), improving access to preventive services for eligible adults in Medicaid (Section 4106), and incentives for prevention of chronic diseases in Medicaid (Section 4108).[47] The ACA scheduled investments totaling US$15 billion over ten years directed toward healthcare programs and providers to promote prevention of disease, early detection, and management of conditions to prevent progression to chronicity. For fiscal year 2010, the ACA dedicated US$500 million to increase the number of primary care professionals, improve community and clinical prevention efforts, and improve research and data collection.[48]

Overall, since the ACA's first open enrollment period for healthcare insurance, the number of uninsured Americans decreased from 41 million to 27 million.[49] Obtaining coverage through the ACA was associated with substantial increases, ranging from 47 to 86 percent, in the probability of having a usual place to access medical care.[50] Gaining access to medical care via health insurance coverage significantly increases patient use of "preventive care, primary care, chronic illness treatment, medications, and surgery."[51] As well, having healthcare insurance improves the health of vulnerable subpopulations such as infants and children and improves specific healthcare outcomes such as control of blood pressure.[52] From a purely cost-benefit perspective, Medicaid expansions prior to the ACA were associated with costs per life saved ranging from US$327,000 to US$867,000, which compares favorably with estimates from the peer-reviewed literature of the effectiveness of other public policies that reduce mortality, indicating a mean cost of US$7.6 million per life saved.[53] Thus, expanding health insurance coverage, as accomplished by the ACA, is a substantially more cost-effective investment of public resources compared with many other government programs.

BOX 4.3

Case Study: Practitioner Variance

Consider two healthcare practitioners, Provider A and Provider B. When you visit Provider A's office, her staff is always polite, friendly, and helpful. Your experience is that of a welcome guest. Provider A is almost always on time and rarely more than ten minutes behind schedule. When she enters the examining or treatment room, Provider A always makes eye contact and authentically asks how you are doing and socializes for a few moments, asking personally engaging questions regarding your family, pets, or hobbies. Provider A continues to make appropriate eye contact during the course of the examination or treatment. She explains terms or procedures she thinks you might not know, and she inquires periodically as to whether you have questions or comments regarding your office visit. Treatment, if any, is rendered efficiently and with care. Instructions for follow-up are typically clear and succinct, and Provider A takes sufficient time to answer your questions and ensure your understanding.

In contrast, a visit to Provider B's office is rarely a pleasant encounter. His staff is frequently brusque and inattentive. Your experience is one of being ordered about and you perceive that your presence is, essentially, an intrusion on the staff's valuable time. Provider B is most often behind schedule and it is not unusual for you to be seen thirty or forty-five minutes later than your appointed time. When Provider B enters the examining or treatment room, he does not apologize for his tardiness. He offers you a curt hello, glances at you briefly, asks you a question or two while predominantly interacting with his computer screen, and silently begins his examination or treatment process. You are impersonally poked and prodded, and blandly instructed to do this or that. Overall, your experience of his interactions with you is that of a product making its way along an assembly line. At the conclusion of the visit, Provider B inquires remotely, as if from a distance, as to whether you have questions. If you do, his responses are short and technical, and he does not attempt to make certain your understanding is sufficient.

Ethical Analysis

1. Compare and contrast interactions with Provider A and Provider B, from the perspective of the biomedical ethical principle of beneficence, that is, the responsibility to do good, and in the specific context of effective healthcare delivery.
2. Presuming delivery of healthcare services in both offices obtains a comparable range of healthcare outcomes, discuss whether the drastic dissimilarity in the providers' respective methods of interacting with patients makes a difference in patient care.
3. What types of training in preprofessional and continuing education would assist healthcare providers in manifesting the biomedical ethical principle of beneficence, beyond a necessarily high quality of professional service rendered?

The scope of the ACA was curtailed in 2012 in *National Federation of Independent Business v. Sibelius*,[54] in which the U.S. Supreme Court ruled that a state can refuse to participate in the ACA expansion of Medicaid without losing all of its Medicaid funds. Instead, per the decision, a state has the option to continue its current, unexpanded Medicaid plan. But, critically, the Court upheld the individual mandate "as within Congress's power under the Taxing Clause."[55] Later, in 2017, in Public Law 115-97, the U.S. Congress repealed the penalty for individuals "who fail to maintain minimum essential health coverage as required by the Patient Protection and Affordable Care Act" (the individual mandate).[56] Although the legislation did not repeal the individual mandate per se, the law reduced the penalty amounts to $0 and zero percent of household income, effectively accomplishing the elimination of the individual mandate.[57] Despite these legislative and judicial inroads, the large majority of the ACA provisions remained intact as of early 2018.

JUSTICE

Overall, as discussed in Chapter 2, although society may not agree on the existence of a right to healthcare, support for universal provision of a decent minimum of healthcare services may be found on other firm grounds. For example, although we do not recognize rights to clean air, clean water, or sanitation, society has agreed that we're going to enact public health measures to ensure that communities have access to these goods and services. Although rights in these areas do not exist, society as a whole benefits from public health rules and regulations. We do these things because we recognize we ought to provide protections for individuals and families, and because our society, on all levels, becomes stronger as a result. Thus, city, state, and federal governments already provide a range of public health services, based on a combination of support and justification from the harm-prevention principle[58] and arguments emphasizing benefits such as facilitating a more productive workforce. Additional arguments from the principle of beneficence make it reasonable to extend public health services to include healthcare services as such.

It is important to note that many researchers and institutions in the United States and worldwide support the concept of the right to health. For example, in 2010 the World Health Organization Secretariat Commission on the Social Determinants of Health published a conceptual framework for action stating, "Rights concepts and standards provide an instrument for turning diffuse social demand into focused legal and political claims."[59] Article 12.1 of the International Covenant on Economic, Social and Cultural Rights, originally drafted in 1966, specifies the "right of everyone to the enjoyment of the highest attainable standard of physical and mental health."[60] Article 12.2(d) specifies that signatories to the Covenant agree to take steps toward the "creation of conditions which would assure to all medical service and medical attention in the event of sickness." More recently, Article 24 of the Convention on the Rights of the Child

FIGURE 4.1 The scales of justice

recognizes the "right of the child to the enjoyment of the highest attainable standard of health."[61] To obtain full implementation of this right, States Parties will provide access to nutritious food and clean drinking water and take into consideration "the dangers and risks of environmental pollution."

Thus, regardless of the presence or absence of generally accepted philosophical grounds supporting a right to health, the requirements for developing methods of redressing health inequalities and attaining greater levels of health equity are broadly recognized by the international community. As almost all developed nations have acknowledged, a primary mechanism for achieving these goals is the provision of universal access to healthcare. Once we have determined that such universal access is a necessary good for our society, we must define a *decent minimum of healthcare services* to be provided to all.

Determining the components of a decent minimum of healthcare services is a necessarily contentious process. Well-intentioned parties must agree to disagree. Societies are best served when the deliberations of governmental agencies are open to the public and public comment is actively sought and incorporated in the final recommendations. When universal healthcare systems are being launched, implementation of access to a consensus decent minimum is key, rather than prolonged deliberations and debate on the specific components of the "basket" of services to be provided. The basket of services can be revised over time in an iterative process of meeting the healthcare needs of all segments of society.

In France, for example, the national health insurance system has covered the entire population since January 2000.[62] The French national health insurance program covers preventive, curative, and rehabilitative services as well as palliative care. Overall, wide-ranging reimbursement is provided for basic medical and diagnostic services, hospital services, outpatient dental care, all other specialized healthcare, long-term nursing care, diagnostic imaging, laboratory testing, prescribed medicines, durable medical equipment, and prevention and public health services.[63] Importantly, in France, copayment exemptions are available for persons with one of thirty specified long-term illnesses including AIDS, cancer, diabetes, and psychiatric illness. French health policy is directed toward reducing health inequalities "on the basis of improved knowledge of public health needs."[64]

In Denmark, the national healthcare system provides extensive benefits and entitlements comprising a "health benefit basket" or "basic package of health services."[65] Danish counties and the Copenhagen Hospital Corporation are responsible for providing free hospital treatment. Outpatient care services provided by general practitioners and private specialists are reimbursed by the county. Hospitals are financed by block grants from the state and county tax revenues.[66] Danish national healthcare includes inpatient and outpatient care, rehabilitative care and home care, laboratory testing and diagnostic imaging, pharmaceuticals, therapeutic devices, maternal and child care, school health services, disease prevention services, and occupational health services.[67] For example, Danish citizens are entitled to free services from general practitioners and partial reimbursement of dental services and physical therapy. Services provided by psychiatrists, ophthalmologists, ear-nose-throat physicians, and other specialists are fully covered.

In general, a decent minimum of healthcare might include annual examinations and necessary testing by pediatricians for children and family physicians for adults; preventive public health services such as vaccinations and screenings; maternity care and well-baby checkups; K-12, college, and workplace wellness programs; community-based prediabetes and cardiovascular health wellness programs; and basic mental health programs. It is important to recognize,

however, that establishing decent minimums for healthcare services and instituting universal healthcare systems are necessary but not sufficient actions for improving the health of children and men and women of all ages. Addressing the *social determinants of health* is also required.

Distribution of the U.S. Healthcare Dollar

In the context of providing a decent minimum of healthcare in the United States, it is useful to assess the current distribution of the U.S. healthcare dollar. The Centers for Medicare and Medicaid Services (CMS) note that in 2016, U.S. healthcare spending was US$3.3 trillion, representing expenditures of greater than US$10,300 per person.[68] In 2016, the U.S. healthcare dollar (CMS) was allocated as follows:

- Hospital care—32 percent
- Physician and clinical services—20 percent
- Prescription drugs—10 percent
- Other professional services, including physical therapy and optometry—3 percent
- Dental services—4 percent
- Other health and residential services, including medical services delivered in community centers and the workplace—5 percent
- Home healthcare—3 percent
- Nursing care facilities and continuing care retirement facilities—5 percent
- Durable medical equipment—2 percent
- Other nondurable medical products, including over-the-counter medications—2 percent
- Government administration and net cost of healthcare insurance—8 percent
- Other—6 percent[69]

Considering healthcare spending from the perspective of the healthcare insurance industry, in 2017 the distribution of the healthcare insurance premium dollar was as follows:

- Physician services—22 percent
- Prescription drugs—22 percent
- Outpatient services—19.7 percent
- Inpatient services—15.8 percent
- Operating costs (administrative costs)—17.8 percent
- Net margin—2.7 percent[70]

Sources of funding for provision of a "health benefit basket" or "basic package of health services" to all Americans could be identified upon critical analysis of the current allocations of the U.S. healthcare dollar.

Nonjudgmental Regard

In association with the biomedical ethical principle of autonomy, which acknowledges and affirms a person's right of self-determination, *nonjudgmental regard* requires healthcare practitioners

to provide appropriate care and treatment to their patients that aligns with the patient's values and conception of the good, regardless of the healthcare provider's own and different perspectives.[71] Nonjudgmental regard is a component of the moral nature and requirements of the provider–patient relationship, which includes the importance of caring, the centrality of trust, responsiveness, and respect.[72] In the realm of healthcare, nonjudgmental regard is a manifestation of the observation of preeminent American political philosopher John Rawls (1921–2002) that "the distinctive character and autonomy of the various elements of society requires that, within some sphere, they act from their own principles designed to fit their peculiar nature."[73]

In *Groundwork of the Metaphysic of Morals*, Immanuel Kant stated that humanity has absolute or unconditional worth by virtue of its rationality and moral agency.[74] Thus, nonjudgmental regard is grounded in respect for the patient's worth as a moral agent.[75] In consequence, healthcare provider interactions with patients, healthcare decision making, and healthcare practice are necessarily all-inclusive endeavors, regardless of the patient's race, gender, religion, socioeconomic status, or what may be perceived by the provider as personal quirks or idiosyncrasies. By virtue of the patient's right of self-determination, that is, her moral agency, she is worthy of the healthcare provider's respect and nonjudgmental regard in the fulfillment of the biomedical ethical principles of beneficence and justice.

Social Determinants of Health

Extensive research has indicated that social, economic, and environmental conditions have equivalent or even greater impact on individual and population health compared with the impact of delivery of healthcare services.[76] Thus, the provision of universal healthcare must be supplemented by broad initiatives to redress health inequalities via improvement in these nonhealthcare factors. For example, the Robert Wood Johnson Foundation emphasized four community-wide actions that would improve health in the United States: increasing access to programs promoting early childhood development; revitalizing low-income neighborhoods; removing obstacles to healthy eating and physical activity; and creating homes and communities with high "health impact" ratings.[77] In general, regarding nonhealthcare influences, "greater attention must be paid to basic social conditions if health reform is to have its maximum effect."[78]

The range of relevant social, economic, and environmental factors has been termed the *social determinants of health* (SDOH). The SDOH are the "circumstances in which people grow, live, work, and age."[79] SDOH include home and community environments; schools and education; conditions of work and leisure; unequal distribution of income, goods, and services; and opportunities of leading a flourishing life.[80] SDOH are responsible for inequities in health, that is, the differences in health seen within and among individuals, families, communities, and countries. Thus, these differences and health disparities overall may be attributed to socioeconomic, political, cultural, and geographic dimensions. Research over the past several decades has demonstrated that enhancing quality of life in the areas of the SDOH can have a significant influence on population health outcomes. Specific remediations addressing SDOH include the following:

- Safe and affordable housing
- Access to education

- Public safety
- Availability of healthy foods
- Local emergency/health services
- Environments free of life-threatening toxins[81]

SDOH include access to the basic material circumstances necessary for health such as general sanitary living conditions, clean water, and adequate nutrition and housing.[82] The World Health Organization (WHO) states that the healthcare system itself is a social determinant of health.[83]

Importantly, inequalities of access to the social determinants of health impact persons across all segments of society, not only those living in poverty. In other words, unequal distribution of resources necessary for health affects children and adults over a range of socioeconomic categories. This phenomenon has been termed the social gradient in health.[84] The social gradient in health is experienced by rich and poor alike. Specifically, at each point in the socioeconomic spectrum, people demonstrate better morbidity and mortality rates than those below them and worse rates than those at positions above them in the hierarchy. A combination of factors is responsible for the development of the social gradient in health including social, environmental, and individual dynamics. These influences include early childhood development, parents' education, household income, neighborhood characteristics, social supports, work environment, perceptions of control and self-efficacy, and perceptions of inequality.[85] The social gradient of health affects those on every rung of the social ladder. For example, "people in the highest income group are healthier than those only slightly less well off."[86]

Income, and therefore utilization of healthcare services, is not the sole criterion responsible for the effects of the social determinants of health. Various studies have demonstrated that only 15 to 43 percent of a person's health status derives from healthcare services.[87] Within societies, income is correlated with life expectancy. But at the level of whole societies (e.g., states of the United States or countries), *inequality of income,* not income level itself, is correlated with life expectancy.[88] Thus, there is a "lack of any clear relationship between socioeconomic status and health between countries."[89] Health is affected by differences in *relative* income. Specifically, nations with the longest life expectancy are not the richest but those with the smallest differential in incomes and the "smallest proportion of the population in relative poverty."[90] The relationship between average life expectancy and income distribution (*not* income level) does not represent an effect of better access to healthcare services, as the relationship persists after controlling for gross domestic product per capita and public expenditures on medical care.

Healthcare outcomes in the United States present a prime example of the impact of the social gradient in health. In 2014, U.S. health expenditure per capita was US$9,403. By comparison, health expenditure per capita was US$6,808 in Sweden, US$4,959 in France, and US$5,292 in Canada.[91] But life expectancy (in 2015) was 79.3 years in the United States, 82.4 years in Sweden, 82.4 years in France, and 82.2 years in Canada.[92] Infant mortality rate (number of deaths of infants under one year old in a given year per 1,000 live births; 2016 estimates) was 5.8 in the U.S., 2.6 in Sweden, 3.3 in France, and 4.6 in Canada.[93] Importantly, relative income poverty (the share of the population with an income of less than 50 percent of the national income) was 17.5 percent in the United States, 8.8 percent in Sweden, 8 percent in France, and 12.2 percent in Canada.[94] The average income of the top 20 percent as a multiple of the average income of the bottom 20 percent was 8.7 percent in the United States, 4.2 percent in Sweden, 4.4 percent in

France, and 5.5 percent in Canada.[95] Thus, high levels of income inequality in the United States are associated with reduced life expectancy and high rates of infant mortality.

The biomedical ethical principle of justice, as manifested in the requirement for *distributive justice*, necessitates public policy and appropriate legislation and regulation addressing the social determinants of health and the social gradient in health. Improving health and reducing health inequities is a duty of society and should be a priority for city, state, and federal governments.[96] WHO states that social justice is "a matter of life and death."[97] To "close the health gap in a generation," WHO recommends broad action in three areas:

- Improving daily living conditions
- Redressing the inequitable distribution of power, money, and resources
- Measuring and understanding the problems and assessing the impact of action[98]

Achieving justice in healthcare is an exceedingly complex task. As a society, we need to choose whether we are committed to ensuring equality of opportunity for the flourishing of every member of our communities. As the social gradient in health extends across all segments of society, ensuring equality of opportunity will benefit everyone, not only those at the lowest socioeconomic levels. Developing and implementing a universal system of healthcare, combined with sustained policy development and activities in the three areas identified by WHO, will help us provide opportunities for safer, stronger, richer, more secure, and more fulfilling lives for us, our families, our communities, and our societies.

Rawls famously stated that "Justice is the first virtue of social institutions, as truth is of systems of thought.... Being first virtues of human activities, truth and justice are uncompromising."[99] Rawls's declaration is itself uncompromising and requires us (as a society) to act upon our inherited moral imperatives and implement fair, equitable, and just healthcare systems. It is useful to recall that the Pledge of Allegiance to the Flag of the United States of America highlights "liberty and justice for all." Applying these stirring sentiments to the field of healthcare, it is certainly time for us to begin to "walk the talk."

Emergency Medical Treatment and Labor Act (EMTALA)

The Emergency Medical Treatment and Labor Act (EMTALA) was passed by Congress in 1986 as part of the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA; Public Law 99-272; Section 1867).[100] EMTALA specifies that Medicare-participating hospitals with emergency departments must provide an appropriate medical screening examination, further medical examination as needed, and such treatment as may be required for any individual who comes to the emergency department and requests examination and treatment for a medical condition, regardless of that individual's health insurance status or other ability to pay for services rendered. EMTALA requires that if an individual has an emergency medical condition, the Medicare-participating hospital is required to stabilize the individual's medical condition or arrange for appropriate transfer to "another medical facility where stabilizing treatment can be provided."[101] Violations of EMTALA may result in termination of a provider agreement and imposition of civil monetary penalties (CMPs). Participating hospitals and responsible

physicians may be liable for CMPs of up to US$50,000 for each negligent violation of respective EMTALA obligations.

Per 42 CFR Part 1003 (Civil Money Penalties, Assessments and Exclusions), aggravating circumstances considered in assessing penalties include "requesting proof of insurance, prior authorization, or a monetary payment prior to appropriately screening or initiating stabilizing treatment for an emergency medical condition, or requesting a monetary payment prior to stabilizing an emergency medical condition."[102] As well, aggravating circumstances include patient harm and premature discharge.[103]

Congress enacted EMTALA to ensure that persons with emergency medical conditions are not denied necessary lifesaving services.[104] As such, EMTALA may be appropriately construed as federal action addressing the social determinants of health and a means of redress of health inequities in the area of access to healthcare services. EMTALA was specifically preserved in the Patient Protection and Affordable Care Act of 2010 (ACA) in §1303(d), which stated that "Nothing in this Act shall be construed to relieve any health care provider from providing emergency services as required by State or Federal law, including section 1867 of the Social Security Act (popularly known as 'EMTALA')."[105]

But EMTALA began as and remains an unfunded mandate. The act requires provision of emergency department (ED) services, but does not make federal funds available as reimbursement for services provided. In 2014, there were more than 141.4 million emergency department (ED) visits in the United States[106] and costs of ED services were approximately US$65 billion.[107] The mean ED expense per person in 2014 was US$1,533.[108] Thus, extrapolating, there was a total of approximately 42.4 million ED cases in 2014. In 2014, the distribution of total expenses by source of payment listed 9 percent as out of pocket (no insurance coverage),[109] potentially representing up to US$5.8 billion in unpaid emergency department services nationally. From another viewpoint, in 2013, aggregate spending on emergency care was estimated to be 5 to 6 percent of national health expenditures.[110] In contrast, the "Just 2%" campaign of the American College of Emergency Physicians (ACEP) asserts that emergency care represented 1.9 percent of the US$2.4 trillion spent on healthcare in the United States in 2008.[111] In 2016, U.S. healthcare spending was US$3.3 trillion.[112] Based on the 2014 estimate of 9 percent no coverage and utilizing the ACEP's more conservative estimate of 1.9 percent of total healthcare services, emergency care expenses in 2016 would be approximately US$62.7 billion and unpaid ED services in 2016 would be approximately US$5.6 billion.

The ACA substantially reduced the number of uninsured nonelderly Americans from an estimated 44 million in 2013 (the year before the ACA's major coverage provisions went into effect) to an estimated 28 million by the end of 2016.[113] Thus, EMTALA continues to guarantee that tens of millions of uninsured Americans will receive emergency medical care. But hospitals bear the burden of uncompensated care rendered in the ED. Those who have health insurance coverage also bear the financial costs of EMTALA in the form of higher prices for medical care, increasing insurance premiums, and increasing taxes.[114]

It is reasonable to conclude that reductions in overall emergency department use would result in decreased stress on all aspects of healthcare institution functioning and decreased financial stress on taxpayers. Various proposals have been promulgated to improve delivery of preventive and primary healthcare services to underserved populations and communities, of which one intended outcome is reduction in use of ED services. In California, Senate Bill No. 4 (SB4; enacted on October 9, 2015)[115] noted that Senate Bill 75 (SB75; enacted on June 24,

2015)[116] had extended eligibility for full Medi-Cal (California Medical Assistance Program) benefits to all children in California, regardless of immigration status. SB4 amended a section of the California Welfare and Institutions Code to read that individuals under nineteen years of age enrolled in Medi-Cal "shall be enrolled in the full scope of Medi-Cal benefits ... pursuant to an eligibility and enrollment plan." SB4 stated, "No child in California should endure suffering and pain due to a lack of access to health care services." As well, SB4 stated, "Expanding access and increasing enrollment in comprehensive health care coverage benefits the health and welfare of all Californians." The immediate impact of SB75 was to extend Medi-Cal to an estimated 200,000 children of eligible low-income families, regardless of immigration status.[117] By providing full Medi-Cal coverage (free or low-cost health coverage for children and adults with limited income and resources[118]) for undocumented immigrant children, SB75 and SB4 took substantive action toward redressing health inequities and reducing emergency department use across California.

Thus, efforts toward reducing utilization of ED services may be reasonably considered as representing sound public policy. Such reductions are facilitated by use of patient-centered medical homes (PCMH), a unique model of delivering primary care services. PCMH provide team-based care including enhanced access and a broad range and scope of services.[119] PCMH deliver preventive care and chronic disease management services optimized with health information technology. The PCMH structure facilitates the ability to "measure, understand, and influence the entire population" of patients participating in the program.[120] Adults and children treated in PCMH have utilized 11 and 17 percent fewer ED services and demonstrated 12 and 23 percent reduced odds of hospitalization, respectively, in comparison with non-PCMH patients.[121]

Key issues associated with implementation of EMTALA include the following:

- Hospitals' lack of capacity in terms of insufficient financial resources to treat uninsured patients and inadequate numbers of available physicians willing to take emergency calls
- Inadequate numbers of other healthcare providers such as nurses or social workers with psychiatric training
- Inadequate emergency department facilities.[122]

Overall, EMTALA has helped redress health inequities for more than thirty years. Additional public policy initiatives, state and federal legislation, and innovative healthcare institution practices are required to provide equitable access to and affordability of healthcare services.

The Four-Box Method: Real-World Applications of the Four Principles of Biomedical Ethics

The four principles of biomedical ethics provide a robust framework for ethical analysis of healthcare decision making. However, many healthcare scenarios involve complex circumstances in which the appropriate ethical path is not readily apparent. These cases are referred to hospital biomedical ethics committees for review, assessment, and recommendations. One systematic, reproducible approach toward achieving effective ethical resolution of such complex

cases involves practical application of the four principles. The "four topics" method, originally described in 1982,[123] is a highly effective tool for analyzing the clinical details and ethical components of complex cases. The "four topics" are as follows:

- Medical indications
- Patient preferences
- Quality of life
- Contextual features[124]

Each "topic" or "box" focuses on specific aspects of a case. The method facilitates creating order out of a jumble of facts, opinions, impressions, and circumstances. The "four topics" or "four boxes," as the method is widely known, enables ethics committee members to identify key issues and concerns, formulate the primary problem or "ethical question," and reach a consensus on an ethically appropriate action plan, one that is supported by the evidence of the case.

The process of implementing the four-box method may be assisted by engaging in specific practices:

- Collect all relevant data that may be useful in resolving the clinical ethical dilemma
- Formulate a specific question that encapsulates the conflict
- When uncertainty persists regarding an ethically appropriate course of action, determine whether there is missing information that would help to resolve the dilemma
- Evaluate the proposed resolution in the context of the four biomedical ethical principles that provide a framework for the ethical standard of care
- Plan the immediate action steps and be sure to consider potential future ethical issues[125]

Medical Indications

The medical indications are the clinical facts of the case. This "box" includes the patient's healthcare problem, the diagnosis, prognosis, treatment options, and goals of treatment. The medical indications "box" includes an assessment of the benefits and harms of treatment and the likelihood of success of the various options. Medical indications include an evaluation of the possible futility of treatment as well as contingency plans in the event of an unsuccessful outcome.[126] Regarding medical indications, the biomedical ethical principles of primary consideration are beneficence and nonmaleficence. The key concern, based on the patient's clinical status and likely prognosis, is whether the proposed treatment will do more good for the patient or cause more harm.

Patient Preferences

The patient preferences "box" represents implementations of the biomedical ethical principle of autonomy, that is, respect for persons. For example, what are the patient's preferences regarding treatment? Has she been informed regarding the potential benefits and the potential harms of proposed treatment? Has the patient understood the various options and given consent? In contrast, if the patient does not at present have capacity for healthcare decision making, has she previously expressed preferences regarding care? Is an advance directive available? Is a do-not-resuscitate order on file? Has an appropriate surrogate decision maker been identified? If an appropriate surrogate is not available, how will the patient's best interests be identified

and upheld? Further, are there conflicts between a patient's preferences for treatment and the recommendations of the healthcare team?

Quality of Life

Quality of life addresses the patient's clinical status, likely outcomes of treatment, and the patient's preferences. Considerations regarding quality of life concern the biomedical ethical principles of beneficence, nonmaleficence, and autonomy. First, what are the patient's preferences regarding quality of life? Does the patient's perspective on quality of life contrast with that of the healthcare team? If the patient lacks capacity for healthcare decision making, is an advance directive available? Has she discussed such preferences with family members or friends? Next, how will proposed treatment impact the patient's quality of life? What benefits might be achieved in terms of activities of daily living, work, and social interactions? What are likely residual deficits even in the presence of overall treatment success? What is the probability that treatment will further worsen the patients' quality of life? If the patient lacks capacity, how may an assessment of appropriate quality of life be made? Do quality of life assessments impact treatment choices, including the possibility of forgoing life-sustaining treatment? Are there plans for comfort care?

Contextual Features

Contextual features enable consideration of nonmedical factors that situate the patient's care in a broader setting. Overall, contextual features are primarily concerned with the biomedical ethical principle of justice. The contextual features "box" includes family and socioeconomic issues that might impact decision making related to the patient's care, as well as issues related to the healthcare team itself and the distribution of scarce resources. Family dynamics, the patient's living situation, and identification of major caregivers comprise important contextual features. Additional considerations include whether family members have a financial interest in the outcome of the patient's care. Are there conflicts of interest on the part of members of the healthcare team or institution that might impact clinical decision making? Are there religious issues or legal issues that might affect selection of appropriate treatment? How is clinical decision making affected by considerations regarding resource allocation? Are there concerns regarding patient confidentiality, especially in relation to the interests of family members and other associates? Does clinical decision making in this case impact public health and safety?

Summary

The four-box method facilitates a systematic analysis of ethical issues involved in complex cases. The consensus recommendations achieved by employment of this method are based on an assessment of the multitudinous and variegated facts, factors, features, and opinions that comprise care of a patient in difficult circumstances. Case analysis utilizing the four-box method enables the hospital biomedical ethics committee to identify the key ethical question at issue and articulate solutions based on considerations of the following:

- Consent
- Capacity
- Confidentiality
- Resource allocation

- Surrogacy
- Substituted judgment
- Best interests

Thus, by encouraging comprehensive inquiry into the ethical components of a complex case, the four-box method enables operationalization, that is, practical implementation, of the four principles of biomedical ethics.

BOX 4.2

Case Study: Distribution of Scarce Healthcare Resources

Large healthcare institutions are often located in the downtown center of major metropolitan areas. Thus, those working in the cluster of nearby business centers and those living in neighboring communities have easy access to quality healthcare services. But families living on the outskirts do not enjoy such fortunate access. Communities at a distance from urban centers frequently have diminished resources and most often represent a lower socioeconomic demographic.

Typically, communities on the fringes of big cities have very limited access to primary care physicians, other medical specialists, and healthcare practitioners generally. These communities have a paucity of green space and limited opportunities to engage in physical activities outdoors. Further, these neighborhoods tend to have very limited access to fresh fruits and vegetables and other healthful nutritious foods. In consequence of these factors and other constrained social determinants of health, health disparities manifesting as increased incidence and prevalence of cardiovascular disease, diabetes, and overweight/obesity are endemic in such communities, as well as increased infant mortality rates and reduced longevity. Overall, obtaining access to healthcare services requires significant expenditures of time and effort, and the costs of those services are often prohibitive. As a result, delivery of preventive healthcare services is most often not accomplished. Treatment is not sought for treatable conditions and the progression of a wide range of disease processes is only rarely abated.

Ethical Analysis

1. From the perspective of the biomedical ethical principle of justice, describe two consequences to society of inequity in the distribution of healthcare resources.
2. Discuss one short-term and one long-term solution to the healthcare inequities noted in the case study.
3. From the perspective of the biomedical ethical principle of justice, discuss the responsibilities, if any, of society toward its less fortunate and less well-off members. Discuss the special responsibilities, if any, of society toward children, the disabled, and the elderly.

BENEFICENCE: KEY TERMS

Cost-Effectiveness Analysis
Cost-effectiveness analysis (CEA) assesses the ratio between the amount of benefit provided by a treatment compared with the cost.

Cost-Utility Analysis
Cost-utility analysis (CUA) evaluates the cost per quality-adjusted life year. In CUA, utility expresses the contrast or trade-off between quantity and quality of life.

Quality of Life
The World Health Organization Quality of Life Group defines quality of life as "a broad multidimensional concept that usually includes subjective evaluations of both positive and negative aspects of life."[127] Quality of life includes all of a person's interactions with his family, friends, and coworkers as well as the ability to perform activities of daily living such as self-care and managing a home environment.

JUSTICE: KEY TERMS

Decent Minimum of Healthcare Services
Overall, a decent minimum of healthcare services includes curative care, rehabilitative care, long-term nursing care, laboratory tests and diagnostic imaging, medications, and therapeutic devices including durable medical equipment. Over the past several decades, in the context of developing systems to provide universal access to healthcare services, national governments in the developed world have struggled to define an appropriate decent minimum of healthcare services for their citizens. The basic services available varies slightly from country to country in the European Union, Australia, and Canada, but the common criteria in designing systems are human dignity, effectiveness, appropriateness, and efficiency.[128]

Distributive Justice
Distributive justice in the context of delivery of healthcare services refers to an equitable distribution of scarce resources. Distributive justice does not imply that everyone should have equal access to everything all the time. Rather, the implication is that competing needs must be balanced fairly and opportunities to obtain medical care must be equitable. For example, it is unjust if only the wealthy have access to certain cancer medications costing more than US$100,000 annually.[129] Distributive justice mandates that members of all socioeconomic groups have the opportunity to obtain such treatment. The requirement for distributive justice applies broadly to basic healthcare services and specifically to services such as organ transplantation and fertility treatment.

Nonjudgmental Regard
Nonjudgmental regard requires that healthcare practitioners promote the good of their patients without preliminarily judging their worth.[130] Healthcare providers must be nonjudgmental

in allocating caring concern and in providing treatment and must maintain respect for their patients' values.

Social Determinants of Health

The social determinants of health (SDOH) are responsible for inequities in health, that is, the differences in health seen within and among individuals, families, communities, and countries. SDOH are the "circumstances in which people grow, live, work, and age."[131] SDOH include access to the basic material circumstances necessary for health such as general sanitary living conditions, clean water, and adequate nutrition and housing. Remediation of the social determinants of health includes safe and affordable housing, access to education, availability of healthy foods, and availability and affordability of local emergency/health services.

BENEFICENCE: DISCUSSION QUESTIONS

1. Based on an internal standard of the good, discuss the physician's moral responsibilities to her patient. Describe a practical example in the context of the biomedical ethical principle of beneficence. What might be the consequences for the patient if the physician failed to uphold his moral responsibility?
2. In your own words, define compassion in the context of healthcare delivery. How is compassion a moral value and how is compassion related to the biomedical ethical principle of beneficence? How is compassion demonstrated and what is your experience as the recipient of compassionate care?
3. In 2017, annual healthcare costs in the U.S. exceeded US$3.2 trillion,[132] yet life expectancy was declining[133] and the infant mortality rate was nearly the highest among developed countries.[134] In consideration of these facts, discuss actions individual healthcare providers can take to enhance the welfare and well-being of their patients. Discuss healthcare public policies that would implement the biomedical ethical principle of beneficence.

JUSTICE: DISCUSSION QUESTIONS

1. In the U.S., healthcare delivery is increasingly a for-profit enterprise. Consider that you are responsible for healthcare public policy at a state or federal level. From the perspective of distributive justice, what modifications, revisions, or large-scale overhaul would you recommend to be undertaken by legislative bodies? Your recommendations might focus on healthcare delivery systems, health insurance standardization, protocols and standards, oversight agencies, or all of the above.
2. When quality of care outcomes are being met, overall cost of care declines.[135] It may be reasonably asserted that U.S. healthcare outcomes, middle-of-the-pack or worse with respect to such measures in other developed nations, are directly associated with the high costs of healthcare. Considering the prevalence of health disparities, discuss two specific and measurable healthcare policies you would take action to implement in your healthcare organization or institution. Describe the critical healthcare needs these measures would address.

3. In his groundbreaking 1963 article, "Uncertainty and the Welfare Economics of Medical Care,"[136] Professor Kenneth J. Arrow described the uniqueness of the healthcare industry in the context of markets. He accurately predicted our current widespread inefficiencies and market failures, owing to the inherent uncertainty and asymmetric distribution of information in medical practice. Applying the biomedical ethical principle of justice,
   - Identify and discuss some of the primary structural flaws in a healthcare system driven by market forces.
   - Consider and describe the relationship between services and fees in such a market system.
   - Discuss the available alternatives. How do other industrialized societies implement such alternatives?

BENEFICENCE: DO-IT-YOURSELF ETHICIST

Healthcare Economics: Cost-Effectiveness Analysis versus Cost-Utility Analysis

1. Compare and contrast CEA and CUA.
2. Which of these methods provides the best assessment of the value of healthcare treatments or protocols?
3. Discuss a particular medical intervention(s) for which one method might provide a more useful assessment than the other.
4. How do you define *value* from the perspective of the healthcare system and from the perspective of the patient.
5. Discuss how healthcare policy decision making might incorporate such value assessments and how the resulting policies might impact delivery of healthcare services.

JUSTICE: DO-IT-YOURSELF ETHICIST

1. In the twenty-first century, many healthcare providers are becoming activists for social justice. Identify the top three healthcare issues impacting the residents of the community in which your healthcare organization is based. Next, create an action plan to address these issues, including a list of specific measurable results, milestones for achievement of those results, and an overall timeline. List the resources needed to accomplish these plans.
2. You have chosen to run for political office at the local, state, or federal level. How does your experience as a healthcare provider provide assistance to your campaign? Describe your political mission and vision. From the perspective of the biomedical ethical principle of justice, how might your election lead to improvement in the healthcare status of the members of your community?
3. Around the globe, attainment of social justice in healthcare is influenced by poverty, lack of access to clean water and sanitation, illiteracy, oppression of women, human rights violations, and government corruption. Write a 750-word op-ed article discussing one

of these issues and submit your article to your local newspaper or a national publication. (If your article is not accepted, keep going. Seek feedback from colleagues and submit your article to a different publication.)

BENEFICENCE: REAL-WORLD APPLICATIONS—ETHICS AS A DOCTRINE OF ACTION

Beneficence in Healthcare Practice

1. How do you, the healthcare provider, assess the potential benefits of proposed treatment?
2. Provide an example of such decision making, including the clinical presentation of your patient and two or three treatment alternatives.
3. How do you assist your patient in making an appropriate choice?
4. In contrast, as a consumer, how would you prefer to involve your healthcare practitioner in the process of treatment decision making?

Public Good versus Individual Good

1. Describe circumstances in which considerations of public good might outweigh considerations of the good of the individual patient.
2. Discuss whether enhancing the public good should generally take precedence over enhancing individual good or vice versa.
3. What are your current ethical considerations as you, the healthcare provider, navigate these potentially slippery slopes?

Healthcare Policy

You are a healthcare policy expert and have been invited to deliver the keynote address at your local business leaders' annual retreat. Your topic is "Healthcare in America." Discuss the impact of the Affordable Care Act on community health and how those outcomes affect state and national welfare. Discuss the benefits and drawbacks of the ACA's individual mandate and how healthcare economics will likely be affected by the loss of that mandate. From the perspective of the biomedical ethical principle of beneficence, discuss your recommendations for improving the ACA and improving the U.S. healthcare system overall.

JUSTICE: REAL-WORLD APPLICATIONS—ETHICS AS A DOCTRINE OF ACTION

Health education and promotion represents a primary method for implementing the biomedical ethical principle of justice. Create a thirty-minute community presentation on the benefits of healthy lifestyle behaviors and the resources offered by your healthcare organization, focusing on the welfare and well-being of individuals and families. Next, identify two colleagues from other healthcare specialties who might participate in these community presentations and help you establish a plan for delivering these talks on a quarterly basis.

REFERENCES

[1]W. H. S. Jones, trans., "The Oath," in Hippocrates, vol. I (Cambridge, MA, Harvard University Press, 1957), 299.

[2]Code of Ethics of the American Medical Association, adopted May 1847 (Philadelphia: Turner Hamilton, 1871).

[3]B. Spilker, *Quality of Life Assessment in Clinical Trials* (New York: Raven Press, 1990), 3–9.

[4]D. M. Eddy, "Cost-Effectiveness Analysis. Is It Up to the Task?" *JAMA* 267, no. 24 (1992): 3342–3348.

[5]M. C. Weinstein, G. Torrance, and A. McGuire, "QALYs: The Basics," *Value Health* 12, suppl. 1 (2009): S5–S9.

[6]D. W. Raisch, "Understanding Quality-Adjusted Life Years and Their Application to Pharmacoeconomic Research," *Annals of Pharmacotherapy* 34, nos. 7–8 (2000): 906–914.

[7]M. R. Gold, D. L. Patrick, G. W. Torrance et al., "Identifying and Valuing Outcomes," in *Cost-Effectiveness in Health and Medicine*, eds. M. R. Gold, J. E. Siegel, L. B. Russell et al. (New York: Oxford University Press, 1996), 82–134.

[8]R. M. Kaplan, "Using Quality of Life Information to Set Priorities in Health Policy," *Social Indicators Research* 33, no. 1/3 (1994): 121–163.

[9]Ibid.

[10]H. E. Klarman, J. O'S. Francis, and G. D. Rosenthal, "Cost Effectiveness Analysis Applied to the Treatment of Chronic Renal Disease," *Medical Care* 6, no. 1 (1968): 48–54.

[11]Ibid., 53.

[12]G. L. Engel, "The Need for a New Medical Model: A Challenge for Biomedicine," *Science* 196, no. 4286 (1977): 129–136; G. L. Engel, "The Biopsychosocial Model and the Education of Health Professionals. *Annals of New York Academy of Science* 310 (1978): 169–181, 1978.

[13]S. Schwartz, J. Richardson, and P. P. Glasziou, "Quality-Adjusted Life Years: Origins, Measurements, Applications, Objections. *Australian Journal of Public Health* 17, no. 3 (1993): 272–278.

[14]Weinstein, Torrance, and McGuire, "QALYs," S8.

[15]Eddy, "Cost-Effectiveness Analysis," 3344.

[16]P. Kind, J. E. Lafata, K. Matuszewski et al., "The Use of QALYs in Clinical and Patient Decision-Making: Issues and Prospects," *Value in Health* 12, suppl. 1 (2009): S27–S30.

[17]J. E. Siegel, G. W. Torrance, L.B. Russell et al., "Guidelines for Pharmacoeconomic Studies. Recommendations from the Panel on Cost Effectiveness in Health and Medicine," Pharmacoeconomics 11, no. 2 (1997): 159–168.

[18]M. Drummond, D. Brixner, M. Gold et al., "Toward a Consensus on the QALY," *Value in Health* 12, suppl. 1 (2009): S31–S35.

[19]T. R. Parmenter, "Quality of Life as a Concept and Measurable Entity," *Social Indicators Research* 33, no. 1/3 (1994): 9–46.

[20]Schwartz, Richardson, and Glasziou, "Quality-Adjusted Life Years," 275.

[21]E. Nord, N. Daniels, and M. Kamlet, "QALYs: Some Challenges," *Value in Health* 12, suppl. 1 (2009): S10–S15.

[22]Drummond, Brixner, Gold, "Toward a Consensus on the QALY," S32.

[23]D. Lakdawalla, J. Shafrin, C. Lucarelli et al., "Quality-Adjusted Cost of Care: A Meaningful Way to Measure Growth in Innovation Cost versus the Value of Health Gains," *Health Affairs* 34, no. 4 (2015): 555–561.

[24]Ibid.

[25]Division of Medical Assistance Programs, Department of Health Services, *Administrative Overview. Office of the Secretary of State, State of Oregon*, 2007, http://sos.oregon.gov/archives/Documents/recordsmgmt/sched/overview-health-medical-assist.pdf.

[26]R. M. Kaplan, "Value Judgment in the Oregon Medical Experiment," *Medical Care* 32, no. 10 (1994): 975–988.

[27]D. C. Hadorn, "The Oregon Priority-Setting Exercise: Quality of Life and Public Policy. *Hastings Center Report* 21, no. 3 (1991): 11–16.

[28]S. Grace, "Oregon Medical Care Plan Rejected by Administration," *Los Angeles Times*, August 4, 1992.

[29]Kaplan, "Value Judgment in the Oregon Medical Experiment," 986.

[30]E. Chen, "Oregon Wins OK to Ration Medical Care," *Los Angeles Times*, March 20, 1993.

[31]Hadorn, "The Oregon Priority-Setting Exercise," 16.

[32]Public Law 111-148: Patient Protection and Affordable Care Act, March 23, 2010,https://www.gpo.gov/fdsys/pkg/PLAW-111publ148/pdf/PLAW-111publ148.pdf.

[33]J. Oberlander, "Long Time Coming: Why Health Reform Finally Passed," *Health Affairs* 29, no. 6 (2010): 1112–1116.

[34]Public Law 111-148, Section 4003(b)(1), 124 Stat. 543.

[35]Ibid.

[36]Community Preventive Services Task Force, *First Annual Report to Congress. 2011*, https://www.thecommunityguide.org/sites/default/files/assets/2011-congress-report-full_1.pdf.

[37]Ibid., 2.

[38]Community Preventive Services Task Force, *2014-2015 Annual Report to Congress*, https://www.thecommunityguide.org/sites/default/files/assets/2015-congress-report-full_0.pdf.

[39]Ibid., 17–18.

[40]Public Law 111-148, Section 2704, 124 Stat. 154.

[41]Ibid., Section 5000A, 124 Stat. 244.

[42]Ibid., 124 Stat. 248.

[43]P. Krugman, "Three Legs Good, No Legs Bad," *New York Times*, July 10, 2017, https://www.nytimes.com/2017/07/10/opinion/obamacare-repeal.html.

[44]Public Law 111-148, Section 2713, 124 Stat. 131; Department of Health and Human Services, *About the ACA: Preventive Care*, https://www.hhs.gov/healthcare/about-the-aca/preventive-care/index.html.

[45]Public Law 111-148, Section 6301, 124 Stat. 727–728.

[46]Ibid., Section 4001, 124 Stat. 538–539.

[47]Ibid., Subtitle B, 124 Stat. 546–564.

[48]Centers for Medicare and Medicaid Services, *Background: The Affordable Care Act's New Rules on Preventive Care*, July 14, 2010, https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/preventive-care-background.html.

[49]S. A. Glied, S. Ma, and A. Borja, *Effect of the Affordable Care Act on Health Care Access* (New York: The Commonwealth Fund, 2017), http://www.commonwealthfund.org/publications/issue-briefs/2017/may/effect-aca-health-care-access.

[50]Ibid., 4.

[51]B. D. Sommers, A. A. Gawande, and K. Baicker, "Health Insurance Coverage and Health. What the Recent Evidence Tells Us," *New England Journal of Medicine* 377, no. 6 (2017): 586–593.

[52]H. Levy and D. Meltzer, "The Impact of Health Insurance on Health," *Annual Review of Public Health* 29 (2008): 399–409.

[53]B. D. Sommers, "State Medicaid Expansions and Mortality, Revisited: A Cost-Benefit Analysis," *American Journal of Health Economics* 3, no. 3 (2017): 392–421.

[54]*National Federation of Independent Business v. Sibelius*, 567 U.S. 519 (2012), https://supreme.justia.com/cases/federal/us/567/519/.

[55]Ibid.

[56]Public Law 115-97, Part VIII–Individual Mandate (Section 11081), December 22, 2017, https://www.congress.gov/bill/115th-congress/house-bill/1.

[57]R. Pear, "Without the Insurance Mandate, Health Care's Future May Be in Doubt," *New York Times*, December 18, 2017, https://www.nytimes.com/2017/12/18/us/politics/tax-cut-obamacare-individual-mandate-repeal.html.

[58]R. Dworkin, ed., *Mill's On Liberty. Critical Essays* (Lanham, MD: Rowman & Littlefield, 1997), 123.

[59]O. Solar and A. Irwin, "A Conceptual Framework for Action on the Social Determinants of Health," Social Determinants of Health Discussion Paper 2 (Policy and Practice) (Geneva: World Health Organization, 2010), 13, http://www.who.int/sdhconference/resources/ConceptualframeworkforactiononSDH_eng.pdf.

[60]International Covenant on Economic, Social and Cultural Rights, United Nations General Assembly Resolution 2200A (XXXI), December 16, 1966, http://www.ohchr.org/Documents/Professional-Interest/cescr.pdf.

[61]Convention on the Rights of the Child, United Nations General Assembly Resolution 44/25, November 20, 1989, http://www.ohchr.org/Documents/ProfessionalInterest/crc.pdf.

[62]M. M. Bellanger, V. Cherilova, and V. Paris, "The 'Health Benefit Basket' in France," *European Journal of Health Economics* 6, suppl. 1 (2005): S24–S29.

[63]Ibid., S25.

[64]Ibid., S28.

[65]L. Bilde, A. Ankjaer-Jensen, and B. Danneskiold-Samsøe, "The 'Health Benefit Basket' in Denmark. *European Journal of Health Economics* 6, suppl. 1 (2005): S11–S17.

[66]Ibid., S13.

[67]Ibid., S14.

[68]Centers for Medicare and Medicaid Services, *National Health Expenditures 2016 Highlights*, https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/downloads/highlights.pdf.

[69]Ibid.; Centers for Medicare and Medicaid Services, *National Health Spending in 2016*, https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/NHE-Presentation-Slides.pdf.

[70]America's Health Insurance Plans, *Where Does Your Premium Dollar Go?* March 2, 2017, https://www.ahip.org/health-care-dollar/.

[71]R. Rhodes, "Two Concepts of Medical Ethics and Their Implications for Medical Ethics Education," *Journal of Medicine and Philosophy* 27, no. 4 (2002): 493–508.

[72]Ibid., 496.

[73]J. Rawls, *Political Liberalism*, exp. ed. (New York: Columbia University Press, 2005), 262.

[74]Immanuel Kant, *Groundwork of the Metaphysic of Morals* (New York: Harper, 2009).

[75]S. Gibson, "On Judgment and Judgmentalism: How Counselling Can Make People Better," *Journal of Medical Ethics* 31, no. 10 (2005): 575–577.

[76]M. Marmot and J. J. Allen, "Social Determinants of Health Equity. *American Journal of Public Health* 104, no. 54, suppl. 4 (2014): S517–S519.

[77]Robert Wood Johnson Foundation, *Beyond Health Care. New Directions for a Healthier America* (2009), http://www.rwjf.org/content/dam/farm/reports/reports/2009/rwjf40483.

[78]B. G. Link and J. Phelan, "Social Conditions as Fundamental Causes of Disease," *Journal of Health and Social Behavior* 35 (1995): 80–94.

[79]World Health Organization Commission on the Social Determinants of Health, *Closing the Gap in a Generation. Health Equity Through Action on the Social Determinants of Health* (WHO: Geneva, Switzerland, 2008), 8, http://apps.who.int/iris/bitstream/10665/43943/1/9789241563703_eng.pdf.

[80]Ibid., 9.

[81]Health People 2020, *Social Determinants of Health*, https://www.healthypeople.gov/2020/topics-objectives/topic/social-determinants-of-health.

[82]A. Denis and D. Kalekin-Fishman, *The ISA Handbook in Contemporary Sociology* (Thousand Oaks, CA: Sage, 2009), 230.

[83]WHO Commission on the Social Determinants of Health, *Closing the Gap in a Generation*, 8.

[84]M. G. Marmot, R. Fuhrer, S. L. Ettner et al., "Contribution of Psychosocial Factors to Socioeconomic Differences in Health," *Milbank Quarterly* 76, no. 3 (1998): 403–448.

[85]Ibid.

[86]R. G. Wilkinson, "The Epidemiological Transition. From Material Scarcity to Social Disadvantage," *Daedalus* 123, no. 4 (1994): 61–77.

[87]The King's Fund, *Broader Determinants of Health*, https://www.kingsfund.org.uk/time-to-think-differently/trends/broader-determinants-health.

[88]R. G. Wilkinson, *Unhealthy Societies. The Afflictions of Inequality* (London: Routledge, 1996).

[89]Wilkinson, "The Epidemiological Transition," 67.

[90]Ibid., 68.

[91]The World Bank, "Health Expenditures Per Capita (Current US$)," http://data.worldbank.org/indicator/SH.XPD.PCAP.

[92]World Health Organization, "Life Expectancy at Birth (Years), 2000–2015," http://gamapserver.who.int/gho/interactive_charts/mbd/life_expectancy/atlas.html.

[93]Central Intelligence Agency, *The World Factbook*. Country Comparison, Infant Mortality Rate, https://www.cia.gov/library/publications/the-world-factbook/rankorder/2091rank.html.

[94]Organisation for Economic Co-operation and Development, OECD Income Distribution Database (IDD): Gini, Poverty, Income, Methods and Concepts, http://www.oecd.org/social/income-distribution-database.htm.

[95]Ibid.

[96]Marmot and Allen, "Social Determinants of Health Equity," S519.

[97]WHO Commission on the Social Determinants of Health, *Closing the Gap in a Generation*, 3.

[98]Ibid., 10.

[99]J. Rawls, *A Theory of Justice*, rev. ed. (Cambridge, MA: Harvard University Press, 1999), 3–4.

[100]Public Law 99-272, Approved April 7, 1986 (100 Stat. 82), https://www.gpo.gov/fdsys/pkg/statute-100/pdf/statute-100-Pg82.pdf.

[101]*Federal Register* 81 (235): 88334–88365, December 7, 2016, 88348, https://www.gpo.gov/fdsys/pkg/FR-2016-12-07/pdf/2016-28293.pdf.

[102]Ibid., 88361, Part 1003, Subpart E, §1003.520.

[103]Ibid., p. 88360, Part 1003, Subpart D, §1003.420.

[104]*Federal Register* 81 (235): 88334–88365.

[105]Patient Protection and Affordable Care Act. Public Law 111-148, enacted March 23, 2010, https://legcounsel.house.gov/Comps/Patient%20Protection%20And%20Affordable%20Care%20Act.pdf.

[106]Centers for Disease Control and Prevention, *National Hospital Ambulatory Medical Care Survey: 2014 Emergency Department Summary Tables*, https://www.cdc.gov/nchs/data/nhamcs/web_tables/2014_ed_web_tables.pdf.

[107]Agency for Healthcare Research and Quality, *Medical Expenditure Panel Survey*. Table 6: Emergency Room Services. Median and Mean Expenses per Person with Expense and Distribution of Expenses by Source of Payment: United States, 2014, https://meps.ahrq.gov/.

[108]Ibid.

[109]Ibid.

[110]M. H. Lee, J. D. Schuur, and B. J. Zink, "Owning the Cost of Emergency Medicine: Beyond 2%. *Annals of Emergency Medicine* 62, no. 5 (2013): 498–505.

[111]American College of Emergency Physicians, *Emergency Care: Just 2%*, http://newsroom.acep.org/Just2PercentCampaign.

[112]Centers for Medicare and Medicaid Services, *National Health Expenditures 2016 Highlights*, https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/downloads/highlights.pdf.

[113]Kaiser Family Foundation, *Key Facts about the Uninsured Population*, updated November 29, 2017, https://www.kff.org/uninsured/fact-sheet/key-facts-about-the-uninsured-population/.

[114]P. Treister, R. Conboy, L. Smittle et al., "The Financial Impact of Uncompensated Care in the Emergency Department," *International Journal of Energy, Environment, and Economics* 2, no. 6 (2017): 104–108.

[115]California Legislative Information, SB-4 Health Care Coverage: Immigration Status, https://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=201520160SB4.

[116]California Legislative Information: SB-75 Health, http://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=201520160SB75.

[117]E. A. Licas, "Mental to dental, 'SB-75 provides all California youth with access to full-scope health coverage,'" *Asian Journal*, November 4, 2016, http://asianjournal.com/news/mental-to-dental-sb-75-provides-all-california-youth-with-access-to-full-scope-health-coverage/.

[118]Covered California, *Medi-Cal Overview*, https://www.coveredca.com/medi-cal/.

[119]D. D. Maeng, T. R. Graf, D. E. Davis et al., "Can a Patient-Centered Medical Home Lead to Better Patient Outcomes? The Quality Implications of Geisinger's ProvenHealth Navigator," *American Journal of Medical Quality* 27, no. 3 (2012): 210–216.

[120]Ibid.

[121]A. DeVries, C. H. W. Li, G. Sridhar et al., "Impact of Medical Homes on Quality, Healthcare Utilization, and Costs," *American Journal of Managed Care* 18, no. 9 (2012): 534–544.

[122]Emergency Medical Treatment and Labor Act Technical Advisory Group, *Extract of Final Report* (Baltimore: Centers for Medicare and Medicaid Services, 2008), https://www.cms.gov/Regulations-and-Guidance/Legislation/EMTALA/downloads/EMTALA_Final_Report_Summary.pdf.

[123]A. R. Jonsen, M. Siegler, and W. J. Winslade, *Clinical Ethics: A Practical Approach to Ethical Decisions in Clinical Medicine*, 7th ed. (New York: McGraw-Hill, 2010).

[124]Ibid.

[125]R. Rhodes and D. Alfandre, "A Systematic Approach to Clinical Moral Reasoning," *Clinical Ethics* 2, no. 2 (2007): 66–70.

[126]J. H. Schumann and D. Alfandre, "Clinical Ethical Decision Making: The Four Topics Approach," *Seminars in Medical Practice* 11 (2008): 36–42.

[127]Centers for Disease Control and Prevention, *Health-Related Quality of Life*, https://www.cdc.gov/hrqol/concept.htm; The WHOQOL Group, "The World Health Organization Quality of Life Assessment (WHOQOL). Development and psychometric properties," *Social Science and Medicine* 46, no. 12 (1998): 1569–1585.

[128]A. Torbica and G. Fattore, "The 'Essential Levels of Care' in Italy: When Being Explicit Serves the Devolution of Powers," *European Journal of Health Economics* 6, suppl. 1 (2005): S46–S52.

[129]A. Pollack, "Questioning a $30,000-a-Month Cancer Drug," *New York Times*, December 4, 2009, http://www.nytimes.com/2009/12/05/health/05drug.html.

[130]R. Rhodes, L. P. Francis, and A. Silvers, *The Blackwell Guide to Medical Ethics* (Oxford, UK: Blackwell, 2007), 80.

[131]WHO Commission on the Social Determinants of Health, *Closing the Gap in a Generation*.

[132]V. J. Dzau, M. B. McClellan, M. McGinnis et al., "Vital Directions for Health and Health Care. Priorities from a National Academy of Medicine Initiative," *JAMA* 317, no. 14 (2017): 1461–1470.

[133]J. Q. Xu, S. L. Murphy, K. D. Kochanek et al., *Mortality in the United States, 2015* (Hyattsville, MD, National Center for Health Statistics, 2016).

[134]J. M. Lorenz, C. V. Ananth, R. A. Polin et al., "Infant Mortality in the United States," *Journal of Perinatology* 36, no. 10 (2016): 797–801.

[135]M. E. Porter and T. H. Lee, "The Strategy That Will Fix Health Care," *Harvard Business Review*, October 2013.

[136]K. J. Arrow, "Uncertainty and the Welfare Economics of Medical Care," *American Economic Review* 53, no. 5 (1963): 941–973. https://web.stanford.edu/~jay/health_class/Readings/Lecture01/arrow.pdf.

CHAPTER 5

History of Legal Systems, Tort Law, Negligence, and Strict Liability

Historical Overview

The purpose of all legal systems is "regulating and harmonizing the human activity within their respective societies."[1] The best-known legal systems in Western civilization are the ***civil law*** and the ***common law***, two different bodies of law, both of which directly affect medical ethics and practice. The civil law tradition, based on Roman Law, developed in continental Europe during the Middle Ages and was applied in the colonies of empires such as Portugal and Spain. The common law tradition emerged in England during the same time period and was applied within the British colonies, including the colonies in North America.

Civil Law Systems

The term "civil law" derives from the Latin *ius civile*, the laws applicable to all Roman citizens. The *Oxford Classical Dictionary* states *ius civile* was the "proper law of and for Roman citizens."[2] The classical period of Roman law is usually dated from the beginning of the Empire in 27 B.C.E. through 235 C.E., marking the death of the jurist Herennius Modestinus.[3] Roman legal scholars wrote more than 2,000 books.

Centuries later, in the first decades of the sixth century, the Emperor Justinian formed a commission of jurists and ordered a compilation of legal texts that was carried out by the jurist and public official Tribonian from 530 through 534 C.E.[4] The compilation later became known as the *Corpus iuris civilis* ("body of civil law").

The largest part of the compilation, the *Digest* (533 C.E.), was composed of short extracts from the works of the classical legal scholars.[5] The *Digest* was comprised of fifty books, and these texts were deemed to have

FIGURE 5.1 The U.S. Supreme Court embodies the rich history of legal systems

the force of law. The *Institutes* (533 C.E.) was a short revision of *Institutiones*, a manual or introduction to the law written by Gaius,[6] a renowned Roman jurist (*circa* 110–180 C.E.).

Although classical Roman law fell into disuse and was forgotten, it was later revived in the Middle Ages on the basis of the discovery in the eleventh century of a single manuscript copy of the *Digest*. That manuscript copy is now known as the *Littera Pisana* or *Florentina*.[7] Subsequently, in 1038, Conrad II (Holy Roman emperor from 1027 to 1039) ordained that Roman law should again be the territorial law of the city of Rome.[8] In 1076, the *Digest* was cited in a ruling of a court in Tuscany.[9] By approximately 1100, Irnerius, an Italian legal scholar, was teaching Roman law at the University of Bologna.[10] Absent the narrow escape of the *Digest* from oblivion,

> very little of the ancient treasure of wisdom would have reached modern times; and a world without the *Digest* would not have been the world that we know.[11]

Per Gaius, the content of *ius civile* is *quod naturalis ratio inter omnes homines constituit*,[12] which translates to "that which natural reason has established among all mankind." Given that legal concepts such as possession, sale, lease, consent, and fault were familiar from ordinary experience, Roman jurists "explained their concepts not by defining them, but by testing them against particular cases."[13] This testing process would become a key feature of civil law as it is understood today.

For example, the *Digest* indicates that if a pruner throws down a branch from a tree and harms someone, he is negligent only if the branch fell down in a public place and he had failed to shout a warning.[14] If a man burns stubble or thorns and the fire spreads to another's crops or vineyard, the man is negligent if he set the fire on a windy day or if he did not take precautions to keep the fire contained. However, if the man took sufficient precautions or if "it was a sudden squall of wind that extended the fire," then he is not at fault for the damage to his neighbor's fields.[15] As stated in the *Digest*, a doctor is negligent if she misuses a drug (e.g., prescribes a medication inappropriately) or neglects aftercare for a surgical patient.[16] Regarding contracts of sale, a sale is invalid if there is "disagreement over the contract itself, the price, or any other element of the sale."[17] Overall, via their methodology, Roman jurists "identified and refined concepts that are basic in modern legal systems."[18]

The Roman jurists founded an intellectual tradition whose method included the ability to identify "the universal element from the mass of opinions and express it in precise terms."[19] They gave "their own opinions as jurists as to how legal concepts applied to particular cases."[20] Thus, Roman law was not based on a set of rules or principles that were articulated by the jurists themselves. Roman law did not have a systematic doctrinal structure (that is, a framework or set of rules or principles). Rather, the method of the Roman jurists required "a stock of concepts of legal significance that they could refine" by putting typical cases (that is, posing hypothetical or illustrative cases) in which the concept would apply.[21]

Following the rediscovery and revival of classical Roman law in the Middle Ages, Roman law became a central component of European legal development. For example, in 1620, the statesman and scholar Hugo Grotius synthesized Roman law and Dutch customary law in *Introduction to Dutch Jurisprudence*[22] (published in 1631). By the 1700s Roman law "had acquired the profound appreciation of European jurists and scholars."[23] The political unification process in Western Europe led to national movements of codification of the private law,[24] which produced comprehensive, systematic legal codes such as the Prussian Civil Code (General State Law) in 1794 and France's Civil Code *(Code Napoléon)* in 1804. The French Civil Code was introduced

into territories conquered by Napoleon and is still in use in Belgium, Luxembourg, and Monaco. During the nineteenth century, the Napoleonic Code was adopted, in whole or in part, in Haiti and the Dominican Republic, and in numerous countries in Latin America, including Chile, Bolivia, and Argentina. Thus, generally, the preponderance of modern civil law "is based on concepts that the Roman jurists identified and refined."[25]

Common Law

The common law, as a legal system, originated and developed in England.[26] In the Middle Ages, the kings of England compiled ordinances and laws, beginning with Alfred (871–899), who set a fashion of legislating, and continuing through Canute (1016–1035), who published a code of laws.[27] After the Norman Conquest in 1066, William of Normandy and Henry Beauclerc (Henry I; 1100–1135) continued the practice of publishing laws.[28] Over time, Henry I and Henry of Anjou (Henry II; 1154–1189) established a uniform system of law.[29] Thus, regarding the history of the law, the effect of the Norman Conquest was to convert the law of England into a *lex terrae*, that is, a law of the land, a true local law. By the second half of the twelfth century, Ranulf de Glanville, chief minister of England under King Henry II, was able to speak of the "law and custom of the realm." A permanent royal court was established and the expression "common law" made its appearance in England.[30]

In English usage, the "common law" was the law of a court. By the thirteenth century, "common law" meant the law of the royal court, which rapidly became "the one law *common* to all the realm."[31] Prior to the Norman settlements, English law had been collected via "the wise men of the shires and the inquests of the king's officials." The *Leges Edwardi Confessoris*, purportedly detailing the law of Edward the Confessor (king of England from 1042 to 1066), may be the result of such a process.[32] In the early 1100s, Henry I had formalized this method by sending his ministers around the country "to hear cases in the local courts," establishing the English circuit system.[33]

By the end of the twelfth century, the King's Court had become "the most powerful institution in the kingdom."[34] The King's Court kept a "strict and unassailable record" of all the cases over which it presided. Any questions or concerns regarding precedent could be resolved by reference to the Plea Rolls,[35] the parchment records of the cases. As of 1292, the Plea Rolls were published in popular form as the Year Books.[36] Thus, between the accession of Henry I in 1100 and the death of Henry III in 1272, the King's Court declared the Common Law of England. The law was found in the form of ***writs*** (a court's written order) and the Plea Rolls of the King's Court. The common law was judiciary law, and it was declared by judges, not by legislators, other officials, or local wise men.[37]

But the three immediate successors of Henry II, Richard I (1189–1199), John (1199–1216), and Henry III (1216–1272), were not as capable as Henry I and Henry II. Royal authority had fallen into weaker hands and, as well, the king's judges seemed to have lost their power of legal invention. The list of writs had almost been closed by the time of the death of Henry III. The progression and evolution of the law in England was revivified by Edward I (1272–1307) who, "consciously or unconsciously, by genius or good luck" propounded the great idea that unification of the many forces that had previously declared the law, that is, kings, landowners, shire leaders, judges, and ecclesiastics, would yield a law that was "infinitely stronger, better, juster, above all, more comprehensive, than the separate laws which have preceded it."[38]

Ultimately, Edward I created the "most effective law-declaring machine" of his time.[39] He furthered the development of "parliaments," and in 1283 he summoned a parliament consisting

of nobles, knights, and burgesses (representatives of boroughs or towns).[40] The popular element, that is, representatives of the people themselves in addition to representatives of the baronage, knighthood, and clergy, was becoming a consistent feature of parliamentary composition. In a time of crisis, Edward concluded that "he could only meet his difficulties if he got the support of the mass of the nation on his side," and he famously enunciated the maxim that "what touches all should be approved by all."[41] Large representative parliaments were held in 1293 and 1294, and in 1295 Edward "assembled a parliament so full and complete"[42] that it became known as the Model Parliament and generally regarded as the first representative parliament. The Parliament of 1295 included earls and barons, two knights selected by the popular court of each shire, two burgesses or citizens from every city or borough town, county members, and members of the clergy, ranging from archdeacons to archbishops (the clerical estate did not long retain its position in parliament). Thus, the Model Parliament was a complete representative body and has been described as "a real gathering of the whole nation."[43]

By 1307, under Edward I, Parliament had become the distinctive feature of English politics. Broadly, the English Parliament "enabled the exponents of all the customs of the realm to meet together and explain their grievances."[44] During the first 200 years of its existence, the basis of parliamentary legislation was the mass of petitions complaining of breach of old customs or requests for confirmation of new customs.[45] Thus, English statecraft had brought together into one body representatives who could declare and enforce the laws of England.[46] Hundreds of years later, in 1651, Thomas Hobbes was able to state in *Leviathan* that "Civil Law is, to every subject, those Rules which the Commonwealth hath commanded him."[47] Hobbes contrasted his definition of civil law with Roman Civil Law, and was essentially describing a centrally located and centrally sourced "law of the land." Hobbes had defined *civil law* as the laws that men are bound to observe because they are members of a Commonwealth.[48]

Overall, as a legal system, the common law incorporates the history of judicial decisions (*precedent*), in which customary law has been defined and developed by the courts.[49] Effectively, the common law consists of all the rules that may be generalized based on judicial decisions.[50] The doctrine of precedent indicates that once a point has been decided, the same result has to be reached for the same problem.[51] In other words, precedent denotes "a decided case that furnishes a basis for determining later cases involving similar facts or issues."[52] Legislative bodies such as the U.S. Congress and English Parliament pass laws (statutes), which may then need to be interpreted by the courts.

The relationship between the common law and statutory law was described in an English court in 1708: "Statutes are not presumed to make any alteration in the common law, further or otherwise than the act does expressly declare."[53] A more recent formulation in 1905 by an Illinois court asserted that "It is a general rule in the construction of statutes that they are not to be construed as changing the common law farther than by their terms they expressly declare."[54]

In the process of common law, disputes are resolved by precedent and *judicial review*.[55] But the concept of the common law is multifaceted and encompasses a range of meanings.[56] For example, the *American Dictionary of the English Language* (1828) defines *common law* as follows:

> Common Law, in Great Britain and the United States, the unwritten law, the law that receives its binding force from immemorial usage and universal reception, in distinction from the written or statute law. That body of rules, principles and customs which have been received from our ancestors, and by which courts have governed in their judicial decisions. The evidence of this law is to be found in the reports of those

> decisions, and the records of the courts. Some of these rules may have originated in edicts or statutes which are now lost, or in the terms and conditions of particular grants or charters; but it is most probable that many of them originated in judicial decisions founded on natural justice and equity, or local customs.[57]

The *New Shorter Oxford English Dictionary* defines *common law* as follows:

> The part of English law that is applied by national courts but is not fully prescribed by statute, purporting instead to be derived from ancient usage and judicial decisions.[58]

Several distinct applications of the term *common law* may be described, including the following:

1. The general or central law of any community, as distinguished from various local customs or other bodies of rules having a specific source. An example is the *ius commune* in Roman law.
2. The centralized system of law developed in the courts of the English kings by the royal justices beginning in the twelfth century.
3. The English law developed by the king's ordinary judges.
4. In America, the body of English legal doctrine that was the basis of the law administered in those states settled from England, and the subsequent development of that law in the United States.[59]

But English law was not simply transplanted in its entirety to the North American colonies as a fully formed doctrine. In the beginning of the seventeenth century, at the time of the founding of the communities at Jamestown, Virginia, and Plymouth, Massachusetts, in 1607 and 1620, respectively, English law itself was unsettled. Fifteen diverse sources of English law have been identified as operating in the early 1600s, including the following:

1. The law of the Crown
2. Parliamentary law and custom
3. The law of nature *(lex naturae)*
4. The common law of England
5. Statute law (laws established by authority of Parliament)
6. Ecclesiastical or canon law
7. Forest law *(lex forestae)*
8. Merchant law *(lex mercatoria)*[60]

The diversity of these sources was experienced differently in various American colonies. Regardless, the evolving English common law was the major influence in the early legal history of the United States.[61] Every jurisdiction, except Connecticut, "expressly received the common law by charter, subsequent legislation, or constitutional provision."[62] A standard theory regarding the influence of English common law in the colonies is that "the common law of England was substantially in force in the colonies from the time of their settlement."[63] Supreme Court Justice Joseph Story famously presented a corresponding theory in *Van Ness v. Pacard*:

> The common law of England is not to be taken in all respects to be that of America. Our ancestors brought with them its general principles, and claimed it as their birthright; but they brought with them and adopted only that portion which was applicable to their situation.[64]

In 1847, in *Commonwealth v. Chapman*, Chief Justice Lemuel Shaw of the Supreme Judicial Court of Massachusetts stated the following:

> A great part of the municipal law of Massachusetts, both civil and criminal, is an unwritten and traditionary law. It has been common to denominate this the common law of England ... To a very great extent, the unwritten law constitutes the basis of our jurisprudence, and furnishes the rules by which public and private rights are established and secured, the social relations of all persons regulated, their rights, duties, and obligations determined, and all violations of duty redressed and punished.[65]

As well, James Kent, Professor of Law at Columbia College and Chancellor of the New York Court of Chancery, stated in 1826 in his *Commentaries on American Law* the following:

> The common law, so far as it is applicable to our situation and government, has been recognized and adopted, as one entire system, by the constitutions of Massachusetts, New York, New Jersey and Maryland. It has been assumed by the courts of justice, or declared by statute, with the like modifications, as the law of the land in every state. It was imported by our colonial ancestors, as far as it was applicable, and was sanctioned by royal charters and colonial statutes.[66]

The role of the courts as lawmakers subsequently ensured the vitality of American common law development.[67] The creative role of the courts evolved in the following areas:

- Judicial review of the constitutionality of legislation
- Judicial interpretation of the Constitution
- Review and elaboration of the common law[68]

Thus, in the United States, the common law has evolved from a "jointly held body of substantive rules" to a body of law that addresses more actively the changing problems in American life.[69]

Distinguishing Ethical Actions versus Legal Actions

It is important to distinguish actions that are ethical versus actions that are legal. The two standards and their associated methods of analysis are not identical. Essentially, as discussed in Chapter 2, ethics is a doctrine of action and involves elucidating the distinctions between right and wrong. Ethics may be considered action from a standpoint internal to the person acting.[70] On a Kantian basis, "in ethics the idea of duty itself motivates the action."[71] In contrast, the sphere of legality is equated with a person's external relationships.[72] In her external actions, the individual responds to the possibility or probability of external coercion,[73] that is, the authority of public law. Thus, the legality of an action focuses on "its consistency with the freedom of all persons."[74] The law may be described as setting out the minimal "moral conditions for the interaction of purposive beings."[75] Ideally, the right and the good are in alignment. But in the world as we experience it, actions may be ethical but not necessarily legal, and actions may be legal but not necessarily ethical.

Tort Law

A *tort* is conduct that is regarded as a legal wrong or injury in which harm is done to another and for which an action will lie, that is, courts will impose civil *liability*.[76] As well, a tort is "a civil wrong, other than breach of contract, for which a remedy may be obtained, usually in the form of damages."[77] Similarly, a tort is "a breach of a duty imposed by law (rather than by contract) which gives a right of action for damages" and was first used in this context in the late 1500s.[78] The term *tort* derives from Latin roots (*torquere, tortus*) that refer to *twisting* or *twisted*.[79] Thus, a tort may be construed as conduct that is twisted, that is, conduct that deviates from existing norms, and this perspective associates torts with wrongdoing in a moral sense.[80]

The primary function of tort law is to provide a remedy for legally recognized harms by rendering a judgment for *damages* against the wrongdoer (the *tortfeasor*). Such damages are most typically in the form of a monetary award and represent compensation for the harm experienced by the plaintiff.[81] Importantly, tort liability requires more than that a person's conduct caused harm to another. Tort liability requires that the wrongdoer was at fault in a legally recognizable manner. Persons are free to act without incurring liability, provided that they are not at fault in those actions.[82]

In the law of torts, legal fault is categorized as *intentional wrongs* and *negligent wrongs*. An intentional wrong is done by a person who intends to act in a manner that the law considers wrongful. Intentional wrong involves harms caused by actions that included an element of intent or willfulness. The intentional wrongdoer is usually consciously aware of the wrongfulness of his action.[83]

For example, in *Curtis v. Porter*, the Supreme Judicial Court of Maine stated that "a person acts intentionally if he subjectively wants or subjectively foresees that harm to another will almost certainly result from his actions."[84] An intentional tort could be alleged against an orthopedic surgeon who fused a patient's fourth and fifth lumbar vertebras, although the patient had only consented to partial discectomy (removal of a portion of an intervertebral disc) at the L4-L5 level. In such a case, the surgeon was aware that the patient had not consented to lumbar fusion, but she performed the procedure regardless.

In another example, in *Mullins v. Parkview Hospital*, a surgical patient had crossed out "I consent to the presence of healthcare learners" on her consent form prior to surgery. But during surgery, the attending anesthesiologist permitted an emergency medical technician (EMT) student to attempt an intubation. In the event, the intubation failed and two days later tests showed that the patient's esophagus had been lacerated, requiring additional surgery and recuperation. The Indiana Court of Appeals[85] found the plaintiffs (the patient and her husband) had adequately stated a claim for *battery* against the anesthesiologist and the EMT student. However, the Indiana Supreme Court held that the trial court had appropriately granted the student summary judgment (a ruling that there was "no genuine issue of material fact" and the defendant was "entitled to prevail as a matter of law"[86]), as "there was no evidence that the student intended the harmful contact with the patient, a requirement of the tort of battery."[87] The Indiana Supreme Court noted that when the anesthesiologist granted the student permission to attempt intubation, the student had no reason to suspect that the patient had modified the consent form. Thus, the student did attempt intubation and harm resulted, but the student did not *intend* battery, that is, unauthorized bodily conduct. The EMT student did not intend to cause harm.

In contrast, a negligent wrong involves the "failure to take a reasonable precaution against risks of harm."[88] As well, negligent wrongs consist of unreasonably risky behavior that actually results in harm.[89] The negligent wrongdoer violates standards of reasonableness. Thus, negligence may involve unjustifiable risk. Negligence may also involve conduct that violates a *reasonable person standard.* For example, in the context of unreasonably risky behavior, consider person X, who walks without permission across person Y's newly turned over garden bed. In itself, although X may have violated Y's right of privacy, such action does not necessarily rise to the level of a negligent harm. But if X was wearing heavy gauge hobnail boots, wasn't paying attention to the ground beneath him, and in the process of walking across Y's property also destroys many valuable new shoots that Y had recently planted, then X's action may be considered a negligent harm. X violated the reasonable person standard and may be at fault and culpable for damages. A reasonable person would reasonably have been aware of the wrongness of trespassing and, if he trespassed anyway, would reasonably have paid attention to what was obviously a newly planted garden.

Overall, fault remains the basis of liability in tort law, although *strict liability* in tort law is liability without proof of fault.[90] Tort liability protects personal and community interests and values. Tort law "establishes the legal rights and obligations that individuals in a society have directly to one another."[91] These legal rights or legal interests include physical liberty, physical security, privacy, reputation, economic opportunity, and economic security.[92] The purpose of the law of torts is to "afford compensation for injuries sustained by one person as the result of the conduct of another."[93] Writing in 1894, Professor John H. Wigmore referenced an English court ruling in 1481, which stated that "A man should so occupy his common that he does no wrong to another."[94] As well, in 1705, Chief Justice Holt averred that "Every man must so use his own as not to do damage to another."[95] But concerns arise regarding freedom of action on the part of the person causing such losses. Tort law attempts to reach a fair balance between "various claims to compensation on the one hand, and freedom of action on the other."[96]

Historically, civil liability in the common law was originally based on the relatively basic concept of trespass.[97] By the late thirteenth century, the King's Court in England issued the writ of trespass to any plaintiff "who could show that he had sustained a physical contact on his person or property, due to the activity of another."[98] Writs of trespass were utilized for all claims that resulted from a direct use of force.[99] The old common law writ of trespass indirectly or directly generated several torts, including battery, assault, trespass to chattels (property other than real estate), and trespass to land.[100] If the plaintiff (the person bringing the action) could convince the court that the defendant had intentionally caused the contact, then the plaintiff would obtain judgment for damages owing to the trespass, unless the defendant could justify his actions. If the plaintiff were unable to establish intent, then to recover damages the plaintiff had to demonstrate "that he had sustained some actual damage, at least as far as trespass to his person was concerned."[101]

For example, suppose that Arthur was repairing the roof on his two-story house. He stumbles and the wooden beam he was carrying slips out of his grasp, falls over the side of his house and strikes Bob, a neighbor who was passing by, on the head. In the time of Edward I, Bob could obtain a writ of trespass and recover damages for his injury. The fact that Arthur had dropped the beam unintentionally was not material to the ruling. Bob had sustained contact resulting from the falling beam, and his injury and recovery of damages were the result of trespass. In contrast, suppose that the falling beam had merely hit the ground and was lying in a path. Later

on, Bob walks by, trips over the beam, and falls down, striking his head on the ground. Bob seeks to obtain a writ entitling him to sue Arthur for damages, but no writ is available that is appropriate to the circumstances. There was no trespass by Arthur against Bob, as the beam had come to rest by the time Bob was injured. Bob's injury was construed as not being caused by any action of Arthur.[102] Thus, regardless of intentionality or fault, physical contact due to the activity of another implied trespass and damages could be recovered in the case of injury. In the absence of such activity and physical contact, the injured party could not obtain a writ of trespass and could not bring an action for damages.

In time the latter circumstances came to be understood as an imbalance of justice, and a new writ was created, "to be issued in situations where harm had occurred otherwise than by a direct or trespassory contact."[103] The new writ became known as "action on the case" or simply "case." Action on the case became a feature of law in the fourteenth century,[104] and the classic example of the falling beam or log, distinguishing between a writ of trespass and action on the case, is described in 1726 in *Reynolds v. Clarke*, in which Judge Fortescue stated, "If a man throws a log into the highway, and in that act it hits me, I may maintain trespass, because it is an immediate wrong; but if as it lies there I tumble over it and receive an injury, I must bring an action upon the case, because it is only prejudicial in consequence."[105]

In action on the case, the plaintiff was required to prove the defendant's fault and the actual harm, as in a 1370 case when a veterinarian undertook to cure the plaintiff's horse but failed as a result of negligence or neglect.[106] As well, a defendant's failure to act could constitute fault, as with a shepherd who failed to keep his sheep, an innkeeper who refused to lodge a potential guest, or a carter who failed to repair a bridge on which the plaintiff was required to cross.[107] Responsibility was "based on a custom of the realm" and the actions of innkeepers and carriers, for example, "had implied in them a duty of carefulness."[108]

Initially, action on the case involved persons who had a relationship based on status or contract, as opposed to actions involving trespass, which typically concerned strangers who had no prior relationship.[109] Over time, action on the case evolved to include cases involving strangers, that is, those who were not in a contractual relation with the plaintiff. For example, in 1677, in *Michael v. Alestree*, the plaintiff had been seriously wounded by "ungovernable horses" who had been brought by a servant into a crowded public square (Lincoln's Inn Fields in London) for the purpose of training the horses to drive a coach. An action was brought against the servant and the servant's master in which the horses were described as ferocious and "not to be managed." The plaintiff's suit was upheld based on the allegation of negligence.[110] By the 1800s, it was not unusual for a plaintiff to sue a stranger in action on the case rather than trespass. Negligence had become a general concept and a plaintiff could sue in case even for a direct injury, provided the plaintiff could indeed prove negligence and actual harm.[111]

But in 1842, a general principle of fault had not yet been fully established. In England, in *Winterbottom v. Wright*,[112] the plaintiff, a mail-coachman, was seriously injured when the coach he was driving broke down and he was thrown from his seat. He sued the defendant, a contractor who had provided the Postmaster General with a mail coach, alleging that the defendant had neglected and failed to perform his duty regarding maintenance of the coach. But the English court ruled that if the plaintiff's suit were upheld, then an "infinity of actions" would result against allegedly negligent third parties. In *Winterbottom* there was no *privity of contract* (mutuality of interest; the relationship between participants in a contract, permitting them to sue each other

but disallowing third parties from doing so[113]) between the plaintiff and the defendant. The court stated the following:

> If the plaintiff can sue, every passenger, or even any person passing along the road, who was injured by the upsetting of the coach, might bring a similar action. Unless we confine the operation of such contracts as this to the parties who entered into them, the most absurd and outrageous consequences, to which I can see no limit, would ensue.[114]

A concurring opinion stated that there was no duty owed to the plaintiff by the defendant. The concurrence noted this was an "unfortunate case" and a "hardship upon the plaintiff" without a remedy and concluded that "Hard cases, it has been frequently observed, are apt to introduce bad law."[115] *Winterbottom v. Wright* was a case of "first impression," that is, no precedent existed regarding these specific circumstances. Particularly, there was no precedent for establishing liability for unintentional harm in relation to a defective product. The more familiar characterization for such cases was the legal doctrine of contract, and as yet the rule of "no liability without privity of contract" prevailed.[116]

In subtle contrast, in 1852, in *Thomas v. Winchester,*[117] Mrs. Thomas had ingested what was thought to be a small dose of dandelion extract. But the extract caused a severe physiological reaction and it was thought that her life was in danger. Subsequently, it was learned that the jar, which Mr. Thomas had purchased from a druggist and had been labeled "1/2 lb. dandelion," in fact contained extract of belladonna, a poisonous drug. The druggist had purchased the jar from the defendant, who was engaged in the manufacture and sale of vegetable extracts for medicinal purposes, such as extract of dandelion. The trial court judge had charged the jury that "if the defendant Winchester was guilty of negligence in putting up and vending the extracts in question, the plaintiffs were entitled to recover."[118] A verdict was rendered for the plaintiff and the defendant appealed.

In *Thomas,* the opinion of the appellate court stated that the question was whether the verdict against the defendant could be upheld, considering that he was a remote vendor of the medicine and there was "no privity or connection between him and the plaintiffs." If no duty was violated by the defendant, except the duty owed to the druggist to whom Winchester had sold the jar, then the plaintiff's lawsuit could not be maintained. The opinion asserted that misfortune to a third person, not party to a contract involving others, "would not be a natural and necessary consequence" of negligence of one of those others. However, in this case, the defendant was "a dealer in poisonous drugs." The defendant's negligence "put human life in imminent danger." The opinion referenced a recent (1851) English case, *Longmeid v. Holliday,*[119] and noted that in a case of negligence involving imminent danger, the party guilty of negligence is liable to the injured party, "whether there be a contract between them or not." Absent imminent danger, "the negligent party is liable only to the party with whom he contracted, and on the ground that negligence is a breach of the contract."[120] The judgment of the trial court was affirmed. Thus, in *Thomas v. Winchester,* although the defendant's actions were deemed negligent and the harm was unintended, the primary legal doctrine involved principles of contract, modified by the presence of imminent danger in the circumstances in question.

Brown v. Kendall, in 1850, involved a different type of case with a different focus. The circumstances of *Brown v. Kendall* involved two dogs belonging to two men, the plaintiff and the defendant. The dogs were engaged in a fierce battle and the defendant tried to separate them by

beating them with a stick. But at one point the defendant raised his stick and unintentionally struck the plaintiff, who at that moment was standing behind the defendant, in the eye, causing a severe injury. The plaintiff sued for damages based on trespass, as direct contact had been caused by the stick that the defendant had set in motion. But the court ruled that although the contact itself represented trespass, "if the injury was unavoidable, and the conduct of the defendant was free from blame, he will not be liable."[121] The opinion of the court noted that

> what constitutes ordinary care will vary with the circumstances of cases. In general, it means that kind and degree of care which prudent and cautious men would use, such as is required by the exigency of the case, and such as is necessary to guard against probable danger.[122]

Thus, if the defendant were doing a lawful act, "he was not liable unless he was wanting in the care which men of ordinary prudence would use under the circumstances."[123] Harm that occurred as a result of unintended contact was "actionable only on the basis of negligence."[124] In *Brown v. Kendall*, the court held that the defendant was not liable and a new trial was ordered. Thus, liability for harm exists only if the injurer were at fault. The liability principle was now clear-cut and "unintended injuries are actionable only where due care is lacking."[125]

In the late 1800s, Justice Oliver Wendell Holmes noted that since the time of King Alfred in ninth-century England, statutes and court decisions have worked to define the care that a prudent man would exercise under specific circumstances. Thus, in assessing claims for negligence, "the way prescribed is that in which prudent men are in the habit of acting."[126] Over time, the fault principle in negligence began to overcome limitations on negligence claims based on privity of contract. In 1916, in the landmark case of *MacPherson v. Buick Motor Company*,[127] the defendant was a manufacturer of automobiles who had sold an automobile to a retail dealer, who then resold the car to the plaintiff. Subsequently, while the plaintiff was driving the car it suddenly collapsed, and he was thrown out and injured. It developed that one of the wheels had been made of defective wood and the spokes had fragmented and crumbled. The wheel had been bought by the defendant from another manufacturer. But Judge Benjamin N. Cardozo of the New York Court of Appeals stated that the defects "could have been discovered by reasonable inspection, and that inspection was omitted."[128] The charge was negligence and the question to be determined was "whether the defendant owed a duty of care and vigilance to anyone but the immediate purchaser."[129] Justice Cardozo referenced *Thomas v. Winchester* and noted that the principle of imminent danger was not limited to inherently dangerous articles such as poisons or explosives. Rather, "If the nature of a thing is such that it is reasonably certain to place life and limb in peril when negligently made, it is then a thing of danger." If the seller knows that the thing will be used by persons other than the purchaser, and used without new tests, then, "irrespective of contract, the manufacturer of this thing of danger is under a duty to make it carefully."[130] Thus, if the manufacturer of a finished product is negligent, where danger is foreseen, liability will follow. Justice Cardozo emphasized the following:

> We have put aside the notion that the duty to safeguard life and limb, when the consequences of negligence may be foreseen, grows out of contract and nothing else. We have put the source of the obligation where it ought to be. We have put its source in the law.[131]

Danger is not to be expected if a product is well constructed. But if danger is to be expected as reasonably certain, then there is a duty of vigilance to ensure safe construction. As Justice Cardozo noted in *MacPherson*, "The more probable the danger, the greater the need of caution."[132] Thus, the defendant's duty to provide a safe, secure product was not limited to its contractual relationship with the car dealer. In *MacPherson*, such duty extended to all users of a potentially dangerous item, article, or product. *MacPherson* established a key exception to the purported rule that "a manufacturer or supplier is never liable for negligence to a remote vendee or other person with whom he has had no contractual relation."[133] Subsequently, the *MacPherson* exception seemed "to have the same certainty the rule once had" and became a "general principle of liability."[134]

Overall, *negligence* may be characterized as "the failure to take a reasonable precaution against risks of harm."[135] As well, negligence may be described as "the breach of a legal duty to take care by an inadvertent act or omission which injures another person."[136] The standard of this legal duty is that of a reasonable person.[137] One who commits a negligent act takes an action he should not have taken in the specific circumstances and exposes others to an unreasonable risk of injury. The negligent "actor" created a risk that was avoidable and he was unjustified in doing so.[138] Thus, a negligent act creates an unjustifiable risk of future harm and is one that a "reasonable person" would not have performed. Importantly, merely having caused harm does not imply that one has committed a tortious act, whether negligent or intentional. Tort law is not intended to "infringe on the autonomy of the defendant as a self-regarding agent"[139] in terms of justifiable and reasonable actions.

For example, in 1928, in the landmark case of *Palsgraf v. Long Island Railroad Co.*,[140] a station guard had attempted to assist a passenger to board a departing train. In the process, a small package that the passenger was carrying was dislodged and fell on the rails. But the package contained fireworks that exploded when the package fell. At the other end of the platform, scales were thrown down by the shock of the explosion and struck the plaintiff, causing injury.[141] The plaintiff sued the railroad. Chief Judge Benjamin Cardozo, writing for the New York Court of Appeals, stated that the conduct of the station guard "was not a wrong in its relation to the plaintiff, standing far away."[142] Relative to the plaintiff, the guard's actions were not negligent, as nothing in the circumstances indicated that the falling package had the potential to imperil persons far removed. Referencing a 1903 decision,[143] Justice Cardozo noted that before assessing a given act as negligent, a duty to the individual complaining must be identified, "the observance of which would have averted or avoided the injury."[144] Justice Cardozo provided an additional example of conduct that might be construed as negligent but did not involve fault causing harm: "One who jostles one's neighbor in a crowd does not invade the rights of others standing at the outer fringe when the unintended contact casts a bomb upon the ground. The wrongdoer as to them is the man who carries the bomb, not the one who explodes it without suspicion of the danger."[145] Thus, the central tort concept of duty requires a relationship between "a particular defendant and a foreseeably endangered plaintiff."[146] In *Palsgraf*, the defendant did not owe a duty to the plaintiff, as she was outside the "range of apprehension" of the risk as reasonably perceived.[147]

Later, in 1968, the landmark case of *Rowland v. Christian*[148] established a tort framework of assessing reasonable conduct under specific circumstances. In *Rowland*, the plaintiff had been seriously injured by a defective faucet while visiting the home of the defendant. The opinion of the California Supreme Court stated that "All persons are required to use ordinary care to

prevent others being injured as the result of their conduct."[149] Departure from this fundamental principle requires balancing of several considerations including the following:

- The foreseeability of harm to the plaintiff
- The closeness of the connection between the defendant's conduct and the injury suffered
- The moral blame attached to the defendant's conduct
- The policy of preventing future harm
- The extent of the burden to the defendant and consequences to the community of imposing a duty to exercise care with resulting liability for breach[150]

The *Rowland* opinion noted that a "guest should not expect special precautions to be made on his account."[151] However, increasing concern for human safety has led to an exception to the general rule limiting liability and extension of an obligation to exercise reasonable care for the protection of the social guest.[152] The common law has moved toward "imposing on owners and occupiers a single duty of reasonable care in all the circumstances."[153] In particular circumstances, some courts had addressed "the issue of the duty of the occupier [owner] on the basis of ordinary principles of negligence."[154] The proper test to be applied to the liability of a possessor of land is "whether in the management of his property he has acted as a reasonable man in view of the probability of injury to others."[155] Thus, the defendant's failure to warn the plaintiff or to repair a defective and dangerous fixture constituted negligence, and the trial court's ruling for the defendant was reversed. In *Rowland,* reasonable conduct supplanted historical, centuries-old rules "associated with the property rights of landowners."[156] *Rowland* affirmed reasonable conduct as a standard, stating that "[a] man's life or limb does not become less worthy of protection by the law nor a loss less worthy of compensation under the law" based upon considerations of status as visitor to a property. Further, *Rowland* noted that "The common law rules obscure rather than illuminate the proper considerations which should govern determination of the question of duty."[157]

Liability in Negligence

Liability in negligence may be imposed for failure to use reasonable care under the circumstances. Negligent conduct is almost always a specific act such as incorrectly reading a patient's chart and providing 100 mg instead of 10 mg of medication. Negligence law is primarily concerned with physical injury to people and to tangible property. Actual harm to the plaintiff must have occurred to substantiate a claim for negligence. In the case of a successful negligence claim, courts award damages to the plaintiff, potentially including damages for financial loss and emotional harm.[158]

Historically, negligence had been focused on a plaintiff and a defendant who stood in some special or contractual relation. But since *Brown v. Kendall,* after the mid-1800s, a framework of negligence, that is, actions involving fault that result in actual harm, became the "dominant or default mode of thinking about tort suits between strangers."[159] As well, *Brown v. Kendall* provided a means of evaluating negligent conduct. In *Brown,* the court stated that ordinary care, that is, the care practiced by reasonable and prudent persons, was the type and level of care "such as is required by the exigency of the case, and such as is necessary to guard against probable danger."[160] In addition to fault, or the failure to employ reasonable care, Justice Holmes asserted in *The Common Law* that liability for negligence required that the defendant's action

constituted a threat of harm. Further, Justice Holmes stated that "unless under the circumstances a prudent man would have foreseen the possibility of harm," a claim for negligence would not be supported.[161] Justice Holmes was describing what came to be termed *risk* and *foreseeability*. Subsequently, negligence came to be understood as unreasonable conduct in the context of unreasonable risk and foreseeability of harm. A defendant would not be liable unless his action brought about demonstrable harm to the plaintiff and the harm was appreciably associated with his unreasonably risky conduct.[162]

Elements of a Case for Negligence

In order to establish a *prima facie* (on first view or first appearance) case for negligence, the plaintiff must be able to prove several elements:

1. The defendant owed a duty to the plaintiff to act with a degree of care for the plaintiff's safety.
2. The defendant's unreasonably risky conduct resulted in a breach of that duty.
3. The defendant's actions caused actual harm to the plaintiff.
4. The defendant's conduct not only caused harm to the plaintiff, but also was a *proximate cause*, that is, the defendant's actions were assessed to have an appreciable relationship to the harm experienced by the plaintiff, and the harm caused was within the scope of the general type of harm risked by the defendant's negligent conduct.
5. The existence and extent of damages based on harm in fact such as physical injury to property or person.[163]

Importantly, even though the plaintiff may prove her *prima facie* case, the defendant may wholly or in part defeat the plaintiff's claim by presenting an affirmative defense based on (1) establishing the plaintiff's fault or (2) the statute of limitations.

Typically, the defendant owes the plaintiff a duty of care. A reasonable person takes sufficient care to ensure that her actions do not cause harm to others. How much care, that is, the extent of care undertaken, depends on the particular circumstances. The *standard of care* represents the "duty of reasonable care under the circumstances."[164] Specifically, as stated by the Supreme Judicial Court of Massachusetts in *Jupin v. Kask*, "every actor has a duty to exercise reasonable care to avoid physical harm to others."[165] For example, driving slowly, in the range of 25 miles per hour, is appropriate in a school zone when children are present. Such care would not be required on a three-lane boulevard with a posted limit of 50 miles per hour. When a defendant owes a duty of reasonable care, he breaches that duty by engaging in conduct that is unreasonably risky. Overall, negligence is conduct that "creates or fails to avoid unreasonable risks of foreseeable harm to others."[166] In other words, negligence is a failure to implement reasonable care under specific circumstances. As noted by the U.S. Court of Appeals for the Seventh Circuit in *Beck v. Dobrowski*, negligence is a failure "to come up to the specified standard of care."[167] In almost all cases, people have a duty to exercise reasonable care when their actions create a risk of physical harm to others.[168]

Regarding *foreseeability*, a defendant whose actions caused harm to another is not ordinarily responsible in a tort claim unless the possibility of such harm is assessed to have been recognizable

by a reasonable person. If the potential harm would have been foreseeable to a reasonable person, then the defendant whose unreasonably risky actions caused that harm is liable for damages.[169]

Rights and Duties in Tort Liability: Corrective Justice

Corrective justice, a pillar of tort law, refers to the rectification of an injustice inflicted by one person on another via the imposition of liability.[170] The principle of corrective justice is based on Aristotelian conceptions of justice as described in the *Nicomachean Ethics*. In his classic treatise, Aristotle stated "the man who acts unjustly has too much, and the man who is unjustly treated too little, of what is good."[171] Per Aristotle, rectification is a species of justice and the law treats the conflicting parties as equals. The injustice that has occurred created an inequality, and "the judge tries to equalize things by means of the penalty, taking away from the gain of the assailant."[172] Aristotle stated that "corrective justice will be the intermediate between loss and gain."[173] The judge restores equality.[174] Thus, owing to the fault (negligent conduct) of the defendant that caused harm to the plaintiff, injustice occurred relative to the baseline equality that had existed between them. Corrective justice reestablishes that initial equality by restoring what rightfully (lawfully) belonged to the injured party. Corrective justice deprives the injurer of the gain and restores the loss of the one who was injured. As such, tort law attempts to make the injured party "whole" via implementation of corrective justice and imposition of damages for liability on the defendant.

Corrective justice responds to the unjust conduct of the defendant and rectifies the inequality that has been created. This rectification "operates correlatively on both parties."[175] The remedy acts on both, simultaneously taking away the defendant's increase and restoring the plaintiff's loss. Corrrelativity implies that the "factors to be considered significant are those that apply equally to both parties."[176] For example, the perception that the defendant is wealthy and could easily withstand a substantial liability payment is not an appropriate consideration as it is one-sided. Importantly, the correlativity of corrective justice is expressed in the existence of the plaintiff's right and the defendant's correlative duty not to interfere with that right.[177] When the plaintiff's right is the basis of the defendant's duty, right and duty are correlated. Conversely, right and duty are correlated when the extent of the defendant's duty includes avoiding interfering with or infringing on the right of the plaintiff.

As well, in negligence law it is not sufficient that the defendant's unreasonably risky conduct resulted in harm to the plaintiff. That harm "has to be to an interest that has the status of a right" and the defendant's conduct has to be wrongful in consideration of that right.[178] Not all plaintiffs' rights are necessarily harmed by defendants' actions. In *Palsgraf v. Long Island Railroad Co.*, Justice Cardozo provided the example of driving a car at speed, which would be reckless, negligent, and wrongful when done in a crowded city street, but would not be so when done on a race course or speedway.[179] In *Palsgraf*, Justice Cardozo stated, "The risk reasonably to be perceived defines the duty to be obeyed, and risk imports relation; it is risk to another or to others within the range of apprehension."[180] Justice Cardozo noted that "Negligence, like risk, is thus a term of relation. ... Negligence is not a tort unless it results in the commission of a wrong, and the commission of a wrong imports the violation of a right."[181] In *Palsgraf*, as noted above, the plaintiff's right to be free from bodily injury was not considered to have been infringed by the actions of the defendant, as such harm was not considered reasonably foreseeable. The defendant's actions and the plaintiff's injury were not correlated.

Of note, regarding gains and losses to be redressed by corrective justice, most tort cases involve plaintiff losses such as medical expenses, lost income, and emotional harm, but no corresponding financial gain by the defendant. For example, a physician-defendant in a medical malpractice lawsuit has not gained financially by having negligently performed surgery on a plaintiff's normal knee. Rather, the equality that is being restored via corrective justice makes the plaintiff whole relative to her prior circumstances at the expense or to the cost of the defendant who, prior to restitution, had more than "he or she ought to have as a matter of corrective justice."[182] The defendant caused the plaintiff's loss and therefore has a relative gain. The award of damages, to the defendant's cost, restores the preexisting condition of equality between the plaintiff and the defendant.

Medical Malpractice

Although historical medical malpractice actions were usually battery claims, based on assertions of illegal touching, most modern medical malpractice lawsuits are based on claims of negligence. A primary difference between medical malpractice actions and other negligence claims is that the duty of a doctor to a patient is based on medical standards of care rather than on a duty of reasonable care or a reasonable person standard. The plaintiff in a medical malpractice action is required to prove breach of the medical standard of care and therefore requires expert testimony to substantiate the duty and the breach. The plaintiff must also prove *factual causation*, that is, that the harm she suffered was caused in fact by the defendant's conduct.[183] In other words, the plaintiff must prove that the harm she experienced would not have occurred absent the conduct of the defendant.[184]

The Medical Standard of Care

The medical standard of care is described as the specific conduct or implementation of procedures considered to be customary by the local relevant medical community at the time of the alleged negligent action.[185] Examples include protocols for establishing an airway, cardiopulmonary resuscitation procedures, and medication choice and dosage. In medical malpractice cases, the medical standard of care is often established by expert testimony. Juries may be told that the physician–defendant has the "duty to possess and use the care, skill and knowledge ordinarily possessed and used under like circumstances by other [physicians] engaged in a similar practice in the same or similar communities."[186] The definition of *reasonable care* is inherent in this instruction. But referring to a medical standard of care in support of physician decision making may be illusory as well as unfair, as there were "virtually thousands of standards of care pertaining to health-care services in the United States today [in 2001]."[187]

In a medical malpractice action, if it is determined that the defendant's specifically identified conduct failed to conform to the medical standard or medical custom in his community of physicians, then his actions would be deemed negligent and he would be liable for damages. If his actions adhered to the relevant medical standard, then he would not be legally negligent.[188] Problematically, the medical standard of care could call for more or less care than would be required by a reasonable person standard in certain circumstances of risks and benefits. For example, customary medical practice among a community of pain medicine specialists might permit daily morphine equivalent dosages of hundreds of milligrams. But a reasonable person

standard might assess such dosages as unreasonably risky in consideration of the potential severe side effects such as respiratory depression and even death.[189] Thus, several courts have indicated that the standard of care for healthcare practitioners is the reasonable care standard generally applied in negligence law.[190] For example, in *Harris v. Groth*, the Supreme Court of Washington held that "the standard of care imposed upon health care providers is one of reasonable prudence and that nonphysicians, if otherwise qualified, may give expert testimony in a medical malpractice case."[191] As well, in *Canterbury v. Spence*, the U.S. Court of Appeals for the D.C. Circuit stated that respect for a patient's right of self-determination "demands a standard set by law for physicians rather than one which physicians may or may not impose upon themselves."[192]

Informed Consent Cases

Informed consent claims are a subset of medical malpractice actions. In an informed consent action, the plaintiff-patient asserts that the physician-defendant failed to provide information regarding the proposed treatment that would have been material to the patient's decision-making. As discussed in Chapter 3, such information consists of the risks and benefits of the proposed treatment, alternatives to proposed treatment as well as their risks and benefits, and the likely impact of proposed treatment on the patient's quality of life. In an informed consent claim, rather than asserting that the procedure or treatment was negligently performed, the plaintiff asserts she would have refused to consent to the procedure had she been appropriately informed.

To establish a claim for negligence in a case alleging failure of informed consent, the plaintiff must prove the following:

1. Required information was not disclosed
2. Actual harm
3. The harm resulted from hazards that had not been disclosed to the patient
4. Factual causation, that is, the plaintiff would not have undergone the medical treatment or procedure if he had been made aware of the risk[193]

Subsequent to *Canterbury v. Spence* in 1972, courts have supported a healthcare provider's duty to disclose all information material to patient decision making, that is, information the healthcare provider can reasonably expect a patient would require to determine whether to undergo recommended treatment.[194] The materiality standard depends on the judge's and jury's judgment regarding what a reasonable person would want to know regarding medical decision making in specific circumstances. Material information is "information which a reasonable patient would consider in deciding whether to undergo the medical procedure."[195] As well, the Supreme Judicial Court of Massachusetts noted in *Vasa v. Compass Medical* that "Doctors have a duty to inform patients of available options for medical treatment and the material risks that each option entails."[196]

Comparative Risk Data and Informed Consent

Comparative risk data have proliferated regarding outcomes and success rates of particular procedures as performed by individual physicians and in specific healthcare institutions.[197] Already, in 1996, the Wisconsin Supreme Court concluded in *Johnson v. Kokemoor* that

> comparative risk data distinguishing the defendant's morbidity and mortality rate from the rate of more experienced physicians was properly before the jury. ... When the duty to share comparative risk data is material to a patient's exercise of informed consent, an ensuing referral elsewhere will often represent no more than a modest and logical next step.[198]

In *Johnson*, the defendant had diagnosed an enlarging aneurysm at the rear of the plaintiff's brain and recommended surgery to clip the aneurysm.[199] But the defendant had failed to divulge the extent of his experience in performing such surgery and had failed to refer the plaintiff to a "tertiary care center staffed by physicians more experienced in performing the same surgery."[200] In the event, the defendant performed surgery in October 1990. The procedure was a technical success. But as a consequence of surgery, the plaintiff "was rendered an incomplete quadriplegic."[201] Overall, the Wisconsin Supreme Court stated its decision "will not always require physicians to give patients comparative risk evidence in statistical terms to obtain informed consent. Rather, we hold that evidence of the morbidity and mortality outcomes of different physicians was admissible under the circumstances of this case."[202] The Court emphasized that

> questions regarding whether statistics are sufficiently material to a patient's decision to be admissible and sufficiently reliable to be non-prejudicial are best resolved on a case-by-case basis. The fundamental issue in an informed consent case is less a question of how a physician chooses to explain the panoply of treatment options and risks necessary to a patient's informed consent than a question of assessing whether a patient has been advised that such options and risks exist.[203]

Thus, in the context of incorporating comparative risk data in the informed consent process, a primary obligation of healthcare providers is to ensure that a patient has been advised regarding options and risks, including the possibility of alternative providers, and that the patient has determined that the information provided is sufficient for her to make an informed decision.

Medical Malpractice Litigation

Overall, medical malpractice litigation can support important social policies. Tort liability compensates injured patients, reinforces sound medical practice, and specifies physician duties of care.[204] Historically, medical malpractice lawsuits surged until the 1970s, buoyed by dramatic increases in use of medical technology, an increasing range of intrusive treatments, and the increasing availability of third-party payments for healthcare services.[205] But tort reform efforts, launched in the 1970s to constrain the quantity of litigation and decrease the costs to defendants of medical malpractice lawsuits, began to exert a modifying effect.

For example, California's Malpractice Insurance Compensation Reform Act (MICRA), signed into law on September 23, 1975, is the classic tort reform statute. MICRA limited recovery of noneconomic damages in medical malpractice litigation to US$250,000. Those opposed to tort reform challenged the constitutionality of the legislation, and MICRA was ultimately upheld by the California Supreme Court in *Fein v. Permanente Medical Group* in 1985.[206] In *Fein*, the Court stated that

> in enacting MICRA the Legislature was acting in a situation in which it had found that the rising cost of medical malpractice insurance was posing serious problems for the health care system in California, threatening to curtail the availability of

> medical care in some parts of the state and creating the very real possibility that many doctors would practice without insurance, leaving patients who might be injured by such doctors with the prospect of uncollectible judgments ... placing a ceiling of $250,000 on the recovery of noneconomic damages is rationally related to the objective of reducing the costs of malpractice defendants and their insurers.[207]

The California Supreme Court emphasized that MICRA placed no limits on a plaintiff's right to recover for all economic damages such as medical expenses or lost earnings.[208] Over the course of more than forty years since MICRA was enacted, numerous legislative challenges and ballot initiatives have attempted to overturn or expand the US$250,000 cap on noneconomic damages. But none have succeeded, including Proposition 46, which was defeated in November 2014 by a margin of 67 to 33 percent.[209] If it had succeeded, Proposition 46 would have raised the cap on noneconomic damages in medical malpractice litigation to US$1.1 million.

Physicians and surgeons are required by the courts to "exercise in diagnosis and treatment that reasonable degree of skill, knowledge, and care ordinarily possessed and exercised by members of the medical profession under similar circumstances."[210] In this overall context, medical malpractice is typically defined as unskillful practice that results in injury to a patient.[211] Plaintiffs and defendants may present competing medical standards of care in attempts to establish negligence or uphold the physician's conduct as having met the standard. Expert testimony is required to establish the prevailing medical standard of care and to demonstrate the failure of the defendant to conform to that standard.

As well, clinical practice guidelines have become crucial in establishing the relevant medical standard of care. Per the Institute of Medicine, "Clinical practice guidelines are statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options."[212] These guidelines provide standardized protocols for management of specific clinical problems and methodologies for utilizing specific procedures and treatments. Clinical practice guidelines are consensus statements based on the assessment of expert panels. In medical malpractice litigation, expert testimony will still be required "to introduce the standard and establish its sources and its relevancy."[213]

Alternative Methods of Tort Reform

Reduction in the risk of medical malpractice litigation and jury trials may be accomplished via contractual or compelled alternative dispute resolution.[214] Historically, arbitration agreements in the healthcare environment have been uncommon, but recent U.S. Supreme Court cases supporting arbitration may impact the implementation of such agreements in the healthcare field.[215] For example, in *AT&T Mobility v. Concepcion*, the Supreme Court held in a 5–4 decision that, per the Federal Arbitration Act, California must enforce arbitration agreements even if the agreement required that consumer complaints be arbitrated on a case-by-case basis rather than on a class-action basis.[216] The Supreme Court indicated that "courts must place arbitration agreements on an equal footing with other contracts ... and enforce them according to their terms."[217] Recent predictions suggest that healthcare contracts will increasingly include arbitration provisions.[218]

Communication and resolution programs are another type of tort reform. In a communication and resolution program, healthcare institutions and liability insurers encourage the

disclosure of unexpected treatment outcomes to affected patients and their families and attempt to achieve resolution.[219] Such resolution may include an apology and an explanation, as well as an offer of reimbursement or compensation.[220] These programs have become more common as healthcare institution risk managers seek to identify methods of controlling liability costs.[221] With a communication and resolution program in place, a healthcare institution would agree to identify and promptly compensate a patient for an avoidable injury. Dispute resolution would be managed by mediation or arbitration. Communication and resolution programs aim to reduce the likelihood of lawsuits by patients or families and stimulate "institutional learning and safety improvement."[222] The success of such programs may be constrained by the healthcare institution's tolerance for risk.

Strict Liability and Product Liability

Strict Liability

Strict liability is imposed on a defendant when he is deemed liable without proof of fault.[223] Strict liability is contrasted with negligence, in which the defendant is determined to have been at fault by having engaged in unreasonably risky conduct. The distinction between strict liability and negligence is a core feature of tort law.[224] Strict liability may be considered to have originated in early tort law, which imposed liability for all direct harms to person or property, regardless of fault. For example, Wigmore referenced a case in England in 1466,[225] in which the plaintiff's attorney asserted that if one was "shooting at butts, and his bow shakes in his hands, and kills a man," the family of the one who was killed would have a "good action of trespass" against the one who was shooting arrows. Even though the shooting was lawful, "the wrong which the other received was against his will."[226] Wigmore also referenced *Weaver v. Ward,*[227] a case in England in 1616 in which the court stated that "no man shall be excused of a trespass ... , except it may be judged utterly without his fault; as if a man by force take my hand and strike you."[228]

Per the Restatement Second of Torts, "One who carries on an abnormally dangerous activity is subject to liability for harm to the person, land or chattels of another resulting from the activity, although he has exercised the utmost care to prevent the harm."[229] The function of strict liability is not to prevent abnormally dangerous activities such as dynamiting or blasting, which ultimately might result in a benefit to the community such as a refurbished business district, but rather to provide compensation in the event of actual harm. Thus, the defendant's enterprise "is required to pay its way by compensating for the harm it causes, because of its special, abnormal and dangerous character."[230]

Modern case law establishing strict liability may be considered to derive from *Rylands v. Fletcher,* decided in England in a series of opinions, initially before the Court of Exchequer in 1865,[231] then before the Exchequer Chamber in 1866,[232] and finally before the House of Lords in 1868.[233] In *Fletcher v. Rylands,* the case before the Court of Exchequer, the defendant had retained a contractor to build a reservoir, which would provide water for the defendant's mill. In excavating the reservoir bed, the contractor came upon several old mine shafts that had been filled with earth. The plaintiff was a lessee of a mine that lay under land near the reservoir. In working the mine, the plaintiff had encountered a warren of long-abandoned workings. Several

days after the reservoir was completed and partially filled with water, the earth filling one of the old shafts gave way and allowed water to flow through the abandoned workings and into the plaintiff's mine.[234] An arbitrator of the facts found the contractors guilty of negligence in constructing the reservoir despite their knowledge of the underlying workings and shafts. The defendant was not negligent in the choice of contractor or selection of the site for the reservoir. The question in *Fletcher v. Rylands* was whether the defendant was liable for damages regardless of proof of negligence. The Court of Exchequer held that the defendant, as he was not guilty of negligence, was not liable for the harm done by the bursting of the reservoir. Both the opinion of the court and the dissenting opinion noted that the case involved "a matter of liability for injury that was both unintentional and not negligent."[235]

The case was then brought to the Court of Exchequer Chamber, where the prior ruling was unanimously reversed.[236] Justice Blackburn delivered the opinion of the court and described a rule of strict liability regarding the circumstances of the case. Justice Blackburn's opinion supports the thesis that "*Rylands* does indeed articulate a general principle of strict liability."[237] Justice Blackburn stated that a neighbor "should be obliged to make good the damage which ensues if he does not succeed in confining it [an escaping element such as cattle or noxious fumes] to his own property."[238] Thus, a "general rule" of strict liability was needed to address the matters in question. The defendant Rylands should bear the cost of the harm he inflicted on the plaintiff Fletcher as "the risk issued from his activity, reasonable though his conduct may have been."[239] This principle of fairness is the basis of strict liability.

In the healthcare context, the general rule of strict liability applies to the use of medical devices, such as vascular stents, pacemakers, artificial joints, and powered wheelchairs. A products liability claim may be based on harm caused by a medical device. The theoretical foundations of products liability have included principles of both negligence and strict liability.

Products Liability

Products liability concerns the scope of liability of those who manufacture, sell, or supply goods for harms caused by defective physical products.[240] The history of products liability law may be traced to its origins in the 1842 case of *Winterbottom v. Wright*.[241] As discussed above, *Winterbottom* established the principle that a negligent manufacturer was not liable for injury caused by a defective product in the absence of privity of contract, that is, when the injured plaintiff was not the person who purchased the product. The *Winterbottom* opinion declared that there was no duty owed to the plaintiff by the defendant, as there was no liability without a direct contractual relationship. In the United States, the privity doctrine reigned until 1916,[242] when Judge Cardozo handed down his landmark ruling in *MacPherson v. Buick Motor Company*.[243] As discussed above, per *MacPherson*, a defendant's duty to provide a safe, secure product is not limited to the defendant's contractual relationship with a dealer of those products. In *MacPherson*, such duty extended to all users of a potentially dangerous item, article, or product.

Judge Cardozo's ruling in *MacPherson* effectively abolished the privity requirement for "actions brought in negligence by injured persons with no direct contractual dealings with defendant manufacturers."[244] Negligence rather than contract doctrine became a primary basis of liability for products liability claims.[245] But it remained difficult to prove negligence on the part of a manufacturer or even a retailer. In consequence, early products liability law developed primarily via the law of warranty.[246] Per the Uniform Sales Act[247] in 1906 and the subsequent Uniform

Commercial Code in early 1960s, "the implied warranty of merchantability was legislatively incorporated into the law of every state."[248] As an implied warranty claim "suggested that the manufacturer had implicitly contracted to provide a reasonably safe product,"[249] a plaintiff in a products liability action was not required to prove fault.

In *Escola v. Coca Cola Bottling Co.*, a case before the California Supreme Court in 1944,[250] the plaintiff, a waitress, was injured when a bottle of Coca Cola exploded in her hand, severing blood vessels, nerves, and muscles. The plaintiff indicated to the court that she was "unable to show any specific acts of negligence,"[251] but it was inferred that the "defendant's negligence was responsible for the defective condition of the bottle at the time it was delivered to the restaurant."[252] The court determined that the bottle was reasonably in some manner defective at the time the defendant relinquished control, and that "sound and properly prepared bottles of carbonated liquids do not ordinarily explode when carefully handled."[253] The court affirmed the judgment of the trial court in favor of the plaintiff.

In his concurring opinion, Justice Roger J. Traynor stated that "the manufacturer's negligence should no longer be singled out as the basis of a plaintiff's right to recover in cases like the present one."[254] Rather, a manufacturer incurs an absolute liability "when an article that he has placed on the market, knowing that it is to be used without inspection, proves to have a defect that causes injury to human beings."[255] There may be no negligence on the part of the manufacturer, even though harm was caused. Justice Traynor described such circumstances as liability without negligence. Public policy could demand that "a manufacturer of goods be responsible for their quality regardless of negligence."[256] He noted that manufacturing processes are beyond the comprehension of the general public and the "consumer no longer has means or skill enough to investigate for himself the soundness of a product."[257] Overall, the manufacturer's liability should "be defined in terms of the safety of the product in normal and proper use, and should not extend to injuries that cannot be traced to the product as it reached the market."[258] Thus, Justice Traynor's concurring opinion "contained broad language on the safety advantages of products liability" and could be interpreted more broadly as referring to absolute liability.[259]

Almost twenty years after *Escola*, in 1963, *Greenman v. Yuba Power Products, Inc.*[260] was the first case explicitly to adopt the doctrine of strict liability in tort law.[261] In *Greenman*, the plaintiff had been using a combination power tool with the capabilities of a saw, drill, and wood lathe. After he had worked on a large piece of wood several times without difficulty, "it suddenly flew out of the machine and struck him on the forehead, inflicting serious injuries."[262] Justice Traynor, writing the opinion for the California Supreme Court, stated that "A manufacturer is strictly liable in tort when an article he places on the market, knowing that it is to be used without inspection for defects, proves to have a defect that causes injury to a human being."[263]

Justice Traynor emphasized that the liability incurred "is not one governed by the law of contract warranties but by the law of strict liability in tort."[264] To establish the manufacturer's liability it was sufficient for the plaintiff to have proved that he was injured while using the product "in a way it was intended to be used as a result of a defect in design and manufacture of which plaintiff was not aware" that made the product unsafe for its intended use.[265] The judgment of the trial court in favor of the plaintiff was upheld. Thus, in *Greenman*, the California Supreme Court "formally adopted a tort theory of recovery for products liability, regardless of fault."[266] Overall, products liability may be invoked when use of a medical device causes harm to a patient.

Commonalities between Strict Liability and Negligence

Importantly, liability imposed in negligence and strict liability are not always clearly distinguished.[267] Certain forms of liability imposed in negligence appear to be similar to strict liability. For example, a defendant may be liable in negligence even though he has done his best and was not capable of exercising reasonable care (the objective standard). As well, a defendant may be liable in negligence for failing to achieve perfect compliance. Also, a defendant may have negligently risked harm in foreseeable circumstances and may be liable in negligence for having caused unforeseeable harms. In all of these circumstances, liability imposed in negligence closely resembles strict liability.[268]

The exercise of reasonable care is judged by an *objective standard*. A defendant who is not able to exercise reasonable care is still held liable for negligence, in the case that his unreasonably risky behavior caused harm to another. As Justice Holmes stated in 1881, "The standards of the law are standards of general application. The law takes no account of the infinite varieties of temperament, intellect, and education which make the internal character of a given act so different in different men."[269] Justice Holmes described the "impossibility of nicely measuring a man's powers and limitations."[270] He noted that when people live in society, a "certain average of conduct" is necessary to the general welfare. Justice Holmes used a "hasty and awkward" person as an example, someone who was "always having accidents and hurting himself or his neighbors."[271] Such a person is required by his neighbors "at his proper peril, to come up to their standard and the courts which they establish decline to take his personal equation into account."[272] Thus, in a case of alleged negligence, all persons, regardless of their capacities and capabilities, are required to meet an objective standard of reasonable care. The immediate impact "is to impose what amounts to strict liability on individuals whose capacities are below average."[273]

Regarding *perfect compliance*, in tort law the "reasonably prudent person always exercises reasonable care."[274] For example, suppose that a section of railroad track has a speed limit of forty-five miles per hour. Reasonable care requires that a train engineer perfectly adhere to that limit. If the engineer exceeded a speed of forty-five miles per hour for only a few seconds, and during that brief interval a passenger were injured, the engineer may be found to be liable in negligence. In other circumstances it may be that perfect compliance is impossible. A homeowner may have dutifully shoveled the snow-covered and icy sidewalk in front of her property to the best of her ability, and yet a passerby may slip and fall and sustain a serious injury. Such a defendant who exercised all the care that was possible may nevertheless be found liable for the harm her conduct had caused.[275] Such a ruling in negligence is essentially that of strict liability, that is, liability without fault.

In cases involving the *thin-skull rule*, the extent of the harm the plaintiff suffered is unforeseeable. For example, consider a defendant who had been participating in an adult community center softball game. He had been taking practice swings, swinging his bat in preparation for his turn at the plate. But on his backswing, his bat inadvertently struck a teammate in the head. The defendant was deemed negligent as he was not in the designated area for taking such practice swings when the injury occurred. Thus, a head injury to a passerby was reasonably foreseeable. However, in this specific instance, the plaintiff suffered a fractured skull, as the bones of his cranium were congenitally thin. Per the thin-skull rule, the defendant is liable for the full extent of the plaintiff's injuries, although a skull fracture was not reasonably

foreseeable. By definition, the defendant is not negligent, that is, not at fault, regarding the plaintiff's unforeseeable injury.[276]

The thin-skull rule is applied only when the defendant's actions would pose risk to normal people.[277] When a defendant has engaged in such unreasonably risky behavior, the thin-skull rule provides that the defendant is liable for all the personal harm caused in fact, even though the injuries may be more extensive than those that would have been experienced by a normal person.[278] As such, the liability imposed by the thin-skull rule may be considered a form of strict liability for being negligent.[279] The plaintiff is entitled to recover for all the harm done, even though the fractured skull (or other similar injury) was not foreseeable. Therefore, the objective standard, perfect compliance, and the thin-skull rule act to incorporate elements of strict liability in cases involving liability in negligence.

Summary

A core idea of tort law is that one has a duty "to refrain from acting toward others in certain ways, and correlatively, with the idea that others have the right not to be acted upon in such ways."[280] Overall, tort law provides redress of the violation of private rights. As well, tort law strives to encourage safety, influence levels of activities on the part of both manufacturers and consumers that could result in injury, and spread the financial burden of losses to those entities that can best bear the costs associated with the activity.[281] Generally speaking, there is no comprehensive statement of strict liability theory in tort law.[282] Modern strict liability may be considered "as an answer to the canonical modern problem of tort law; namely, how to address the recurring harms that are the inescapable by-product of industrial activity."[283] Importantly, liability in negligence may frequently consist of what may be understood as strict liability.[284]

Tort law components of negligence and strict liability impact healthcare providers and healthcare institutions on a daily basis. Healthcare institutions and healthcare providers owe a duty of care to their patients, and patients have correlative rights including the right of autonomy and the right of bodily integrity. Tort law helps ensure a focus on the completeness, appropriateness, and effectiveness of provider–patient interactions, including an emphasis on patient safety and optimal patient outcomes. It may be reasonably asserted that tort law helps ensure optimal functioning of the healthcare system as a whole.

KEY TERMS

Battery

The defendant in a civil action is subject to liability for *simple battery* when he intentionally touches the body of the plaintiff, causing bodily contact, in a way not authorized by the plaintiff or accounted for by her apparent wishes, and the contact is either against the will of the plaintiff or harmful.[287] For example, in *Marchbanks v. Borum,*[288] the Court of Appeals of Mississippi declared, "One commits a battery by the very touching of another person without his consent." In *Mims v. Boland,* the Court of Appeals of Georgia stated, "A physician who undertakes to treat another without express or implied consent of the patient is guilty of at least a technical battery."[289]

BOX 5.1

Case Study: Medical Malpractice?

In scenario A, a forty-eight-year-old moderately obese male is undergoing laparoscopic surgery in a local hospital to remove his gallbladder (cholecystectomy). During the course of the procedure, a poorly placed vascular clip slips and damages the cystic artery, the primary supplier of blood to the gallbladder.[285] The resulting small bleed is not observed by the surgical team and the procedure is deemed a success. The patient is discharged after an overnight stay and returns home. Within twenty-four hours he begins to feel lightheaded, dizzy, and weak, but he ignores these symptoms. The following night the patient is awakened at approximately 4:00 a.m. by severe abdominal pain. He is too lethargic to get out of bed but manages to reach his cellphone on his nightstand and calls 911. The emergency team arrives within eight minutes and finds the patient in shock. He goes into cardiac arrest before the ambulance reaches the hospital. Resuscitation attempts do not revive him and he is pronounced dead by Emergency Department medical staff. Subsequently, the man's family files a claim against the surgeon and the hospital for wrongful death due to medical malpractice. At the trial, medical experts for the defendants testified that bleeding complications following laparoscopic cholecystectomy are the "second most common cause of death in patients undergoing the procedure," with several studies demonstrating incidences ranging from 1 to 2 percent.[286]

In scenario B, a fifty-four-year-old moderately obese female is undergoing laparoscopic surgery in a local hospital to remove her gallbladder. During the procedure the patient goes into cardiac arrest. Resuscitation attempts are not successful and she is pronounced dead by the surgeon. Subsequently, the woman's family files a claim against the surgeon and the hospital for wrongful death due to medical malpractice. At the trial, medical experts for the defendants testified that hospital records demonstrated the surgeon and her team had conformed to prevailing medical standards of care.

Ethical and Legal Analysis

1. Compare and contrast scenarios A and B from the perspective of medical malpractice. Analyze the likelihood of the plaintiffs' success in each scenario.
2. Discuss the benefits to society of framing medical malpractice in the context of tort liability.
3. Discuss the potential benefits to society if medical malpractice could be addressed in the context of strict liability.
4. Discuss hospital policies and procedures that potentially could help to avoid patient outcomes such as those obtained in scenarios A and B.

Civil Law

The term "civil law" derives from the Latin *ius civile*, the laws applicable to all Roman citizens. Following the rediscovery and revival of classical Roman law in the Middle Ages, Roman law became a central component of European legal development. Examples include the Prussian Civil Code (General State Law; 1794) and France's Civil Code (*Code Napoléon;* 1804). Generally, the preponderance of modern civil law "is based on concepts that the Roman jurists identified and refined."[290] Civil law is still influential in continental Europe, Scotland, and Latin America.[291]

Common Law

Common law, as a legal system, originated and developed in England in the Middle Ages.[292] By the thirteenth century, "common law" meant the law of the royal court, which rapidly became "the one law *common* to all the realm."[293] The common law was judiciary law, and it was declared by judges, not by legislators, other officials, or local wise men.[294] Overall, the common law incorporates the history of judicial decisions (precedent), in which customary law has been defined and developed by the courts.[295] Effectively, the common law consists of all the rules that may be generalized based on judicial decisions.[296]

Factual Cause

In a case of negligence, the plaintiff must prove that the defendant's alleged negligence was the factual cause of the plaintiff's damages, that is, the harm the plaintiff suffered was caused in fact by the defendant's conduct.[297] The plaintiff must prove that the harm she experienced would not have occurred absent the conduct of the defendant.[298]

Foreseeability

Regarding foreseeability, a defendant whose actions caused harm to another is not ordinarily responsible in a tort claim unless the possibility of such harm is assessed to have been recognizable by a reasonable person. If the potential harm would have been foreseeable to a reasonable person, then the defendant whose unreasonably risky actions caused that harm is liable for damages.[299] Thus, "the creation of risks from which injury is reasonably foreseeable is grounds for liability, because of the failure to modulate one's action in view of its potential to cause others to suffer."[300] Foreseeability of harm is necessary to demonstrate negligence.

Judicial Review

Judicial review is a court's review "of a lower court's or an administrative body's factual or legal findings."[301] As well, judicial review is a court's power "to review the actions of other branches or levels of government."[302] Utilizing judicial review, a court has the power to invalidate executive and legislative actions as being unconstitutional. Regarding the right of judicial review, John Marshall, speaking before the Virginia Ratifying Convention in 1788, stated that "if they [the Congress] were to make a law not warranted by any of the powers enumerated, it would be considered by the judges as an infringement of the Constitution which they are to guard." Further, "They would not consider such a law as coming under their jurisdiction. They would declare it void."[303] Later, in 1803, in *Marbury v. Madison,* Chief Justice John Marshall delivered the unanimous opinion of the U.S. Supreme Court establishing the principle of judicial review. In *Marbury,* Chief Justice Marshall stated that

"It is emphatically the province and duty of the Judicial Department to say what the law is. Those who apply the rule to particular cases must, of necessity, expound and interpret that rule. If two laws conflict with each other, the Courts must decide on the operation of each. ... The judicial power of the United States is extended to all cases arising under the Constitution.[304]

Liability

Liability is the state or condition of being accountable or legally obligated.[305] As well, liability is a "legal responsibility to another or to society."[306] If one is *liable,* one is bound or obliged by law, or answerable at law.[307]

Negligence

Negligence is the "failure to exercise the standard of care that a reasonably prudent person would have exercised in a similar situation."[308] A negligent wrong involves the "failure to take a reasonable precaution against risks of harm."[309] Thus, the negligent wrongdoer violates standards of reasonableness. As well, negligent wrongs involve unreasonably risky behavior that causes actual harm.[310]

Precedent

Precedent refers to the history of judicial decisions. The doctrine of precedent indicates that once a point has been decided, the same result must be reached for the same problem.[311] In other words, precedent denotes "a decided case that furnishes a basis for determining later cases involving similar facts or issues."[312]

Prima facie case

In tort law, a *prima facie* case is established when a plaintiff has provided testimony about facts that demonstrate all the elements necessary for the tort that is claimed.[313] When a *prima facie* case is made, the case then goes to a jury.

Proximate Cause

Proximate cause is demonstrated when the defendant's actions were assessed to have a significant relationship to the harm experienced by the plaintiff, and the harm caused was within the scope of the general type of harm risked by the defendant's negligent conduct.[314] Importantly, in *Zwiren v. Thompson,* the Supreme Court of Georgia noted that proximate cause "is always to be determined on the facts of each case upon mixed considerations of logic, common sense, justice, policy, and precedent."[315]

Reasonable Person Standard

A reasonable person takes sufficient care to ensure that her actions do not cause harm to others. The extent of care undertaken depends on the particular circumstances. Thus, the *standard of care* represents the "duty of reasonable care under the circumstances."[316] The standard of one's legal duty to take reasonable precautions against the risk of causing harm is the standard of a reasonable person.[317] A negligent act creates an unjustifiable risk of future harm and is one that a "reasonable person" would not have performed.

Risk
Risk is assessed in relation to reasonable behavior and represents "the existence and extent of the possibility of harm."[318] An element of a case for negligence requires establishing that the defendant had a duty of care for the plaintiff's safety and the defendant's unreasonably risky conduct resulted in a breach of that duty.

Strict Liability
Strict liability in tort law is liability without a finding of fault.[319] The "general rule" of strict liability, as stated by Justice Blackburn in *Fletcher v. Rylands*,[320] is that the defendant should bear the cost of the harm he inflicted on the plaintiff as "the risk issued from his activity, reasonable though his conduct may have been."[321] In 1963, *Greenman v. Yuba Power Products, Inc.*[322] was the first case explicitly to adopt the doctrine of strict liability in tort law.[323]

Tort
A tort is "a civil wrong, other than breach of contract, for which a remedy may be obtained, usually in the form of damages."[324] A tort may be construed as an action that deviates from existing norms or standards of conduct, and a tort may be considered as wrongdoing in a moral sense.[325] The primary function of tort law is to provide a remedy for legally recognized harms by rendering a judgment for damages against the wrongdoer.

Writs
A writ is a court's written order commanding the person addressed by the writ to perform or refrain from performing a specified act.[326] The first known Register of Writs dates from 1227.[327] At that time, the common law of England was found in the form or writs and in the Plea Rolls (records of proceedings) of the King's Court.[328]

DISCUSSION QUESTIONS

1. Compare and contrast civil and common law systems and provide at least two characteristic features of each system.
2. Discuss the vitality of the common law in the United States and describe the creative role of the courts in the evolution of U.S. common law.
3. Summarize the facts before the court in *MacPherson v. Buick Motor Co.*[329] Discuss the key features of the ruling and the subsequent impact of *MacPherson* on negligence theory in tort law.
4. Discuss the principles of corrective justice and their applicability to tort liability. Include an analysis of Aristotelian conceptions of justice.[330]
5. Compare and contrast a medical standard of care with the reasonable person standard and apply these standards in a hypothetical medical malpractice lawsuit.
6. Summarize the facts before the Court of Exchequer in *Fletcher v. Rylands*[331] and discuss the key features of Justice Blackburn's opinion in the appeal before the Court of Exchequer Chamber.[332]
7. Analyze *Fletcher v. Rylands* (subsequently generally known as *Rylands v. Fletcher*) in the context of strict liability as applied to healthcare practice.

DO-IT-YOURSELF ETHICIST

1. Analyze a medical standard of care for a particular specialty (e.g., internal medicine, geriatrics, or orthopedics) as it would apply to a hypothetical treatment scenario. Describe a situation in which the medical standard of care was upheld and a situation in which a practitioner failed to uphold the medical standard of care. How would a case for negligence be made in the latter scenario?
2. You are the general counsel for your local healthcare institution. You've chosen "Negligence versus Strict Liability" as the topic for your annual presentation to your institution's medical staff. First, discuss two key differences between liability in negligence and strict liability. Next, discuss elements of strict liability that may be located in negligence rulings, with specific reference to the objective standard, perfect compliance, and the thin-skull rule. Provide examples for each of these forms of liability.

REAL-WORLD APPLICATIONS—ETHICS AS A DOCTRINE OF ACTION

1. You are the risk manager at an urban healthcare institution. Describe three action plans your department will implement and oversee in the next fiscal year to reduce the incidence of medical malpractice lawsuits brought against your institution and its medical staff.
2. You are the president of a statewide medical ethics advocacy group. You have been asked to testify before your state legislature's Joint Committee on Health and Human Services regarding a bill that would raise the cap on noneconomic damages in medical malpractice litigation. You intend to present a balanced analysis to the legislators. Present the details of two arguments supporting and two arguments opposing such an initiative.

REFERENCES

[1]J. Dainow, "The Civil Law and the Common Law: Some Points of Comparison," *American Journal of Comparative Law* 15, no. 3 (1996): 419–435.

[2]M. Cary, J. D. Denniston, J. W. Duff et al., *The Oxford Classical Dictionary*, 1st ed. (London: Oxford University Press, 1949), 464.

[3]J. Gordley, *The Jurists. A Critical History* (Oxford, UK: Oxford University Press, 2013), chap. 1.

[4]Cary, Denniston, and Duff, *Oxford Classical Dictionary*, 473.

[5]Gordley, *Jurists*.

[6]A. H. J. Greenidge, "Historical Introduction," in *Institutes of Roman Law by Gaius*, trans. and ed., E. Poste (London, Oxford at the Clarendon Press, 1904), li.

[7]A. D. E. Lewis and D. J. Ibbetson, eds., *The Roman Law Tradition* (Cambridge, UK: Cambridge University Press, 1994), 2.

[8]F. W. Maitland, "A Prologue to a History of English Law," in *Committee of the Association of American Law Schools: Select Essays in Anglo-American Legal History*, vol. I (Boston: Little, Brown, 1907), 31, referencing M. Conrat, *Geschichte der Quellen und Literatur des Römischen Rechts im Früheren Mittelalter* (Leipzig, Germany: J. C. Hinrichs, 1891), 62.

[9]Ibid., 31, referencing Conrat, 67.

[10]Ibid., 31.

[11]Ibid., 17.

[12]Cary, Denniston, and Duff, *Oxford Classical Dictionary*, 464.

[13]Gordley, *The Jurists*, 8.

[14]A. Watson, ed., *The Digest of Justinian*, vol. 1, rev. ed. (Philadelphia: University of Pennsylvania Press, 1998) *Digest* 9.2.3]. 288.

[15]Ibid., *Digest* 9.2.30.3, 288.

[16]Ibid., *Digest* 9.2.8, 279.

[17]A. Watson, ed., *The Digest of Justinian*, vol. 2, rev. ed. (Philadelphia: University of Pennsylvania Press, 1998), *Digest* 18.1.9, 57.

[18]Gordley, *The Jurists*, 10.

[19]P. Stein, *Regulae Iuris: From Juristic Rules to Legal Maxims* (Edinburgh, UK: University Press, 1966), 38.

[20]Gordley, *The Jurists*, 16.

[21]Ibid., 18.

[22]C. Herbert, trans., *The Introduction to Dutch Jurisprudence of Hugo Grotius* (London: van Voorst, 1845).

[23]Dainow, "The Civil Law and the Common Law," 421.

[24]Ibid.

[25]Gordley, *The Jurists*, 18.

[26]Dainow, "The Civil Law and the Common Law," 421.

[27]Maitland, "A Prologue to a History of English Law," 28.

[28]Ibid.

[29]E. Jenks, "The Development of Teutonic Law," in *Committee of the Association of American Law Schools: Select Essays in Anglo-American Legal History*, vol. I (Boston: Little, Brown, 1907), 49.

[30]Ibid., 50.

[31]Ibid.

[32]Ibid.

[33]Ibid., 51.

[34]Ibid.

[35]Ibid.

[36]Ibid., 52.

[37]Ibid.

[38]Ibid., 54.

[39]Ibid., 55.

[40]T. F. Tout, *Edward the First* (London: Macmillan, 1893), 143.

[41]Ibid., 143–144.

[42]Ibid., 144.

[43]Ibid., 144–145.

[44]Jenks, "The Development of Teutonic Law, 65.

[45]Ibid.

[46]Ibid., 67.

[47]T. Hobbes, *Leviathan*, reprinted from the 1651 ed. (Oxford, UK: Clarendon Press, 1909), 203.

[48]Ibid.

[49]E. Bruncken, "The Common Law and Statutes," *Yale Law Journal* 29, no. 5 (1920): 516–522.

[50]Dainow, "The Civil Law and the Common Law," 424–425.

[51]Ibid., 425.

[52]B. A. Garner, ed., *Black's Law Dictionary*, 10th ed. (St. Paul, MN: West, 2014), 1366.

[53]*Arthur v. Bokenham*, 11 Mod. 148, 150 (Eng. C. P., 1708).

[54]*Davis v. Abstract Construction Co.*, 121 Ill. App. 121, 129 (1905).

[55]M. J. Cohen, "Common Law in the American Legal System: The Challenge of Conceptual Research," *Law Library Journal* 81, no. 1 (1989): 13–32.

[56]Ibid., 13.

[57]N. Webster, *An American Dictionary of the English Language*, vol. 1 (New York: Converse, 1828).

[58]L. Brown, ed., *The New Shorter Oxford English Dictionary on Historical Principles*, Thumb Index ed. (New York: Oxford University Press, 1993), 453.

[59]Cohen, "Common Law in the American Legal System," 18.

[60]E. Coke, *The First Part of the Institutes of the Laws of England*, 19th ed. (Philadelphia, Robert H. Small, 1853), L.1.C.1. Sect. 3. 11.a. and 11.b.

[61]Cohen, "Common Law in the American Legal System," 20.

[62]Ibid.

[63]W. B. Stoebuck, "Reception of English Common Law in the American Colonies," *William & Mary Law Review* 10, no. 2 (1968): 393–426.

[64]*Van Ness v. Pacard*, 27 U.S. 137, 144 (1829).

[65]*Commonwealth v. Chapman*, 13 Met. 68, 54 Mass. 68, 69 (1847).

[66]J. Kent, *Commentaries on American Law*, 6th ed. (New York: William Kent, 1848), 472–473.

[67]Cohen, "Common Law in the American Legal System," 24–25.

[68]Ibid., 25.

[69]Ibid., 27, 29.

[70]E. J. Weinrib, "Law as a Kantian Idea of Reason," *Columbia Law Review* 87, no. 3 (1987): 472–508.

[71]Ibid., 501.

[72]Ibid., 487.

[73]Ibid., 501.

[74]Ibid., 487.

[75]Ibid., 503.

[76]D. D. Dobbs, P. T. Hayden, and E. M. Bublick, *Hornbook on Torts*, 2nd ed. (St. Paul, MN: West Academic, 2016), 3.

[77]Garner, *Black's Law Dictionary*, 1717.

[78]Brown, *New Shorter Oxford English Dictionary*, 3345.

[79]Ibid.

[80]Dobbs, Hayden, and Bublick, *Hornbook on Torts*, 4.

[81]Ibid.

[82]Ibid.

[83]Ibid.

[84]*Curtis v. Porter*, 784 A.2d 18, 23 (Me., 2001).

[85]*Mullins v. Parkview Hosp., Inc.*, 830 N.E.2d 45, 62 (Ind. Ct. App. 2005).

[86]Garner, *Black's Law Dictionary*, 1664.

[87]*Mullins v. Parkview Hosp., Inc.*, 865 N.E.2d 608, 609 (Ind. 2007).

[88]K. W. Simons, "Negligence," *Social Philosophy and Policy* 16, no. 2 (1999): 52–93.

[89]Dobbs, Hayden, and Bublick, *Hornbook on Torts*, 4.

[90]Ibid., 5.

[91]J. Thomas, "Which Interests Should Tort Protect?" *Buffalo Law Review* 61, no. 1 (2013): 1–80.

[92]Dobbs, Hayden, and Bublick, *Hornbook on Torts*, 5.

[93]C. A. Wright, "Introduction to the Law of Torts," *Cambridge Law Journal* 8, no. 3 (1944): 238–246.

[94]J. H. Wigmore, "Responsibility for Tortious Acts: Its History III," *Harvard Law Review* 7, no. 8 (1894): 441–463, 453, referencing Justice Brian, in 20 Edw. IV. 10, pl. 10 (1481).

[95]Ibid., referencing Chief Justice Holt, in *Tenant v. Goldwin*, 2 Ld. Raym. 1089 (1705).

[96]Wright, "Introduction to the Law of Torts," 243.

[97]C. O. Gregory, "Trespass to Negligence to Absolute Liability," *Virginia Law Review* 37, no. 3 (1951): 359–397.

[98]Ibid., pp. 361–362.

[99]Dobbs, Hayden, and Bublick, *Hornbook on Torts*, 86.

[100]Ibid.

[101]Gregory, "Trespass to Negligence to Absolute Liability," 362.

[102]Ibid., 362–363.

[103]Ibid., 363.

[104]Ibid.

[105]*Reynolds v. Clarke*, 1 Str. 634, 93 Eng. Rep. 747, 748 (K.B. 1726).

[106]*Waldon v. Marshall*, Y.B. Mich., 43 Ed. 3, f. 33, pl. 38 (1370), referenced in C. H. S. Fifoot, *History and Sources of the Common Law: Tort and Contract* (New York: Greenwood Press, 1970), 81.

[107]Dobbs, Hayden, and Bublick, *Hornbook on Torts*, 190, referencing *Steinson v. Heath*, 3 Lev. 400, 83 Eng. Rep. 750 (K.B. 1694).

[108]P. H. Winfield, "The History of Negligence in the Law of Torts," *Law Quarterly Review* 42 (1926): 184–201.

[109]Dobbs, Hayden, and Bublick, *Hornbook on Torts*, 191.

[110]*Michael v. Alestree*, 2 Lev. 172, 83 Eng. Rep. 504 (1676), referenced in T. Beven, *Principles of the Law of Negligence*, vol. 1, *General Relations*, 2nd ed. (London: Stevens and Haynes, 1895), 693; and B. A. Rich and M. B. Wailes, eds., *American Law Reports Annotated*, vol. XX (Rochester, NY: Lawyers Co-operative, 1922), 144.

[111]Dobbs, Hayden, and Bublick, *Hornbook on Torts*, 192.

[112]J. H. Wigmore, *Select Cases on the Law of Torts*, vol. I (Boston: Little, Brown, 1912), 940–942, referencing *Winterbottom v. Wright*, 10 Meeson & Wellsby 109, 152 Eng. Rep. 402 (1842).

[113]Garner, *Black's Law Dictionary*, 1394.

[114]Wigmore, *Select Cases on the Law of Torts*, 942.

[115]Ibid.

[116]R. L. Rabin, "The Historical Development of the Fault Principle: A Reinterpretation," *Georgia Law Review* 15 (1980–1981): 925–961.

[117]*Thomas v. Winchester*, 6 N.Y. 397 (1852).

[118]Ibid., referenced in Wigmore, *Select Cases on the Law of Torts*, 943–944.

[119]*Longmeid v. Holliday*, 155 Eng. Rep. 752 (1851).

[120]Wigmore, *Select Cases on the Law of Torts*, 944–945.

[121]*Brown v. Kendall*, 60 Mass. (6 Cush.) 292 (1850), referenced in Wigmore, *Select Cases on the Law of Torts*, 962–964.

[122]Ibid.

[123]O. W. Holmes, *The Common Law* (London: Macmillan, 1882), 106.

[124]Gregory, "Trespass to Negligence to Absolute Liability," 366.

[125]Rabin, "The Historical Development of the Fault Principle," 926.

[126]Holmes, *The Common Law*, 111–112.

[127]*MacPherson v. Buick Motor Company*, 111 N.E. 1050, 217 N.Y. 382 (1916).

[128]Ibid., at 385.

[129]Ibid.

[130]Ibid., at 389.

[131]Ibid., at 390.

[132]Ibid. at 394.

[133]*Carter v. Yardley & Company*, 319 Mass. 92, 100, 64 N.E. 2d 693 (1945).

[134]E. H. Levi, "An Introduction to Legal Reasoning," *University of Chicago Law Review* 15, no. 3 (1948): 501–574, 517–518.

[135]Simons, "Negligence," 54.

[136]Winfield, "The History of Negligence in the Law of Torts," 184.

[137]Ibid., 196.

[138]Simons, "Negligence,", 56.

[139]R. L. Rabin, "Law for Law's Sake," *Yale Law Journal* 105, no. 8 (1996): 2261–2283.

[140]*Palsgraf v. Long Island Railroad Co.*, 162 N.E. 99, 248 N.Y. 339 (NY 1928).

[141]Ibid., at 341.

[142]Ibid.

[143]*West Virginia Central Railroad Co. v. Fuller*, 54 A. 669, 96 Md. 652, 666 (Md. 1903).

[144]*Palsgraf v. Long Island Railroad Co.*, at 342, referencing prior rulings.

[145]Ibid., at 343.

[146]Rabin, "Law for Law's Sake," 2266.

[147]*Palsgraf v. Long Island Railroad Co.*, at 344.

[148]*Rowland v. Christian*, 443 P.2d 561, 69 Cal. 2d 108 (Cal. 1968).

[149]Ibid., at 112.

[150]Ibid., at 113.

[151]Ibid., at 114.

[152]Ibid., referencing *Oettinger v. Stewart*, 24 Cal. 2d 133, 138–139 (1944).

[153]Ibid., at 116, referencing *Kermarec v. Compagnie Generale Transatlantique*, 358 U.S. 625, 631, 79 S. Ct. 406, 3 L. Ed. 2d 550 (1959).

[154]Ibid., at 118.

[155]Ibid., at 119.

[156]R. L. Rabin, "The Pervasive Role of Uncertainty in Tort Law: Rights and Remedies," *DePaul Law Review* 60, no. 2 (2011): 431–452, 435.

[157]*Rowland v. Christian*, at 118.

[158]Dobbs, Hayden, and Bublick, *Hornbook on Torts*, 189.

[159]Ibid., 194.

[160]*Brown v. Kendall*.

[161]Holmes, *The Common Law*, 96.

[162]Dobbs, Hayden, and Bublick, *Hornbook on Torts*, 196.

[163]Ibid., 197–198.

[164]Ibid.

[165]*Jupin v. Kask*, 447 Mass. 141, 147, 849 N.E.2d 829 (2006).

[166]Dobbs, Hayden, and Bublick, *Hornbook on Torts*, 200.

[167]*Beck v. Dobrowski*, 559 F.3d 680, 682 (7th Cir. 2009).

[168]Restatement of the Law Third, *Torts: Liability for Physical and Emotional Harm* (Philadelphia: American Law Institute, 2010), §7(a), 77.

[169]Dobbs, Hayden, and Bublick, *Hornbook on Torts*, 211.

[170]E. J. Weinrib, "Corrective Justice in a Nutshell," *University of Toronto Law Journal* 52, no. 4 (2002): 349–356.

[171]Aristotle, *Nicomachean Ethics*, Book V, chap. 3, 1131b15-25, in *The Basic Works of Aristotle*, ed. R. McKeon (New York: Random House, 1941), 1007.

[172]Ibid., Book V, chap. 3, 1132a5-10, 1008.

[173]Ibid., Book V, chap. 3, 1132a15-20, 1008.

[174]Ibid., Book V, chap. 3, 1132a20-25, 1009.

[175]Weinrib, "Corrective Justice in a Nutshell," 350.

[176]Ibid., 351.

[177]Ibid., 352.

[178]Ibid.

[179]*Palsgraf v. Long Island Railroad Co.*, at 344.

[180]Ibid.

[181]Ibid., at 345.

[182]Weinrib, "Corrective Justice in a Nutshell," 355.

[183]Dobbs, Hayden, and Bublick, *Hornbook on Torts*, 312.

[184]Restatement of the Law Third, *Torts*, §26.

[185]Dobbs, Hayden, and Bublick, *Hornbook on Torts*, 503.

[186]*Burns v. Metz*, 513 N.W.2d 505, 245 Neb. 428 (1994).

[187]E. D. Kinney, "The Brave New World of Medical Standards of Care," *Journal of Law and Medicine Ethics* 29, nos. 3–4 (2001): 323–334.

[188]Dobbs, Hayden, and Bublick, *Hornbook on Torts*, 506.

[189]A. Baldini, M. Von Korff, and E. H. B. Lin, "A Review of Potential Adverse Effects of Long-Term Opioid Therapy: A Practitioner's Guide. The Primary Care Companion to CNS Disorders," *Primary Care Companion for CNS Disorders* 14, no. 3 (2012): pii, doi:10.4088/PCC.11m01326.

[190]Dobbs, Hayden, and Bublick, *Hornbook on Torts*, 507.

[191]*Harris v. Groth*, 99 Wash. 2d 438, 439, 663 P.2d 113 (1983).

[192]*Canterbury v. Spence*, 464 F.2d 772 (1972).

[193]Dobbs, Hayden, and Bublick, *Hornbook on Torts*, 515.

[194]Ibid., 516–517.

[195]*Moure v. Raeuchle*, 529 Pa. 394, 405, 604 A.2d 1003 (1992).

[196]*Vasa v. Compass Medical*, 456 Mass. 175, 177–178 (2010).

[197]B. R. Furrow, "Medical Malpractice Liability: Of Modest Expansions and Tightening Standards," in *The Oxford Handbook of U.S. Health Law*, eds. I. G. Cohen, A. K. Hoffman, and W. M. Sage (New York: Oxford University Press, 2017), 421–443.

[198]*Johnson v. Kokemoor*, 545 N.W.2d 495, 199 Wis. 2d 615, 652–653 (1996).

[199]Ibid., at 624.

[200]Ibid., at 621.

[201]Ibid., at 624.

[202]Ibid., at 646.

[203]Ibid., at 647.

[204]Furrow, "Medical Malpractice Liability," 421.

[205]Ibid.

[206]*Fein v. Permanente Medical Group*, 695 P.2d 665, 38 Cal. 3d 137, 211 Cal. Rptr. 368 (1985).

[207]Ibid., at 158–159.

[208]Ibid., at 159.

[209]J. Maa and J. H. Sutton, "The Defeat of Proposition 46 in California: A Case Study of Successful Surgeon Advocacy," *Bulletin of the American College of Surgeons*, January 1, 2016, http://bulletin.facs.org/2016/01/the-defeat-of-proposition-46-in-california-a-case-study-of-successful-surgeon-advocacy/.

[210]*Bardessono v. Michels*, 478 P.2d 480, 3 Cal. 3d 780, 788, 91 Cal. Rptr. 760 (1970).

[211]Furrow, "Medical Malpractice Liability," 423.

[212]R. Graham, M. Mancher, D. M. Wolman et al., eds., *Clinical Practice Guidelines We Can Trust* (Washington, DC: National Academies Press, 2011), 4, http://www.nationalacademies.org/hmd/Reports/2011/Clinical-Practice-Guidelines-We-Can-Trust.aspx.

[213]Furrow, "Medical Malpractice Liability," 425.

[214]Ibid., 431.

[215]Ibid.

[216]*AT&T Mobility v. Concepcion*, 131 S. Ct. 1740 (2011).

[217]Ibid.

[218]M. Gilles, "Operation Arbitration: Privatizing Medical Malpractice Claims," *Theoretical Inquiries in Law* 15, no. 2 (2014): 671–696.

[219]Furrow, "Medical Malpractice Liability," 432.

[220]M. M. Mello, R. C. Boothman, T. McDonald et al., "Communication-And-Resolution Programs: The Challenges and Lessons Learned from Six Early Adopters," *Health Affairs* 33, no. 1 (2014): 20–29.

[221]Furrow, "Medical Malpractice Liability," 432.

[222]M. M. Mello and T. H. Gallagher, "Malpractice Reform. Opportunities for Leadership by Health Care Institutions and Liability Insurers," *New England Journal of Medicine* 362, no. 15 (2010): 1353–1356.

[223]Dobbs, Hayden, and Bublick, *Hornbook on Torts*, 777.

[224]K. S. Abraham, "Strict Liability in Negligence," *DePaul Law Review* 61, no. 2 (2012): 271–302.

[225]J. H. Wigmore, "Responsibility for Tortious Acts: Its History. III," *Harvard Law Review* 7, no. 8 (1894): 441–463, 457, referencing Year Book (Y.B.) 6 Edw. IV. 7, 18 (1466).

[226]Ibid.

[227]Ibid., 457–458, referencing *Weaver v. Ward*, Hobart 134, 80 Eng. Rep. 284 (K.B. 1616).

[228]Ibid., 458.

[229]Restatement of the Law Second, *Torts* (Philadelphia, American Law Institute, 1977), §519.

[230]Ibid., §519, Comment d.

[231]As *Fletcher v. Rylands*, 159 Eng. Rep. 737 (Exch. Div.), 3 H. & C. 774 (1865).

[232]As *Fletcher v. Rylands*, L. R. 1 Exch. 265 (1866).

[233]As *Rylands v. Fletcher*, L. R. 3 H. L. (E. & I. App.) 330 (1868).

[234]F. H. Bohlen, "The Rule in Rylands v. Fletcher. Part I," *University of Pennsylvania Law Review* 59, no. 5 (1911), 50 (New Series): 298–326.

[235]G. C. Keating, "Recovering Rylands: An Essay for Robert Rubin," *DePaul Law Review* 61, no. 2 (2012): 543–594.

[236]*Fletcher v. Rylands*, L. R. 1 Exch. 265 (1866).

[237]Keating, "Recovering Rylands," 560.

[238]*Fletcher v. Rylands*, L. R. 1 Exch. 265 (1866).

[239]Keating, "Recovering Rylands," 562.

[240]Dobbs, Hayden, and Bublick, *Hornbook on Torts*, 797.

[241]Wigmore, *Select Cases on the Law of Torts*.

[242]D. Owen, "Products Liability Law Restated," *South Carolina Law Review* 49, winter (1998): 273–292.

[243]*MacPherson v. Buick Motor Company*.

[244]Owen, "Products Liability Law Restated," 274.

[245]Ibid.

[246]Ibid., 275.

[247]Ibid.

[248]Ibid.; Uniform Commercial Code §2-314 states the following: "(1) Unless excluded or modified (§2-316), a warranty that the goods shall be merchantable is implied in a contract for their sale if the seller is a merchant with respect to goods of that kind." https://www.law.cornell.edu/ucc/2/2-314.

[249]Dobbs, Hayden, and Bublick, *Hornbook on Torts*, 800.

[250]*Escola v. Coca Cola Bottling Co.*, 150 P.2d 436, 24 Cal. 2d 453 (Cal. 1944).

[251]Ibid., at 457.

[252]Ibid., at 459.

[253]Ibid.

[254]Ibid., at 461.

[255]Ibid.

[256]Ibid., at 463.

[257]Ibid.

[258]Ibid., at 468.

[259]G. T. Schwartz, "The Beginning and End of the Rise of American Tort Law," *Georgia Law Review* 26, no. 3 (1992): 601–702, 638.

[260]*Greenman v. Yuba Power Products, Inc.*, 377 P.2d 897, 59 Cal. 2d 57 (Cal. 1963).

[261]Owen, "Products Liability Law Restated," 277.

[262]*Greenman v. Yuba Power Products, Inc.*, 260.

[263]Ibid., at 62.

[264]Ibid., at 63.

[265]Ibid., at 64.

[266]K. Graham, "Strict Products Liability at 50: Four Histories," *Marquette Law Review* 98, no. 2 (2014): 555–624.

[267]Abraham, "Strict Liability in Negligence," 271–272.

[268]Ibid.

[269]Holmes, *The Common Law*, 108.

[270]Ibid.

[271]Ibid.

[272]Ibid.

[273]Abraham, "Strict Liability in Negligence," 286.

[274]Ibid., 288.

[275]Ibid.

[276]Ibid., 292.

[277]Dobbs, Hayden, and Bublick, *Hornbook on Torts*, 356.

[278]Ibid.

[279]Abraham, "Strict Liability in Negligence," 292–293.

[280]J. C. P. Goldberg and B. C. Zipursky, "Tort Law and Moral Luck," *Cornell Law Review* 92, no. 6 (2007): 1123–1175, 1155–1156.

[281]Abraham, "Strict Liability in Negligence," 300.

[282]Ibid., 276.

[283]Keating, "Recovering Rylands," 582.

[284]Abraham, "Strict Liability in Negligence," 297.

[285]R. Kaushik, "Bleeding Complications in Laparoscopic Cholecystectomy: Incidence, Mechanisms, Prevention and Management," *Journal of Minimum Access Surgery* 6, no. 3 (2010): 59–65.

[286]Ibid.

[287]Dobbs, Hayden, and Bublick, *Hornbook on Torts*, 60–61.

[288]*Marchbanks v. Borum*, 806 So.2d 278 (Miss. Ct. App. 2001).

[289]*Mims v. Boland*, 110 Ga. App. 477, 138 S.E.2d 902 (1964) at 481.

[290]Gordley, *The Jurists*, 18.

[291]Garner, *Black's Law Dictionary*, 300.

[292]Dainow, "The Civil Law and the Common Law," 421.

[293]Jenks, "The Development of Teutonic Law, 50.

[294]Ibid., 52.

[295]Bruncken, "The Common Law and Statutes."

[296]Dainow, "The Civil Law and the Common Law," 424–425.

[297]Dobbs, Hayden, and Bublick, *Hornbook on Torts*, 312.

[298]Restatement of the Law Third, *Torts*, §26.

[299]Dobbs, Hayden, and Bublick, *Hornbook on Torts*, 211.

[300]Rabin, "Law for Law's Sake," 2267, referencing E. J. Weinrib, *The Idea of Private Law* (Cambridge, MA: Harvard University Press, 1995), 152.

[301]Garner, *Black's Law Dictionary*, 976.

[302]Ibid.

[303]J. R. Saylor, "Judicial Review Prior to *Marbury v. Madison*," *Southwestern Law Journal* 7 (1953): 88–96, 94–95, referencing J. Elliott, *The Debates in the Several State Conventions on the Adoption of the Federal Constitution*, vol. 3 (Philadelphia: Lippincott, 1901), 553.

[304]*Marbury v. Madison*, 5 U.S. 137, 177, 178 (1803), https://www.law.cornell.edu/supremecourt/text/5/137.

[305]Garner, *Black's Law Dictionary*, 1053.

[306]Ibid.

[307]Brown, *New Shorter Oxford English Dictionary*, 1575.

[308]Garner, *Black's Law Dictionary*, 1196.

[309]Simons, "Negligence," 54.

[310]Dobbs, Hayden, and Bublick, *Hornbook on Torts*, 4.

[311]Dainow, "The Civil Law and the Common Law," 425.

[312]Garner, *Black's Law Dictionary*, 1366.

[313]Dobbs, Hayden, and Bublick, *Hornbook on Torts*, 39.

[314]Ibid., 199.

[315]*Zwiren v. Thompson*, 276 Ga. 498, 578 S.E.2d 862, 865 (Ga. 2003).

[316]Dobbs, Hayden, and Bublick, *Hornbook on Torts*, 198.

[317]Winfield, "History of Negligence in the Law of Torts," 196.

[318]Garner, *Black's Law Dictionary*, 1524.

[319]Dobbs, Hayden, and Bublick, *Hornbook on Torts*, 5.

[320]*Fletcher v. Rylands*, L. R. 1 Exch. 265 (1866),, at 279–280.

[321]Keating, "Recovering Rylands," 562.

[322]*Greenman v. Yuba Power Products, Inc.*

[323]Owen, "Products Liability Law Restated," 277.

[324]Garner, *Black's Law Dictionary*, 1717.

[325]Dobbs, Hayden, and Bublick, *Hornbook on Torts*, 4.

[326]Garner, *Black's Law Dictionary*, 1845.

[327]Jenks, "The Development of Teutonic Law, 51.

[328]Ibid., 52.

[329]*MacPherson v. Buick Motor Company.*

[330]Aristotle, *Nicomachean Ethics*, Book V, chap. 3, 1131b19-25, 1132a5-10.

[331]*Fletcher v. Rylands*, 159 Eng. Rep. 737 (Exch. Div.), 3 H. & C. 774 (1865).

[332]*Fletcher v. Rylands*, L. R. 1 Exch. 265 (1866).

Figure Credit

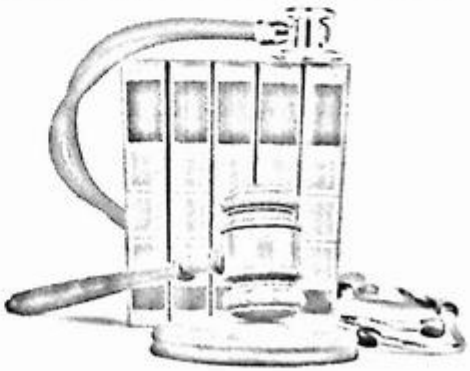
Fig. 5.1: Copyright © 2012 Depositphotos/Slickspics.

CHAPTER 6

Landmark Court Decisions and Legislation in the Context of Healthcare Ethics

Throughout the more than 200-year history of U.S. jurisprudence, many cases such as *Griswold v. Connecticut* are considered landmark decisions, significant for the issues being addressed and the content and impact of the courts' rulings. As critical examples of how theory develops into practice, Chapter 6 discusses several of these landmark cases in the context of healthcare ethics and biomedical ethical decision making. The reader will note that, as the opinions in *Quinlan, Saikewicz, Storar, Conroy,* and *Cruzan* indicate, end-of-life decision making on behalf of an incompetent patient by a guardian, surrogate, or close family members concerns moral, ethical, philosophical, religious, and medical disciplines, society at large, and profound questions of law. Another category of jurisprudence with profound implications for biomedical ethical decision making concerns considerations and practices related to human reproduction. The two representative cases discussed—*Planned Parenthood of Southeastern Pennsylvania v. Casey* and *Davis v. Davis*—involved, respectively, provisions of the Pennsylvania Abortion Control Act of 1982 and the disposition of "frozen embryos." *Casey* detailed an undue burden standard, which might balance state interests against individual liberties. *Davis v. Davis* delineated the moral status of human preembryos (and, by implication, human embryos) as entities entitled to special respect owing to their potential for human life. As well, *Davis v. Davis* enumerated the right to procreational autonomy, which includes the right to procreate and the right to avoid procreation. As presented, both cases are cited extensively, and their holdings continue to guide legal and biomedical ethical decision making.

FIGURE 6.1 The legal context for healthcare decision-making



Griswold v. Connecticut

Griswold v. Connecticut involved considerations that may be primarily related to the biomedical ethical principle of autonomy. The case concerned the executive director of the Planned Parenthood League of Connecticut and its medical director, a licensed physician, who had been convicted as accessories for providing married persons with information and medical advice on how to prevent conception and prescribing a contraceptive device or materials.[1] At the time, a Connecticut statute made it a crime for any person to use any drug or device to prevent conception. The appellants claimed that the statute, as applied, violated the Fourteenth Amendment. In *Griswold*, the U.S. Supreme Court reversed a ruling of the Supreme Court of Errors for Connecticut and held that "the Connecticut statute forbidding use of contraceptives violates the right of marital privacy which is within the penumbra of specific guarantees of the Bill of Rights."[2]

The *Griswold* opinion was delivered in 1965 by Justice William O. Douglas. Justice Douglas noted that the First Amendment has been construed to include other rights, such as the right to educate one's children as one chooses. The rights of freedom of speech and freedom of the press include "freedom of inquiry, freedom of thought, and freedom to teach."[3] Without these and other peripheral rights, the specific rights guaranteed by the First Amendment would be "less secure."[4] Justice Douglas cited *NAACP v. Alabama*, which recognized the "freedom to associate and privacy in one's associations."[5] Freedom of association was a "peripheral First Amendment right."[6] Overall, Justice Douglas stated that "the First Amendment has a penumbra where privacy is protected from governmental intrusion."[7] The rights guaranteed by the First Amendment have extensions implicated by those rights, whose "existence is necessary in making the express guarantees fully meaningful."[8] Additionally, the Fifth Amendment "enables the citizen to create a zone of privacy."[9] *Boyd v. United States* described the Fourth and Fifth Amendments as protections against governmental invasions of the sanctity of a person's home and "the privacies of life."[10] Further, the Ninth Amendment states the following:

> The enumeration in the Constitution, of certain rights, shall not be construed to deny or disparage others retained by the people.[11]

Justice Douglas noted a "wide range of questions" regarding the merits of the case that implicate the due process clause of the Fourteenth Amendment,[12] which declares that

> No State shall make or enforce any law which shall abridge the privileges or immunities of citizens of the United States; nor shall any State deprive any person of life, liberty, or property, without due process of law; nor deny to any person within its jurisdiction the equal protection of the laws.[13]

Thus, zones of privacy are created by "several fundamental constitutional guarantees."[14] These metaphorical zones or regions, extending outward (penumbras) from the specific constitutional guarantees, are necessary to provide protection for the rights specifically guaranteed under the First, Fourth, Fifth, and Ninth Amendments.[15] The right to privacy, "older than the Bill of Rights"[16] and "no less important than any other right carefully and particularly reserved to the people,"[17] could be reasonably located within zones of privacy associated with specific constitutional guarantees. A right to privacy is required to protect these other constitutionally guaranteed rights. Further, per the due process clause of the Fourteenth Amendment, no state

shall interfere with or abridge these rights, including the zone of privacy. The Connecticut statute at issue violated the right of marital privacy and was held to be unconstitutional.

Justice Douglas's opinion established, for the first time, a constitutional right to privacy, but his *Griswold* colleagues felt compelled to express numerous concurring and dissenting opinions. The *Griswold* decision includes six written opinions. Justice Arthur Goldberg, in a concurring opinion joined by Chief Justice Earl Warren and Justice William J. Brennan Jr., asserted that the concept of liberty protects fundamental personal rights and "is not confined to the specific terms of the Bill of Rights."[18] Justice Goldberg noted that the concept of liberty includes the right of marital privacy and is supported by decisions of the Supreme Court and "the language and history of the Ninth Amendment."[19] He stated the following:

> The language and history of the Ninth Amendment reveal that the Framers of the Constitution believed that there are additional fundamental rights, protected from governmental infringement, which exist alongside those fundamental rights specifically mentioned in the first eight constitutional amendments.[20]

Justice Goldberg referenced commentary by James Madison, the future president, and Justice Joseph Story.[21] Madison, principal author of the Ninth Amendment, had stated that "no language is so copious as to supply words and phrases for every complex idea."[22] The Ninth Amendment had been proposed to allay concern that particular mention of certain rights in a bill of specifically enumerated rights "would be interpreted as a denial that others were protected."[23] In a discussion of the meaning of the Ninth Amendment, Justice Story had stated that "a positive declaration in such a bill of rights that the enumeration of certain rights shall not be construed to deny or disparage others retained by the people" would be a "conclusive answer" to attempts to disparage other rights or "argumentative implications in favor of other powers."[24] In *Griswold*, Justice Goldberg stated that

> the Ninth Amendment shows a belief of the Constitution's authors that fundamental rights exist that are not expressly enumerated in the first eight amendments, and an intent that the list of rights included there not be deemed exhaustive.[25]

Overall, Justice Goldberg averred that he was not "turning somersaults with history in arguing that the Ninth Amendment is relevant in a case dealing with a state's infringement of a fundamental right."[26] The Ninth Amendment is relevant in "showing the existence of other fundamental personal rights" and

> lends strong support to the view that the "liberty" protected by the Fifth and Fourteenth Amendments from infringement by the Federal Government or the States is not restricted to rights specifically mentioned in the first eight amendments.[27]

But not all the *Griswold* justices were in agreement. Justice Hugo Black, joined by Justice Potter Stewart, dissented, stating "I get nowhere in this case by talk about a constitutional 'right of privacy' as an emanation from one or more constitutional provisions."[28] Justice Black expressed concern that his colleague's arguments utilizing the due process clause and the Ninth Amendment would ultimately enable the Supreme Court and the federal judiciary to "invalidate any legislative act which the judges find irrational, unreasonable or offensive."[29] Justice Black offered a contrasting interpretation of the language of the Ninth Amendment, stating the amendment was passed not to broaden the powers of the Supreme Court or any other department of the

federal government, but rather "to limit the Federal Government to the powers granted expressly or by necessary implication."[30] Per Justice Black, the Ninth Amendment was enacted "to protect state powers against federal invasion," not to provide "a weapon of federal power to prevent state legislatures from passing laws they consider appropriate to govern local affairs."[31]

Many arguments have been made by legal scholars and renowned jurists regarding appropriate interpretations of the due process clause and the Ninth Amendment. One such argument, written thirty years prior to *Griswold* and providing support for locating unnamed rights in the First, Fourth, Ninth, and Fourteenth Amendments, stated the Ninth Amendment must be

> a positive declaration of existing, though unnamed rights, which may be vindicated under the authority of the Amendment whenever and if ever any governmental authority shall aspire to ungranted power in contravention of "unenumerated rights."[32]

Subsequent to the *Griswold* decision, the ruling's privacy doctrine was utilized in 1972 in *Eisenstadt v. Baird* to protect access to contraceptives by unmarried persons.[33] The *Eisenstadt* court stated the following:

> If the right of privacy means anything, it is the right of the individual, married or single, to be free from unwarranted governmental intrusion into matters so fundamentally affecting a person as the decision whether to bear or beget a child.[34]

In 1973, in *Roe v. Wade*,[35] the Supreme Court declared that the right of privacy "is broad enough to encompass a woman's decision whether or not to terminate her pregnancy."[36] Per *Roe*, the right of privacy was "founded in the Fourteenth Amendment's concept of personal liberty and restrictions upon state action."[37]

Later, though, the Supreme Court began to delimit the right of privacy. In 1986, in *Bowers v. Hardwick*,[38] the Court held that the Constitution does not confer a fundamental right regarding intimate homosexual conduct. The *Bowers* court stated "the proposition that any kind of private sexual conduct between consenting adults is constitutionally insulated from state proscription is unsupportable."[39] Although *Bowers* was subsequently overturned in 2003 in *Lawrence v. Texas*,[40] the *Lawrence* court relied on protected liberty interests rather than on a right of privacy. *Lawrence* noted that although a specific *liberty interest* may be "unsupported by history and tradition," it is nevertheless "still protected from state laws that are not rationally related to any legitimate state interest."[41]

In 1989, *Webster v. Reproductive Health Services*[42] concerned the constitutionality of a 1986 Missouri statute that regulated the performance of abortions.[43] The statute prohibited use of public employees and facilities to perform or assist an abortion not necessary to save a mother's life, and made it unlawful to use public funds, employees, or facilities for the purpose of "encouraging or counseling" a woman to have an abortion not necessary to save her life.[44] The appellees had "asserted violations of various rights, including the privacy rights of pregnant women seeking abortions, [a] woman's right to an abortion, [and] the right to privacy in the physician–patient relationship."[45] Citing *Maher v. Roe*,[46] the *Webster* court noted that a state may "make a value judgment favoring childbirth over abortion" through the "allocation of other public resources, such as hospitals and medical staff."[47] The Court upheld the Missouri act's restrictions "on the use of public employees and facilities for the performance or assistance of nontherapeutic

abortions."[48] Thus, the *Webster* ruling "suggested a weakening of abortion rights"[49] and a narrowing of the right to privacy.

In 1990, in *Cruzan v. Director, Missouri Dept. of Health*,[50] the Supreme Court held that the state of Missouri could require clear and convincing evidence of an incompetent person's wishes regarding withdrawal of life-sustaining treatment, further delimiting the right to privacy asserted in *Griswold*. The *Cruzan* court noted that most state courts have based a right to refuse treatment on the common law right to informed consent or on a constitutional right to privacy, or both. But Chief Justice William Rehnquist, delivering the opinion of the Court, observed that "Although many state courts have held that a right to refuse treatment is encompassed by a generalized constitutional right of privacy, we have never so held."[51] Chief Justice Rehnquist referenced *Youngberg v. Romeo*,[52] noting that whether a person's constitutional rights, which may include a right to privacy, have been violated "must be determined by balancing his liberty interests against the relevant state interests."[53] The *Cruzan* opinion also referenced *In re Estate of Longeway*,[54] in which the Illinois Supreme Court noted that the U.S. Supreme Court had never ruled on whether a right of privacy guaranteed a right to refuse medical care.[55] The *Cruzan* opinion indicated that, per the *Longeway* court, "the boundaries of a federal right of privacy were uncertain."[56]

Thus, overall, at the highest level of jurisprudence, the standing of a purported constitutional right to privacy gained and then lost support. For example, in 1992, in *Planned Parenthood of Southeastern Pennsylvania v. Casey*,[57] the Supreme Court reaffirmed the central holding of *Roe v. Wade* that "viability marks the earliest point at which the State's interest in fetal life is constitutionally adequate to justify a legislative ban on nontherapeutic abortions."[58] But rather than basing their ruling on a right to privacy, the *Casey* majority located their opinion in constitutional liberty interest, for example, a person's right of self-determination and "the freedom to decide matters of the highest privacy,"[59] combined with the "force of *stare decisis*."[60]

Nevertheless, per *Griswold*, the "penumbras of specific guarantees of the Bill of Rights"[61] may continue to be explored as a basis for identifying rights of individuals. For example, in a specific healthcare context, if the Ninth Amendment may be understood as providing support for the existence of unenumerated rights, then it is reasonable to consider that a right to healthcare may be so supported. As discussed in Chapter 10, a right to healthcare may be found in the World Health Organization Constitution and is implicit in the universal healthcare systems of many nations in the European Union, Africa, Asia, and Oceania. It is not yet clear whether such a right may be supported by the U.S. legislature and judicial system.

In re Quinlan

Drawing upon decades of earlier court opinions and ethical and moral writings, *In re Quinlan* attracted national attention. The case involved considerations that may be primarily related to the biomedical ethical principles of autonomy and nonmaleficence. On the night of April 15, 1975, twenty-one-year-old Karen Ann Quinlan ceased breathing for at least two fifteen-minute intervals. She was taken by ambulance to a local hospital, where it was found that "her pupils were unreactive and she was unresponsive even to deep pain."[62] Several days later a follow-up examination found her comatose with evidence of loss of cortical (higher brain) function. Ultimately, Karen's condition progressed to that of a persistent vegetative state, with "no awareness

of anything or anyone around her and existing at a primitive reflex level."[63] She was maintained on a respirator, required artificial nutrition and hydration, and was supported by twenty-four-hour nursing assistance. Experts asserted that Karen could not survive without the assistance of the respirator.[64] She was allegedly not competent and Joseph Quinlan, Karen's father, had sought to be appointed her guardian. He proposed that a letter of guardianship should contain "an express power to him as guardian to authorize the discontinuance of all extraordinary medical procedures"[65] that were sustaining Karen's life, as there was no hope of her eventual recovery. Instead, the trial court appointed a guardian ad litem (for the purpose of the lawsuit) to represent the allegedly incompetent Karen's interests. Joseph Quinlan appealed this judgment. The Supreme Court of New Jersey stated this case was of "transcendent importance"[66] as it concerned questions related to the definition and existence of death; the prolongation of life through artificial means developed by medical technology; the impact of such indeterminate artificial prolongation of life on "the rights of the incompetent, her family and society in general"; and "the bearing of constitutional right and the scope of judicial responsibility" regarding the "extraordinary" request of the plaintiff; as well as "the right of the plaintiff, Joseph Quinlan, to guardianship of the person of his daughter."[67]

The chief justice of the New Jersey Supreme Court, Richard J. Hughes, delivering the opinion of the court, noted that the consensus of the treating physicians and qualified experts who testified in the trial was that "removal from the respirator would not conform to medical practices, standards and traditions."[68] But the *Quinlan* opinion noted that no form of treatment that could cure or improve Karen's condition was known or available.[69] Additionally, developments in medical technology "have obfuscated the use of the traditional definition of death."[70] In support of its deliberations, the *Quinlan* court cited the allocution of Pope Pius XII on November 24, 1957, in which the pope posed the question whether an anesthesiologist has the right or is bound, "in all cases of deep unconsciousness, even in those that are considered to be completely hopeless in the opinion of the competent doctor, to use modern artificial respiration apparatus, even against the will of the family."[71] The pope asserted that because such methods go beyond ordinary means, there is no obligation to use such treatments nor to give the physician permission to use them. The pope stated, "The rights and duties of the family depend in general upon the presumed will of the unconscious patient if he is of age and *sui juris*."[72] Regarding the "proper and independent duty of the family," they are required to use only ordinary means of treatment.[73] Further, interruption of attempts at resuscitation, even when it causes the arrest of circulation, "is never more than an indirect cause of the cessation of life."[74] Thus, in his role as a moral leader, Pope Pius XII distinguished between ordinary and extraordinary modes of treatment. The papal allocution also implies that the will of a patient, or the presumed will of an unconscious patient, determines treatment in "hopeless" medical circumstances. If an attempt at resuscitation constitutes "such a burden for the family that one cannot in all conscience impose it upon them," then those attempts may be discontinued.[75]

The *Quinlan* opinion discussed an *amicus curiae* (friend of the court) brief submitted by the New Jersey Catholic Conference. The brief included a position statement by Bishop Lawrence B. Casey, who referenced the November 24, 1957, allocution of Pope Pius XII. Bishop Casey's position statement declared the following:

> Competent medical testimony has established that Karen Ann Quinlan has no reasonable hope of recovery from her comatose state by the use of any available medical procedures. The continuance of mechanical (cardiorespiratory) supportive

> measures to sustain continuation of her body functions and her life constitute extraordinary means of treatment. Therefore, the decision of Joseph Quinlan to request the discontinuance of this treatment is, according to the teachings of the Catholic Church, a morally correct decision.[76]

Bishop Casey's position statement also noted the following:

> In the present public discussion of the case of Karen Ann Quinlan it has been brought out that responsible people involved in medical care, patients and families have exercised the freedom to terminate or withhold certain treatments as extraordinary means in cases judged to be terminal, i.e., cases which hold no realistic hope for some recovery, in accord with the expressed or implied intentions of the patients themselves. To whatever extent this has been happening it has been without sanction in civil law. Those involved in such actions, however, have ethical and theological literature to guide them in their judgments and actions.[77]

The *amicus* brief essentially described the parameters for assessment of the potential futility of proposed medical treatment. Medical treatment, if determined to be nonbeneficial, that is, without the potential for some recovery as against merely supporting continuation of body functions, could be considered extraordinary, rather than ordinary. Such treatment could be legitimately terminated or withheld, based on the preferences and desires, expressed or implied, of the patient.

The *Quinlan* court noted that the claimed interests of the state were essentially the "preservation and sanctity of human life and defense of the right of the physician to administer medical treatment according to his best judgment."[78] But the present treatment served only a maintenance function. Use of the respirator could not cure or improve Karen's condition, but at best could "only prolong her inevitable slow deterioration and death."[79] Therefore, the interests of the patient, as seen by her surrogate, that is, her guardian, must be evaluated as predominant. The *Quinlan* opinion referred to *Griswold*, noting that the Supreme Court had "found the unwritten constitutional right of privacy to exist in the penumbra of specific guarantees of the Bill of Rights 'formed by emanations from those guarantees that help give them life and substance.'"[80] The court indicated the state's interests weaken and the individual's right to privacy grows "as the degree of bodily invasion increases and the prognosis dims. Ultimately there comes a point at which the individual's rights overcome the state interest."[81] The court stated that Karen's right of privacy could be asserted on her behalf by her guardian. Her parent and family were permitted "to render their best judgment" regarding whether Karen would permit her "non-cognitive, vegetative existence to terminate by natural forces."[82]

Additionally, Chief Justice Hughes noted that courts, in exercising a *parens patriae* responsibility (that is, the power of the state to act as guardian for those who are unable to care for themselves) to protect individuals under disability, have sometimes authorized the carrying out of medical decisions under the doctrine of *substituted judgment*.[83] In his opinion, Chief Justice Hughes referenced *Strunk v. Strunk*[84] and *Hart v. Brown*[85]. *Strunk v. Strunk* concerned the petition of a family for authority to proceed with a kidney transplantation procedure from Jerry Strunk, a twenty-seven-year-old incompetent with a mental age of approximately six years, to his twenty-eight-year-old brother, Tommy Strunk. The county court had found that the procedure would be beneficial to Jerry as he was greatly dependent on his brother, and "his well-being would be jeopardized more severely by the loss of his brother than by the removal of a kidney."[86]

The Department of Mental Health of the Commonwealth of Kentucky had entered the case as *amicus curiae* and recommended that Jerry be permitted to undergo the surgery.[87] In *Strunk v. Strunk*, the Court of Appeals of Kentucky stated, "The right to act for the incompetent in all cases has become recognized in this country as the doctrine of substituted judgment and is broad enough not only to cover property but also to cover all matters touching on the well-being of the ward. The doctrine has been recognized in American courts since 1844."[88] Based on the doctrine of substituted judgment, *Strunk v. Strunk* affirmed the ruling of a circuit court permitting the kidney transplantation procedure.

Hart v. Brown concerned the request of parents of seven-year-old identical twins, Kathleen Hart and Margaret Hart, for kidney transplantation surgery, with Margaret as the donor and Kathleen as the recipient. It had been determined that without a kidney transplant, Kathleen would soon die. The defendant hospital had refused the use of its facilities unless the court declared that "the parents and/or guardians ad litem of the minors have the right to give their consent to the operation."[89] In *Hart v. Brown*, the Connecticut Superior Court stated, "The right to act for an incompetent has been recognized as the 'doctrine of substituted judgment' and is broad enough to cover all matters touching on the well-being of legally incapacitated persons."[90] Thus, the court stated it had the power to act in this matter. A psychiatrist had testified that, if successful, the procedure "would be of immense benefit to the donor." A clergyman testified that the decision of the parents was morally and ethically sound. Margaret had been informed of the surgery and "insofar as she may be capable of understanding she desires to donate her kidney so that her sister may return to her."[91] The *Hart v. Brown* opinion stated that the parents "would be able to substitute their consent for that of their minor children after a close, independent and objective investigation of their motivation and reasoning," which had been accomplished.[92]

The *Quinlan* opinion also noted that applying to a court to confirm or refute medical decision making is generally inappropriate and recommended that hospital ethics committees, "composed of physicians, social workers, attorneys, and theologians," should serve to review the individual circumstances of ethical dilemmas.[93] The ethics committee should consider in its deliberations the "feelings of the family of an incompetent relative."[94] Further, decision making within healthcare "should be controlled primarily within the patient–doctor–family relationship."[95] The *Quinlan* court ruled that if the hospital ethics committee (or similar body) of the institution at which Karen was then hospitalized agreed "that there is no reasonable possibility of Karen's ever emerging from her present comatose condition to a cognitive, sapient state, the present life-support system may be withdrawn."[96] No civil or criminal liability would attach to this action on the part of any participant.[97]

Thus, in its landmark ruling, the Supreme Court of New Jersey established the right of a competent patient, or in the case of lack of competence, the right of the patient's guardian, family, or other person appropriately designated to speak for the patient, to withhold or discontinue medical treatment that was deemed nonbeneficial, that is, without the potential to cure or improve the patient's condition. The *Quinlan* court distinguished between ordinary and extraordinary modes of treatment, supported by a 1957 allocution of Pope Pius XII. Further, *Quinlan* invoked an unwritten constitutional right of privacy in support of an individual's rights overcoming state interests in circumstances involving end-of-life decision making. The necessity for consultation with hospital ethics committees and an outline of the activities of such committees were delineated in the *Quinlan* ruling.

Overall, the outcomes of Joseph Quinlan's legal action to regain control of his daughter's medical treatment established the foundations for ethical and legal assessments of medical recommendations and practices at the end of life. Of note, more than ten years later, the Supreme Court of New Jersey stated that, "given the fundamental societal questions that must be resolved" regarding decision making concerning life-sustaining medical treatment, "the Legislature is the proper branch of government to set guidelines in this area."[98]

Superintendent of Belchertown State School v. Saikewicz

Decided in the year following the *Quinlan* ruling, the 1977 case of *Superintendent of Belchertown State School v. Saikewicz*[99] involved similar considerations, that is, those related to the biomedical ethical principles of autonomy and nonmaleficence. The case concerned Joseph Saikewicz, a sixty-seven-year-old resident of the Belchertown State School, a facility of the Massachusetts Department of Mental Health. Saikewicz had profound mental retardation, with an I.Q. of 10 and a mental age of less than three years. He had been diagnosed with acute myeloblastic leukemia and a petition for appointment of a guardian alleged he was in need of urgent medical treatment. A guardian ad litem filed a report indicating Saikewicz's illness was incurable and chemotherapy was medically indicated. However, the likely significant adverse side effects, the inability of the ward to understand the treatment to which he would be subjected, and the likely fear and pain he would suffer as a result outweighed the limited possible benefits of such treatment.[100] Therefore, the guardian ad litem recommended that "not treating Mr. Saikewicz would be in his best interests."[101] The two attending physicians recommended against chemotherapy. The probate court judge agreed with the recommendations of the guardian ad litem, and ordered that no treatment be administered to Saikewicz for his condition of acute myeloblastic leukemia.[102] He further ordered that "all reasonable and necessary supportive measures be taken, medical or otherwise, to safeguard the well-being" of Saikewicz and to reduce as far as possible any suffering or discomfort he might experience.[103] Subsequently, the probate court ruling was appealed.

In *Saikewicz*, the Supreme Judicial Court of Massachusetts stated, "We recognize at the outset that this case presents novel issues of fundamental importance that should not be resolved by mechanical reliance on legal doctrine."[104] Insights from those in the fields of "health care, moral ethics, philosophy, and other disciplines" were sought to assist in establishing a legal framework on which "the activities of health care personnel and other persons can find support."[105] In *Saikewicz*, the areas of determination included the following:

1. The nature of the right of any person, competent or incompetent, to decline potentially life-prolonging treatment.
2. The legal standards that control the decision whether potentially life-prolonging, but not lifesaving, treatment should be administered to a person who is not competent to make the choice.[106]

In the *Saikewicz* opinion, Justice Paul J. Liacos stated that the court takes the view that "the substantive rights of the competent and the incompetent person are the same in regard to the right to decline potentially life-prolonging treatment."[107] The distinguishing factors consist in how

the state should approach the "preservation and implementation of the rights of an incompetent person."[108] In this context, Justice Liacos referenced *Griswold v. Connecticut*,[109] especially, "the unwritten constitutional right of privacy found in the penumbra of specific guaranties of the Bill of Rights."[110] Additionally, per *In re Quinlan*,[111] the constitutional right to privacy of an incompetent person may be asserted by that person's guardian in certain circumstances, as contrasted with appropriate identification of state interests.[112] Regarding the "difficult question" of the right of an individual to refuse medical treatment, *Saikewicz* noted that countervailing state interests are "(1) the preservation of life; (2) the protection of the interests of innocent third parties; (3) the prevention of suicide; and (4) maintaining the ethical integrity of the medical profession."[113] The most significant of the asserted state interests is the preservation of life. However, the *Saikewicz* opinion stated that the "interest of the State in prolonging a life must be reconciled with the interest of an individual to reject the traumatic cost of that prolongation."[114] Further, *Saikewicz* asserted that the "value of life as so perceived is lessened not by a decision to refuse treatment, but by the failure to allow a competent human being the right of choice."[115]

Regarding medical decision making for incompetent patients, in the context of balancing an individual's rights versus the state interest in preserving life, *Saikewicz* discussed at length the substituted judgment standard governing such decision making. In cases involving an incompetent patient, the guardian and/or close family members must strive to ascertain what the patient's wishes and preferences would have been. This assessment is based on their knowledge of and past experiences with that person, and the goal is to substitute their judgment for the likely judgment of the patient faced with the present medical circumstances. *Saikewicz* stated that the substituted judgment standard demonstrates "straightforward respect for the integrity and autonomy of the individual."[116] The decision in cases such as this "should be that which would be made by the incompetent person, if that person were competent."[117] It was necessary to analyze whether Saikewicz's guardian appropriately assessed the patient's best interests and appropriately utilized the substituted judgment standard.

The *Saikewicz* opinion noted that the probate judge described six factors militating against administration of chemotherapy.[118] One factor identified the patient's inability to cooperate with the treatment. Fear, confusion, and disorientation might result and he might require physical restraints. A second factor was the quality of life possible for Saikewicz even if treatment brought about remission.[119] A review of the probate court record disclosed "the judge's concern that special care be taken to respect the dignity and worth of Saikewicz's life precisely because of his vulnerable position."[120] If, per the substituted judgment standard, the evidence demonstrated that an incompetent individual would have chosen to forgo potentially life-sustaining treatment, then the judge should issue the appropriate order. If the judge was not persuaded by the evidence "or finds that the interests of the State require it, then treatment shall be ordered."[121] Overall, the *Saikewicz* opinion stated, "Finding no State interest sufficient to counterbalance a patient's decision to decline life-prolonging medical treatment in the circumstances of this case, we conclude that the patient's right to privacy and self-determination is entitled to enforcement."[122] The probate court ruling was upheld.

Superintendent of Belchertown State School v. Saikewicz has been cited extensively since the 1977 ruling by the Supreme Judicial Court of Massachusetts. For example, the *Saikewicz* findings appear prominently in *Deciding to Forego Life-Sustaining Treatment: A Report on the Ethical, Medical, and Legal Issues in Treatment Decisions*, a 1983 publication of the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral

Research,[123] and *Saikewicz* supports a discussion of personal autonomy in a 1996 review of treatment of the terminally ill.[124] The *Saikewicz* ruling applied the substituted judgment standard to a case involving an incompetent patient. *Saikewicz* held that the unwritten constitutional right of privacy of an incompetent person could be asserted in certain circumstances as against state interests. As of 2017, *Saikewicz* had been cited in more than 150 opinions, including three cases decided by the U.S. Supreme Court.

In re Storar

In re Storar, as did *Quinlan* and *Saikewicz,* involved considerations that may be primarily associated with the biomedical ethical principles of autonomy and nonmaleficence. *In re Storar,* decided by the Court of Appeals of the state of New York in 1981, concerned two cases in which the guardians of incompetent patients "objected to the continued use of medical treatments or measures to prolong the lives of the patients who were diagnosed as fatally ill with no reasonable chance of recovery."[125] Although both patients, Brother Joseph C. Fox and John Storar, had since died, the opinion of Judge Solomon Wachtler noted that the underlying issues were of public importance and recurred in other courts throughout the state.

In *Matter of Eichner,*[126] Fox, an eighty-three-year-old member of the Society of Mary, was in a persistent vegetative state and being maintained by a respirator. There was substantial evidence that Fox had stated on more than one occasion, dating to discussions in 1976 regarding the Quinlan case, that he would not want his life prolonged by artificial measures "if his condition were hopeless."[127] Father Philip Eichner, the director of the society, requested that the hospital remove the respirator, but the hospital refused to do so without court authorization. The appellate division had ruled that a patient's right to decline treatment was guaranteed by common law, that is, informed consent doctrine, and by the Constitution. This right is not lost when a patient becomes incompetent. If a now-incompetent patient had not made his or her wishes known while competent, "an appropriate person should be appointed to express the right on his behalf by use of 'substituted judgment.'"[128]

Matter of Storar[129] concerned John Storar, a fifty-two-year-old with a profound cognitive disability. He had been a resident of a state facility since the age of five. In 1979 it was determined that he had bladder cancer. Blood transfusions were required and Storar's life expectancy was assessed to be between three and six months. His mother requested that the transfusions be discontinued, and the director of the center brought a proceeding seeking authorization to continue treatment. Storar's mother petitioned the court for an order prohibiting the transfusions. Experts testified that, in the patient's clinical circumstances, transfusions may only prolong suffering. The court ruled that permission to continue the transfusions should be denied, and held that "a person has a right to determine what will be done with his own body and, when he is incompetent, this right may be exercised by another on his behalf."[130]

Regarding the Eichner case, *In re Storar* noted that common law consistently supports "the right of the competent adult to make his own decision by imposing civil liability on those who perform medical treatment without consent."[131] Current law identified a patient's right to determine the course of her own medical treatment "as paramount," as against a physician's obligation to provide necessary medical care.[132] Fox had made a decision, prior to becoming incompetent, regarding discontinuing life-sustaining treatment and the evidence regarding this decision was

"clear and convincing." The Court of Appeals agreed that "this is the appropriate burden of proof and that the evidence in the record satisfies this standard."[133]

Regarding the Storar case, *In re Storar* noted that Storar was never competent at any time in his life. Judge Wachtler's opinion noted that "Mentally, John Storar was an infant and that is the only realistic way to assess his rights in this litigation."[134] A parent or guardian has the right to consent to treatment on behalf of a child. But a parent may not deprive a child of lifesaving treatment, even if this preference is based on constitutional grounds such as religious beliefs. Such a preference to decline treatment "must yield to the State's interests, as *parens patriae,* in protecting the health and welfare of the child."[135] The Court of Appeals referenced *Jehovah's Witnesses v. King County Hospital,*[136] which involved the refusal of parents to authorize a life-saving blood transfusion to a child, as a classic example of the preeminence of state interests in such circumstances. *In re Storar* concluded that "the application for permission to continue the transfusions should have been granted"[137] and the order of the appellate division should be reversed.

In his dissenting opinion, Judge Hugh R. Jones asserted that "in the circumstances the blood transfusions were extraordinary treatments." Further, Storar's mother, over the course of her son's lifetime, was "acutely sensitive to his best interests." Her son's "best interests were of crucial importance to her," and in her opinion "it would have been in John's best interests to discontinue the transfusions." Therefore, in Judge Jones's opinion, the lower courts "had power to authorize the withdrawal of extraordinary life support measures and ... grant Mrs. Storar's cross application to discontinue blood transfusions for her son, John."[138]

Overall, *In re Storar* affirmed the "clear and convincing evidence" standard required to evaluate putative statements of now-incompetent individuals regarding their desires and preferences for withholding or withdrawal of life-sustaining treatment at the potential end of life. Additionally, *In re Storar* upheld the state's interest in preserving the life of a child, as against the best interests of that child declared by the child's parent or parents. The *In re Storar* opinion regarding the Eichner and Storar cases was problematical, and "not only has created confusion, but also has served to obscure the position taken by the Court of Appeals relative to other similar cases both in New York and other jurisdictions."[139] As Judge Jacob D. Fuchsberg noted in his dissenting opinion:

> In this extraordinarily sensitive area of litigation, each new case is bound to present its own peculiar circumstances. Judicial freedom to react to its factual refinements ... on a largely ad hoc basis, is essential. ... To lay down law, then, is needlessly to tie our hands against the time when we are confronted by an appeal we have to decide. To reach out to do so prematurely is not to adjudicate, but legislate. ... It is unwise to undercut a great strength of the common-law process, the evolution of law step by step as it moves from case to case.[140]

In re Conroy

As in *Quinlan, Saikewicz,* and *In re Storar, In re Conroy* involved considerations that may be primarily associated with the biomedical ethical principles of autonomy and nonmaleficence. *In re Conroy,* decided by the Supreme Court of New Jersey in 1985, considered whether life-sustaining treatment could be withheld or withdrawn from incompetent elderly patients with "severe and

permanent mental and physical impairments and a limited life expectancy."[141] The plaintiff had sought permission to have a nasogastric feeding tube removed from his ward, Claire Conroy, an eighty-four-year-old woman with "serious and irreversible physical and mental impairments who resided in a nursing home."[142] Conroy was capable of minimal interaction with her environment, and was not comatose or in a persistent vegetative state. She was characterized by experts as awake, but severely demented. Her mental condition would probably never improve.[143] It was determined that if the feeding tube were removed, Conroy would likely die of dehydration in about one week. A specialist in internal medicine who had examined Conroy and testified as an expert on behalf of her guardian had noted that Conroy likely had only a few months to live. Therefore, the specialist considered nasogastric feeding extraordinary medical treatment as it went "beyond the necessities of life." As Conroy was "hopelessly ill with no possibility of returning to any sort of cognitive function," and with the possibility that she was suffering, the expert could recommend removal of the feeding tube.[144]

The guardian, Conroy's nephew, had known her for more than fifty years. He testified that all she and her sisters wanted was to "die in their own house." He stated that he now sought removal of the nasogastric tube because, in his opinion, his aunt "would not have allowed [the nasogastric tube] to be inserted in the first place."[145] Conroy was a Roman Catholic. Rev. Joseph Kukura, a Roman Catholic priest and associate professor of Christian Ethics at the Immaculate Conception Seminary in Mahway, New Jersey, had testified that acceptable church teaching could be located in the "Declaration on Euthanasia," published by the Vatican Congregation for the Doctrine of the Faith.[146] Father Kukura stated that life-sustaining procedures could be withdrawn if they were extraordinary, which he defined as "all procedures, operations or other interventions which are excessively expensive, burdensome or inconvenient or which offer no hope of benefit to a patient."[147] In these circumstances, recovery and returning to cognitive function were not reasonable possibilities, and therefore removal of the feeding tube would be ethical and moral.[148]

The trial court permitted removal of the feeding tube, but the guardian ad litem appealed. While the appeal was pending, Conroy died with the nasogastric tube in place. The appellate division decided to resolve the meritorious issues, "finding that they were of significant public importance and that this type of case was capable of repetition."[149] The appellate division reversed the trial court's ruling, finding that the state's interest in preserving life outweighed Conroy's right of privacy. The court held that "the right to terminate life-sustaining treatment based on a guardian's judgment was limited to incurable and terminally ill patients who are brain dead, irreversibly comatose, or vegetative."[150] Additionally, the court held that a guardian's decision could never be used to withhold nourishment from an incompetent patient who was not "comatose, brain dead, or vegetative," and whose death was not "irreversibly imminent."[151]

The Supreme Court of New Jersey reversed the ruling of the appellate division. Justice Sidney M. Schreiber, delivering the opinion of the court, noted that this case "raises moral, social, technological, philosophical, and legal questions involving the interplay of many disciplines."[152] Justice Schreiber noted that these issues were better addressed by the state legislature where the viewpoints of all interested institutions and disciplines could be presented and the subjects dealt with comprehensively.[153] In the matter before the court, Justice Schreiber noted that the "starting point in analyzing whether life-sustaining treatment may be withheld or withdrawn from an incompetent patient is to determine what rights a competent patient has to accept or reject medical care."[154] The right of a person to control his or her own body is long recognized

in the common law. No right is more carefully protected by the common law "than the right of every individual to the possession and control of his own person, free from all restraint or interference of others, unless by clear and unquestionable authority of law."[155] The doctrine of informed consent "is a primary means developed in the law to protect this personal interest in the integrity of one's body."[156] The patient's ability to control her bodily integrity through informed consent "is significant only when one recognizes that this right also encompasses a right to informed refusal."[157] Therefore, a competent adult patient "generally has the right to decline to have any medical treatment initiated or continued."[158]

However, a person's right to decline life-sustaining treatment is not absolute and may be required to yield to the interests of society in sustaining the person's life. Referencing *Saikewicz*[159] and other cases, *Conroy* noted that four state interests have been commonly identified that may limit a person's right to refuse medical treatment.[160] Those state interests are "preserving life, preventing suicide, safeguarding the integrity of the medical profession, and protecting innocent third parties."[161] The state's interest in preserving life "may be seen as embracing two separate but related concerns: an interest in preserving the life of the particular patient, and an interest in preserving the sanctity of all life."[162] However, the state interest in preserving life will not usually prevent a competent person from declining life-sustaining treatment for herself. The state interest generally gives way to the person's much stronger interest in directing the course of her own life.[163] (Of note, the fourth asserted state interest in protecting innocent third parties supports court requirements for "competent adults to undergo medical procedures against their will if necessary to protect the public health."[164])

Persons who are not competent to make their own medical decisions retain the right of self-determination, even though the person is not able to assert that right on her own behalf.[165] The goal of decision making on behalf of an incompetent patient should be to determine and act on, "insofar as possible, the decision that the patient would have made if competent," upholding the patient's right to consent to or refuse medical treatment.[166] The *Conroy* court held that "life-sustaining treatment may be withheld or withdrawn from an incompetent patient when it is clear that the particular patient would have refused the treatment under the circumstances involved."[167] This was termed a *subjective* standard that considered what the particular patient would have done if able to choose for herself. Evidence of such intentions could consist of a written document such as an advance directive (then termed a "living will"), an "oral directive that the patient gave to a family member, friend, or health care provider," or a durable power of attorney or appointment of a healthcare proxy "authorizing a particular person to make the decisions on the patient's behalf if he is no longer capable of making them for himself."[168]

The *Conroy* court recognized that many adults do not clearly make known their desires and preferences regarding medical decision making in potential end-of-life circumstances, such as preferences regarding withholding or withdrawal of life-sustaining treatment. Additionally, other incompetent persons, such as minor children, may not be able to exert a right of self-determination and clearly establish their wishes. To enable appropriate decision making for these persons, *Conroy* held that life-sustaining treatment could be withheld or withdrawn from an incompetent patient "if it is manifest that such action would further the patient's best interests in a narrow sense of the phrase," based on satisfaction of a *limited-objective* or *pure-objective* test.[169] Per *Conroy*, the limited-objective standard "permits the termination of treatment for a patient who had not unequivocally expressed his desires before becoming incompetent, when it is clear that the treatment in question would merely prolong the patient's suffering."[170] The

limited-objective standard would be fulfilled when there was some trustworthy evidence that the patient would have refused treatment and the decision maker is satisfied that the burdens of the patient's continued life with treatment (such as pain and suffering) would outweigh the likely benefits.[171] Medical evidence would be required to establish that the burdens of treatment would exceed the benefits. Medical evidence to be considered would include life expectancy, prognosis, level of functioning, and treatment options.[172]

In the absence of trustworthy evidence that the patient would have declined treatment, life-sustaining treatment may still be withheld or withdrawn by fulfillment of the pure-objective standard of the patient's best interests. In the pure-objective test, "the net burdens of the patient's life with the treatment should clearly and markedly outweigh the benefits that the patient derives from life."[173] Subjective evidence that the patient would not have wanted treatment is not required under this application of best interests standards. However, life-sustaining treatment should not be withdrawn from an incompetent patient who had "previously expressed a wish to be kept alive in spite of any pain that he might experience."[174] The *Conroy* court emphasized that if the evidence is insufficient to satisfy either of the best interests standards, then withdrawing life-sustaining treatment from a patient such as Conroy could not be justified.

Importantly, the *Conroy* court rejected "any distinction between withholding and withdrawing life-sustaining treatment." The court stated "the line between active and passive conduct in the context of medical decisions is far too nebulous to constitute a principled basis for decisionmaking."[175] Also, the *Conroy* court considered as "unpersuasive" the purported distinction between "ordinary" and "extraordinary" treatment. The court stated, "To draw a line on this basis for determining whether treatment should be given leads to a semantical milieu that does not advance the analysis."[176] Further, "the ordinary/extraordinary distinction is irrelevant except insofar as the particular patient would have made the distinction."[177]Overall, the *Conroy* court concluded that state legislatures are "better equipped" to develop a comprehensive plan to resolve the myriad variations of circumstances involving use or withdrawal of life-sustaining treatment, including the case of a "severely deformed newborn" or a "never-competent adult suffering from a painful and debilitating illness."[178]

The California Health Care Decisions Law (filed with the secretary of state on October 10, 1999, and effective on July 1, 2000) is an example of such legislation.[179] The law, incorporated in the California Probate Code,[180] provides for "the creation, form, and revocation of advance health care directives, and for the manner of making health care decisions for patients without surrogates."[181] The law authorizes a patient's duly appointed surrogate (designated, for example, in an advance directive or power of attorney for healthcare) to make healthcare decisions on behalf of that patient "to the same extent the principal could make health care decisions if the principal had the capacity to do so."[182] The California Probate Code defines *capacity* as follows:

- The ability to understand the nature and consequences of a decision.
- The ability to make and communicate a decision.
- In the case of proposed healthcare treatment, the ability to understand the benefits, risks, and alternatives of that treatment.[183]

The surrogate shall make healthcare decisions in accordance with the patient's individual instructions, if any, "and any other wishes to the extent known to the agent."[184] If the patient's desires and preferences are not known, then the surrogate shall make healthcare decisions in

accordance with the surrogate's determination of the patient's best interests. In determining these best interests, the surrogate shall take into account the patient's "personal values to the extent known to the agent."[185] As well, the California Health Care Decisions Law states that a healthcare decision made by a surrogate for a patient is effective without judicial approval.[186]

Regarding advance healthcare directives, the California Probate Code states that an adult having capacity may give individual healthcare instructions, which may be oral or written.[187] Further, an adult having capacity may execute a power of attorney for healthcare, which "may authorize the agent to make health care decisions and may also include individual health care instructions."[188] California Probate Code Sections 4700–4701 presents the advance healthcare directive form. The form states, "You have the right to give instructions about your own health care. You also have the right to name someone else to make health care decisions for you." Part 1 of the form is a power of attorney for healthcare. Part 2 is for specific instructions regarding healthcare decision making and the appointment of a surrogate healthcare decision maker for circumstances in which the signee has lost capacity.[189]

The California Probate Code defines a "request regarding resuscitative measures" as a written document signed by (1) an individual with capacity or a legally recognized healthcare decision maker and (2) the individual's physician, that directs a healthcare provider regarding resuscitative measures. A "request regarding resuscitative measures" includes a prehospital "do not resuscitate" form and/or a physician orders for life sustaining treatment (POLST) form. A POLST form is "a request regarding resuscitative measures that directs a health care provider regarding resuscitative and life-sustaining measures." A patient's duly appointed surrogate may sign the POLST form only if the patient lacks capacity.[190]

Cruzan v. Director, Missouri Dept. of Health

Cruzan v. Director, Missouri Dept. of Health primarily concerned the biomedical ethical principles of autonomy and nonmaleficence. On the night of January 11, 1983, twenty-five-year-old Nancy Cruzan lost control of her car on a road in Jasper County, Missouri, and the vehicle overturned. A highway patrol trooper found her lying face down in a ditch without detectable pulmonary or cardiac function. Paramedics were able to restore Nancy's breathing and heartbeat at the accident scene and she was transported in an unconscious state to a hospital. Nancy was in a coma for three weeks and was subsequently assessed to be in a persistent vegetative state. Artificial nutrition and hydration (ANH) had been established via a gastrostomy feeding tube.[191] When it was determined that there was no likelihood of Nancy's regaining her cognitive faculties, her parents requested that hospital employees terminate ANH procedures. But the hospital would not honor this request without court approval. A state trial court found that "A person in Nancy's condition had a fundamental right under the State and Federal Constitutions to refuse or direct the withdrawal of 'death prolonging procedures.'"[192] The trial court also found that Nancy's "expressed thoughts at age 25 in somewhat serious conversation with a housemate friend that, if sick or injured, she would not wish to continue her life unless she could live at least halfway normally suggests that, given her present condition, she would not wish to continue on with her nutrition and hydration."[193] Consequently, the trial court authorized termination of ANH. The state of Missouri appealed the decision, and in 1988, in *Cruzan v. Harmon*,[194] the Supreme Court of Missouri reversed the trial court decision by a divided vote.

The *Cruzan v. Harmon* opinion noted that the single issue presented was whether a guardian may "order that all nutrition and hydration be withheld from an incompetent ward who is in a persistent vegetative state."[195] To this issue, *Cruzan v. Harmon* noted that the state's interest in life embraced two concerns, "an interest in the prolongation of the life of the individual patient and an interest in the sanctity of life itself."[196] *Cruzan v. Harmon* asserted that an individual's common law right to refuse treatment must be balanced against the state's interest in life. The court stated that

> we do not believe her right to refuse treatment, whether that right proceeds from a constitutional right of privacy or a common law right to refuse treatment, outweighs the immense, clear fact of life in which the state maintains a vital interest.[197]

Further, *Cruzan v. Harmon* asserted that the common law right to refuse treatment, founded in personal autonomy, is not "exercisable by a third party absent formalities."[198] The court noted the absence of "clear and convincing, inherently reliable evidence"[199] that Nancy would have requested termination of life-supporting treatment. *Cruzan v. Harmon* averred that the "doctrine of substituted judgment" was herein "contrary to the state's vital interests in preserving life and in assuring the safekeeping of those who cannot care for themselves."[200] The court held that Nancy's co-guardians did not have the authority to order withdrawal of artificial nutrition and hydration. The evidence presented at trial regarding her wishes was "inherently unreliable" and thus "insufficient to support the co-guardians claim to exercise substituted judgment on Nancy's behalf."[201] Thus, *Cruzan v. Harmon* established the requirement, in Missouri, for clear and convincing evidence of an incompetent person's desires and preferences regarding medical treatment in end-of-life circumstances, in order to uphold a guardian's substituted judgment and directive to withdraw life-sustaining treatment.

The Cruzans appealed the decision to the U.S. Supreme Court. In 1990, in *Cruzan v. Director, Missouri Dept. of Health*, the Court ruled that the "United States Constitution does not forbid Missouri to require that evidence of an incompetent's wishes as to the withdrawal of life-sustaining treatment be proved by clear and convincing evidence."[202] The *Cruzan* opinion noted that most state courts have based an individual's right to refuse treatment on the common law right to informed consent, referring to *Saikewicz*[203] and *In re Storar*.[204] *Cruzan* averred that a competent person has a liberty interest under the due process clause of the Fourteenth Amendment to refuse unwanted medical treatment. Whether that constitutional right has been violated "must be determined by balancing the liberty interest against relevant state interests."[205] Importantly, the *Cruzan* court asserted that, under certain circumstances, a competent person has a "constitutionally protected right to refuse lifesaving hydration and nutrition."[206] But this does not mean that an incompetent person possesses the same right, as that person is not able to make a voluntary and informed decision to exercise such a right. The Court ruled that it was permissible for Missouri to apply a clear and convincing evidence standard in this case, as "Missouri has a general interest in the protection and preservation of human life."[207] The state is also entitled to "guard against potential abuses by surrogates who may not act to protect the patient."[208] Also, as against making judgments regarding quality of life, the state may "simply assert an unqualified interest in the preservation of human life to be weighed against the constitutionally protected interests of the individual."[209]

Overall, the *Cruzan* opinion observed, "This is the first case in which we have been squarely presented with the issue of whether the United States Constitution grants what is in common

parlance referred to as a 'right to die.'"[210] In this context, the Court referenced the 1897 ruling in *Twin City Bank v. Nebeker,* which stated that, in deciding "a question of such magnitude and importance ... it is the part of wisdom not to attempt by any general statement to cover every possible phase of the subject."[211] The Court ruled that the due process clause does not require a state to accept the substituted judgment of close family members "in the absence of substantial proof" that their views reflect the patient's preferences and desires.[212] The *Cruzan* court asserted that "a State may apply a clear and convincing evidence standard in proceedings where a guardian seeks to discontinue nutrition and hydration of a person diagnosed to be in a persistent vegetative state"[213] and affirmed the ruling of the Supreme Court of Missouri in *Cruzan v. Harmon.*

Several justices wrote concurring and dissenting opinions. Although concurring with Chief Justice Rehnquist's opinion, Justice Sandra Day O'Connor narrowed her interpretation of the *Cruzan* decision. Justice O'Connor emphasized that "the Court does not today decide the issue whether a State must also give effect to the decisions of a surrogate decisionmaker."[214] Such a duty might be "constitutionally required to protect the patient's liberty interest in refusing medical treatment."[215] The *Cruzan* ruling "does not preclude a future determination that the Constitution requires the States to implement the decisions of a patient's duly appointed surrogate."[216] States may develop other approaches to protect "an incompetent individual's liberty interest in refusing medical treatment."[217]

In his dissenting opinion, Justice Brennan referenced *Rasmussen v. Fleming,* which stated "Some patients, however, want no part of a life sustained only by medical technology. Instead, they prefer a plan of medical treatment that allows nature to take its course and permits them to die with dignity."[218] Justice Brennan stated that "Nancy Cruzan has a fundamental right to be free of unwanted artificial nutrition and hydration, which right is not outweighed by any interests of the State."[219] He noted that family members "have a unique knowledge of the patient which is vital to any decision on his or her behalf."[220] Further, "The testimony of close friends and family members ... may often be the best evidence available of what the patient's choice would be."[221] As against the Missouri ruling requiring clear and convincing evidence of an incompetent person's preferences regarding termination of life-sustaining treatment, Justice Brennan observed that "No proof is required to support a finding that the incompetent person would wish to continue treatment."[222] Thus, the Missouri ruling does not meet the constitutional standard of imposing "only those procedural requirements that serve to enhance the accuracy of a determination of Nancy Cruzan's wishes or are at least consistent with an accurate determination."[223]

In his dissenting opinion, Justice John Paul Stevens stated, "This case is the first in which we consider whether, and how, the Constitution protects the liberty of seriously ill patients to be free from life-sustaining medical treatment."[224] He observed that medical technology has "transformed the political and social conditions of death."[225] In consequence, the Missouri ruling "insists, without regard to Nancy Cruzan's own interests, upon equating her life with the biological persistence of her bodily functions."[226] As against the Court's ruling, Justice Stevens asserted, "The opposition of life and liberty in this case are thus not the result of Nancy Cruzan's tragic accident, but are instead the artificial consequence of Missouri's effort and this Court's willingness, to abstract Nancy Cruzan's life from Nancy Cruzan's person."[227]

The *Cruzan* court recognized that the case being considered was the first to specifically concern whether the Constitution grants a "right to die." With this question as background, the Court stated that a competent person has the constitutional right to refuse unwanted medical

treatment, including ANH. This right is established by the due process clause of the Fourteenth Amendment. However, this right does not extend to individuals who are incompetent, that is, do not possess the capacity for medical decision making. The 5–4 ruling upheld the Missouri decision requiring clear and convincing evidence that an incompetent patient would have desired the withdrawal of life-sustaining treatment, prior to acting on the order of a surrogate decision maker to withdraw such treatment. The dissenting justices described the artificial opposition of life and liberty resulting from the Missouri standard. Rather, per Justice Stevens, "the best interests of the individual, especially when buttressed by the interests of all related third parties, must prevail over any general state policy that simply ignores those interests."[228] Additionally, per Justice O'Connor, in the future the Court might rule that the Constitution protects the decisions of a patient's duly appointed surrogate. Overall, the need for clear and convincing evidence is appropriate. The question in *Cruzan* and all similar circumstances and cases relates to the nature of the evidence required. Per Justice Brennan, if the family's wishes are clear and convincing, that should be sufficient evidence of the patient's desires.

Planned Parenthood of Southeastern Pennsylvania v. Casey

As did *Griswold v. Connecticut*, *Planned Parenthood of Southeastern Pennsylvania v. Casey* primarily involved considerations that may be related to the biomedical ethical principle of autonomy. In 1992, in *Casey*, the U.S. Supreme Court declared it was "imperative to review once more the principles that define the rights of the woman and the legitimate authority of the state respecting the termination of pregnancies by abortion procedures."[229] Essentially, in *Casey*, personal autonomy was contrasted with state interests, specifically with the state interest in preservation of life. The Pennsylvania statute under review, that is, the Pennsylvania Abortion Control Act of 1982, required among other provisions that (1) a woman be provided certain information at least twenty-four hours prior to an abortion procedure; (2) unless certain exceptions applied, "a married woman seeking an abortion must sign a statement indicating that she has notified her husband of her intended abortion"; and (3) with the exception of a judicial bypass option, the informed consent of one of her parents is required for a minor to obtain an abortion.[230] (With a judicial bypass, a court could authorize the performance of an abortion based on a determination that "the young woman is mature and capable of giving informed consent and has in fact given her informed consent, or that an abortion would be in her best interests."[231])

The Court concluded that the central holding of *Roe v. Wade*[232] should be retained and reaffirmed.[233] The Court stated that the *Roe* central holding has three parts:

> First is a recognition of the right of the woman to choose to have an abortion before viability and to obtain it without undue interference from the State. Before viability, the State's interests are not strong enough to support a prohibition of abortion or the imposition of a substantial obstacle to the woman's effective right to elect the procedure. Second is a confirmation of the State's power to restrict abortions after fetal viability, if the law contains exceptions for pregnancies which endanger the woman's life or health. And third is the principle that the State has legitimate interests from the outset of the pregnancy in protecting the health of the woman and the life of the fetus that may become a child. These principles do not contradict one another; and we adhere to each.[234]

Constitutional protection of a woman's decision to terminate her pregnancy derives from the due process clause of the Fourteenth Amendment, which declares that no state shall "deprive any person of life, liberty, or property, without due process of law."[235] *Casey* referenced the concurring opinion of Justice Louis D. Brandeis in *Whitney v. California*, in which Justice Brandeis stated "it is settled that the due process clause of the Fourteenth Amendment applies to matters of substantive law as well as to matters of procedure. Thus, all fundamental rights comprised within the term liberty are protected by the Federal Constitution from invasion by the States."[236]

The *Casey* opinion also utilized "the force of *stare decisis*"[237] in support of its ruling. *Stare decisis* may be translated as "let the decision stand," and refers to respecting the precedent established by prior decisions. *Stare decisis* may also be translated as "to stand by things decided," and implies not changing what has already been established by precedent. But *stare decisis* is not an "inexorable command."[238] Prior holdings may be reexamined, "informed by a series of prudential and pragmatic considerations designed to test the consistency of overruling a prior decision with the ideal of the rule of law, and to gauge the respective costs of reaffirming and overruling a prior case."[239] These considerations include assessing whether the law has proven intolerable as it defies practical workability, or whether the law "is subject to a kind of reliance that would lend a special hardship to the consequences of overruling and add inequity to the cost of repudiation."[240] The court stated that the central holding of *Roe* had not been found unworkable. Regarding reliance, the court stated that "people have organized intimate relationships and made choices that define their views of themselves and their places in society" based on the parameters established by *Roe*, and "the certain cost of overruling *Roe* for people who have ordered their thinking and living around that case" could not be dismissed."[241] *Casey* also asserted that *Roe* "stands at an intersection of two lines of decisions," that is, (1) the protection of individual liberty as related to intimate relationships and the family, established by *Griswold v. Connecticut* and the succession of cases exemplified by *Griswold*, and (2) as a rule of "personal autonomy and bodily integrity, with doctrinal affinity to cases recognizing limits on governmental power to mandate medical treatment or to bar its rejection."[242] Thus, *Casey* stated that within the bounds of normal *stare decisis* analysis, "the stronger argument is for affirming *Roe*'s central holding," rather than overruling *Roe*.[243] Further, the *Casey* court stated that overruling *Roe*'s central holding "would seriously weaken the Court's capacity to exercise the judicial power and to function as the Supreme Court of a Nation dedicated to the rule of law."[244]

The *Casey* opinion stated, "The woman's right to terminate her pregnancy before viability is the most central principle of *Roe v. Wade*. It is a rule of law and a component of liberty we cannot renounce."[245] But, in contrast to this liberty is "the interest of the State in the protection of potential life."[246] The *Roe v. Wade* court established the state's "important and legitimate interest in potential life."[247] In consequence of this state interest, *Casey* asserted that it does not follow that the state is prohibited from taking steps to ensure that a woman's choice to terminate her pregnancy before viability "is thoughtful and informed."[248] For example, the woman could be informed that "there are procedures and institutions to allow adoption of unwanted children as well as a certain degree of state assistance if the mother chooses to raise the child herself."[249] Regarding jurisprudence relating to all other liberties, *Casey* acknowledged that "not every law which makes a right more difficult to exercise is, *ipso facto*, an infringement of that right."[250] The abortion right is similar. Critically, the *Casey* court stated, "Only where state regulation imposes an undue burden on a woman's ability to make this decision does the power of the

State reach into the heart of the liberty protected by the Due Process Clause."[251] Per *Casey*, not all government intrusions into matters fundamentally affecting a person are necessarily unwarranted.[252] In the case before the Court, *Casey* clarified that a finding of an *undue burden* meant that "a state regulation has the purpose or effect of placing a substantial obstacle in the path of a woman seeking an abortion of a nonviable fetus."[253] Per *Casey*, an undue burden is an "unconstitutional burden."[254]

The *Casey* court summarized that "Our adoption of the undue burden analysis does not disturb the central holding of *Roe v. Wade*, and we reaffirm that holding. Regardless of whether exceptions are made for particular circumstances, a state may not prohibit any woman from making the ultimate decision to terminate her pregnancy before viability."[255] Regarding the Pennsylvania Abortion Control Act of 1982, *Casey* held that the informed consent requirement, including a mandatory twenty-four-hour waiting period (with the exception of a medical emergency) and notice of the availability of informational materials relating to the consequences to the fetus, was not an undue burden on the right protected by *Roe*. As well, *Casey* held that the parental consent requirement with a judicial bypass procedure was constitutional. Finally, *Casey* held invalid the Pennsylvania statute's requirement that "a married woman seeking an abortion must sign a statement indicating that she has notified her husband of her intended abortion."[256]

Overall, the influence of *Casey* has been profound and, as of 2017, the case has been cited in more than 1,100 decisions. The U.S. Supreme Court has cited the 1992 *Casey* ruling more than two dozen times.[257] For example, in 2016, in *Whole Woman's Health v. Hellerstedt*, the Court applied the undue burden standard in holding that two provisions in a Texas law (Texas House Bill 2, 2013) requiring that (1) physicians who perform abortions have admitting privileges at a local hospital and (2) abortion facilities meet minimum standards for ambulatory surgical centers under Texas law violated the Constitution.[258] The admitting-privilege and surgical-center requirements placed a "substantial obstacle" in a woman's path to abortion access[259] and therefore constituted an undue burden on a woman's constitutional right to seek abortion.[260] The undue burden standard utilized in *Casey* has been cited in Supreme Court decisions in other cases involving abortion[261] and in *Washington v. Glucksberg*,[262] a case involving an asserted right to physician-assisted suicide.

Davis v. Davis

As in *Griswold* and *Casey*, *Davis v. Davis* primarily involved considerations that may be associated with the biomedical ethical principle of autonomy. In *Davis v. Davis*,[263] autonomy manifested as considerations related to a right to privacy and a right to *procreational autonomy*. *Davis v. Davis* involved the disposition of cryogenically preserved products of in vitro fertilization, commonly referred to as "frozen embryos." The case began as a divorce action, but the parties, Junior Lewis Davis and Mary Sue Davis, could not agree on who was to have "custody" of seven "frozen embryos" stored in a Knoxville, Tennessee, fertility clinic. The trial court had determined that the embryos were "human beings" from the moment of fertilization and awarded "custody" to Mary Sue Davis, directing that she be "permitted the opportunity to bring these children to term through implantation."[264] The Court of Appeals reversed, finding that Junior Lewis Davis has a "constitutionally protected right not to beget a child where no pregnancy has

taken place" and holding that "there is no compelling state interest to justify ordering implantation against the will of either party."[265] The Court of Appeals held that the parties shared an interest in the embryos and remanded the case to the trial court for entry of an order vesting the Davises with joint control. Mary Sue Davis then sought review by the Supreme Court of Tennessee. In 1992, the court granted review owing to "the obvious importance of the case in terms of the development of law regarding the new reproductive technologies."[266] Prior to the court's review, Mary Sue Davis remarried and wanted authority to donate the embryos to a childless couple. Junior Lewis Davis was opposed to such donation and preferred that the "frozen embryos" be discarded.

The court noted that when the Davises enrolled in the Knoxville clinic's in vitro fertilization program, they did not execute a written agreement specifying the disposition of any unused embryos that might result from the cryopreservation process. Additionally, at that time there was no Tennessee statute governing such disposition and none had been enacted since.[267] The court also noted the absence of any case law that might have guided a decision in this case. Instead, there was "the benefit of extensive comment and analysis in the legal journals."[268] But the court indicated that utilizing any of the proposed methods for disposition of "frozen embryos" in unanticipated or disputed circumstances would establish a "bright-line test" that might fail to account for future developments in scientific knowledge and reproductive technologies or ethical considerations related to such developments. The court determined that the interests of each party must be weighed to resolve the dispute fairly and responsibly.[269]

The Supreme Court of Tennessee observed that one of the fundamental issues posed by the case concerned whether the preembryos "should be considered 'persons' or 'property' in the contemplation of the law."[270] The Court of Appeals held, correctly, that "they cannot be considered 'persons' under Tennessee law."[271] Further, referencing *Roe v. Wade*, the Supreme Court of Tennessee noted that preembryos do not enjoy protection as "persons" under federal law. In *Roe*, the U.S. Supreme Court had concluded "the unborn have never been recognized in the law as persons in the whole sense."[272] Regarding consideration of preembryos as "property," the Supreme Court of Tennessee referenced ethical standards established by the American Fertility Society:

> The preembryo is due greater respect than other human tissue because of its potential to become a person and because of its symbolic meaning for many people. Yet, it should not be treated as a person, because it has not yet developed the features of personhood, is not yet established as developmentally individual, and may never realize its biologic potential.[273]

The court concluded that preembryos are neither "persons" nor "property," but represented "an interim category that entitles them to special respect because of their potential for human life."[274] The interest the Davises have in the preembryos is not a true property interest. But they do have an interest "in the nature of ownership, to the extent that they have decision-making authority concerning disposition of the preembryos, within the scope of policy set by law."[275] However, if the parties fail to agree, the disposition of the preembryos would "turn on" the parties' exercise of their constitutional right to privacy and a right to procreational autonomy.[276] The court referenced *Meyer v. Nebraska*, in which the U.S. Supreme Court stated that the liberty guaranteed by the Fourteenth Amendment denotes the right of an individual to marry, establish a home, and bring up children.[277] The court discussed the Declaration of Rights in the Tennessee

Constitution and concluded "there is a right of individual privacy guaranteed under and protected by the liberty clauses of the Tennessee Declaration of Rights."[278] In *Davis v. Davis*, the specific individual freedom in dispute was the right to procreate. The Supreme Court of Tennessee held that "the right of procreation is a vital part of an individual's right to privacy. Federal law is to the same effect."[279] The court stated that "a right to procreational autonomy is inherent in our most basic concepts of liberty"[280] and referenced *Griswold v. Connecticut*, *Roe v. Wade*, and *Bellotti v. Baird*,[281] among other cases decided by the U.S. Supreme Court.

The court observed that the right of procreational autonomy consists of two rights of equal significance, that is, "the right to procreate and the right to avoid procreation."[282] Both are subject to protections and limitations. Regarding procreational autonomy in the context of in vitro fertilization, the court stated that "decisional authority rests in the gamete-providers alone."[283] Further, with respect to Tennessee public policy, "the state's interest in potential human life is insufficient to justify an infringement on the gamete-providers' procreational autonomy."[284] When one party wishes to continue the IVF process and the other does not, a method of balancing the competing interests is required. In *Davis v. Davis*, the court held that the

> relative interests of the parties in using or not using the preembryos must be weighed. Ordinarily, the party wishing to avoid procreation should prevail, assuming that the other party has a reasonable possibility of achieving parenthood by means other than use of the preembryos in question. If no other reasonable alternatives exist, then the argument in favor of using the preembryos to achieve pregnancy should be considered. However, if the party seeking control of the preembryos intends merely to donate them to another couple, the objecting party obviously has the greater interest and should prevail.[285]

The judgment of the appeals court was upheld in favor of Junior Lewis Davis. The Knoxville fertility clinic was "free to follow its normal procedure in dealing with unused preembryos, as long as that procedure is not in conflict with this opinion."[286]

Summary

The opinions and holdings in these landmark cases have provided decades of guidance for ethical and legal decision making in circumstances that are necessarily difficult and involve complex ethical assessments. Each situation is unique, and the decision making process is guided and supported by the various frameworks developed by these cases.

KEY TERMS

Liberty Interest
Per the due process clause of the Fourteenth Amendment, no state shall deprive any person of life, liberty, or property without due process of law.[294] Thus, the provision of due process is required when a person's interest in life, liberty, or property is threatened. A liberty interest is a right that the due process clause confers on an individual. An example of a liberty interest is a competent person's right to refuse medical treatment.[295]

BOX 6.1

Case Study: The Right to Make Medical Decisions

In 2015, the Supreme Court of Connecticut ruled that seventeen-year-old Cassandra C., the minor daughter of the appellant (respondent mother) was "not competent to refuse a course of medical treatment that would provide her with her only chance of survival."[287] Cassandra had been diagnosed with Hodgkin's lymphoma and she and her mother refused to obtain appropriate medical treatment. Certain medical providers reported these circumstances to the state Department of Children and Families and the commissioner of that department filed a neglect petition, seeking an order of temporary custody of Cassandra. The trial court granted temporary custody and then ordered that Cassandra be returned to her home on the condition that she and her mother cooperate with Cassandra's medical care providers. Cassandra then began chemotherapy, but ran away from home before treatment could be completed. The commissioner filed a motion to reopen the evidence "in order to consider evidence regarding [Cassandra's] subsequent behaviors and whether she is competent to make life/death decisions regarding her medical care."[288] The trial court granted the motion. At the conclusion of an evidentiary hearing, the trial court judge stated that Cassandra was "as yet incapable of acting independently concerning her own life threatening medical condition."[289] The trial court "ordered that Cassandra remain in the custody and care of the department and that she be removed from her home, and authorized the department to make all medical decisions for her."[290] An appeal was filed claiming that the trial judge "improperly had found that Cassandra was not competent to make her own medical decisions and had violated the respondents' constitutional due process right to bodily and family integrity." The Supreme Court of Connecticut affirmed the trial court's ruling, noting that Cassandra was not a mature minor under any standard. (A sufficiently mature minor could be deemed competent to consent to medical treatment or refuse medical treatment.)

Ethical and Legal Analysis

1. Apply the rulings in *Griswold v. Connecticut*[291] and *Cruzan v. Director, Missouri Dept. of Health*[292] to *In re Cassandra C.* Contrast a state's interest in preserving the welfare of a minor child versus the right of parents to make medical decisions on behalf of their child and a purported right of privacy protecting such decision making.
2. Presume that Cassandra C. was evaluated to be a mature minor and competent to make her own medical decisions. In *Cruzan* the U.S. Supreme Court stated that a state may "simply assert an unqualified interest in the preservation of human life to be weighed against the constitutionally protected interests of the individual."[293] Discuss circumstances in which the biomedical ethical principle of autonomy might be outweighed by state interests and other considerations related to the purported good of society.

Substituted Judgment

Per *Hart v. Brown*, "The right to act for an incompetent has been recognized as the 'doctrine of substituted judgment.'"[296] Per *Superintendent of Belchertown State School v. Saikewicz*,[297] medical decisions made on behalf of an incompetent patient by a guardian, healthcare surrogate or healthcare proxy, or close family members should be based on knowledge of and past experiences with that person. The goal is to substitute their judgment for the likely judgment of the patient faced with the present medical circumstances. A medical decision determined by substituted judgment "should be that which would be made by the incompetent person, if that person were competent."[298]

Undue Burden Standard

Per *Planned Parenthood of Southeastern Pennsylvania v. Casey*,[299] a finding of an undue burden meant that a state regulation had the purpose or effect of placing a substantial obstacle in the path of a person seeking to fulfill a constitutional right[300] or a constitutionally protected liberty interest. An undue burden is an unconstitutional burden.[301] For example, in *Casey*, the U.S. Supreme Court held that the Pennsylvania Abortion Control Act of 1982 requirement that "a married woman seeking an abortion must sign a statement indicating that she has notified her husband of her intended abortion" was unconstitutional.[302]

DISCUSSION QUESTIONS

1. In *Griswold v. Connecticut*, the U.S. Supreme Court stated that "specific guarantees in the Bill of Rights have penumbras, formed by emanations from those guarantees that help give them life and substance."[303] Discuss the meaning and implications of *Griswold*'s penumbras and emanations. Describe the legal basis for an unenumerated right that might be located within these purported constitutional regions.
2. Discuss the parameters of the doctrine of substituted judgment, as detailed in *Strunk v. Strunk*,[304] *Hart v. Brown*,[305] *In re Quinlan*,[306] and elsewhere. In what circumstances do state interests prevail over an individual's rights? When might the courts be required to resolve such a dispute?
3. Define the legal principle of *stare decisis* and discuss the application of this doctrine in *Planned Parenthood of Southeastern Pennsylvania v. Casey*. As discussed in *Casey* and elsewhere, describe circumstances in which the U.S. Supreme Court might choose to overrule precedent.
4. Describe the clear and convincing evidence standard as examined and utilized in *Cruzan v. Director, Missouri Dept. of Health*. Discuss the implications of Justice Brennan's observation in his dissenting opinion that no proof was required to support a finding that the incompetent person would wish to continue treatment.[307]

DO-IT-YOURSELF ETHICIST

1. Write a 500-word op-ed article for submission to a national newspaper regarding a purported right to healthcare referencing, per *Griswold*, the "penumbras and emanations" of the Bill of Rights.[308] Provide arguments, including legal citations, supporting and denying the existence of such a right.

2. You have been requested to present a talk to your local hospital's ethics committee on methods of evaluating the best interests of incompetent adult patients. Analyze the limited-objective and pure-objective tests, per *In re Conroy*.[309] Describe other potentially useful tests of a patient's best interests. As well, discuss how to resolve differences of opinion regarding those best interests.
3. You are preparing a legal brief in a case similar to *Superintendent of Belchertown State School v. Saikewicz*.[310] *Saikewicz* stated that the "interest of the State in prolonging a life must be reconciled with the interest of an individual to reject the traumatic cost of that prolongation."[311] Present both sides of this argument, contrasting state interests versus the rights of an individual to maintain personal autonomy and bodily integrity and to refuse medical treatment.

REAL-WORLD APPLICATIONS—ETHICS AS A DOCTRINE OF ACTION

1. More than a generation has passed since the 1992 ruling in *Davis v. Davis*.[312] As a legal expert in the field of reproductive rights, you have been requested to present an update on procreational autonomy[313] to your state legislature's health and human services committee. Discuss the possible applications of procreational autonomy in modern society, ethical and moral considerations related to such applications, and the limitations of this unenumerated right, including potentially opposed state interests.
2. You have been invited to speak at the quarterly meeting of your local medical society's biomedical ethics committee. The topic is the Ninth Amendment of the Bill of Rights.[314] Discuss the implications, in the field of healthcare, of Justice Joseph Story's characterization of the Ninth Amendment as "a positive declaration in such a bill of rights that the enumeration of certain rights shall not be construed to deny or disparage others retained by the people."[315]

REFERENCES

[1]*Griswold v. Connecticut*, 381 U.S. 479 (1965).

[2]Ibid., at 479, 480.

[3]Ibid., at 482.

[4]Ibid., at 483.

[5]*NAACP v. Alabama*, 357 U.S. 449 (1958), at 462.

[6]*Griswold v. Connecticut*, at 483.

[7]Ibid.

[8]Ibid.

[9]Ibid., at 484.

[10]*Boyd v. United States*, 116 U.S. 616, 630 (1886).

[11]U.S. Constitution, Amendment IX, https://www.archives.gov/founding-docs/bill-of-rights-transcript.

[12]Ibid., at 481.

[13]U.S. Constitution, Amendment XIV, Section 1, https://www.archives.gov/founding-docs/amendments-11-27.

[14]*Griswold v. Connecticut*, at 485.

[15]D. Helscher, "*Griswold v. Connecticut* and the Unenumerated Right of Privacy," *Northern Illinois Law Review* 15, no. 1 (1994): 33–61.

[16]*Griswold v. Connecticut*, at 486.

[17]*Mapp v. Ohio*, 367 U.S. 643, 656 (1961).

[18]*Griswold v. Connecticut*, at 486.

[19]Ibid., at 487.

[20]Ibid., at 488.

[21]Ibid., at 489, 490.

[22]J. E. Cooke, ed., *The Federalist* (Middletown, CT: Wesleyan University Press, 1961), No. 37 (James Madison), 236.

[23]*Griswold v. Connecticut*, at 488, 489.

[24]J. Story, *Commentaries on the Constitution of the United States*, 5th ed. (Boston: Little, Brown, 1891), 626–627.

[25]*Griswold v. Connecticut*, at 492.

[26]Ibid., at 493.

[27]Ibid.

[28]Ibid., at 509.

[29]Ibid., at 511.

[30]Ibid., at 520.

[31]Ibid.

[32]K. H. Kelsey, "The Ninth Amendment of the Federal Constitution," *Indiana Law Journal* 11, no. 4 (1936): 309–323.

[33]*Eisenstadt v. Baird*, 405 U.S. 438 (1972).

[34]Ibid., at 453.

[35]*Roe v. Wade*, 410 U.S. 113 (1973).

[36]Ibid., at 153.

[37]Ibid.

[38]*Bowers v. Hardwick*, 478 U.S. 186 (1986).

[39]Ibid.

[40]*Lawrence v. Texas*, 539 U.S. 558 (2003).

[41]Ibid., at 593, note 3.

[42]*Webster v. Reproductive Health Services*, 492 U.S. 490 (1989).

[43]Missouri Senate Committee Substitute for House Bill No. 1596, 83rd General Assembly, 2nd Reg. Sess. (1986).

[44]Missouri Revised Statutes §§ 188.205, 188.210, 188.215.

[45]*Webster v. Reproductive Health Services*, at 502.

[46]*Maher v. Roe*, 432 U.S. 464 (1977).

[47]*Webster v. Reproductive Health Services*, at 510.

[48]Ibid., at 511.

[49]D. O. Conkle, "Three Theories of Substantive Due Process," *North Carolina Law Review* 85 (2006): 63–148.

[50]*Cruzan v. Director, Missouri Dept. of Health*, 497 U.S. 261 (1990).

[51]Ibid., footnote 7.

[52]*Youngberg v. Romeo*, 457 U. S. 307, 321 (1982).

[53]*Cruzan v. Director, Missouri Dept. of Health*, at 279.

[54]*In re Estate of Longeway*, 133 Ill.2d 33 (1989), 549 N.E.2d 292 (1989).

[55]Ibid., at 43.

[56]*Cruzan v. Director, Missouri Dept. of Health*, at 276.

[57]*Planned Parenthood of Southeastern Pennsylvania v. Casey*, 505 U.S. 833 (1992).

[58]Ibid., at 860.

[59]Ibid., at 915.

[60]Ibid., at 853.

[61]*Griswold v. Connecticut*, at 479.

[62]*In re Quinlan*, 70 N.J. 10, 23 (1976), 355 A. 2d 647.

[63]Ibid., at 25.

[64]Ibid.

[65]Ibid., at 18.

[66]Ibid., at 19.

[67]Ibid., at 19, 20.

[68]Ibid., at 25.

[69]Ibid., at 26.

[70]Ibid., at 27.

[71]Ibid., at 31; Pius XII, "The Prolongation of Life. An Address to an International Congress of Anesthesiologists," November 24, 1957, National Catholic Bioethics Quarterly 9, no. 2 (2009): 327–332.

[72]Pius XII, "The Prolongation of Life," 331.

[73]Ibid.

[74]Ibid.

[75]Ibid.

[76]*In re Quinlan*, at 32.

[77]Ibid., at 33.

[78]Ibid., at 40.

[79]Ibid.

[80]Ibid., quoting *Griswold v. Connecticut*, at 484.

[81]Ibid., at 41.

[82]Ibid.

[83]Ibid., at 44.

[84]*Strunk v. Strunk*, 445 S.W.2d 145 (1969).

[85]*Hart v. Brown*, 29 Conn. Super. Ct. 368, 289 A.2d 386 (1972).

[86]*Strunk v. Strunk*, at 146.

[87]Ibid.

[88]Ibid., at 148.

[89]*Hart v. Brown*, at 369.

[90]Ibid., at 370.

[91]Ibid., at 375.

[92]Ibid.

[93]*In re Quinlan*, at 49.

[94]Ibid., at 50.

[95]Ibid.

[96]Ibid., at 54.

[97]Ibid.

[98]*In re Farrell*, 108 N.J. 335, 342 (1987).

[99]*Superintendent of Belchertown State School v. Saikewicz*, 373 Mass. 728 (1977), 370 N.E.2d 417.

[100]Ibid., at 729–731.

[101]Ibid., at 730.

[102]Ibid., at 735.

[103]Ibid.

[104]Ibid., at 736.

[105]Ibid.

[106]Ibid.

[107]Ibid.

[108]Ibid.

[109]*Griswold v. Connecticut*.

[110]*Superintendent of Belchertown State School v. Saikewicz*, at 739.

[111]*In re Quinlan*.

[112]*Superintendent of Belchertown State School v. Saikewicz*, at 739.

[113]Ibid., at 741.

[114]Ibid., at 742.

[115]Ibid.

[116]Ibid., at 751.

[117]Ibid., at 752.

[118]Ibid., at 753.

[119]Ibid., at 754.

[120]Ibid.

[121]Ibid., at 757.

[122]Ibid., at 759.

[123]President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, *Deciding to Forego Life-Sustaining Treatment. A Report on the Ethical, Medical, and Legal Issues in Treatment Decisions* (Washington, DC: U.S. Government Printing Office, 1983).

[124]J. D. Bleich, "Treatment of the Terminally Ill. Survey of Recent Halakhic Periodical Literature," *Tradition* 30, no. 3 (1996): 51–87.

[125]*In re Storar*, 52 N.Y.2d 363, 369 (1981), 420 N.E.2d 64, 438 N.Y.S.2d 266.

[126]*Matter of Eichner (Fox)*, 73 A.D.2d 431 (1980).

[127]*In re Storar*, at 372.

[128]Ibid.

[129]*Matter of Storar*, 78 A.D.2d 1013 (1980).

[130]*In re Storar*, at 375.

[131]Ibid., at 377.

[132]Ibid.

[133]Ibid., at 379.

[134]Ibid., at 380.

[135]Ibid., at 381.

[136]*Jehovah's Witnesses v. King County Hospital*, 278 F. Supp. 488 (1967).

[137]*In re Storar*, at 382.

[138]Ibid., at 391.

[139]L. J. Dunn Jr., "The Eichner/Storar Decision: A Year's Perspective," *Journal of Law, Medicine, and Ethics* 10, no. 3 (1982): 117–141.

[140]*In re Storar*, at 393.

[141]*In re Conroy*, 98 N.J. 321, 335 (1985), 486 A.2d 1209.

[142]Ibid.

[143]Ibid., at 337, 338.

[144]Ibid., at 339.

[145]Ibid., at 340.

[146]Sacred Congregation for the Doctrine of the Faith, *Declaration on Euthanasia*, May 5, 1980, http://www.vatican.va/roman_curia/congregations/cfaith/documents/rc_con_cfaith_doc_19800505_euthanasia_en.html.

[147]*In re Conroy*, at 340.

[148]Ibid.

[149]Ibid., at 341.

[150]Ibid.

[151]Ibid.

[152]Ibid., at 344.

[153]Ibid., at 344, 345.

[154]Ibid., at 346.

[155]Ibid.

[156]Ibid.

[157]Ibid., at 347.

[158]Ibid.

[159]*Superintendent of Belchertown State School v. Saikewicz*.

[160]*In re Conroy*, at 348, 349.

[161]Ibid.

[162]Ibid., at 349.

[163]Ibid., at 350.

[164]Ibid., at 353; Jacobson v. Massachusetts, 197 U.S. 11 (1905).

[165]*In re Conroy*, at 359.

[166]Ibid., at 360.

[167]Ibid.

[168]Ibid., at 361.

[169]Ibid., at 365.

[170]Ibid., at 366.

[171]Ibid., at 365.

[172]Ibid., at 366.

[173]Ibid.

[174]Ibid., at 367.

[175]Ibid., at 369, 370.

[176]Ibid., at 371.

[177]Ibid.

[178]Ibid., at 387.

[179]AB 891, Health Care Decisions Law, ftp://www.leginfo.ca.gov/pub/99-00/bill/asm/ab_0851-0900/ab_891_bill_19991010_chaptered.html.

[180]California Probate Code Division 4.7, Health Care Decisions, Sections 4600–4806, https://leginfo.legislature.ca.gov/faces/codes_displayexpandedbranch.xhtml?tocCode=PROB&division=4.7.&title=&part=&chapter=&article.

[181]AB 891, Health Care Decisions Law.

[182]California Probate Code Division 4.7: Health Care Decisions, Section 4683.

[183]Ibid., Section 4609.

[184]Ibid., Sections 4684 and 4714.

[185]Ibid.

[186]Ibid., Section 4750.

[187]Ibid., Section 4670.

[188]Ibid., Section 4671.

[189]Ibid., Sections 4700–4701, http://ag.ca.gov/consumers/pdf/ProbateCodeAdvancedHealthCareDirectiveForm-fillable.pdf.

[190]Ibid., Section 4780.

[191]*Cruzan v. Harmon*, 760 S.W.2d 408 (Mo. 1988).

[192]*Cruzan v. Director, Missouri Dept. of Health*, at 268.

[193]Ibid., at 268.

[194]*Cruzan v. Harmon.*

[195]Ibid., at 410.

[196]Ibid., at 419.

[197]Ibid., at 424.

[198]Ibid., at 425.

[199]Ibid.

[200]Ibid., at 426.

[201]Ibid.

[202]*Cruzan v. Director, Missouri Dept. of Health.*

[203]*Superintendent of Belchertown State School v. Saikewicz.*

[204]*In re Storar.*

[205]*Cruzan v. Director, Missouri Dept. of Health*, at 262.

[206]Ibid.

[207]Ibid.

[208]Ibid.

[209]Ibid.

[210]Ibid., at 277.

[211]*Twin City Bank v. Nebeker*, 167 U.S. 196, 202 (1897).

[212]*Cruzan v. Director, Missouri Dept. of Health*, at 285–286.

[213]Ibid., at 284.

[214]Ibid., at 289.

[215]Ibid.

[216]Ibid., at 292.

[217]Ibid.

[218]*Rasmussen v. Fleming*, 154 Ariz. 207, 211 (1987), 741 P.2d 674, 678.

[219]*Cruzan v. Director, Missouri Dept. of Health*, at 302.

[220]Ibid., at 325.

[221]Ibid.

[222]Ibid., at 316.

[223]Ibid.

[224]Ibid., at 331.

[225]Ibid., at 339.

[226]Ibid., at 344, 345.

[227]Ibid., at 351.

[228]Ibid., at 350.

[229]*Planned Parenthood of Southeastern Pennsylvania v. Casey*, at 845.

[230]Ibid., at 844.

[231]Ibid., at 899 .

[232]*Roe v. Wade.*

[233]*Planned Parenthood of Southeastern Pennsylvania v. Casey*, at 846.

[234]Ibid.

[235]Ibid.

[236]*Whitney v. California*, 274 U.S. 357, 373 (1927).

[237]*Planned Parenthood of Southeastern Pennsylvania v. Casey*, at 853.

[238]Ibid., at 854.

[239]Ibid.

[240]Ibid.

[241]Ibid., at 856.

[242]Ibid., at 857.

[243]Ibid., at 861.

[244]Ibid., at 865.

[245]Ibid., at 871.

[246]Ibid.

[247]*Roe v. Wade*, at 163.

[248] *Planned Parenthood of Southeastern Pennsylvania v. Casey* at 872.
[249] Ibid.
[250] Ibid., at 873.
[251] Ibid., at 874.
[252] Ibid., at 875.
[253] Ibid., at 877.
[254] Ibid.
[255] Ibid., at 879.
[256] Ibid., at 898.
[257] J. Daar, "Assisted Reproductive Technologies and Abortion," in *The Oxford Handbook of U.S. Health Law*, eds. I. G. Cohen, A. K. Hoffman, and W. M. Sage (New York: Oxford University Press, 2017), 330–353.
[258] *Whole Woman's Health v. Hellerstedt*, 579 U.S. ___ (2016), 19–39, Docket No. 15-274.
[259] Ibid., 21–28.
[260] Ibid., 28–36.
[261] Stenberg v. Carhart, 530 U.S. 914 (2000); Gonzales v. Carhart, 550 U.S. 124 (2007).
[262] *Washington v. Glucksberg*, 521 U.S. 702 (1997).
[263] *Davis v. Davis*, 842 S.W.2d 588 (Tenn. 1992).
[264] Ibid., at 589.
[265] Ibid.
[266] Ibid., at 590.
[267] Ibid.
[268] Ibid.
[269] Ibid., at 591.
[270] Ibid., at 594.
[271] Ibid.
[272] *Roe v. Wade*, at 162.
[273] Davis v. Davis, at 596; Ethics Committee of the American Fertility Society, "Ethical Considerations of the New Reproductive Technologies," Fertility and Sterility 53, no. 6, suppl. 2 (1990): 1S–104S, 34S–35S.
[274] *Davis v. Davis*, at 597.
[275] Ibid.
[276] Ibid., at 598.
[277] *Meyer v. Nebraska*, 262 U.S. 390, 399 (1923).
[278] *Davis v. Davis*, at 600.
[279] Ibid.
[280] Ibid., at 601.
[281] *Bellotti v. Baird*, 443 U.S. 622 (1979).
[282] *Davis v. Davis*, at 601.
[283] Ibid., at 602.
[284] Ibid.
[285] Ibid., at 604.
[286] Ibid., at 605.
[287] *In re Cassandra C.*, SC19426, 316 Conn. 476, 112 A.3d 158 (2015), http://www.jud.ct.gov/external/supapp/Cases/AROcr/CR316/316CR38.pdf.
[288] Ibid.
[289] Ibid.
[290] Ibid.
[291] *Griswold v. Connecticut*.
[292] *Cruzan v. Director, Missouri Dept. of Health*.
[293] Ibid., at 262.
[294] U.S. Constitution, Amendment XIV, Section 1, https://www.archives.gov/founding-docs/amendments-11-27.
[295] *Cruzan v. Director, Missouri Dept. of Health*, at 262.
[296] *Hart v. Brown*, at 370.
[297] *Superintendent of Belchertown State School v. Saikewicz*.
[298] Ibid., at 752.
[299] *Planned Parenthood of Southeastern Pennsylvania v. Casey*.
[300] Ibid., at 877.
[301] Ibid.
[302] Ibid., at 898.
[303] *Griswold v. Connecticut*, at 484.
[304] *Strunk v. Strunk*.
[305] *Hart v. Brown*.
[306] *In re Quinlan*.
[307] *Cruzan v. Director, Missouri Dept. of Health*, at 316.
[308] *Griswold v. Connecticut*, at 484.
[309] *In re Conroy*, at 365.
[310] *Superintendent of Belchertown State School v. Saikewicz*.
[311] Ibid., at 742.
[312] *Davis v. Davis*.
[313] Ibid., at 601.
[314] U.S. Constitution, Amendment IX, https://www.archives.gov/founding-docs/bill-of-rights-transcript.
[315] Story, *Commentaries on the Constitution*.

Figure Credit

Fig. 6.1: Copyright © 2016 Depositphotos/Billiondigital.

CHAPTER 7

Informed Consent and the Patient–Physician Relationship, Informed Consent and Medical Research, and Patient Rights and Responsibilities

Informed Consent and the Patient–Physician Relationship

Overall, informed consent represents a primary implementation of the biomedical ethical principle of autonomy. It may be considered that a medical standard of disclosure reflects a more limited type of informed consent with respect to patient autonomy, as the physician, supported by the prevailing standard in his professional community, determines the specific information to be disclosed. In contrast, a reasonable person standard reflects a more expansive type of informed consent, in that the decisional requirements of a reasonable patient determine the content and extent of information disclosed. Informed consent requires the following:

- The patient has the capacity to reason and make judgments.
- The consent decision must be made voluntarily and without coercion.
- The patient must have a clear understanding of the risks and benefits of the proposed treatment and treatment alternatives.
- The patient must have sufficient understanding of the nature of the disease and the prognosis.

But achieving meaningful informed consent remains an elusive process. Research suggests that physicians rarely satisfy even minimal standards of disclosure in obtaining informed consent.[1] One study noted that discussions leading to clinical decisions in primary care settings "did not fulfill the criteria considered integral to informed decision making" such as evaluating the risks and benefits of proposed treatment and assessing the patient's understanding of the content of the discussion.[2] Although patient comprehension is essential to achieving informed consent, research has repeatedly demonstrated that patients retain little of the information disclosed during discussions involving consent to treatment.[3] Additionally, some patients may think they do not have a choice regarding signing the consent form. Others may feel compelled to do so. For example, a questionnaire study reported that 30 percent of women undergoing elective and emergency surgery believed they had no choice regarding signing the consent

FIGURE 7.1 Patient decision-making

form.[4] However, in contrast, promoting the patient's understanding and fostering authentic participation are critical to informed decision making.[5]

Despite the pervasive requirements for obtaining informed consent, and although it has been fairly stated that "the doctrine of informed consent is the bedrock of ethical medical practice,"[6] the practice has become "more informal than informed."[7] The promise of informed consent to safeguard patients and strengthen patient–physician relationships has yet to fulfill the right of self-determination envisioned by Justice Cardozo in *Schloendorff v. Society of New York Hospital* in 1914.[8] In the United States, the structure of the fee-for-service healthcare delivery system causes time to be the limiting factor in the effectiveness of physician–patient interactions. For example, a national survey reported in 2000 that 83 percent of family physicians in health maintenance organizations felt they needed more time than was allotted for new patients.[9] In numerous countries in the developed world, physicians struggle with time management as they are pressured to deliver an increasing number of services and simultaneously deliver patient-centered care.[10] Average time allocations for a new patient visit were thirty-two minutes in the United States, sixteen minutes in Germany, and eleven minutes in the United Kingdom.[11] However, one study has shown that the mean time needed to obtain consent for various orthopedic surgeries, including hip and knee replacements, was sixteen minutes.[12] Elsewhere, a median of twelve minutes was needed to obtain consent for carotid artery surgery in a simulation-based study.[13] It is reasonable to conclude that time pressures mitigate against the possibility of effective informed consent conversations and deliberations. Under the pressure of time, informed consent may easily be construed by a physician as an administrative annoyance, another hoop that needs to be jumped through to perform billable services and move on to the next patient. Thus, it has been asserted that "most patients sign a form they never read and that their physician never discusses with them,"[14] resulting in widespread failure to obtain appropriate informed consent. For example, one study reported that only 9 percent of 3,552 clinical decisions met the criteria for completeness of informed decision making.[15]

Given these issues, it is necessary to identify organizational policies that provide solutions for both physicians and patients. The components of informed consent need to be the primary inputs in development of such policies. Informed consent requires disclosure of information[16] that includes the following:

- The patient's clinical status and the diagnosis
- The characteristics, risks, and benefits of proposed treatment, including estimates of the probabilities of those risks and benefits
- Alternatives to proposed treatment, including the potential outcomes of no treatment
- The relationship of proposed treatment to the patient's life goals and the likelihood of the patient's achieving those goals

- The physician's recommendations
- An assessment of the patient's understanding of the information presented

Institution-wide training of medical staff and selected administrative staff may be needed. Ideally, such training has been included in preprofessional education curricula and continuing education programs. Emphasis should be placed on the benefits of an effective informed consent process in the following areas:

- Upholding the patient's right of self-determination
- Enhancing the physician–patient relationship and optimizing healthcare outcomes
- Improving patient satisfaction
- Reducing risk to the healthcare institution and the individual provider

Various presentation and multimedia tools have been utilized to optimize the process of obtaining informed consent. These decisions aids include computer-based consent tools, video educational tools, and using "repeat back" methods.[17] One electronic informed consent tool enabled "an ease of communication between clinicians and patients of complex material" and resulted in "a well-received informed consent process that provided value to all stakeholders."[18] In a study involving women considering gynecological laparoscopy, watching an informational video in addition to participating in standard consent procedures resulted in significantly higher (56 percent; $p < 0.001$) median scores on knowledge assessments compared with participating in standard consent procedures alone.[19] In the repeat back method, the patient is requested to explain, in her own words, the information presented by the healthcare practitioner. Then the practitioner clarifies and revises her explanation, periodically reassessing until the patient demonstrates recall and comprehension.[20] Repeat back methods have demonstrated significantly higher levels of comprehension ($p = 0.03$) in informed consent discussions of proposed elective surgeries and only required an additional 2.6 minutes ($p < 0.0001$).[21]

Overall, the process of obtaining informed consent benefits all parties, including healthcare institutions. Informed consent is both a legal requirement, mandated by every state,[22] and an ethical obligation. Engaging the patient in a discussion of his healthcare problem, the nature and ramifications of proposed treatment, alternatives to treatment, and his wishes and preferences associated with quality of life and his life plan was originally intended to uphold and respect the patient's individual autonomy and right of self-determination. Informed consent was never conceived, either in case law or from the perspective of biomedical ethics, as a *pro forma* exercise devoid of content and meaning. Obtaining informed consent is not merely another bureaucratic procedure, one more set of documents to sign and store in the patient's medical record. Rather, informed consent enshrines the primary responsibility of the healthcare provider, that is, the duty to care for her patient, and memorializes the right of the patient to participate equally in the healthcare process as an informed partner in the patient–physician relationship.

Healthcare Decision Making on Behalf of Children

It is generally accepted that parents and guardians are responsible for providing necessary goods and services for their children, including healthcare.[23] Overall, parents and guardians "have the right and duty to make decisions for their minor children,"[24] including decisions related to the child's health and well-being. But if a parent or guardian refuses to provide specific recommended medical treatment, a third party may petition the court to order the treatment against the parent's or guardian's wishes.[25] In such a case, the state may assert its *parens patriae* interests in the area of protecting the health and well-being of a minor. *Parens patriae* power "derives from the inherent equitable authority of the sovereign to protect those persons within the state who cannot protect themselves because of an innate legal disability."[26] For example, state interests may supersede those of the parents "if the parents refuse life-saving or therapeutic treatment for the minor."[27] With certain exceptions, minors may not authorize healthcare treatment for themselves without the permission of a parent or guardian.[28] Of note, medical decision making involving the care of an older child or adolescent should include, where feasible, the *assent* of the patient in conjunction with parental choice and physician recommendations.[29] Assent to testing and/or treatment of an older child or adolescent should include "helping the patient achieve a developmentally appropriate awareness of the nature of his or her condition," informing the patient regarding the likely impact and outcomes of testing and treatment, "soliciting an expression of the patient's willingness to accept the proposed care," and ensuring that there was no undue inducement or pressure to accept testing or treatment.[30] As well, states may grant decision-making authority (without the need for parental involvement) "to certain minors who are otherwise unemancipated but who have decision-making capacity."[31] Such individuals are described as *mature minors*.[32]

A *best interests standard* has been utilized when needed to assess the appropriateness of medical decision making by parents or guardians of a minor or by a mature minor.[33] But in a pluralistic society, defining the best interests of a child is complicated by religious, social, and cultural morays on "what constitutes acceptable child rearing and child welfare."[34] Parties may reasonably disagree regarding what treatment, if any, is in the best interests of a particular child. However, parents may breach their obligations toward their children and legal action may be required to override parental prerogatives.[35] Parental authority is not absolute and the state may intercede when parents act contrary to the best interests of a child,[36] such as in cases of neglect and abuse[37] and when the child's life is endangered.

A harm-based standard or *harm principle* has been proposed as a "basis for identifying the threshold for state action."[38] Rather than basing the necessity for state intervention on a child's best interests, which may be variously interpreted and argued, the harm principle justifies such intervention by assessing that the likely outcome of parental medical decision making exceeds a threshold level of harm to the child. For example, utilizing the harm principle, state interference with parental medical decision making is justified when (1) parents are placing their child at significant risk of serious harm by refusing to consent to treatment; (2) harm is imminent and immediate action is required to prevent such harm; (3) the proposed treatment is necessary to prevent serious harm to the child; and (4) most parents would concur that the state intervention was reasonable.[39] In contrast to determinations of best interests, in which a standard of reasonableness is applied to risk-benefit calculations regarding choice of treatment, the harm principle may represent "a more realistic framework to apply in pediatric surrogate medical decision-making, especially when there is a concern about the child's safety."[40]

Informed Consent for Those Who Have Never Had Decision-Making Capacity

In a discussion regarding experimentation with human subjects, the philosopher Hans Jonas described "the inflexible principle that utter helplessness demands utter protection."[41] This consideration is appropriately applied to medical decision making on behalf of persons who have never had decision-making capacity, including minor children and adults who have never attained such mental capability. As noted above, parents or guardians generally are responsible for medical decision making for minor children under their care. For an adult who has never attained mental capacity for medical decision making, a surrogate must decide for that person "whether to initiate and maintain medical interventions."[42] Most typically, the surrogate is a family member, but may be a "judicially appointed guardian or even a court."[43] Of note, adults lacking decision-making capacity are vulnerable and "unable to assert independent judgment or to effectively protest against any ill-considered surrogate decisions."[44]

Numerous ethical challenges confront surrogate decision making on behalf of never-competent persons, including assessing well-being, assessing quality of life, and ensuring the intrinsic human dignity of the individual for whom medical decisions are being undertaken.[45] As such, the choices of surrogate decision makers should occur within the context of the biomedical ethical principles of autonomy and justice. Further, medical decisions must not deprive the incompetent person of an opportunity such that the patient's development as a person is interfered with insofar as such development is possible.[46]

Temporary Loss of Medical Decision-Making Capacity in a Psychiatric Setting

Historically, there has been a common perception that persons with mental illness have diminished capacity to provide informed consent.[47] In certain circumstances, such an individual may be declared legally incompetent in the case where the patient has been assessed to lack capacity to make medical decisions on his or her behalf.[48] However, contrasting research has demonstrated that medical decision-making capacity is retained in a majority of psychiatric patients.[49] Diagnostic categories alone (e.g., depression, schizophrenia, Alzheimer's disease) do not equate with the presence or absence of medical decision-making capacity.[50] Thus, a prior or current psychiatric diagnosis in itself is not sufficient to determine that the patient in question lacks capacity for medical decision making. Such capacity is appropriately assessed in the context of the patient's current decisions and her underlying values.[51]

When evaluating a patient's capacity for medical decision making, "it is essential for physicians to obtain a mental status examination and formal assessment of cognitive function."[52] These procedures should be followed by use of an instrument such as the MacArthur Competence Assessment Tool for Treatment (MacCAT-T) to assess a patient's capacity to make treatment decisions.[53] The MacCAT-T utilizes a semistructured interview format to evaluate a patient's capacity for medical decision making in the areas of understanding information related to his condition and the proposed treatment, reasoning about the likely risks and benefits of proposed

treatment, appreciating his clinical circumstances and the consequences of his choice, and the ability to communicate his choice.[54]

Importantly, medical decision-making capacity may be optimized or restored by treating reversible disorders that affect cognition, such as mania or metabolic delirium, with reassessment of capacity following treatment.[55] As well, educational interventions[56] or alternate forms of communication such as visual aids may be utilized to enhance understanding and improve medical decision-making capacity.[57] Ultimately, as with any patient, if a patient with a psychiatric disorder has been assessed to lack capacity for medical decision making, those decisions made on her behalf should be in alignment with the patient's known values and preferences to respect her best interests and dignity as a human being.

Informed Consent for the Participation of Human Subjects in Medical Research: Standard of Care Research

As discussed in Chapter 3, the first principle of the Nuremberg Code (1947) declared that voluntary consent of human subjects is absolutely essential for participation in medical research.[58] Subsequent events, such as the inappropriate and unethical use of children as research subjects in the Willowbrook Hepatitis Experiments[59] and violations of the human rights of research subjects in the Tuskegee Syphilis Study,[60] led in 1991 to incorporation in the Code of Federal Regulations (CFR) of general requirements for informed consent for participation of human subjects in medical research (45 CFR 46, Subpart A, Basic HHS Policy for Protection of Human Research Subjects, is known as the "Common Rule").[61] But not all research is conducted in identical circumstances and issues have arisen regarding the nature and content of informed consent in studies involving "community consent" and studies involving treatment acknowledged as a "standard of care."

The SUPPORT (Surfactant, Positive Pressure, and Pulse Oximetry Randomized Trial) study, conducted between 2005 and 2009,[62] was an example of research focused on treatment that is deemed to be standard, that is, generally agreed upon, widely utilized, well-documented care that is accepted by medical experts as proper treatment. The SUPPORT project was directed at treatment of preterm extremely low birth weight (ELBW) infants. These infants require oxygen support and the study attempted to identify an ideal range of oxygen saturation that would minimize retinopathy (possibly leading to blindness) without increasing adverse outcomes such as lung damage, cerebral palsy, and death of the infant.[63] SUPPORT compared the results of randomizing more than 1,300 ELBW infants to oxygen saturation protocols at 85–89 percent (the lower end of the then currently used range at various institutions of 85–95 percent oxygen saturation) versus 91–95 percent (the upper end). In the study, severe retinopathy occurred less often among surviving infants in the lower-oxygen-saturation group, but death before discharge occurred more frequently in this group compared with those infants in the higher-oxygen-saturation group.[64] Critically, the SUPPORT data suggested "there is one additional death for approximately every two cases of severe retinopathy that are prevented."[65]

Subsequently, parents of several infants who had been enrolled in SUPPORT filed a lawsuit (*Looney v. Moore*) alleging the infants suffered "serious injuries as a result of participating in the study."[66] On August 13, 2015, the U.S. District Court for the Northern District of Alabama

found that the plaintiffs failed "to create a genuine issue of material fact as to whether their participation in the SUPPORT study probably caused their injuries."[67] Further, the plaintiffs were unable to establish that a lack of informed consent or a breach of fiduciary duty "probably caused the infant Plaintiffs' injuries."[68] As such, the court granted the defendants' motions for summary judgment as to all of the plaintiffs' claims, that is, the court decided the case in favor of the defendants.

Regarding the informed consent component, the *Looney* court was not ruling on the appropriateness or sufficiency of the informed consent process in the SUPPORT study or whether the informed consent forms met applicable standards, but rather whether a lack of informed consent had probably caused injuries to the infant research subjects.[69] An ethical analysis of the SUPPORT informed consent documents could not have been a factor in the *Looney* ruling, which was necessarily based on an assessment of issues of material fact related to proximate cause. But the ethics of the SUPPORT informed consent procedures was of great concern to regulatory agencies, scholars, and the general public. The SUPPORT study had necessarily incorporated an informed consent process as mandated by 45 CFR 46.116.[70] However, the study outcome of one additional death for approximately every two cases of severe retinopathy prevented "sparked a furor among bioethicists and public-safety advocates."[71] In May 2011, the Office for Human Research Protections (OHRP) received an email about SUPPORT alleging the researchers had not obtained informed consent.[72] The OHRP conducted a for-cause compliance evaluation and issued a determination letter on March 7, 2013, to the University of Alabama, Birmingham (the lead coordinating institution for SUPPORT). The determination letter stated that "the conduct of this study was in violation of the regulatory requirements for informed consent, stemming from the failure to describe the reasonably foreseeable risks of blindness, neurological damage and death."[73]

In the event, the OHRP determination letter was brought to the attention of the public by a consumer advocacy group. An article describing SUPPORT and related ethical issues[74] and a subsequent editorial[75] appeared in *The New York Times*. The *Times* article noted that the risks of the study were not properly communicated to the parents. The *Times* editorial asserted that the research study failed to meet the "most basic standard" of providing an informed consent document that "accurately described the risks and benefits of the research." Prominent scholars, bioethicists, and physicians weighed in on both sides. Some argued that the consent form "addressed the prevalent knowledge fairly and reasonably."[76] The investigators did not fail to obtain appropriate informed consent from the parents. Further, the OHRP determination would potentially inhibit the ability of "clinical research to answer important questions in daily practice."[77] Others asserted the SUPPORT informed consent documents were "seriously inadequate."[78] None of the consent forms used at the various study sites mentioned death as a possible risk of the oxygen protocols used in the study. Further, information that the "oxygen interventions in the study differed from usual clinical care" should have been disclosed in the consent forms.[79] Overall, the primary controversy centered on whether the requirements for informed consent in *comparative effectiveness research*, also known as *standard of care research*, needed to fulfill the basic elements of consent as identified in 45 CFR 46.116(a).[80]

Comparative effectiveness research (CER) or standard of care research compares outcomes among patients who have been randomized with protocols utilizing "different treatments that are both in widespread use."[81] Presumably, the results of CER studies assist physicians in selecting the best or optimal alternative between two differing therapies that both represent standards

of care. The ethical justification for CER is asserted to be the condition of *clinical equipoise*, in that the treatments being assessed are generally deemed to be of equivalent clinical effectiveness or utility. Clinical equipoise has been defined in the *Federal Register*:

> When the relative benefits and risks of the proposed intervention, as compared to standard therapy, are unknown, or thought to be equivalent or better, there is clinical equipoise between the historic intervention and the proposed test intervention.[82]

In other words, in the circumstances of clinical equipoise, there is "no good reason for thinking one [treatment] is better than another,"[83] thus fulfilling a primary ethical condition for conducting a randomized clinical trial. Of interest is the assertion that decisions regarding the existence of clinical equipoise in a particular treatment comparison are "a matter of science, not ethics."[84]

However, the provision of standard of care treatment as a component of a randomized clinical trial (a medical research protocol) does not equate to provision of such treatment in the clinical setting (the treatment of a patient by a healthcare provider in the context of the physician–patient relationship). Research subjects are not patients, and medical research must always be distinguished from medical treatment. The OHRP determination letter essentially identified these distinctions. The letter noted that the SUPPORT study consent form template "did not mention any risks relating to the randomization between the higher and lower levels of oxygen," although sufficient information had been available to know "that participation might lead to differences in whether an infant survived, or developed blindness, in comparison to what might have happened to a child had that child not been enrolled in the study."[85] The OHRP letter indicated that the U.S. Department of Health and Human Services (HHS) regulations (45 CFR 46.116(a)(2)[86]) require that informed consent documents include a description of any reasonably foreseeable risks and discomforts.[87]

The OHRP letter concluded that "the anticipated risks and potential benefits of being in the study were not the same as the risks and potential benefits of receiving standard of care."[88] Subsequently, HHS held a public meeting on August 28, 2013, on how IRBs assess risks of randomized clinical trials involving standard of care treatments and "what reasonably foreseeable risks of the research should be disclosed to research subjects in the informed consent process."[89] On October 20, 2014, the OHRP released its "Draft Guidance on Disclosing Reasonably Foreseeable Risks in Research Evaluating Standards of Care" and defined medically recognized standards of care as "treatments or procedures that have been accepted by medical experts as appropriate treatments or procedures for a given type of disease or condition and are commonly used by healthcare professionals."[90] Risk refers to the likelihood that harm or discomfort will occur as a result of participation in medical research, as well as the nature and magnitude of those harms or discomforts. The OHRP Draft Guidance stated, "The risks of research in a study include those risks of therapies that some participating subjects would face that are or could be different from the risks of therapies they would have faced without participating in the research study."[91]

Thus, it may be appropriately generalized that although treatment methods utilized in comparative effectiveness research may be similar to standard of care methods used in clinical practice, participation in such a research study entails unique risks. Those reasonably foreseeable risks must be disclosed to potential research subjects (or their parents, as in the SUPPORT study) in informed consent documents, per the general requirements for informed consent specified in the Common Rule. In standard of care research, "care" is altered "for the goal of obtaining

knowledge to help future patients."[92] The treatment protocol is chosen based on research aims rather than clinical judgment as to what is best for the patient. Harms for which patient-subjects are at risk may be identical to those in usual care, but owing to randomization and the purposes of research the probabilities of those harms occurring alter and may even be higher. Thus, informed consent documents in standard of care research must disclose those risks, so that potential research subjects are provided sufficient information on which to base an informed decision regarding their best interests. Optimally designed informed consent conversations and documents for any medical research study should emphasize the distinctions between research and treatment, and avoid implying that participation in the research study confers additional benefit to the patient-subject than would possibly be obtained by receiving treatment outside the study, that is, via usual care.

Informed Consent for the Participation of Human Subjects in Medical Research: Community Consultation versus Community Consent

Ethical decision making is frequently complex and ethical analysis of many situations, especially in healthcare, may identify conflict between or among competing ethical principles. For example, medical research directed toward finding new and more effective treatments for severe traumatic injury and sudden cardiac death is appropriately considered a public good and in society's best interests. But patients who have suffered such injuries are unable to provide consent for participation in what is termed *resuscitation research* or *emergency medicine research*. Emergency medicine research (EMR) investigates the use of medications and medical devices in the treatment of life-threatening situations in which the patient has lost consciousness or has otherwise lost the capacity for medical decision making, such as head injury, stroke, and heart attack. Including such a person in a resuscitation research study without her consent would violate her right of self-determination and the biomedical ethical principle of autonomy. But the new knowledge obtained via such research would likely provide future benefit to many members of society, thus fulfilling the biomedical ethical principles of beneficence and justice. Congressional hearings were held in October 1994 and the U.S. Food and Drug Administration (FDA) sponsored a public forum in January 1995 to evaluate the need and mechanisms for exceptions from informed consent in research conducted in emergency settings.[93] Subsequently, in October 1996, the Code of Federal Regulations published a new regulation, 21 CFR 50.24 (Title 21: Food and Drugs; Part 50: Protection of Human Subjects; Subpart B: Informed Consent of Human Subjects; 50.24: Exception from informed consent requirements for emergency research).[94]

The new regulation stated that an IRB may approve a clinical investigation without requiring informed consent of the research subjects, providing that numerous basic requirements have been documented.[95] The first condition requires the following:

1. The human subjects are in a life-threatening situation.
2. Available treatments are unproven or unsatisfactory.
3. The collection of valid scientific evidence is necessary to determine the safety and effectiveness of particular interventions.

The second condition notes that obtaining informed consent is not possible for the following reasons:

1. The subjects will not be able to give their informed consent as a result of their medical condition.
2. The intervention under investigation must be administered before consent from the subjects' legally authorized representatives is feasible.
3. There is no reasonable way to identify prospectively the individuals likely to become eligible for participation in the clinical investigation.

The third condition requires that participation in the research holds out the prospect of direct benefit to the subjects for the following reasons:

1. Subjects are facing a life-threatening situation that necessitates intervention.
2. Risks associated with the investigation are reasonable in relation to what is known about the medical condition of the potential class of subjects, the risks and benefits of standard therapy, if any, and what is known about the risks and benefits of the proposed intervention or activity.

The FDA recognized that, in the conduct of EMR, the individual's right of self-determination would be overridden for the research to proceed. Such an abrogation of a person's basic human rights could only be possible in the context of ethically valid competing interests, that is, the likely benefit to the person (now the research subject) and the likely benefit to society deriving from new knowledge obtained via conduct of the research study. In 21 CFR 50.24, in addition to the conditions listed above for IRB approval of EMR, the FDA included a further layer of "protections of the rights and welfare of the subjects":

1. Consultation with representatives of the communities in which the clinical investigation will be conducted and from which the subjects will be drawn.
2. Public disclosure to the communities in which the clinical investigation will be conducted and from which the subjects will be drawn, prior to initiation of the clinical investigation, of plans for the investigation and its risks and expected benefits.
3. Public disclosure of sufficient information following completion of the clinical investigation to apprise the community and researchers of the study and its results.[96]

The FDA Guidance for Institutional Review Boards and Clinical Investigators[97] notes that broader consultation with the community from which the research subjects will be drawn is needed for approval of emergency medicine research. Public community meetings would provide opportunities to discuss the research protocol, facilitate forthright presentations of the likely risks and benefits, and enable community members to present their concerns and objections. Additionally, as part of the community consultation process, the FDA Guidance recommends establishing a panel of community members from which the research subjects will be drawn. Membership in the IRB should be enhanced by adding members who are representative of the community. Various other methods should be developed "to ensure community involvement and input into the IRB's decision-making process."[98]

The FDA requirements for community consultation as part of an IRB approval process for proposed EMR generated a great number of comments.[99] Many questions arose regarding the appropriate and acceptable formats for the community consultations, such as meetings, radio

broadcasts, and newspaper advertisements. Comments inquired regarding the specific members of the community that need to be informed and how the IRB was to assess the effectiveness of the consultations. In the *Federal Register*, in October 1996, the FDA responded that "the IRB needs to provide an opportunity for broad community discussion."[100] The IRB is responsible for "listening and considering" the community's potential support and concerns "and then ultimately deciding whether the investigation should be modified, approved, or disapproved."[101] Reasonably, challenges of interpretation regarding the content and characteristics of the mandated community consultations persisted. Overall, the community consultation process was considered the least well defined of the requirements detailed in 21 CFR 50.24.[102]

Community consultation has been characterized as encouraging a "troubling displacement of individual autonomy."[103] As emergency medicine treatment is likely conducted primarily in poorer, low-income communities, considerations regarding the right of self-determination, equity, and justice should be especially emphasized. Thus, the requirement for community consultation was created to provide special protections "whenever an exception from informed consent is granted for emergency research."[104] Community consultation, performed conscientiously and intentionally, manifests respect for the autonomy of the person-subject as well as respect for the unique concerns and qualities of the community in which the proposed research will be conducted.

It is crucial to delineate the fundamental ethical goals of community consultation, which include enhanced protection and enhanced benefits,[105] in addition to the primary purpose of upholding the patient's right of self-determination. Regarding enhanced protection, community consultation may help identify concerns related to privacy, security of study data, the impact of the study on the community as a whole, and social justice. Conversations regarding enhanced benefits might focus on providing rehabilitative services for survivors of emergency medicine treatment and improvement of delivery of healthcare services in the community. Overall, community consultation helps to emphasize to the researchers their responsibility to attend to important community concerns.

Community consultation is distinct from *community consent*. Community consultation provides a mechanism for ensuring that the rights of patient-subjects are upheld in emergency medicine research, that is, in circumstances in which these persons are not able to make medical decisions on their own behalf. Community consent involves obtaining permission or approval to conduct a research study within a community. Valid community consent requires the presence of legitimate political institutions and leaders, such as are found in most aboriginal societies.[106] However, overall, numerous ethical concerns have arisen and ethical failures have ensued in the conduct of biomedical research done in developing countries.

Innovation, desire, and courage are required to implement the principles outlined in the *Belmont Report*—respect for persons, beneficence, and justice—in the real world. Developing protocols and policies relating to community consultation speak to the desire of all parties to obtain outcomes that benefit individuals, communities, and society, while simultaneously protecting the rights of patient-subjects and supporting the welfare of the community in which the research is done.

Patient Rights and Patient Responsibilities

The origins of the concept of rights are controversial from a scholarly perspective. Regarding early discussions of rights, the ancient Greeks used the noun phrase τό δίκαιον (*to dikaion*), literally meaning "the just (thing)." The expression *to dikaion* often signified an act required by justice. Various contemporaneous decrees upheld what could be termed just claims of individuals.[107] Aristotle, too, used the term *to dikaion*. In the *Nicomachean Ethics*, Aristotle indicated that what is equal is just. If disputants have gone to a judge and the judge restores equality, then the disputants say they have "their own."[108] Effectively, the disputants have had their rights restored. By the fourth century B.C.E., *to dikaion* had taken on the meaning of "subjective right." Later, in the thirteenth century C.E., Thomas of Aquino (1225–1274) stated in his *Summa Theologica* that justice denotes a kind of equality.[109] The right in an act of justice is established by its relation to other individuals. A thing is said to be just when it is the determining factor in an act of justice. Aquinas asserted that "right is the object of justice."[110] Subsequently, in the fourteenth century, the medieval Franciscan philosopher William of Ockham (c. 1287–1347) referred to "liberties conceded by God and by nature to all men."[111] Around 1400, the French theologian Jean Gerson (1363–1429) provided a useful definition of a right as "a faculty or power belonging to anyone according to right reason."[112] More recently, in *Leviathan* (published in 1651), Thomas Hobbes (1588–1679) described "the true Liberty of a Subject,"[113] that is, the things a member of a society commanded by a sovereign may, without injustice, refuse to do. Hobbes defined the law of nature as "the dictate of right reason."[114] Hobbes taught that we are under an "eternal obligation" to practice equity, that is, acts of justice, that are merciful and benevolent. We practice justice or equity because the law demands it.[115] Per Hobbes, the law of nature is a *command*, and one's duty is to "follow what is prescribed by law."[116] Later, in *Two Treatises of Civil Government* (originally published in 1690), in a discussion of the origins of societies and governments, John Locke (1632–1704) referred to the powers an individual has within "the permissions of the law of nature."[117]

Thus, overall, rights are associated with equality and justice. Rights may have a divine origin and may be located in a law of nature, per Hobbes and Locke, whose teachings continue to resonate and have relevance in today's societies. For example, the founding document of government in the United States, the Declaration of Independence, stated that all men [all persons] are created equal and have unalienable rights including life, liberty, and the pursuit of happiness.[118] A primary source for the rights enumerated in the Declaration of Independence is Locke's *Second Treatise of Civil Government*.[119]

Early in the twentieth century, W. N. Hohfeld published a fundamental analysis of legal rights,[120] which has been described as a "great model of philosophy."[121] Hohfeld identified four distinct legal conceptions of the term *right*, that is, right, privilege, power, and immunity. In elucidating the concept of *right*, Hohfeld indicated that the correlative of *right* is *duty*, that is, the existence of a duty implies that a right is held and, conversely, the existence of a right implies that a duty is owed. If a duty exists, then a person has a right to expect that the duty will be fulfilled. Hohfeld referenced *Lake Shore & M. S. R. Co. v.* Kurtz[122], which indicated that "A duty or a legal obligation is that which one ought or ought not to do. 'Duty' and 'right' are correlative terms. When a right is invaded, a duty is violated."

> In other words, if X has a right against Y that he shall stay off the former's land, the correlative (and equivalent) is that Y is under a duty toward X to stay off the place.[123]

Thus, if the purported right exists, then person A has a claim against person (or institution or government) B, in that person B has a duty toward person A. In these circumstances, person A has a *claim-right* against person B. A claim-right involves the existence of a duty. Person A has a claim against B if and only if person B has a duty to person A. For example, your friend requests that you lend him a book and he promises to return the book within a month. Based on his promise, your friend has incurred a duty to return your book, and you have a claim-right against him for that book's timely return.

In terms of healthcare, providers and institutions have a well-recognized duty to care, originating 2,400 years ago in the time of Hippocrates and his students. We can locate an initial formulation of the duty to care in the Hippocratic Oath:

> Into whatsoever houses I enter, I will enter to help the sick, and I will abstain from all intentional wrong-doing and harm.[124]

Much later, in 1803, Thomas Percival's *Medical Ethics* listed ministering to the sick as the first principle of medical conduct.[125] In 1847, *Medical Ethics* provided the basis for the AMA Code of Ethics. Article I, Section 1, stated that a physician should be "ever ready to obey the calls of the sick."[126] The historically based duty to care, implicit in these foundational documents and owed to all patients of all healthcare practitioners and institutions, establishes the existence of claim-rights of patients against those healthcare institutions and practitioners. But such claim-rights remained amorphous until the courts began to rule on cases involving alleged battery and patient consent.

As discussed in Chapter 3, the legal requirement for patient participation in healthcare decision making via the process of informed consent was essentially launched in *Pratt v. Davis*[127] and *Mohr v. Williams*,[128] supported in *Schloendorff*,[129] and effectively incorporated in case law by *Salgo v. Leland Stanford Jr. University Board of Trustees et al.* in 1957.[130] The *Salgo* court used the term "informed consent" for the first time,[131] requiring that physicians provide "full disclosure of facts necessary to an informed consent"[132] on the part of the patient. Over the ensuing decades, as the complexity of medical technology and medical decision making increased and the cost of healthcare skyrocketed, considerations regarding the quality of healthcare delivery, quality improvement, and patient outcomes assessment became paramount. A framework of additional patient rights evolved as healthcare institutions attempted to improve the process of healthcare delivery, with the intention of enhancing the patient experience, improving patient outcomes, and lowering costs. These subsequently enumerated patient rights are not legal rights, as such, but rather they are de facto rights, that is, promises the healthcare institution makes to the patient and obligations it declares it will fulfill on the patient's behalf. Thus, patients now have many "rights" beyond the primary right of self-determination as enumerated in *Schloendorff* that is enshrined in the doctrine of informed consent.

Patient Rights

Patient rights, as made available to patients at their specific healthcare institutions, generally include the following:[133]

- The right to be treated with respect, consideration, and dignity
- The right to receive communication in a language you can understand

- The right to receive respectful and compassionate treatment without discrimination as to race, religion, age, gender or gender identity, national origin, disability, or source of payment
- The right to receive emergency care if needed
- The right to receive care in a clean and safe environment
- The right to receive complete and understandable information from your physician regarding your diagnosis, prognosis, risks and benefits of treatment, likely outcomes of treatment, and alternatives to proposed treatment
- The right to provide written informed consent and participate in healthcare decision making
- The right to create an advance directive and appoint a healthcare proxy or surrogate decision maker
- The right to refuse treatment and be told of the effects such refusal may have on your health
- The right to choose or refuse to participate in medical research
- The right to privacy and confidentiality of communication and all information and medical records pertaining to your care
- The right to access your medical records
- The right to add information to your medical records
- The right to spiritual services
- The right to participate in your discharge planning and receive a written discharge plan
- The right to receive an itemized bill and an explanation of all charges

Overall, these rights, granted by healthcare institutions to their patients, support patient care from admission through discharge. The delineation and promulgation of patient rights represent an acknowledgment, by the healthcare institution and its healthcare providers, of the duty to care for the welfare and well-being of their patients. Implicit in that duty are claim-rights of patients upon healthcare providers and healthcare institutions for appropriate delivery of care. As well, the patient is a guest in the healthcare provider's office or the institution at which a patient is admitted for treatment. The patient–physician relationship that is established is a reciprocal interaction, in that each party has inherent responsibilities. Thus, holders of rights have corresponding responsibilities. For example, the patient is responsible for providing an environment in which the physician's actions may obtain maximum effect. In other words, the patient, too, is responsible for her health. In general, patient responsibilities may be located in Kant's categorical imperative: *"Act only on that maxim whereby you can at the same time will that it should become a universal law."*[134] Per Kant and, as discussed in Chapter 2, per renowned commentators in the Talmud[135] and the writers of the Gospels,[136] it is our duty to act toward others as we would have them act toward ourselves. Our actions are good, that is, our actions are ethical, in that if everyone performed those actions the world would be benefited.

Patient Responsibilities

Many healthcare institutions include a "Patient Bill of Rights and Responsibilities" in their packages of materials for incoming patients[137] and inform their patients that patient responsibilities are corollaries to patient rights. In general, if you are a patient, you are responsible for the following:

- Providing accurate and complete information regarding personal identification, current and past illnesses, hospital stays, medications, and other matters related to your health
- Providing a copy of your advance directive if you have one
- Becoming knowledgeable about your healthcare and your treatment plan
- Asking questions of your healthcare provider or nurse if you do not understand your treatment plan or what is expected of you
- Actively participating in healthcare decisions
- Following your healthcare provider's instructions and the agreed-upon treatment plan
- Telling your healthcare provider if there is a change in your condition or if problems develop during treatment
- Telling your healthcare provider if you believe you cannot follow through with your treatment
- Providing accurate information regarding health insurance or other sources of payment and paying your bills in a timely manner
- Treating all healthcare staff, other patients, and visitors with respect and courtesy
- Following all institution or office rules and safety regulations
- Assisting in maintaining a quiet environment and respecting the privacy of others
- Keeping appointments, being on time, or cancelling on a timely basis

An additional primary patient responsibility is to *pursue a healthy lifestyle.*[138] Although it may not be suitable for healthcare institutions to highlight this particular patient responsibility in their in-patient welcome materials, it is certainly appropriate and even necessary for individual healthcare providers to emphasize this responsibility in their consultations/conversations with patients and in their treatment of patients. Thus, overall, in the context of patient rights, patient responsibilities, and the healthcare provider's duty to care, it is the responsibility of both patients and healthcare providers to work together so as to achieve optimal delivery of healthcare services and obtain optimal outcomes.

Patient Abuse

The four principles of biomedical ethics mandate that all healthcare providers and staff ensure that their actions and activities manifest respect for persons and uphold the dignity of patients as human beings. In this regard, as an example of a professional code of conduct, the American Nurses Association Code of Ethics for Nurses states that "the nurse's primary commitment is to the patient ... the nurse promotes, advocates for, and protects the rights, health, and safety of the patient."[139] Patient abuse represents a breach of the duty of professional ethical conduct and

includes physical abuse, verbal abuse, and failure to act on behalf of a patient.[140] Failure to act is considered neglect as such failure may lead to physical or psychological harm. Importantly, these commitments are the expectation for all healthcare providers.

In the healthcare context, elder abuse may be considered a subset of patient abuse. For example, the California Welfare and Institutions Code defines *abuse of an elder or dependent adult* as any of the following:

- Physical abuse, neglect, abandonment, isolation, abduction, or other treatment with resulting physical harm or pain or mental suffering
- The deprivation by a care custodian of goods or services that are necessary to avoid physical harm or mental suffering
- Financial abuse[141]

The California Welfare and Institutions Code defines *mental suffering* as "fear, agitation, confusion, severe depression, or other forms of serious emotional distress that is brought about by forms of intimidating behavior, threats, harassment, or by deceptive acts performed or false or misleading statements made with malicious intent to agitate, confuse, frighten, or cause severe depression or serious emotional distress of the elder or dependent adult."[142]

Per the California Welfare and Institutions Code, *physical abuse* includes the following:

- Assault
- Battery
- Assault with a deadly weapon
- Unreasonable physical constraint
- Sexual assault
- Use of psychotropic medication for a period beyond that for which the medication was ordered pursuant to the instructions of a physician or surgeon[143]

Manifestations of physical abuse include abrasions, lacerations, bruises, fractures, burns, pain, depression, and delirium.[144] Manifestations of verbal or psychological abuse include subtle signs of intimidation, evidence of isolation of the victim, depression, and anxiety.[145]

Per the California Welfare and Institutions Code, *neglect* means "the negligent failure of any person having the care or custody of an elder or a dependent adult to exercise that degree of care that a reasonable person in a like position would exercise."[146] Neglect includes the following:

- Failure to assist in personal hygiene, or in the provision of food, clothing, or shelter
- Failure to provide medical care for physical and mental health needs
- Failure to protect from health and safety hazards
- Failure to prevent malnutrition or dehydration[147]

Manifestations of neglect include malnutrition, dehydration, poor hygiene, pressure ulcers or bedsores, and delirium.[148]

In the U.S., the federal and state governments and the District of Columbia all have statutes to protect older adults from neglect, physical abuse, and psychological abuse.[149] The large majority

BOX 7.3

Case Study: Failure of Informed Consent

A twenty-year-old student athlete, a right-handed starting pitcher on his college varsity baseball team, had injured his right shoulder. The team orthopedic surgeon ordered a magnetic resonance imaging study that showed a full-thickness tear of the supraspinatus (one of the four rotator cuff muscles). Arthroscopic surgery was recommended and the student signed an informed consent form, agreeing to undergo right shoulder arthroscopy and repair of the supraspinatus injury.

However, during the arthroscopic procedure the surgeon not only repaired the torn supraspinatus, but also repaired a small tear in the glenoid labrum (an internal fibrocartilaginous rim supporting the ball-and-socket structure of the shoulder joint) and removed two small bone spurs. Surgery appeared to have been successful, but two weeks after the procedure the student began to experience a persistent achy pain in the right shoulder. Within another two weeks, the achy pain had progressed to a sharp pain upon any attempt to elevate the right arm. Physical therapy was not helping, and ultimately the student was unable to participate in the current baseball season. Subsequently, in the claim against the orthopedic surgeon for medical malpractice, it was determined that the student had never been informed that additional procedures might be done during the arthroscopy.

Ethical Analysis

1. Discuss the failure to obtain appropriate informed consent in this case. Describe the types of information that should have been provided to the student to ensure he was fully informed. Discuss patient responsibilities in an informed consent process.
2. In the course of the malpractice action, the surgeon alleged he was acting in the patient's best interest by performing the additional arthroscopic procedures. In his professional opinion, the additional structural repair was necessary to optimize the postsurgical outcome. Discuss whether the surgeon's actions violated specific biomedical ethical principles and how these violations, if any, impacted patient rights.
3. Consider an alternate scenario in which the student obtained an optimal recovery. Discuss whether a positive outcome makes a failure to uphold patient rights retrospectively permissible.

of elder abuse legislation in the U.S. is state legislation. State laws related to elder abuse may be located in many state legal codes.[150] For example, California law mandates that certain individuals report known or suspected instances of abuse of an elder or dependent adult. California law states that

> Any person who has assumed full or intermittent responsibility for the care or custody of an elder or dependent adult, whether or not he or she receives compensation, including administrators, supervisors, and any licensed staff of a public or

> private facility that provides care or services for elder or dependent adults, or any elder or dependent adult care custodian, health practitioner, clergy member, or employee of a county adult protective services agency or a local law enforcement agency, is a mandated reporter.[151]

Thus, all healthcare providers and all employees in short- and long-term healthcare facilities are mandated reporters.

California law requires that

> Any mandated reporter who, in his or her professional capacity, or within the scope of his or her employment, has observed or has knowledge of an incident that reasonably appears to be physical abuse, abandonment, abduction, isolation, financial abuse, or neglect, or is told by an elder or dependent adult that he or she has experienced behavior, including an act or omission, constituting physical abuse, abandonment, abduction, isolation, financial abuse, or neglect, or reasonably suspects that abuse, shall report the known or suspected instance of abuse ...[152]

A mandated reporter who witnesses an incident of abuse, receives information or evidence regarding an alleged abuse, or is told by an elder or dependent adult of an incident that reasonably appears to constitute abuse, is required to make a report to local law enforcement. As well, concerned parties may report an incident of abuse to a local elder abuse hotline or adult protective services hotline.[153]

Regarding prevalence of elder abuse, a 2008 national survey indicated the rate was nine percent and a 2010 national telephone survey indicated the rate was ten percent.[154] In 2018, the World Health Organization (WHO) reported that approximately one in six older people experienced some form of abuse in 2017.[155] WHO stated that elder abuse constitutes a violation of human rights and includes physical abuse, sexual abuse, psychological abuse, abandonment, and neglect.[156] Regarding prevention of elder abuse, WHO recommended public and professional awareness campaigns, caregiver support interventions, caregiver training on dementia, residential care policies, and mandatory reporting of abuse to authorities.[157]

KEY TERMS

Informed Consent

Informed consent is required prior to initiation of any form of healthcare treatment. Informed consent refers to the process by which a patient is informed of the nature of the proposed treatment, the treatment's potential benefits and inherent risks, and alternatives to the proposed treatment. Informed consent requires that the patient indicate comprehension of the information provided. Informed consent must be given freely and obtained in the absence of coercion or undue influence.

DISCUSSION QUESTIONS

1. It could be reasonably asserted that patient rights include the right to receive appropriate and effective care. But in this context it is useful to recall the enormous waste in the U.S. healthcare system whose annual costs are more than US$3 trillion. In 2010, approximately 30 percent of healthcare expenditures were squandered on unnecessary procedures.[158] As the chair of your healthcare institution's resource optimization initiative, what efficiencies would you recommend to minimize such needless practices? How would you promote a campaign to improve delivery of effective healthcare services and avoid provision of unnecessary services in your organization? How would the availability of new resources impact patient care, patient outcomes, and patient satisfaction?

DO-IT-YOURSELF ETHICIST

1. During an office visit, a patient tells you she is going to stop taking her current medication for major depression as it is making her sleepy. In the context of the biomedical ethical principle of autonomy, describe your conversation with this patient. What types of communication skills are required in such a discussion? Is agreement necessary? How do you achieve resolution?
2. As a healthcare provider whose primary concern is the welfare and well-being of your patients, list three actions you can take on a daily basis to ensure that your patients' right of self-determination is upheld. What resources do you need to support you and your staff in this ongoing process?
3. How do the concepts manifested in enumerations of patient rights and responsibilities apply to your rights and responsibilities as a citizen? Evaluate three such comparisons.

REAL-WORLD APPLICATIONS—ETHICS AS A DOCTRINE OF ACTION

1. As a member of your healthcare institution's patient advocacy committee, you are tasked with upgrading your institution's "Patient Bill of Rights and Responsibilities." Using the above discussions regarding patient rights and responsibilities as a framework, discuss two additional patient rights and two additional patient responsibilities you would recommend as upgrades to your institution's policies. Discuss the necessity for these additions and how their inclusion will enhance delivery of healthcare services and improve patient outcomes and patient satisfaction.
2. Discuss three resources and/or specific activities that your institution can make available to your community on a regular basis that will assist community members to (1) better understand their right of autonomy regarding healthcare decision making and (2) help them to become more effective decision makers.

REFERENCES

[1]D. E. Hall, A. V. Prochazka, and A. S. Fink, "Informed Consent for Clinical Treatment," *Canadian Medical Association Journal* 184, no. 5 (2012): 533–540.

[2]C. H. Braddock III, S. D. Fihn, W. Levinson et al., "How Doctors and Patients Discuss Routine Clinical Decisions. Informed Decision Making in the Outpatient Setting," *Journal of General Internal Medicine* 12, no. 6 (1997): 339–345.

[3]C. Lavelle-Jones, D. J. Byrne, P. Rice et al., "Factors Affecting Quality of Informed Consent," *BMJ* 306, no. 6882 (1993): 885–890.

[4]A. Akkad, C. Jackson, S. Kenyon et al., "Informed Consent for Elective and Emergency Surgery: Questionnaire Study," *BJOG* 111, no. 10 (2004): 1133–1138.

[5]C. H. Braddock III, K. A. Edwards, N. M. Hasenberg et al., "Informed Decision Making in Outpatient Practice. Time to Get Back to Basics," *JAMA* 282, no. 24 (1999): 2313–2320.

[6]M. Kirsch, "The Myth of Informed Consent," *American Journal of Gastroenterology* 95, no. 3 (200): 588–589.

[7]Ibid.

[8]R. J. Morse and R. F. Wilson, "Realizing Informed Consent in Times of Controversy: Lessons from the SUPPORT Study," *Journal of Law, Medicine, and Ethics* 44, no. 3 (2016): 402–418.

[9]M. L. Linzer, T. R. Konrad, J. Douglas et al., "Managed Care, Time Pressure, and Physician Job Satisfaction. Results from the Physician Worklife Study," *Journal of General Internal Medicine* 15, no. 7 (2000): 441–450.

[10]T. R. Konrad, C. L. Link, R. J. Shackelton et al., "It's About Time: Physicians' Perceptions of Time Constraints in Primary Care Medical Practice in Three National Healthcare Systems," *Medical Care* 48, no. 2 (2010): 95–100.

[11]Ibid.

[12]C. Braddock III, P. L. Hudak, J. J. Feldman et al., "Making in Surgery," *Journal of Bone and Joint Surgery, American Volume* 90, no. 9 (2008): 1830–1838.

[13]S. A. Black, D. Nestel, T. Tierney et al., "Gaining Consent for Carotid Surgery: A Simulation-Based Study of Vascular Surgeons," *European Journal of Vascular and Endovascular Surgery* 37, no. 2 (2009): 134–139.

[14]Morse and Wilson, "Realizing Informed Consent," 405.

[15]Braddock et al., "Informed Decision Making in Outpatient Practice," 2313.

[16]The Joint Commission, *2009 Requirements Related to the Provision of Culturally Competent Patient-Centered Care. Hospital Accreditation Program (HAP)*, Informed consent (Standard RI.01.03.01) (Oakbrook Terrance, IL: Joint Commission, 2009).

[17]K. M. Cordaso, "Obtaining Informed Consent from Patients: Brief Update Review," in *Making Health Care Safer II: An Updated Critical Analysis of the Evidence for Patient Safety Practices. Evidence Report/Technology Assessment Number 211*, ed. Agency for Healthcare Research and Quality (Rockville, MD: U.S. Department of Health and Human Services, 2013), 465.

[18]C. Decker, S. V. Arnold, and O. Olabiyi, "Implementing an Innovative Consent Form: The PREDICT Experience," *Implementation Science* 3 (2008): 58, https://implementationscience.biomedcentral.com/articles/10.1186/1748-5908-3-58.

[19]V. Mason, A. McEwan, D. Walker et al., "The Use of Video Information in Obtaining Consent for Female Sterilisation: A Randomised Study," *BJOG* 110, no. 12 (2003): 1062–1071.

[20]Cordaso, "Obtaining Informed Consent from Patients," 467.

[21]A. S. Fink, A. V. Prochazka, W. G. Henderson et al., "Enhancement of Surgical Informed by Addition of Repeat Back: A Multicenter, randomized Consent Controlled Clinical Trial," Annals of Surgery 252, no. 1 (2010): 27–36.

[22]D. M. Studdert, M. M. Mello, M. K. Levy et al., "Geographic Variation in Informed Consent Law: Two Standards for Disclosure of Treatment Risks," *Journal of Empirical Legal Studies* 4, no. 1 (2007): 103–124, 105.

[23]*Yale Diagnostic Radiology v. Estate of Harun Fountain*, 267 Conn. 351 (2004), https://www.leagle.com/decision/2004618267conn3511604.

[24]K. Hickey, "Minors' Rights in Medical Decision Making," *JONA's Healthcare Law Ethics and Regulation* 9, no. 3 (2007): 100–104, 103.

[25]State of Connecticut Judicial Branch: Legal Guide—Medical Treatment of Minors, https://www.jud.ct.gov/juv_infoguide/IJCP_MedicalTreatmentMinors.html#fnContent39.

[26]*In re Grady*, 426 A.2d 467, 85 N.J. 235, 259 (1981).

[27]Hickey, "Minors' Rights in Medical Decision Making," 103.

[28]*State v. William B.*, 76 Conn. App. 730, 741–742, AC21592 (2003).

[29]American Academy of Pediatrics Committee on Bioethics, "Informed Consent, Parental Permission, and Assent in Pediatric Practice," *Pediatrics* 95, no. 2 (1995): 314–317.

[30]Ibid., 315–316.

[31]Ibid., 316.

[32]G. S. Sigman, "Exploration for Physicians of the Mature Minor Doctrine," *Journal of Pediatrics* 119, no. 4 (1991): 520–525.

[33]D. S. Diekema, "Parental Refusals of Medical Treatment: The Harm Principle as Threshold for State Intervention," *Theoretical Medicine and Bioethics* 25, no. 4 (2004): 243–264.

[34]American Academy of Pediatrics Committee on Bioethics, "Informed Consent, Parental Permission, and Assent in Pediatric Practice," 315.

[35]Ibid.

[36]Diekema, "Parental Refusals of Medical Treatment," 244.

[37]*Parham v. J.R.*, 442 U.S. 584 (1979).

[38]Diekema, "Parental Refusals of Medical Treatment," 250.

[39]Ibid., 252.

[40]A. L. Katz and S. A. Webb, "Informed Consent in Decision-Making in Pediatric Practice," *Pediatrics* 138, no. 2 (2016), doi:10.1542/peds.2016-1485.

[41]H. Jonas, "Philosophical Reflections on Experimenting with Human Subjects," *Daedalus* 98, no. 2 (1969): 219–247, 240.

[42]N. L. Cantor, "The Bane of Surrogate Decision-Making: Defining the Best Interests of Never-Competent Persons," *Journal of Legal Medicine* 26, no. 2 (2005): 155–205.

[43]Ibid., 156.

[44]Ibid.

[45]Ibid., 172.

[46]E-H. W. Kluge, "Incompetent Patients, Substitute Decision Making, and Quality of Life: Some Ethical Considerations," *Medscape Journal of Medicine* 10, no. 10 (2008): 237.

[47]B. A. Pescosolido, J. Monahan, B. G. Link et al., "The Public's View of the Competence, Dangerousness, and Need for Legal Coercion of Persons with Mental Health Problems," *American Journal of Public Health* 89, no. 9 (1999): 1339–1345.

[48]Ibid., 1339.

[49]D. Okai, G. Owen, H. McGuire et al., "Mental Capacity in Psychiatric Patients. Systematic Review," *British Journal of Psychiatry* 191 (2007): 291–297.

[50]J. M. Baruth and M. I. Lapid, "Ethics Case. Influence of Psychiatric Symptoms on Decisional Capacity in Treatment Refusal," *AMA Journal of Ethics* 19, no. 5 (2017): 416–425, 419.

[51]Ibid.

[52]Ibid., 421.

[53]T. Grisso, P. S. Appelbaum, and C. Hill-Fotouhi, "The MacCAT-T. A Clinical Tool to Assess Patients' Capacities to Make Treatment Decisions," *Psychiatric Services* 48, no. 11 (1997): 1415–1419.

[54]Ibid., 1416.

[55]Baruth and Lapid, "Ethics Case," 421.

[56]W. T. Carpenter Jr., J. M. Gold, A. C. Lahti et al., "Decisional Capacity for Informed Consent in Schizophrenia Research," *Archives of General Psychiatry* 57, no. 6 (2000): 533–538.

[57]Baruth and Lapid, "Ethics Case," 421.

[58]"The Nuremberg Code," in *Doctors of Infamy: The Story of the Nazi Medical Crimes*, eds. A. Mitscherlich and F. Mielke (New York: Schuman, 1949), xxiii–xxv. Also, the Nuremberg Code may be located online on the National Institutes of Health website, https://history.nih.gov/research/downloads/nuremberg.pdf.

[59]S. Goldby, "Experiments at the Willowbrook State School," *The Lancet* 297, no. 7702 (1971): 749; M. H. Pappworth, "The Willowbrook Experiments," *The Lancet* 297, no. 7710 (1971): 1181.

[60]*Final Report of the Tuskegee Syphilis Study Ad Hoc Advisory Panel, April 24, 1973*: Initial Recommendation, October 25, 1972 (Washington, DC: U.S. Department of Health, Education and Welfare, 1973), 18.

[61]45 CFR 46.116 General Requirements for Informed Consent, https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46.

[62]W. A. Carlo, N. N. Finer, M. C. Walsh et al., "Target Ranges of Oxygen Saturation in Extremely Preterm Infants," *New England Journal of Medicine* 362, no. 21 (2010): 1959–1969.

[63]Ibid., 1960.

[64]Ibid., 1959.

[65]Ibid., 1967.

[66]*Looney et al. v. Moore et al.*, WL 4773747 (N.D. Ala. 2015) (Case No. 2:13-cv-00733-KOB), 18 F.Supp.3d 1338 (Ala. 2014).

[67]Ibid.

[68]Ibid.

[69]The SUPPORT consent documents are available at https://www.citizen.org/sites/default/files/support-study-consent-form.pdf.

[70]45 CFR 46.116.

[71]Morse and Wilson, "Realizing Informed Consent," 402.

[72]Office of Inspector General, Department of Health and Human Services, *Memorandum Report, September 15, 2014*, 3, https://oig.hhs.gov/oei/reports/oei-01-14-00560.pdf.

[73]Letter from Lisa R. Buchanan, Compliance Oversight Coordinator, OHRP Division of Compliance Oversight, to Richard B. Marchase, Vice President for Research & Economic Development, University of Alabama at Birmingham, March 7, 2013, 2, https://www.hhs.gov/ohrp/sites/default/files/ohrp/detrm_letrs/YR13/mar13a.pdf.

[74]S. Tavernise, "Study of Babies Did Not Disclose Risks, U.S. Finds," *New York Times*, April 10, 2013.

[75]"Editorial: An Ethical Breakdown," *New York Times*, April 15, 2013.

[76]J. M. Drazen, C. G. Solomon, and M. F. Greene, "Informed Consent and SUPPORT," *New England Journal of Medicine* 368, no. 20 (2013): 1929–1930.

[77]Ibid.

[78]R. Macklin, L. Shepherd, and A. Dreger, "The OHRP and SUPPORT, Another View," *New England Journal of Medicine* 369, no. 2 (2013): e3.

[79]Ibid.

[80]45 CFR 46.116.

[81]J. D. Lantos and C. Feudtner, "SUPPORT and the Ethics of Study Implementation," *Hastings Center Report* 45, no. 1 (2015): 30–40.

[82]*Federal Register* 60, no. 183: 49086–49103, September 21, 1995 (60 FR 49086, 49093), https://www.gpo.gov/fdsys/pkg/FR-1995-09-21/pdf/95-23239.pdf.

[83]M. Angell, "The Ethics of Clinical Research in the Third World," *New England Journal of Medicine* 337, no. 12 (1997): 847–849.

[84]L. D. Richardson, R. Rhodes, D. F. Ragin et al., "The Role of Community Consultation in the Ethical Conduct of Research Without Consent," *American Journal of Bioethics* 6, no. 3 (2006): 33–35.

[85]Letter from Buchanan, 7.

[86]45 CFR 46.116.

[87]Letter from Buchanan, 9.

[88]Ibid.

[89]Office for Human Research Protections, Department of Health and Human Services, "Draft Guidance on Disclosing Reasonably Foreseeable Risks in Research Evaluating Standards of Care," October 20, 2014, https://www.hhs.gov/ohrp/regulations-and-policy/requests-for-comments/draft-guidance-disclosing-risk-in-standards-of-care/index.html.

[90]Ibid.

[91]Ibid.

[92]L. Shepherd, "SUPPORT and Comparative Effectiveness Trials: What's at Stake?" *Hastings Center Report* 45, no. 1 (2015): 44–45.

[93]U.S. Food and Drug Administration (FDA), *Exception from Informed Consent for Studies Conducted in Emergency Settings: Regulatory Language and Excerpts from Preamble—Information Sheet. Guidance for Institutional Review Boards and Clinical Investigators*, https://www.fda.gov/RegulatoryInformation/Guidances/ucm126482.htm.

[94]21 CFR 50.24, https://www.ecfr.gov/cgi-bin/text-idx?SID=23f295b5efc6976b867ed90aa3fd18ba&mc=true&node=se21.1.50_124&rgn=div8.

[95]Ibid.

[96]Ibid.

[97]FDA, *Exception from Informed Consent*.

[98]Ibid.

[99]*Federal Register* 61(192): 51349–51573, October 2, 1996 (61 FR 51349, 51513), https://www.gpo.gov/fdsys/pkg/FR-1996-10-02/pdf/FR-1996-10-02.pdf.

[100]Ibid., 51514.

[101]Ibid., 51514–51515.

[102]S. N. Vaslef, C. B. Cairns, and J. M. Falletta, "Ethical and Regulatory Challenges Associated with the Exception from Informed Consent Requirements for Emergency Research," *Archives of Surgery* 141, no. 10 (2006): 1019–1023.

[103]K. F. C. Holloway, "Accidental Communities: Race, Emergency Medicine, and the Problem of Poly-HemeÒ," *American Journal of Bioethics* 6, no. 3 (2006): 7–17.

[104]Richardson et al., "Role of Community Consultation," 33.

[105]N. Dickert and J. Sugarman, "Ethical Goals of Community Consultation in Research," *American Journal of Public Health* 95, no. 7 (2005): 1123–1127.

[106]C. Weijer, G. Goldsand, and E. J. Emanuel, "Protecting Communities in Research: Current Guidelines

and Limits of Extrapolation," *Nature Genetics* 23, no. 3 (1999): 275–280.

[107]F. D. Miller Jr., ed., *A Treatise of Legal Philosophy and General Jurisprudence*, vol. 6, *A History of the Philosophy of Law from the Ancient Greeks to the Scholastics* (Dordrecht, The Netherlands: Springer, 2007), 103–104.

[108]Aristotle, *Nicomachean Ethics*, Book V, chap. 4, 1132a15–30, in R. McKeon ed., *The Basic Works of Aristotle* (New York: Random House, 1941), 1008–1009.

[109]Thomas of Aquino: *Summa Theologica. Second Part of the Second Part*, Question 57, Article 1: Whether Right Is the Object of Justice, trans. Fathers of the English Dominican Province (Cincinnati, OH: Benziger Bros., 1947).

[110]Ibid.

[111]P. Boehner, *Collected Articles on Ockham*, ed. E. M. Buytaert (St. Bonaventure, NY: Franciscan Institute, 1958), 466.

[112]B. Tierney, "The Idea of Natural Rights, Origins and Persistence," *Northwestern Journal of International Human Rights* 2, no. 1 (2004): 1–12.

[113]T. Hobbes, *Leviathan*, reprinted from 1651 ed. (Oxford, UK: Clarendon Press, 1909), 166.

[114]T. Hobbes, *De Cive or The Citizen*, introduction by S. P. Lamprecht (New York: Appleton-Century-Crofts, 1949, 32.

[115]A. E. Taylor, "The Ethical Doctrine of Hobbes," *Philosophy* 13, no. 52 (1938): 406–424.

[116]Hobbes, *Leviathan*, 155.

[117]J. Locke, *Two Treatises of Civil Government*, introduction by W. F. Carpenter (London: J.M. Dent, 1924) (last reprinted 1943), 181.

[118]The Unanimous Declaration of the Thirteen United States of America, *Journals of the Continental Congress*, vol. 5, July 4, 1776, 510, https://memory.loc.gov/cgi-bin/ampage?collId=lljc&fileName=005/lljc005.db&recNum=93.

[119]A. J. Beveridge, "Sources of the Declaration of Independence," *Pennsylvania Magazine of History and Biography* 50, no. 4 (1926): 289–315.

[120]W. N. Hohfeld, *Fundamental Legal Conceptions as Applied in Judicial Reasoning, and Other Legal Essays* (New Haven, CT: Yale University Press, 1919).

[121]T. D. Perry, "A Paradigm of Philosophy: Hohfeld on Legal Rights," *American Philosophical Quarterly* 14, no. 1 (1977): 41–50.

[122]*Lake Shore & M. S. R. & Co. v. Kurtz*, 10 Ind. App. 60, 37 N. E. 303, 304 (1894).

[123]Hohfeld, *Fundamental Legal Conceptions*, 38.

[124]W. H. S. Jones, trans., "The Oath," in *Hippocrates*, vol. I (Cambridge, MA, Harvard University Press, 1957), 301.

[125]T. Percival, "Medical Ethics: Or, a Code of Institutes and Precepts, Adapted to the Professional Conduct of Physicians and Surgeons," in *The Works, Literary, Moral, and Medical, of Thomas Percival, M.D.*, vol. II (London: Cruttwell, 1807), chap. I, Precept I.

[126]Code of Ethics of the American Medical Association, adopted May 1847 (Philadelphia: Turner Hamilton, 1871).

[127]*Pratt v. Davis*, 118 Ill. App. 161 (1905); 37 *Chicago Legal News* 213.

[128]*Mohr v. Williams*, 95 Minn. 261, 104 N.W.12 (1905).

[129]*Schloendorff v. Society of New York Hospital*, 211 N.Y. 125, 105 N.E. 92, 93 (1914).

[130]*Salgo v. Leland Stanford Jr. University Board of Trustees et al.*, 317 P.2d 170, 154 Cal.App.2d 560 (1957).

[131]J. H. Krause, "Reconceptualizing Informed Consent in an Era of Health Care Cost Containment," *Iowa Law Review* 85 (1999): 261–386.

[132]*Salgo v. Leland Stanford Jr. University Board of Trustees et al.*, at 578.

[133]New York State Department of Health: *Your Rights as a Hospital Patient in New York State*, Section 2, rev. 2016, https://regs.health.ny.gov/content/section-4057-patients-rights; Johns Hopkins Hospital, *Patient Bill of Rights and Responsibilities*, https://www.hopkinsmedicine.org/patient_care/_documents/patient_rights/jhh/JHH_8.5x11_2sided.pdf.

[134]Immanuel Kant, "Fundamental Principles of the Metaphysic of Morals," in *Kant's Critique of Practical Reason and Other Works on the Theory of Ethics*, ed. T. K. Abbott, 6th ed. (London, Longmans, Green, and Co., 1909), 38.

[135]*Babylonian Talmud*, Shabbat 31a.

[136]King James Version, *The Scofield Study Bible* (New York, Oxford University Press, 2003), 1342.

[137]Mount Sinai Health System, *Patient Rights, Responsibilities and References*, last revised December 8, 2015, http://www.wehealny.org/services/BIMG/forms/PRREnglish.pdf; Johns Hopkins Hospital, *Patient Bill of Rights and Responsibilities*, 135.

[138]B. Chauhan and J. Coffin, "The New Era of Healthcare: Incorporating Patients' Rights and Responsibilities in Diabetes Management," *Journal*

of Medical Practice Management 29, no. 4 (2014): 245–247.

[139]American Nurses Association, *Code of Ethics for Nurses with Interpretive Statements* (Silver Spring, MD: American Nurses Association, 2015), v.

[140]J. K. Albina, "Patient Abuse in the Health Care Setting: The Nurse as Patient Advocate," *Association of Perioperative Registered Nurses Journal* 103, no. 1 (2016): 73–81.

[141]California Welfare and Institutions Code, "Definitions," §15610.07, https://leginfo.legislature.ca.gov/faces/codes_displayText.xhtml?lawCode=WIC&division=9.&title=&part=3.&chapter=11.&article=2.

[142]Ibid., §15610.53.

[143]Ibid., §15610.63.

[144]M. S. Lachs and K. A. Pillemer, "Elder Abuse," *New England Journal of Medicine* 373, no. 20 (2015): 1947–1956.

[145]Ibid., 1948.

[146]California Welfare and Institutions Code, "Definitions," §15610.57.

[147]Ibid.

[148]Lachs and Pillemer, "Elder Abuse," 1949.

[149]U.S. Department of Justice, "State Elder Abuse Statutes," https://www.justice.gov/elderjustice/elder-justice-statutes-0.

[150]National Center on Elder Abuse, "Public Policy: State Laws," https://ncea.acl.gov/whatwedo/policy/state.html.

[151]California Welfare and Institutions Code, "Mandatory and Nonmandatory Reports of Abuse," §15630(a), https://leginfo.legislature.ca.gov/faces/codes_displaySection.xhtml?lawCode=WIC&sectionNum=15630.

[152]Ibid., §15630(b)(1).

[153]California Department of Social Services, "Adult Protective Services (APS) County Contact Information," http://www.cdss.ca.gov/inforesources/County-APS-Offices.

[154]Lachs and Pillemer, "Elder Abuse," 1949.

[155]World Health Organization, "Elder Abuse," http://www.who.int/news-room/fact-sheets/detail/elder-abuse.

[156]Ibid.

[157]Ibid.

[158]H. Brody, "Medicine's Ethical Responsibility for Health Care Reform—The Top Five List," *New England Journal of Medicine* 362, no. 4 (2010): 283–285, http://www.nejm.org/doi/full/10.1056/NEJMp0911423.

Figure Credit

Fig. 7.1: Copyright © 2017 Depositphotos/BrianAJackson.

CHAPTER 8

End-of-Life Decision Making

Imagine the unimaginable. Consider a person, living a happy life, essentially minding his or her own business. Something happens. For example, the person might suffer a stroke (a cardiovascular accident) and be rendered unconscious. The person's spouse or partner finds their loved one prostrate, not responding, and calls 911. The emergency medical technicians (EMTs) arrive and the person is transported to the hospital, where numerous tests are done. The person is placed on artificial hydration and nutrition and everybody waits. The patient (the formerly independent person has become a "patient") appears to be asleep. Magnetic resonance imaging (MRI) shows there has been substantial bleeding into the brain. Importantly, no one knows what the person will be like when she wakes up. Will she have full capacity? In other words, will she be able not only to think for herself, but will she be able to express herself clearly? Will she be able to state her preferences and desires regarding medical treatment? Will she be able to make medical care decisions for herself? Will she be capable of understanding what is being said to her and able to respond appropriately? Additionally, will she be able to move her body purposefully? Will she be able to eat and drink on her own? Will she be able to walk around? Will she be able to read and watch TV? In other words, will she be the same person she was before she had her illness?

FIGURE 8.1 Aged, vibrant trees

The main problem facing patients and families is that, in such dire medical circumstances, everything we take for granted in terms of our functioning and capabilities as human beings is overturned. Even the most basic activities require incredible neurologic complexity. A person may wake up from a period of unconsciousness, and this could be a joyful outcome. But the person may now be incapable of feeding himself, attending to

physical needs, reading, writing, or any cognitive comprehension. Many people, if they had the choice, might elect to avoid such a possible scenario by stating in advance their desire not to be resuscitated.

Imagine another very difficult situation. A young person is driving his car and is hit head-on by a drunk driver. The young person had neglected to fasten his seatbelt and is launched through the windshield by the collision. Remarkably, he is alive when the EMTs and police arrive. He is breathing on his own, but he is unconscious. Artificial hydration and nutrition (ANH) is started at the hospital. Weeks go by and the patient remains unconscious. In this case, MRI has shown some bleeding into the brain, but the patient also has a *contrecoup* injury. His brain has been injured by banging into the bones on the opposite side of his skull. The patient may never wake up. If he does, it is unknown what capabilities will be retained. Remarkably, after several more months he does open his eyes. But it is demonstrated that he is unaware of his environment and unaware of himself. Essentially, he goes through sleep and wake cycles, but he is not conscious. He is in a vegetative state and after thirty days he is declared to be in a persistent vegetative state.

The clinical circumstances involving three young people, all of whom were in a persistent vegetative state, were at the center of subsequent legal battles and three landmark cases involving end-of-life decision making. As background to a discussion of these three cases, the characteristics of a persistent vegetative state will first be described.

Persistent Vegetative State

It is useful to distinguish between being conscious, being in a coma, and being in a persistent vegetative state (PVS). A person who is conscious demonstrates wakefulness (arousal; level of consciousness) and awareness (awareness of the environment and of self; content of consciousness).[1] Thus, a person in a coma is unconscious, as such a person is neither awake nor aware. A person in a PVS may be awake at times, but he is not aware of self or environment,[2] and such a person is also characterized as being unconscious. The distinguishing feature between coma and PVS is that, in a PVS, the person is awake. As the Multi-Society Task Force (MSTF) on PVS stated in 1994, "Awareness requires wakefulness, but wakefulness can be present without awareness."[3]

The term *persistent vegetative state* was first used in 1972 to describe the condition of severely brain-damaged patients in whom coma has progressed to a state of wakefulness in the absence of detectable awareness.[4] The clinical criteria for the diagnosis of PVS were established in 1990 by the AMA Council on Scientific Affairs and the Council on Ethical and Judicial Affairs.[5] A PVS is characterized by complete lack of awareness of the self and environment, accompanied by sleep-wake cycles. There is either partial or complete preservation of brainstem functioning. The patient can breathe on her own and does not require respiratory support. But ANH is required as the patient is unconscious, even though, in a wake cycle, her eyes are open. The Quality Standards Subcommittee (QSS) of the American Academy of Neurology published further definitions to clarify a diagnosis of PVS.[6] The QSS stated that a vegetative state may be defined as being persistent at one month. A PVS may be judged permanent at twelve months following a traumatic injury and at three months following a nontraumatic injury. The QSS states that criteria for diagnosis of PVS include no evidence of purposeful or voluntary responses to visual, auditory, or tactile stimuli and "no evidence of language comprehension or expression."[7]

Regarding the possibility of being maintained in a PVS, a 2003 study concluded that a substantial majority of people "would choose (prospectively) to reject life-sustaining treatment in a PVS if the operative assumption were that they would never recover consciousness."[8] Of course, critical information is required to assist one in making an informed prospective choice, that is, when one is crafting an *advance directive*. The key undertaking for physicians and patient advocates is to summarize such data in the best way possible so that an individual's advance directive represents her desires and preferences for what she wants to have happen in specific circumstances. The MSTF indicated that for adult patients in a PVS for three months following a traumatic brain injury, the probability of achieving moderate disability or making a good recovery at twelve months was 16 percent. The MSTF noted that patients with moderate disability are independent and can resume almost all activities of daily living. Each person needs to consider whether such odds are worth pursuing. In contrast, for adult patients in a PVS for three months after a nontraumatic brain injury (for example, as a result of stroke, heart attack, diabetic coma, or drowning), the probability of achieving moderate disability or making a good recovery at twelve months was 1 percent. These odds are considerably longer. For adult patients who had suffered a traumatic injury and were in a PVS for six months, only 4 percent were anticipated to achieve moderate disability or make a good recovery at twelve months. Zero percent of adult patients in a PVS for six months after a nontraumatic injury were expected to achieve moderate disability or make a good recovery at twelve months.[9] These data may also be viewed from the perspective of incidence, that is, actual outcomes, in contrast to probabilities. Of 434 patients in a PVS one month following a traumatic injury, 17 percent achieved moderate disability at twelve months and 7 percent achieved good recovery at twelve months. Of 169 patients in a PVS one month following a nontraumatic injury, only 3 percent achieved moderate disability at twelve months and only 1 percent achieved good recovery at twelve months.

Thus, at three months following a traumatic brain injury, some people might assess a 16 percent chance of a moderate or good recovery at twelve months to be acceptable. Such a person might state in her advance directive that she does not wish to be maintained on life-sustaining treatment if she continues to be in a persistent vegetative state six months following a traumatic brain injury, allowing for a possible recovery at up to six months. Others would assess the same 16 percent chance as unacceptable. Those individuals could state in their advance directives that they do not wish to be maintained on life-sustaining treatment beyond three months following a traumatic brain injury. In scenarios involving a PVS following a nontraumatic brain injury, such as in a stroke, heart attack, or diabetic coma, the likelihood of a moderate or good recovery is considerably poorer. An advance directive could state that a person does not wish to be maintained on life-sustaining treatment if he or she continued to be in a PVS three months following a nontraumatic brain injury.

Ultimately, of course, it is not possible to account for every scenario or clinical circumstance. But by including a few specific statements in an advance directive regarding two or three possible situations, the individual has empowered his surrogate to take appropriate action on his behalf. The surrogate will take such appropriate action in consideration of the patient's stated preferences and in the context of the specific clinical circumstances, that is, what has actually happened to the patient (the medical history) and the patient's current situation (the diagnosis, test results, and anticipated outcome).

Returning to the discussion of the young car-crash victim in a PVS, his family is dismayed, to say the least. It does not appear as if he will ever recover, but his body continues to function.

The choices are difficult for all involved. Naturally, as the patient was a young person, he never considered that anything like this could ever happen. People in their twenties may not often consider end-of-life circumstances. But the lack of such planning has placed this person's life and his family's well-being in a precarious situation. As discussed below, in the absence of an advance directive the possibility exists for the application of either *substituted judgment* or the *best interests standard*. But in the current scenario, as the patient had never made any statement about what to do if he were ever in such circumstances, everyone's options are limited. Had he sat down for an hour and composed an advance directive, the entire situation would be much different. An advance directive provides guidance. With an advance directive there is a legal framework from which to proceed. In the absence of such a document, medical decision making becomes challenging and potentially contentious.

Landmark Cases: Quinlan, Cruzan, Schiavo

Advance directives (formerly known as living wills) are a relatively new development in how we think about our interactions with doctors and hospitals. Historically, physicians were trusted advisers who could be counted on to make decisions with our best interests in mind. However, today, owing to advances in medical technology, patients may be kept alive in clinical circumstances in which, previously, natural processes and the normal course of events would have caused the patient to die. But in certain scenarios, being kept alive may not be in the patient's best interest. In critical end-of-life situations, if a patient has lost the cognitive ability to make her own decisions, what may be done to the patient in a hospital with the intention of saving the patient's life may have nothing at all to do with what the patient would have wanted for herself.

Physicians, nurses, and medical staff are trained to keep patients alive. Further, there is a legal presumption that a patient would wish measures to be taken to save his life. The quality of life that is the outcome of these life-preserving procedures is not a consideration. The patient may be left with a permanent requirement for a feeding tube (artificial nutrition and hydration), a breathing machine (a ventilator), or both. The patient may be left with a permanent loss of cognitive capacity and may never again be able to talk with family and friends, understand what is being said, or be able to recognize loved ones. A more extreme result of medical intervention to save a person's life is a persistent vegetative state, in which the patient is permanently unaware of self and environment.

Thus, the need for an advance directive is the direct result of modern developments in medical technology. Current technological innovations came about as a result of the desire to save more lives, and countless people have greatly benefited from cardiopulmonary resuscitation (CPR), feeding tubes, and ventilators. But the formidable problem in using such techniques and devices is that the ultimate outcome is unknown. Medical and emergency personnel can never predict how well a patient is going to function once she is brought back from the brink of death. Some patients will do well and thrive, possibly with minor or moderate but acceptable limitations and deficits. But others will be severely, permanently, impaired. Many people, given the choice, would not wish to "live like a vegetable." Many people would not wish to live a life in which they have substantially lost awareness of themselves and their environment. Many people would not wish to continue an existence in which they could not, in some form or another, read a book, watch television, or interact in any way at all with family and friends. Many people would choose not to undergo live-saving measures if the outcome would be such severe loss of quality of life.

As medical technology is omnipresent, at least in urban areas, it becomes important for individuals to provide themselves with a defense against unwanted, unasked-for medical interventions. Technology in the medical case, as in all others, is a mixed blessing. Such technology is good for some, but not good at all for others.

Karen Ann Quinlan

This dichotomy became very apparent, for the first time, in the case of Karen Ann Quinlan. On April 15, 1975, Karen, aged twenty-one, ceased breathing for two fifteen-minute periods. The cause of her cessation of respiration was unclear. She was taken to a local New Jersey hospital where an examination showed that her pupils were nonreactive and she was unresponsive, even to deep pain. Several days later a follow-up examination found her comatose with evidence of loss of cortical (higher brain) function. Ultimately, Karen's condition progressed to that of a PVS. She was maintained on a respirator, required artificial nutrition and hydration, and was supported by twenty-four-hour nursing assistance.

Ultimately, Joseph Quinlan, Karen's father, petitioned the court to be appointed his daughter's guardian. As her guardian, her father planned to authorize the discontinuance of all extraordinary medical procedures that were sustaining Karen's life. The Supreme Court of New Jersey declared that "no external compelling state interest could compel Karen to endure the unendurable."[10] The court ruled that Joseph Quinlan had the right to choose an attending physician. If the responsible attending physician determined that there was no reasonable possibility of Karen's returning to a cognitive, self-aware state, and that life-sustaining treatment should be discontinued, then upon agreement of the hospital ethics committee, the present life-sustaining procedures and equipment could be withdrawn. As a result of this ruling, the mechanical ventilator was discontinued. Subsequently, Karen survived in a PVS for almost an additional ten years and died in 1985.

Nancy Cruzan

A second landmark case involved Nancy Cruzan, a resident of the state of Missouri. On January 11, 1983, the twenty-five-year-old lost control of her car, was flung from her vehicle, and landed face-down in a water-filled ditch. Paramedics resuscitated her, even though they found no vital signs. Nancy was in a coma for three weeks and then was diagnosed as being in a PVS. Her parents wanted life support to be withdrawn, but the Missouri state hospital opposed their request. A trial court found that evidence of a conversation Nancy had had with a friend, in which she stated she would not want to live in such circumstances (as in a vegetative state), was sufficient to permit termination of artificial nutrition and hydration.[11]

But, in 1988, the Supreme Court of Missouri overturned the trial court's decision, ruling that such a conversation was insufficient.[12] The court ruled that no person can assume a choice for an incompetent patient (one who has lost cognitive capacity to reason and make judgments) in the absence of documentation required by the Missouri Living Will Statute or clear and convincing evidence required to prove a patient's intentions. A casual discussion with a roommate was deemed insufficient to meet the clear and convincing evidence standard. Further, the Missouri Supreme Court ruled that the Missouri guardianship statute did not provide authority for Nancy's parents to authorize termination of her nutrition and hydration support. The problem was that Nancy had not executed an advance directive/living will, nor had she appointed a surrogate to make decisions on her behalf.

The Cruzans appealed the Missouri Supreme Court decision to the U.S. Supreme Court. In 1990, in *Cruzan v. Director, Missouri Department of Health*, the Supreme Court ruled that Missouri has the right to apply a clear and convincing evidence standard in such a case. The state may "simply assert an unqualified interest in the preservation of human life to be weighed against the constitutionally protected interests of the individual."[13] Missouri recognizes that a surrogate may act for an incompetent patient, but requires that withdrawal of treatment be proved by clear and convincing evidence.

In her concurrence, Justice O'Connor narrowed her interpretation of this decision. She noted that few individuals provide "explicit oral or written instructions regarding their intent to refuse medical treatment should they become incompetent." Justice O'Connor stated that a surrogate decision maker's instructions regarding medical treatment may be constitutionally protected in the sense of upholding a patient's liberty interest under the due process clause of the Fourteenth Amendment. She indicated that a future court determination may rule that the Constitution requires the states to implement the decisions of a patient's duly appointed surrogate.

In the event, the Cruzans took their case back to the Missouri courts, having identified additional witnesses testifying to Nancy's wishes and desires regarding end-of-life circumstances. In December 1990, clear and convincing evidence was established and removal of the feeding tube was permitted. Twelve days later Nancy died, eight years after the auto crash that left her in a PVS.

Importantly, *Cruzan* affirmed that "a competent person has a constitutionally protected liberty interest in refusing unwanted medical treatment," including a constitutionally protected right to refuse lifesaving nutrition and hydration. The problem immediately arises of how to protect the rights of a person who is not competent to make medical decisions. The Supreme Court expressly stated in *Cruzan* that a competent person's constitutionally protected right to refuse lifesaving treatment "does not mean that an incompetent person should possess the same right, since such a person is unable to make an informed and voluntary choice to exercise that hypothetical right or any other right."[14] Thus, it is reasonable to conclude that additional rights and safeguards of those rights are required.

Terri Schiavo

Terri Schiavo, aged twenty-six, collapsed in her home on February 25, 1990. The cause of her collapse was later determined to be cardiac arrest resulting from a potassium imbalance. She was in a coma for several months, and subsequently emerged with a sleep-wake cycle, that is, her eyes would open following a sleep period. But Terri did not demonstrate any evidence of self-awareness or awareness of her environment. In other words, her cardiac arrest resulted in a PVS. She never regained consciousness.

After several years of attempts at various treatments, Michael Schiavo, Terri's husband, began to understand that her condition was irreversible and assert that his wife would not have wanted to be kept alive in a PVS. In contrast, Terri's parents insisted that their daughter be continued on life-sustaining artificial hydration and nutrition. Michael Schiavo took the matter to a Florida trial court (Sixth Circuit Court of Florida).[15] The trial court found in 2000 that Terri "did make statements which are credible and reliable with regard to her intention given the situation at hand," that is, she would not want to continue living in a condition such as that of a persistent vegetative state. The trial court found that Terri's oral declarations rose to the level of clear and convincing evidence of her preferences and intentions and ordered that Terri's guardian (Michael

Schiavo) was authorized to proceed with the discontinuation of life support. But Terri's parents, Robert and Mary Schindler, appealed the trial court's ruling permitting the withdrawal of the feeding tube that was keeping their daughter alive.

As the case progressed through the courts, the Schindlers maintained that new treatments might restore cognitive function to their daughter. They believed that Terri responded to them. A videotape was made public in which Terri appeared to be smiling and moaning in response to her mother's voice and appeared to follow a balloon with her eyes. However, the eyes of a person in a PVS may move about when the person is awake. The person may breathe, open her mouth, and yawn. But in a PVS there is no evidence of awareness of self or environment, no meaningful response to stimuli, and no receptive or expressive language.[16] Despite the presence of reflex behaviors that give the appearance of conscious interaction to those who hold onto hope for a miraculous recovery, restoration of consciousness after three months is rare in adults with PVS as a consequence of nontraumatic injury.[17] By the early 2000s, Terri Schiavo had been in a PVS for more than ten years. All available medical evidence indicated that recovery was not possible.

In 2001, the Florida Second District Court of Appeal upheld the trial court's decision.[18] The court stated that the trial judge had "clear and convincing evidence" upon which to base his decision. Subsequently, the Schiavo case played out in public view. An attempt was made to bring the case to the Florida Supreme Court, but the court declined to review the decision of the Second District Court of Appeal. Then redress was sought via the Florida state legislature. The legislature obliged and on October 21, 2003, passed Chapter 2003-418, "Act for the Relief of the Parents of Theresa Marie Schiavo" ("Terri's Law").[19] The law gave Governor Jeb Bush the authority "to issue a one-time stay to prevent the withholding of nutrition and hydration under certain circumstances" based on a set of criteria that applied specifically to Terri's clinical situation. The percutaneous endoscopic gastrostomy (PEG) tube was reinserted, but a year later the Florida Supreme Court declared Chapter 2003-418 unconstitutional, as it violated the separation of powers.[20]

Following refusal by the U.S. Supreme Court to hear an appeal, Judge George W. Greer (the trial court judge) ordered that the PEG tube be withdrawn on March 18, 2005. Three days later the U.S. Congress passed S.686 titled, "For the relief of the parents of Theresa Marie Schiavo,"[21] which was signed by President George W. Bush the same day. This act provided that a Florida U.S. District Court would hear a suit based on the "alleged violation of any right" of Terri relating to withholding or withdrawal of lifesaving treatment. But the U.S. District Court denied the Schindlers' request for a temporary restraining order,[22] stating a substantial likelihood of success on the merits of the claims had not been demonstrated. Specifically, violation of Terri's right to equal protection under the law, guaranteed by the Fourteenth Amendment, had not been demonstrated. Her life and liberty interests had been adequately protected. The court concluded that her "life and liberty interests were adequately protected by the extensive process provided in the state courts." Terri died on March 31, 2005.

One of the many conclusions that may be drawn from these three compelling, tragic cases is the importance of having an advance directive in place. Karen Quinlan, Nancy Cruzan, and Terri Schiavo each lived for many years in a PVS. In each case extensive time, effort, and resources were expended in attempts to obtain appropriate court decisions. State supreme courts were involved in the Quinlan and Cruzan cases. A district court of appeal was involved in the Schiavo case, as well as a state legislature and the U.S. Congress. The existence of a notarized advance directive, one that clearly stated the patient's preferences and desires concerning end-of-life circumstances and designated a person or persons to act as the patient's surrogate, would have facilitated much

more prompt resolution of each of these cases. Such a document would have provided answers to questions regarding clear and convincing evidence, questions such as those raised in Missouri as well as Florida. Interested parties might choose to challenge a decision to terminate life support, but the existence of an appropriately formatted advance directive would likely trump such attempts to interfere with a person's wishes regarding decision making at the end of life.

Creating an advance directive requires the willingness to set aside time to draw up a basic document and to consider potentially difficult and possibly deeply upsetting issues and circumstances. Various resources are available to provide assistance in this process. For example, a local hospital may periodically offer brief training sessions on completing an advance directive template. Taking these modest actions may greatly ease the burdens on patients and their loved ones if the unthinkable comes to pass. If the worst happens and an advance directive is not available, then the patient's future welfare and well-being may be at the mercy of the court system. A family's life savings and other assets could be swept away in an unending sea of hospital and long-term care expenses. Awareness of these possibilities will likely cause reasonably prudent people to take the necessary actions, specifically, to draw up an advance directive, have it notarized, inform selected friends and loved ones about the existence of such a document, and have the advance directive added to one's medical records.

Patient Rights

The U.S. Supreme Court long ago affirmed the principle of patient autonomy, that is, the patient's right to choose or refuse medical treatment. In the landmark 1914 Supreme Court decision, *Schloendorff v. Society of New York Hospital*,[23] Justice Benjamin Cardozo wrote, "Every human being of adult years and sound mind has a right to determine what shall be done with his own body." This frequently cited ruling enshrined the right of individual decision making with respect to healthcare. But the need for legal guidelines regarding medical decision making on behalf of a patient not of "sound mind" was not a consideration in the early part of the twentieth century. Life-and-death decisions were much more straightforward 100 years ago. It was a matter of course that a legal guardian would support lifesaving medical procedures on behalf of a patient who was not of sound mind, that is, one who lacked capacity.

But there was no cardiopulmonary resuscitation back then. There was no technology to provide artificial nutrition and hydration. These methods and tools for prolonging life had not been developed or invented as yet, and there was no notion of extending life beyond the body's own natural stopping point. Now, in the early part of the twenty-first century, indiscriminate application of life-preserving procedures may be reasonably construed as a roll of the dice with respect to predicting the capabilities and level of consciousness of the individual whose life has been brought back from the brink. A person might go to sleep one night, in the comfort of her home, fully in command of all her faculties and resources as a human being. But having suffered a massive stroke overnight, she might revive to a semblance of consciousness forty-eight hours later, bereft of all her higher cognitive functions and unable to care for any of her bodily processes. In the worst case, the person (now a patient) will never regain any of her lost abilities and will persist in such a state for months, years, or even more than a decade. This minimal level of existence, this highly compromised quality of life, has been thrust upon the patient by medical professionals with the best intentions, whose sole criterion is to preserve life at any cost. Justice

Cardozo, writing in 1914, did not account for the circumstance in which a person, no longer of sound mind, might wish to refuse medical procedures such as life-sustaining treatment, if only he or she were capable of doing so. Herein lies the necessity for writing an advance directive.

The cases of Karen Quinlan, Nancy Cruzan, and Terri Schiavo all emphasize the need for protecting one's rights and interests in the case in which one is no longer able to speak for oneself. But special requirements may inhere in the process of safeguarding these rights. In 1990, in *Cruzan*,[24] the Supreme Court affirmed that states have the right to "simply assert an unqualified interest in the preservation of human life to be weighed against the constitutionally protected interests of the individual." At issue was the means of expression and the appropriateness of such expression of the constitutionally protected interests ("rights") of an individual not of "sound mind." As states retain an unqualified interest in the preservation of human life, a state may appropriately require stringent evidence supporting a choice to terminate life. In *Cruzan*, the state of Missouri required *clear and convincing evidence* that Nancy would not want her life to be preserved in a PVS. Ultimately, clear and convincing evidence was established and removal of a feeding tube was permitted. But Nancy had had to persist in a vegetative state for eight years until the courts resolved her status and she was legally allowed to die.

Thus, based on the 1914 *Schloendorff* decision, individuals who have capacity to make medical decisions (that is, individuals who are of "sound mind") have the right to refuse cardiopulmonary resuscitation and artificial nutrition and hydration. An advance directive formalizes these preferences at a time when the person is of sound mind. Additionally, many jurisdictions, including the states of New York and California, have legislated the right to appoint a surrogate to make medical decisions on an individual's behalf when the individual is not of sound mind, and an advance directive embodies this right. However, it is important to recognize that casual conversation with a friend or even a spouse regarding one's desire not to live "like a vegetable" may fail the clear and convincing evidence test in many jurisdictions. Hospital ethics committees may find such assertions on the part of well-meaning family members and friends insufficient to withhold or withdraw life-sustaining treatment. If a person is concerned regarding the possibility of his or her life being prolonged by medical treatment in circumstances that she or he would find unacceptable, the person must formalize her preferences and wishes in an advance directive. A lucid, consistent document, whose existence is known by a family member and/or close friend, will help fulfill a clear and convincing evidence standard.

In his dissenting opinion in *Cruzan*,[25] Justice Stevens referenced the dissenting opinion of Judge Blackmar of the Supreme Court of Missouri in *Cruzan v. Harmon*. Judge Blackmar had written, "It is unrealistic to say that the preservation of life is an absolute, without regard to the quality of life. ... It is appropriate to consider the quality of life in making decisions about the extraordinary medical treatment."[26] Emergency responders usually do not know how long a person has been unconscious or for how long his or her heart has stopped. Without instructions to the contrary, these well-meaning professionals will attempt to restore a heartbeat or attempt to ensure the person is receiving proper nutrition to maintain life if she or he is unconscious. But such good intentions may have quite negative outcomes, in the case in which the person whose life has been "saved" wakes up to an unacceptably diminished quality of life. Advance directives were designed to counter such possibilities and ensure the ability to assert the *negative right* to refuse medical care.

When one is sitting in the comfort of one's home, facing a computer screen or reading on a portable device, such scenarios may seem far-fetched or unlikely. But the purpose of an advance

directive is to guard against the worst. People have the right to declare their preferences regarding refusal of medical treatment in an emergency situation, in an end-of-life situation, or otherwise. People have the right to refuse treatment, regardless of the nature of the outcome. If one would not wish to continue living if being alive required being attached to tubes and machines twenty-four hours a day for months or years, then it is critically important to memorialize one's wishes in an advance directive. Based on the biomedical ethical principle of autonomy, that is, a patient's right to choose or refuse treatment, medical providers are required to honor a patient's stated wishes, even in life-or-death circumstances. They may try to persuade the patient's family to institute treatment or maintain current treatment. But the patient's surrogate is empowered to uphold the patient's desires and make sure her rights are observed, provided the patient has documented clear and convincing evidence of her wishes.

Again, it is important to consider these things when a person is well. Unforeseen events are by their very nature unexpected and unpredictable. By creating an advance directive, if the worst does occur, an individual has protected his future and, by implication, the future of his loved ones. An advance directive is one's best protection against uncertainty. Without formal documentation of a person's wishes and preferences, her friends and loved ones will have to expend great quantities of time and energy to try to ensure that she lives or dies on her own terms. Memorializing one's preferences in an advance directive is the best strategy for all concerned.

Advance Directives

An advance directive is a legal document by which an individual can specify personal preferences and desires regarding healthcare decision making in circumstances in which the person is not able to speak on his or her own behalf. An advance directive provides a formal record of one's wishes in situations requiring medical decision making, in the case in which a person, having previously had the cognitive capacity to make one's preferences known, has lost such capacity, temporarily or permanently. However, if one has not enacted a formal advance directive, one's medical treatment is determined by the medical standards of the community. Typically, any and all available lifesaving measures will be utilized when needed, based on the presumption that saving a life is always better than the alternative. This is probably not what many people would want, given the significant loss of quality of life that typically accompanies lifesaving treatment following prolonged loss of consciousness associated with traumatic brain injury and heart attack.[27] In many cases one's life, as such, has been saved. But much of what one has always taken for granted, such as speaking, writing, reading, feeding oneself, and generally taking care of oneself, has been lost or substantially compromised. An advance directive helps to counter such eventualities by formalizing what a person wants and

FIGURE 8.2 Signing an advance directive

does not want done in a severe healthcare emergency. The origins of advance directives may be traced to the endorsement of a model living will by the Euthanasia Society of America in 1967[28] and description of the concepts and framework of a living will in 1969.[29]

The most important thing about an advance directive is having one. Preparation time will help a great deal in creating an effective document. There are numerous official websites that offer instructions on how to compose a suitable and appropriate advance directive. For example, the New York State Bar Association makes relevant forms freely available, including a New York health care proxy form provided by the New York State Department of Health.[30] On the West Coast, California Probate Code Section 4701 enumerates a highly detailed, comprehensive advance healthcare directive form.[31] This well-designed template contains a section for designating one's agent (durable power of attorney for healthcare), specific statements regarding one's agent's authority and when such authority becomes effective, and several sections regarding instructions for healthcare, such as end-of-life decisions. The state of West Virginia provides a combined medical power of attorney and living will form.[32]

Other important resources include community groups and church/synagogue groups. Senior citizen activist groups such as AARP provide assistance in composing advance directives. For example, "Advance Directive: Creating a Living Will and Health Care Power of Attorney"[33] provides valuable definitions for key concepts and several useful links, including a page where one may download state-specific advance directive forms.[34] Spending a few hours over the course of two or three days will enable a person to investigate and assess potential choices in preparation for writing an advance directive.

Most of the advance directive templates include a section labeled "other wishes" or "optional" where one may specify, in one's own words, personal desires and preferences regarding medical decision making. It is critically important to be as specific as possible. Merely saying "I want to die in peace" is far from sufficient. Most hospital staff will interpret this in their own way, and their understanding of "dying in peace" may differ vastly from the person's intentions. For example, a patient may not want to be kept alive in unacceptable circumstances, but what is actually happening is the patient is being given pain-killing medication to dull the senses and keep the patient "peaceful."

The two main components of a person's specifications or orders are the procedures one wants to avoid and the quality of life that one will find acceptable. Writing an advance directive may be very challenging. It may be upsetting to think about types of medical treatment and their consequences, or to consider which compromises to quality of life one would deem acceptable, especially as people are generally accustomed to being healthy and well. Most people will continue to be healthy. But the unexpected may happen, and a few hours spent in researching and composing an advance directive may make all the difference in providing an optimal outcome in dire medical circumstances.

Medical treatments that will likely be of concern and about which one may want to specify special instructions include CPR, artificial nutrition and hydration, artificial respiration, surgical procedures, and dialysis. Importantly, a person needs to be as precise as possible when communicating one's wishes and preferences. A person could state, "Do not resuscitate me if the amount of time I've been unconscious is unknown or greater than four minutes." One could specify, "If after thirty days I have not regained my ability to feed myself, and I am unable to communicate my preferences or desires via speech, writing, or other method, then I want any and all lifesaving measures, such as artificial nutrition/hydration/ventilation, to be discontinued."

Then, one should be as clear as possible about the quality of life one finds acceptable. A person could state, "I don't want to live like Karen Quinlan, Nancy Cruzan, or Terri Schiavo. In other words, I don't want to live for longer than thirty days in a persistent vegetative state. I don't want to live if I am unable to communicate or have lost the mental capacity to think for myself. I don't want to live if I can't meaningfully read a book or watch TV. I don't want to be dependent on others for the maintenance of my physical functioning." Specifying the quality of life that is acceptable will help others, that is, the person's family, friends, and hospital staff, understand one's intentions and help them to uphold the person's wishes and desires.

Advance Directive Outcomes

Despite a person's best efforts, hospital staff may be reluctant to implement one's preferences and desires regarding medical decision making. It is important to recognize that implementing a decision to terminate life support is not made by one staff member on his or her own. For example, the attending physician on the day shift may support such a course of action, but the night shift attending physician does not. Or the hospital ethicist is in favor of upholding the patient's advance directive instructions, but members of the nursing staff believe another month of watchful waiting is appropriate. Hospital administrators may be concerned with adverse publicity. Hospital legal advisors may recommend caution in the face of resistance by family members who were not named as the patient's surrogate. Most hospitals are required to have institution-wide ethics committees to manage their approach to such important issues. The formation of hospital biomedical ethics committees has been based on the 1992 mandate of the Joint Commission (then the Joint Commission for the Accreditation of Healthcare Organizations) that U.S. hospitals establish procedures for consideration and education regarding ethical issues in patient care.[35] Committee membership typically includes representatives from the major hospital medical departments, the nursing department, and the social work department; hospital administrators; the hospital ethicist; and community clergy and other interested citizens. Ultimately, the clarity and specificity of a patient's advance directive will help all concerned parties reach the conclusions that one wished them to reach regarding one's medical care.

Advance directives are not only for those who are over age sixty-five. All adults older than age twenty could benefit from the security potentially provided by an advance directive. Each of the three signature court cases in this arena, concerning Karen Quinlan, Nancy Cruzan, and Terri Schiavo, involved women in their twenties. As noted above, it was not sufficient for Terri to have told her husband and close friends that she would not want to "live like that," that is, in a PVS. Beyond telling family and friends about one's desires and preferences, an advance directive helps ensure, as much as is reasonably possible, that these preferences regarding medical treatment are followed and upheld.

Importantly, when writing an advance directive, one specifies the person who is legally empowered to make medical decisions on one's behalf. Such a person, known as a *surrogate* or *healthcare proxy*, is the person authorized by the patient to make medical decisions for her if she has become unable to do so. Both California and New York specify that one's healthcare proxy or surrogate has the power to direct the provision, withholding, or withdrawal of artificial hydration and artificial nutrition, as well as use of or withholding of cardiopulmonary resuscitation. A person may provide his surrogate or healthcare proxy with as much authority as he wishes.

Once one's advance directive documents are completed one may, in some jurisdictions, register these legal papers with a state agency. California, for example, maintains an Advance Health Care Directive Registry.[36] Additional steps to take include distributing copies of the advance directive and healthcare proxy form to one's proxy or surrogate, close family members, family physician, and attorney. A person may instruct her family physician to include a copy of her advance directive in her medical record. Also, one could carry a wallet-sized card specifying the location of one's advance directive documents.

Implementing an Advance Directive

Thinking about one's own death may be extraordinarily difficult. It may be stressful and upsetting to even consider such a possibility. But presuming that one chooses to engage in the task of writing an advance directive, the first activity should focus on what living circumstances are acceptable. Does one wish to maintain life at any cost? For many, this is a self-evident proposition. Life itself is a primary good. For such persons, an advance directive is not needed. Medical science has the ability to prolong life for those with a serious illness far beyond what would occur if nature were left to take its course. Of course, without such intervention, the person's physiological life-sustaining mechanisms would fail and he or she would die. From many points of view, these measures provide appropriate and valuable extension of life. But if life-at-any-cost does not represent an acceptable outcome or is not a match for one's philosophy of living, enacting an advance directive helps provide a mechanism for safeguarding one's future.

In the worst case, a person may suffer a serious brain injury that causes him to lose not only substantial functional ability, but also the capacity for decision making. The most extreme scenario is a PVS. In a less extreme situation a person may regain consciousness following a stroke, but has lost the ability to understand others or to make herself understood. Such circumstances represent damage to regions of the brain known as *Broca's area* or *Wernicke's area*. The loss of ability to understand or express speech is termed *aphasia*. The ongoing challenge for medical personnel is to assess the likelihood of such a person regaining his ability to communicate. Aphasia may be permanent. From one's current perspective as a person with full decision-making capacity, one may consider various potential scenarios and decide one would not wish to continue to live under such constraints. But for one's surrogate to be able to make one's preferences and desires known, one's choices need to be specified in an advance directive.

Once a patient has been resuscitated via CPR and/or brought back to consciousness by means of various medical procedures, applying the specifications in an advance directive may be problematic if one has not been sufficiently precise. For example, one's surrogate may personally find it very difficult to "pull the plug," that is, to insist on removal of life-sustaining therapy such as artificial nutrition and hydration. One can counter this natural reluctance in two ways. First, as discussed above, by being as specific as possible in the section of the advance directive that identifies preferences and wishes. Second, the person who will serve as one's surrogate must be carefully selected and the content of the advance directive must be discussed with that person, regardless of whether he or she is a family member or friend. In the discussion, one will emphasize that the surrogate will be carrying out the wishes one has specified. A person's surrogate will speak on one's behalf, stating the choices one has specified in one's advance directive. Importantly, it should be made clear to the surrogate that he or she is not the person making

the decision, for example, to remove life-sustaining treatment. The patient is the one who has made that decision. The surrogate will make the patient's choices known, in the event that the patient is not able to do so.

Circumstances vary under which the provisions of an advance directive become applicable, depending on one's state of residence. For example, the California advance care directive form[37] (California Probate Code Section 4701) provides a "Choice Not to Prolong Life" checkbox. This choice would apply when (1) there is an incurable or irreversible condition that will result in death within a relatively short time; (2) the patient is unconscious, and there is a reasonable degree of medical certainty that consciousness will not be regained; or (3) "the likely risks and burdens of treatment would outweigh the expected benefits."[38] The California advance care directive form also states "you may strike any wording you do not want."[39] Thus, the conditions for implementing an advance directive are somewhat fluid and may be subject to interpretation by the ethics committee of the hospital in which one is a patient. A person will assist all parties concerned in following one's preferences for end-of-life care by ensuring that (1) one's surrogate understands one's precise wishes and (2) the instructions listed in the advance directive are as specific as possible.

In another jurisdiction, the New Jersey Department of Health indicates that life-sustaining treatment (LST) may be withheld or withdrawn when (1) a person is permanently unconscious or in a terminal condition, (2) LST would only prolong an imminent death or would likely be ineffective, or (3) LST would likely be of more harm than benefit.[40] Again, a person's advance directive statement, that in the case of prolonged loss of cognitive awareness one would consider that the risks and burdens of treatment would outweigh the expected benefits, may help fulfill requirements such as those in New Jersey for implementation of one's end-of-life care requests. For example, a person could state, "I wish life-sustaining treatment to be withheld or withdrawn if I have been deemed permanently unconscious or if my condition is terminal. I wish life-sustaining treatment to be withheld or withdrawn if such treatment would only prolong an imminent death or would likely be ineffective." Reiterating in one's advance directive the language of one's home state's requirements, and adding appropriate qualifiers, may assist the responsible parties, that is, a person's surrogate and hospital staff, in upholding one's stated preferences and wishes.

Physician Orders for Life-Sustaining Treatment (POLST)

Physician orders for life-sustaining treatment (POLST) forms supplement a patient's advance directive, which designates a surrogate decision maker. These documents are mutually supportive. A POLST form specifically details medical orders and informs emergency personnel regarding which treatments a person wishes to be performed during a medical emergency. As with an advance directive, a patient's POLST form should represent the outcome of conversations regarding healthcare decision making between the patient and her family, and between the patient and her healthcare provider. Overall, POLST orders restricting medical interventions have been associated with lower use of life-sustaining treatment.[41] Optimally, all adult patients of all ages and in all medical circumstances have completed both an advance directive and a POLST form, and both are included in the patient's medical record.

As well, POLST documentation is intended to be used in all community settings and guides medical decision making for patients who are likely to die within the next twelve months.[42] For example, POLST forms provide standardized medical orders for patients who are frail or have advanced, progressive illnesses.[43] Inclusion of POLST documentation in a patient's medical record assists healthcare providers in honoring patient treatment preferences and helps ensure that these preferences are upheld across a range of patient care settings, including long-term care, assisted living, and hospice facilities.

Many states have approved physician order forms that incorporate a patient's desires and preferences regarding medical treatment in end-of-life circumstances. For example, the New York State Department of Health has approved a MOLST (medical orders for life-sustaining treatment) form, which documents a patient's treatment preferences regarding use of life-sustaining treatment. The MOLST form is the only authorized form in New York for documenting nonhospital do-not-resuscitate (DNR) and do-not-intubate (DNI) orders. Additional information on New York's MOLST form is located online (https://www.health.ny.gov/professionals/patients/patient_rights/molst/). In California, the physician orders for life-sustaining treatment (POLST) form was developed by the Coalition for Compassionate Care of California and is approved by the California Emergency Medical Services Authority. As does the MOLST form, the POLST form documents a patient's desires and preferences regarding medical treatment in end-of-life circumstances. Additional information on California's POLST form is located online (http://www.emsa.ca.gov/DNR_and_POLST_Forms).

Ultimately, in consideration of the potential finality of end-of-life decision making, many more parties than the patient may be involved in a patient's medical care. As discussed above, the Supreme Court has affirmed in *Cruzan v. Director, Missouri Department of Health* that "a competent person has a constitutionally protected liberty interest in refusing unwanted medical treatment."[44] The *Cruzan* decision enshrines a constitutionally protected right to refuse lifesaving nutrition, hydration, and ventilation. Thus, if one is conscious and has capacity to make medical decisions, one has the right to refuse treatment. When a person has lost capacity for medical decision making, one's advance directive and surrogate, in combination with the POLST form that has been included in the medical record of one's primary care physician, represent the best means for having one's wishes and preferences fulfilled.

The evolution of methods intended to uphold a patient's autonomy and maintain respect for persons in the context of medical decision making in end-of-life circumstances, ranging from advance directives, to durable power of attorney for healthcare (DPOA), to documents combining an advance directive and DPOA, to POLST, has been described as a trajectory from a legal transactional approach to a communications approach.[45] Overall, at present, POLST documentation supplements an advance directive and bridges the gap between the patient's preferences, desires, and goals and "implementation of the actual plan of care as embodied in the physician's orders."[46]

End-of-Life Decision Making and LGBT Communities

Since 2010, beginning with the 2010 Presidential Memorandum on Hospital Visitation,[47] several federal initiatives have addressed the healthcare concerns of lesbian, gay, bisexual, and transgender (LGBT) persons. In his 2010 memorandum, President Barack Obama noted the failure to

respect the wishes of many Americans, including gay and lesbian persons, widows or widowers with no children, and members of religious orders, "to have their wishes respected concerning who may visit them or make medical decisions on their behalf."[48] The memorandum requested the secretary of health and human services to take actions to ensure that all hospitals participating in Medicare and Medicaid are in full compliance with federal regulations "promulgated to guarantee that all patients' advance directives, such as durable powers of attorney and health care proxies, are respected, and that patients' representatives otherwise have the right to make informed decisions regarding patients' care."[49] Thus, the 2010 presidential memorandum upheld the right of all persons to specify their wishes and preferences regarding healthcare decision making in end-of-life and other circumstances in which the patient has lost the ability to make such decisions for herself or himself.

But in the absence of formal documentation, such as an appropriately executed advance directive, health care proxy, or durable power of attorney for healthcare, LGBT patients and their families may discover in a healthcare crisis that "years of domestic partnership do not afford them the default status of decision maker they thought they had."[50] Without such documentation, LGBT patients who lose decision-making capacity face a significant risk that someone other than their spouse or life partner will make critical end-of-life decisions for them.[51] LGBT persons may be proactive on their own behalf and take steps to formalize an advance directive that specifically designates a surrogate decision maker. As well, primary care providers and other healthcare practitioners need to assist LGBT patients by engaging in conversations regarding end-of-life circumstances and decision making. But recent studies have indicated that few LGBT people (approximately one in ten) engage in end-of-life conversations with their primary healthcare providers.[52] Thus, healthcare providers should encourage LGBT patients to identify the patients' desires and wishes in the context of such decision making and in the selection of a trusted surrogate decision maker. Healthcare providers may also offer guidance to LGBT patients related to the tasks of completing an advance directive and other necessary documents.

Healthcare Decision-Making Capacity and Legal Competence

Consider the circumstances in which a previously healthy and well person has suffered a traumatic brain injury with resultant loss of consciousness, or has been found unconscious, cause unknown, in his or her home. The person cannot now communicate her wishes, desires, and preferences regarding what she wants done in terms of medical care. Consider that at a certain point, the previously unconscious person (now a patient) wakes up. Her eyes are open, she responds to stimuli, and she is aware of her environment. But, at present, the patient cannot communicate. She is unable to demonstrate the ability to understand verbal or written instructions or queries and cannot speak clearly or write legibly. Speech is nothing more than garbled syllables. Attempts at writing produce meaningless scrawls. As a result of these losses, temporary or otherwise, the patient has lost the capacity to make healthcare decisions on her own behalf. At present, she requires another individual to make such decisions for her. These circumstances involve the concepts of *capacity* and *competence*.

Capacity refers to a person's present level of decision-making capability. But the nature of the choice needs to be specified, as well as the conditions under which it is to be made.[53] For example, a poststroke patient and a patient with a traumatic brain injury may both be able

to point to his or her preference for breakfast when shown a picture of scrambled eggs and a picture of oatmeal. The patients have capacity to make that decision. But when asked whether they desire medication to help ensure a good night's sleep, neither patient is able to respond appropriately. Neither patient has the capacity to make such a medical decision. Thus, patients may be capable of making choices that do not require higher levels of reasoning, such as those involving food or clothing or even whether they wish to watch TV or page through an illustrated book. But choices involving higher cognitive functions, such as the ability to follow a chain of reasoning, may not be possible. Capacity is decision-relative and the context needs to be specified. The question regarding decision-making capability becomes, "Does the patient have the capacity to perform a particular decision-making task, at a particular time and under specified conditions?"

In contract, *competence* is a legal construct. In most jurisdictions only a court can determine whether a person is incompetent.[54] Thus, when legislatures draft competence statutes, they may determine the type and degree of clinically assessed lack of capacity that will allow a judge to declare an individual legally "incompetent."[55] Theories of competence to make medical decisions most commonly focus on cognitive capacity. Among jurisdictions, there are no uniform standards to identify "relevant abilities that, when impaired, constitute incompetence."[56]

Therefore, in critical care and end-of-life decision making, medical staff are required to assess a patient's capacity to make medical decisions. Such capacity is evaluated based on four key criteria:

- The ability to understand risks and benefits
- The ability to apply risks and benefits to one's own situation
- The ability to make a reasoned decision consistent with one's beliefs and values
- The ability to express a preference and communicate that decision[57]

All criteria must be fulfilled in rendering a determination that a patient has the capacity to make medical decisions on his own behalf, that is, to accept or refuse a particular medical procedure or service. These criteria are necessarily rigorous as they are intended to fulfill two complementary goals, those of (1) protecting and promoting the patient's health and well-being and (2) respecting the patient's right of self-determination.

For example, following either a stroke or a traumatic brain injury, medical staff may recommend drainage of an intracranial hemorrhage or other fluid accumulation. There may be substantial risks associated with such a procedure and significant risks related to taking no action. One patient may not be able to understand the risks and benefits. Another patient may not be able to express a preference. A third may state she does not want the procedure, but this appears inconsistent with the patient's well-known long-term plans for caring for her grandchildren, and she is unable to effectively explain her choice. In all cases the patient has not fulfilled the criteria required for a determination of capacity. Other parties will then make such a decision on behalf of the patient. To ensure that treatment choices in dire medical circumstances will uphold one's desires and preferences, each person must ask, "Who do I want making these decisions? Do I want a medical team, none of whom knows me, to make life-or-death decisions for me? Or do I want a family member, good friend, or other loved one to make difficult choices on my behalf if I'm not capable of doing so?" For such a person, one who knows and cares about us on a close, personal level, to provide assistance in a critical time of need, plans must be made in advance. A *surrogate decision maker,* one who will make medical decisions for a patient when the patient is

not capable of making those decisions, needs to be identified in advance, ideally in an advance directive that has been witnessed, notarized, and submitted to a state registry.

Surrogate Decision Making

A *surrogate decision maker* or *healthcare proxy* is identified in a person's advance directive as the individual who will assert the person's rights and interests in the area of healthcare decision making if the person has become unable to speak on her or his own behalf. In other words, the surrogate is the living embodiment of the judgments or choices the person would make if she were capable of doing so. The surrogate will, in effect, execute the terms of the person's advance directive.

A surrogate decision maker may be required to make life-or-death decisions for a family member or friend. Thoughtful, well-considered decision making is required. A surrogate is assisted substantially by the existence of an advance directive. The presence of such a formal document legitimizes the surrogate's assertions regarding the patient's preferences and desires. Importantly, a surrogate is charged with asserting and upholding the patient's preferences and desires, rather than the surrogate's own wants and needs or understandably selfish desire to keep the patient alive. The function of a surrogate decision maker is to carry out a patient's specific choices. The surrogate is not expressing her personal choice. Rather, the surrogate is fulfilling a process known as *substituted judgment*. The substituted judgment standard requires surrogate decision making to be based on the incapacitated patient's known preferences and values.[58] The surrogate applies those preferences and values to the patient's condition and prognosis, and takes action based on a match between the clinical circumstances and the patient's expressly stated wishes and desires. The surrogate asserts the previously expressed choices of the patient, rather than the desires and preferences of the surrogate. Thus, the main concern in choosing a surrogate is to select a person who is most likely to speak accurately on one's behalf and authentically state one's preferences.

Substituted Judgment versus Best Interests Standard

In substituted judgment, a surrogate decision maker attempts to establish what healthcare decisions the patient would have made if the patient were competent to make a decision. These conclusions can be based on the patient's desires and preferences expressed in previous verbal statements or the surrogate's knowledge of the patient's beliefs and values. In the best case, the surrogate bases her judgment on the preferences and desires the patient has expressly stated in his advance directive. Importantly, in substituted judgment the surrogate is not "substituting" her judgment regarding what should be done. Rather, in effect, the surrogate is speaking for the patient and "substituting" the patient's judgment regarding the clinical circumstances and medical decision making required by those circumstances. Problematically, a patient's preferences may have changed over time. Desires for appropriate medical decision making expressed in an advance directive that is more than two or three years old may not accurately reflect the patient's more recent perspectives. For example, 10 percent of survey respondents who would have refused artificial ventilation in 1999 had changed their minds three years later.[59] In 2014, a meta-analysis demonstrated that in seventeen studies, only 70 percent of patients' preferences for end-of-life care were stable over time.[60] Thus, the surrogate decision maker may be required

to interpret what the patient, at present, would want done, based on knowledge of the patient's current life circumstances. Such substituted judgment may require that interested parties, that is, the surrogate decision maker, the medical team, the hospital ethics committee, and possibly the patient's family, reach a consensus on the medical treatment that will serve the patient's best interests.

If no advance directive exists and the patient's preferences and desires have not been communicated to family or friends, the *best interests standard* is utilized. In such circumstances, the hospital medical team, supported by input from the hospital ethics committee and the patient's close relatives and/or close friends, will make medical decisions based on the patient's best interests, that is, based on the most likely best medical outcome. The basis for a best interest decision is what a reasonable person would choose after considering all the options and alternatives. Optimally, a patient has created an advance directive and designated a surrogate decision maker. The surrogate will then utilize substituted judgment, if such dire circumstances arise.

Hospital Ethics Committees

The need for hospital ethics committees began to be recognized as details of prominent medical cases involving controversial decision making reached a broad public. The case of Karen Ann Quinlan,[61] discussed above, was reported extensively in the press, captured the public's attention, and prompted widespread expressions of sympathy and indignation directed at her circumstances and suffering. In the early 1980s, similar public scrutiny focused on the case of "Baby Jane Doe," who was born with spina bifida (unfused segments of the spinal column), hydrocephalus (abnormal accumulation of fluid surrounding the brain), and microcephaly (a condition in which a baby's head is much smaller than expected with potential developmental defects of the brain).[62] Surgery was recommended to repair the spinal defect and reduce the accumulation of cerebrospinal fluid. The infant's parents refused to consent to surgery as the likely outcomes included severe mental retardation, paralysis, and a long-term bedbound state. A lawsuit to enforce surgical treatment was brought in New York and, at the federal level, the Department of Health and Human Services (DHHS) filed suit to obtain the child's medical records. Ultimately, the DHHS suit reached the U.S. Court of Appeals, which ruled that DHHS did not have authority to interfere with "treatment decisions involving defective newborn infants."[63]

These cases and others highlighted ethical issues created by advances in medical technology. It had become possible to indefinitely prolong life for children and adults regardless of the consequences to quality of life. In end-of-life circumstances, persons who were no longer capable of fulfilling physiological needs could be kept alive with the use of artificial nutrition and hydration, and those who could not breathe on their own could be maintained for years on an artificial respirator. *In re Quinlan* had stated, "Developments in medical technology have obfuscated the use of the traditional definition of death."[64] Conflicts arose in specific cases regarding the appropriateness of certain medical and surgical interventions and the utilization of life-sustaining treatment. Owing to the broad range of treatment that had become available by the early 1970s, patients could demand treatment that was not deemed appropriate by medical personnel. Similarly, families of patients who had been assessed to lack decision-making capacity could insist that "everything be done" to keep their loved ones alive. Disagreements among members of a patient's healthcare team could interfere with effective case management. These various scenarios, occurring weekly and even daily in hospitals across the United States and

around the world, identified the need for systematic methods of analyzing the ethical concerns involved in a case, resolving conflicts, and proposing solutions. The *Quinlan* court specifically referred to hospital ethics committees, noting that such a committee serves "to review the individual circumstances of ethical dilemma and which has provided much in the way of assistance and safeguards for patients and their medical caretakers."[65] Hospital ethics committees were established to address these many problems.

Hospital ethics committees were a relative rarity prior to the 1980s. In a survey conducted in the United States and reported in 1983, approximately 1 percent of 602 randomly selected hospitals were identified as having an ethics committee.[66] Remarkably, by 1986, more than 60 percent of American hospitals had ethics committees.[67] In 1992 the Joint Commission for the Accreditation of Healthcare Organizations (now the Joint Commission) mandated that American hospitals establish a "mechanism" to consider and address ethical issues in patient care.[68] At present, all U.S. hospitals with greater than 400 beds and all federal hospitals have such a mechanism for ethics consultation.[69]

Hospital ethics committee members may include medical and nursing staff, social workers, hospital chaplains, legal and risk management personnel, and representatives from the community, including bioethicists, religious leaders, and interested parties. A typical hospital ethics committee holds regular monthly meetings and convenes during the month as needed to consult on specific cases. The function of the hospital ethics committee is not to direct care but rather to provide recommendations for care. An ethics consultation is typically called when treatment decisions involve circumstances such as the following:

- Consideration of a patient's capacity for decision making
- Determination of an appropriate surrogate decision maker
- Family conflict regarding medical treatment
- Withholding or withdrawal of life-sustaining treatment
- Other assessments of medically nonbeneficial treatment

For example, medical staff may have concerns regarding ethical treatment in end-of-life circumstances. In another case, the desires and demands for treatment on the part of the patient and/or the patient's family may conflict with the recommendations of the patient's healthcare team. A primary function of the ethics consultation is to identify the key ethical issue and reach a consensus regarding means for resolution.

Additionally, hospital ethics committees can serve as a critical resource for the institution itself in the areas of education and policy formation and review.[70] Regarding education, both brief in-service and half- or full-day programs may be offered, addressing topics such as informed consent, capacity assessments, confidentiality, advance directives, substituted judgment and the best interests standard, and assessments of nonbeneficial treatment. Hospital ethics committees may assist in institutional policy development regarding many of these areas.

Family Conferences

The hospital ethics committee may propose a *family conference* during which the attending physician and hospital ethicist review the risks and benefits of the available treatment options and attempt to arrive at agreement regarding the choice of treatment that would best serve the patient's interests.

A family conference may be convened at the recommendation of the hospital ethics committee. For example, a terminally ill patient may have lapsed into a coma, at which point life-sustaining treatment such as artificial nutrition and hydration (ANH) may no longer be in the patient's best interest. The attending physician has requested a meeting with the hospital ethics committee to assess the appropriateness of withdrawal of ANH. The committee agrees that withdrawal of ANH is appropriate, given that the patient's terminal condition would likely result in death within several weeks with or without life-sustaining treatment. A family conference is proposed to provide an opportunity for discussion of the patient's medical status and the family's concerns, and to inform the family of the healthcare team's recommendations. The family conference also provides an opportunity to address the family's requests regarding the timing of withdrawal of ANH, such as waiting two or three days for the arrival of a family member who lives across the country and who wishes to pay a final visit to her loved one.

In another case, a family conference may be convened when patients or family members are requesting treatment with which the healthcare team is not in agreement. For example, a patient with dementia may have previously expressed a desire that the healthcare team "do everything" to keep the patient alive. But at present the patient's condition has advanced substantially so that he is no longer able to interact meaningfully with others or his environment and requires the assistance of healthcare staff to obtain sufficient food and water. For example, the patient may have experienced 10 percent weight loss in the previous six months. Or the patient may have suffered one or more episodes of aspiration pneumonia. In consequence, a hospital ethics committee consultation has been requested by the attending physician. After thorough discussion of the case with the attending physician, bed nurse, and social worker, the committee recommends that the patient's code status be revised to DNR/DNI (do not resuscitate/do not intubate). Additionally, the committee recommends that a conference with the patient's family be convened to review their loved one's medical status, propose this revision, and solicit the agreement of the designated surrogate decision maker.

Frequently, in potential end-of-life circumstances, interactions among family members and members of the healthcare team may be contentious, acrimonious, or worse. Family members themselves may strongly disagree about treatment choices for their loved one. One daughter may wish that her elderly parent be allowed to "die in peace," whereas a second daughter demands that "everything be done" to keep her parent alive. The convening power of the hospital ethics committee[71] brings stakeholders together and establishes a forum for the purpose of mediating conflicts. This convening power enables concerned parties to "accurately discern what is at stake for patients ethically and clinically."[72] Convening a family conference provides an opportunity for conflict resolution and identification of treatment solutions that are acceptable to all concerned parties.

Additionally, from the perspective of the hospital ethics committee itself, convening a committee meeting allows for inclusion of diverse healthcare specialists concerned in the case. New insights and plans for action may emerge via cross-fertilization of perceptions and viewpoints.[73] The convening power of the hospital ethics committee facilitates the identification of effective solutions to the ethical problem at hand. The process may lead to the development of frameworks, protocols, and other necessary procedures to facilitate resolution of ethical problems posed by future cases and even avoid the generation of such ethical problems in the first place.

Medical Futility/Nonbeneficial Treatment

The concepts of *medical futility* and the physician's responsibility to provide treatment that is appropriate to a patient's clinical circumstances were addressed by Hippocrates and his students more than 2,400 years ago. In *Prognostikon,* Hippocrates stated that "to restore every patient to health is impossible."[74] It was necessary to determine how much a disease has exceeded "the strength of men's bodies" so as to be able to "declare beforehand those who will die and those who will get better."[75] Thus, treatment that could not provide assistance was to be avoided.

Medical futility or nonbeneficial treatment, in modern terms, has both qualitative and quantitative components.[76] As with several other issues in healthcare ethics, the need for an assessment of medical futility derives from advances in medical science and medical technology. Many patients being kept alive by modern medical procedures may have a severely diminished quality of life or may even be unconscious, possibly in a persistent vegetative state. At a certain point, questions arise regarding the nature of the benefit being provided to the patient. Medically futile or nonbeneficial treatment is defined as treatment that does not provide appreciable improvement to the patient as a whole. For example, treatment that maintains a patient in an unconscious state but does not result in other improvement in the patient's condition, or treatment that does not reduce a patient's total dependence on intensive medical care, should be deemed medically futile or nonbeneficial after an agreed-upon duration.[77]

An assessment of medical futility may be resisted by the patient or the patient's family as being a subjective determination by healthcare staff. Of note, discussions with patients or family members may be facilitated by use of the term "nonbeneficial treatment" rather than "medically futile treatment." Regardless, the patient or family members may assert that quality of life is a personal evaluation that cannot be appropriately made by another or that preservation of life should be attempted in all circumstances. But patients do not have a right to demand treatment that does not provide a demonstrable benefit[78] and physicians are ethically and professionally obligated to resist administering such treatment.[79] Importantly, patient autonomy asserts the right of patients, as self-determining individuals, to choose or decline proposed treatment, but does not extend to a right to demand treatment. Numerous religious leaders support such clarification regarding appropriate use of medical treatment. For example, in 1995, in *Evangelium Vitae,* Pope John Paul II stated the following:

> It needs to be determined whether the means of treatment available are objectively proportionate to the prospects of improvement. To forego extraordinary or disproportionate means is not the equivalent of suicide or euthanasia; it rather expresses acceptance of the human condition in the face of death.[80]

In considerations of medical futility or the possible provision or cessation of treatment deemed to be nonbeneficial, it is necessary to distinguish between withholding treatment versus withdrawing treatment. For example, in 1991, the AMA Council on Ethical and Judicial Affairs stated that CPR may be withheld if, "in the judgment of the treating physician, an attempt to resuscitate the patient would be futile."[81] Thus, regarding withholding treatment, consent is not needed if such treatment is deemed to be futile or nonbeneficial. Similarly, the Canadian Critical Care Society Position Paper stated in 2000 that an intensive care unit team should be under no obligation to provide life support at the behest of a patient's surrogate decision makers "if this care will not be effective and is not in accord with standard medical practice or norms."[82]

But decision making regarding withdrawal of life-sustaining treatment (LST) requires appropriate participation of the family. The medical team cannot unilaterally implement withdrawal of a patient's LST. LST may have been determined to be medically futile or nonbeneficial, that is, not having resulted in a benefit to the patient or other demonstrable positive change in the patient's status. But withdrawal of LST has permanent, irrevocable consequences in that the patient will expire shortly thereafter, typically within two weeks. As the patient's best interests appropriately include the welfare and well-being of his family, kindness, understanding, and compassion are essential components of the end-of-life treatment process. Shared decision making regarding final measures such as withdrawal of LST requires a consensus among the medical team, the hospital ethics committee, and family members. Importantly, as background to medical decision making regarding withdrawal of life-sustaining treatment, the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research stated in 1983 that

> Achieving medically and morally appropriate decisions does not require changes in statutes concerning homicide or wrongful death, given appropriate prosecutorial discretion and judicial interpretation.[83]

The president's commission stated that "Families, health care institutions, and professionals should work together to make decisions for patients who lack decision-making capacity."[84] The court system should only be involved when there is unresolvable disagreement regarding "matters of substantial import." Regarding the decision to withdraw life-sustaining treatment, the president's commission referenced Judge Robert Meade's ruling in *Matter of Eichner*[85] that "it is important that the law not create a disincentive to the fullest treatment of patients by making it impossible for them in at least some extreme circumstances to choose to end treatment which has proven unsuccessful."[86] Hospitals naturally wish to avoid wrongful death suits, but the overriding considerations mandating shared decision making at the end of life are the biomedical ethical principles of autonomy (respect for persons), beneficence, nonmaleficence, and justice.

Once withdrawal of life-sustaining treatment has been assessed to be the appropriate course of action by the medical team in consultation with the hospital ethics committee, based on a determination that treatment would be nonbeneficial or medically futile, convening a family conference brings the patient's family members into the decision-making process. Forthright, clear communication enhances mutual trust and lessens the possibility of conflict. Ultimately, mutually agreed-upon solutions are obtained by open discussions regarding treatment options and their relation to the patient's values and preferences. For example, medical staff can strongly indicate that a particular approach will not likely achieve the family's goal of restoring their loved one to consciousness and meaningful interaction with others. With the patient's goals foremost, the lack of probability of an objectively meaningful medical outcome is placed in a context that may support the family in choosing appropriate actions. Families might be amenable to a negotiated time-frame for continued life support with a clearly defined end-point. On such a basis, it might be agreed that life support would continue for an additional fourteen or thirty days, to enable a final assessment of lack of benefit and provide an opportunity for out-of-town family members to pay a last visit to their loved one. Overall, the hope is that with appropriate care, compassion, and respect for all concerned, effective medical decision making may be obtained in end-of-life circumstances that is based on the patient's desires, preferences, welfare, and best interests.

Palliative Care

Worldwide, increasing numbers of people experience the impact of chronic disease. Many of these disorders, including cancer, AIDS, heart failure, chronic pulmonary disease, and end-stage renal disease, ultimately progress to end-of-life clinical circumstances. For example, in 2007 it was estimated that two-thirds of the 10 million new cancer cases each year result in death of the patient within a year of diagnosis. Further, as of 2007, 3 million patients die annually from AIDS.[87] The World Health Organization (WHO) estimates that between 2015 and 2050 the proportion of the world's population over age sixty will nearly double, increasing from 12 to 22 percent.[88] Thus, globally, there is a substantial unmet need for palliative care.

Palliative care specifically refers to treatment directed toward improving the quality of life of patients with serious illnesses. The palliative care model incorporates total pain management[89] and additional methods for reducing the symptom burden of the patient's disease. For example, cancer pain is frequently undertreated despite its known prevalence. A 2008 review indicated that 43 percent of cancer patients received less than optimal pain relief.[90] Additionally, one-third of patients with advanced chronic obstructive pulmonary disease or severe congestive heart failure have severe pain.[91] By providing active surveillance and effective treatment, palliative care specialists assist chronically ill patients in obtaining appropriate pain control. Regarding management of complex symptomatology, the palliative care model includes a focus on components of chronic disease such as fatigue, lack of restful sleep, depression, anxiety, urinary urgency, and constipation, all of which contribute substantially to loss of function and impaired quality of life.

Palliative care also addresses psychosocial issues concerning the patient, the patient's caregivers, and family members. WHO states that palliative care "provides relief from pain and other distressing symptoms, ... integrates the psychological and spiritual aspects of patient care, ... and uses a team approach to address the needs of patients and their families."[92] Palliative care services are important not only in end-of-life circumstances but across the entire spectrum of illness and disease, regardless of the age of the patient. The Centers for Medicare and Medicaid Services defines palliative care as

> patient and family-centered care that optimizes quality of life by anticipating, preventing, and treating suffering. Palliative care throughout the continuum of illness involves addressing physical, intellectual, emotional, social, and spiritual needs and to facilitate patient autonomy, access to information, and choice.[93]

Palliative care has a curative intent and a palliative focus. This method of treatment is applicable at any stage of the course of a serious disease and ideally is begun at the time of diagnosis,[94] regardless of the age of the patient. Palliative care is characterized as "advanced illness management" and is specifically distinguished from hospice care, which is reserved for patients with a terminal illness, that is, those with a life expectancy of six months or less.[95] Palliative care provides care that focuses on the patient's goals of care and, as such, is distinct from medical management, that is, the aims of treatment. Goals of care are dynamic and responsive to the patient's circumstances. Palliative care specialists assist the patient and her family in articulating their goals of care, provide effective pain management based on the patient's specific requirements, and actively address quality-of-life concerns.

Quality-of-life issues include effective communication at the time of diagnosis, advance care planning, and caregiver assessment.[96] Effective communication includes clarifying the diagnosis

and prognosis, identifying end-of-life goals, and developing a meaningful and appropriate treatment plan.[97] Patients who discuss end-of-life issues with their physicians report greater satisfaction with their care. Patients participating in these discussions preferred therapies focused on relieving pain and discomfort rather than life-extending treatment and were more likely to complete do-not-resuscitate orders.[98] Importantly, caregivers are at increased risk for depression, cardiovascular disease, and other chronic illnesses, and may have up to a 60 percent increased morality rate compared with age-matched controls.[99] Palliative care specialists actively address the well-being of caregivers by providing support and validation, and may make specific recommendations for the caregiver's own care.

Overall, palliative care has been characterized as an international human right. For example, in 2002 the Cape Town Declaration asserted that palliative care is a right of every adult and child with a life-limiting disease. Further, palliative care should be provided at all levels of care.[100] In his message for the Fifteenth World Day of the Sick, Pope Benedict XVI stressed the need for more palliative care centers, noting that care of the sick "is a right belonging to every human being."[101] In terms of the practical implementation of these asserted rights, the business case for inpatient specialist palliative care is well established, as evidenced by the rapid growth of such programs in more than 60 percent of U.S. hospitals.[102] By providing value-based medicine palliative care is an inherently cost effective service, a feature of increasing importance to healthcare systems in resource-constrained environments.

The Rule of Double Effect

The rule of double effect may provide moral justification for an action that results in serious harm, if the action was done to promote a good and the harm was a foreseen yet unintended outcome. The rule of double effect may be considered to derive from Thomas of Aquino's *Summa Theologica*. In discussing whether it is lawful to kill a man in self-defense, Thomas stated, "Nothing hinders one act from having two effects, only one of which is intended, while the other is beside the intention."[103] He explained that the moral character of an act is based on what is intended, and not according to an outcome that may be reasonably assessed as accidental. Thomas noted that "the act of self-defense may have two effects, one is the saving of one's life, the other is the slaying of the aggressor."[104] The act of self-defense is not unlawful, "since one's intention is to save one's own life."[105] Thomas added a critical caveat in that, "though proceeding from a good intention, an act may be rendered unlawful, if it be out of proportion to the end."[106] Thus, if a person used more than necessary violence in an act of self-defense, such action would be deemed unlawful. The rule of double effect has practical application in biomedical ethical decision making. As well, the rule of double effect has been described as "one of the most practical in the study of moral theology."[107]

Per the rule of double effect, a person may lawfully (in the moral sense) perform an action that she foresees will produce a good result and a bad effect provided that four conditions are met:

1. The action is good in itself.
2. The intention is solely to produce the good outcome, rather than intending the harm.
3. The good effect is not produced by means of the bad effect.
4. There is a sufficient proportionately grave reason for permitting the bad effect.[108]

Therefore, bringing about or risking a serious harm may be justified, provided that the intended good result is sufficiently weighty and sufficiently critical. For example, a cancer patient may require radiation therapy and chemotherapy to prolong his life. The foreseen harms may be significant, including debilitating nausea and vomiting, gastrointestinal dysfunction, kidney damage, and anemia. The medical team is morally justified in proceeding with the recommended treatment, as the harms, although foreseen, are not the intended outcomes. Rather, the medical care directed at improving the patient's health and well-being is good in itself and the good outcome is proportionately greater than the serious harms produced as side effects of treatment.

Previously, the rule of double effect had been applied to end-of-life decision making in the hospice care setting. The good of using opioid medication to relieve a terminally ill patient's pain and suffering was contrasted with the possible serious side effect of respiratory depression that could hasten the patient's death. It was asserted that the rule of double effect would provide moral support or justification for use of pain-killing opioids. In the case of a terminally ill patient, the good of sufficient pain relief outweighed the foreseen harm. For example, in *Vacco v. Quill*, the Supreme Court stated, "Just as a State may prohibit assisting suicide while permitting patients to refuse unwanted lifesaving treatment, it may permit palliative care related to that refusal, which may have the foreseen but unintended 'double effect' of hastening the patient's death."[109]

Importantly, it has been reported that the peer-reviewed literature contains few data to support the conjecture that appropriate use of opioid medication hastens death in terminally ill patients with cancer or other chronic diseases.[110] Rather, respiratory depression "is not a significant limiting factor in the management of patients with pain" as tolerance develops to this effect with repeated doses.[111] As well, numerous studies have demonstrated that appropriate doses of opioids do not cause respiratory distress.[112] One literature review found no significant relationships between opioid dose, change of dose, and time of death in patients with advanced illness.[113] However, respiratory depression with use of opioids does occur,[114] and the rule of double effect may provide appropriate moral justification in the context of hospice care, that is, care for patients with a terminal illness and a life expectancy of six months or less.

Specifically, a sufficient quantity of opioid medication may be used in the palliative care of a terminally ill patient to control the intense discomfort of dying. These measures are referred to as terminal sedation[115] or *palliative sedation*.[116] Such treatment may have the effect of shortening the patient's life. But the demise of the patient is not the intention of treatment. Rather, easing the patient's suffering is the intended result. The medical team's action is good in itself and there is a proportionately grave reason for engaging in such treatment. Although precipitating the patient's death is a foreseen harm, the rule of double effect provides an appropriate moral basis in support of the medical team's decision making.

Physician-Assisted Suicide

The End of Life Option Act[117] was signed into law in Sacramento, California, on October 5, 2015,[118] and went into effect on June 9, 2016.[119] California joined Oregon, Washington, and Vermont as the fourth state in the United States to enact a law allowing assisted suicide for terminally ill patients. The California law permits a terminally ill adult patient with medical decision-making capacity to be prescribed an aid-in-dying medication[120] if certain conditions are met.[121]

The End of Life Option Act has numerous specifications and safeguards to ensure appropriate utilization of the aid-in-dying process. The act specifies that an eligible individual must meet the following conditions:

- Is an adult, that is, eighteen years old or older[122]
- Is a California resident[123]
- Has received from his or her primary care physician a diagnosis of a terminal illness, that is, an "incurable and irreversible disease that has been medically confirmed and will, within reasonable medical judgment, result in death within six months"[124]
- Has the capacity to make medical decisions,[125] as assessed by the individual's attending physician, consulting physician, psychiatrist, or psychologist
- Has voluntarily requested an aid-in-dying drug[126]
- Has the physical and mental ability to self-administer the aid-in-dying drug[127]

In Oregon, the Death with Dignity Act[128] was enacted on October 27, 1997. The Oregon law "allows terminally ill Oregonians who meet specific qualifications to end their lives through the voluntary self-administration of a lethal dose of medications, expressly prescribed by a physician for that purpose."[129] Eligibility requirements include being eighteen years of age or older, a resident of Oregon, capable of making and communicating healthcare decisions for oneself, and diagnosed with a terminal illness that will likely lead to death within six months.[130] During 2017, 218 persons received prescriptions for lethal medications under the provisions of the Oregon Death with Dignity Act (DWDA), compared with 204 during 2016.[131] As of January 19, 2018, the Oregon Health Authority had been notified of 143 individuals who had died during 2017 from ingesting the prescribed lethal medications, compared with 138 during 2016.[132] Since the law was enacted in 1997, 1,967 people have received prescriptions written under the Oregon DWDA, and 1,275 of those persons have died from ingesting the medications.[133]

In 1997, in *Washington v. Glucksberg*, the Supreme Court considered whether the state of Washington's prohibition against causing or aiding a suicide was in violation of the Fourteenth Amendment to the U.S. Constitution.[134] The petitioners had asserted "the existence of a liberty interest protected by the Fourteenth Amendment that extends to a personal choice by a mentally competent, terminally ill adult to commit physician-assisted suicide."[135] The Court noted that Washington's ban on assisted suicide was reasonably related to the promotion and protection of various state interests, including protecting "depressed or mentally ill persons, or those who are suffering from untreated pain, from suicidal impulses," protecting the ethics and integrity of the medical profession, and protecting "vulnerable groups—including the poor, the elderly, and disabled persons—from abuse, neglect, and mistakes."[136] The Court was also concerned with protecting disabled and terminally ill people from prejudice, inaccurate and negative stereotypes, and societal indifference.[137] The Court held that the Washington statute[138] in question does not violate the Fourteenth Amendment. However, the Court noted that its holding permitted a national debate to continue regarding the morality, legality, and practicality of physician-assisted suicide.[139] Subsequently, the Washington Death with Dignity Act (RCW 70.245) was enacted on November 4, 2008 and went into effect on March 5, 2009. The legislation allows terminally ill adults seeking to end their life to request a lethal dose of medication from a medical or osteopathic physician.

Concerns of potential biomedical ethical significance regarding physician-assisted suicide (PAS) include incompatibility with the physician's role and responsibility as a healer, devaluation

of human life, coercion of vulnerable persons including those with lower socioeconomic status, and a slippery slope of utilization, that is, use of PAS for persons not deemed to be terminally ill.[140] However, states that have legalized PAS do not compel participation by healthcare providers or entities. For example, the End of Life Option Act specifies that participation in aid-in-dying activities is voluntary. Persons or entities may choose, "for reasons of conscience, morality, or ethics," not to engage in such activities.[141] In 2017, the Oregon Health Authority reported that patients participating in the DWDA process were concerned with losing autonomy, loss of dignity, and being a burden on family, friends, and caregivers.[142] In 2017, in Oregon, more than 90 percent of those participating in the DWDA process were enrolled in hospice. More than 31 percent had private insurance and 68 percent were covered by Medicare, Medicaid, or other governmental insurance.[143] More than 94 percent were white, more than 52 percent were married, and more than 69 percent had attended college or had received a baccalaureate degree of higher.[144] The California Department of Public Health reported that, in 2016, 191 individuals had prescriptions written for aid-in-dying medication and 111 ingested the drug.[145] Of those who died in 2016 pursuant to the End of Life Option Act, more than 76 percent were between sixty and eighty-nine years of age and more than 11 percent were ninety years of age or older. More than 89 percent of decedents were white and more than 83 percent were receiving hospice and/or palliative care. More than 72 percent had at least some level of college education.[146] Thus, the vast majority of persons participating in the physician-assisted suicide process have not been members of vulnerable groups such as racial/ethnic minorities or those with lower socioeconomic status.

As examples of state laws permitting PAS, the Oregon and California statutes require certification by both an attending physician and a consulting physician that the patient has an incurable and irreversible terminal disease. The attending physician must refer the patient to a mental health specialist, if indicated, to determine whether the patient is not suffering from impaired judgment owing to depression or other psychiatric disorder and has the capacity to make medical decisions for himself or herself. The patient must make two oral requests to receive a prescription for an aid-in-dying drug, a minimum of fifteen days apart, and a written request. The written request must be signed and dated, in the presence of two witnesses, only one of whom may be "related to the qualified individual by blood, marriage, registered domestic partnership, or adoption or be entitled to a portion of the individual's estate upon death."[147] Overall, it may be reasonably considered that the above noted ethical concerns are effectively addressed by the statutory requirements permitting PAS and the demographic data reported by the Oregon Health Authority and the California Department of Public Health. In contrast, it has been stated that a goal of society "should be to make dying less, not more, medical. PAS is neither a therapy nor a solution to difficult questions raised at the end of life."[148] As well, the American College of Physicians "does not support the legalization of physician-assisted suicide, the practice of which raises ethical, clinical, and other concerns."[149]

Importantly, PAS and palliative sedation are morally distinct practices. Palliative sedation is directed toward relieving intolerable pain and suffering where alternative interventions have been exhausted or are otherwise inadvisable.[150] Administration of sedation is based on the level of consciousness reduction necessary to sufficiently relieve symptoms.[151] Appropriately administered, palliative sedation does not entail administration of a lethal agent and is not intended to cause death.[152] Per the rule of double effect, the risk of hastening death may be reasonably considered as a tolerable side effect.[153] In contrast, in PAS, relief of suffering is accomplished via death of the patient.

Nonsecular Perspectives on End-of-Life Decision Making

Nonsecular perspectives provide important considerations in end-of-life decision making. The beliefs and value systems of a cross section of patients are diverse rather than uniform, and beliefs and value systems of healthcare providers may not necessarily align or otherwise be in agreement with those of the patients for whom they are caring. Judaism, Islam, and Catholicism each provide unique contributions to medical ethics and end-of-life care issues. As a best practice, in the context of values and preferences associated with end-of-life decision making, healthcare practitioners should always confirm with patients or their families regarding their particular faith practices.

Judaism

Jewish concepts of medical care near the end of life may be described as hope in the face of terminal illness.[154] This hope derives from II Kings 20:1, which relates a visit from the prophet Isaiah to King Hezekiah of Judah. Hezekiah had fallen dangerously ill and Isaiah had been sent by God to inform the king that he was going to die. Upon receiving this news, Hezekiah "turned his face to the wall" and prayed to God.[155] God then instructed Isaiah to return to Hezekiah and say to him that God will heal him and add fifteen years to his life. The hope introduced by King Hezekiah into the circumstances of dire illness are perpetuated today in the practices of palliative medicine and hospice care.

Jewish medical ethics is based on *halacha*, God's law, whose foundations are delineated in the Torah (the five Books of Moses). *Halachic* equivalents to the four principles of biomedical ethics may be derived by analysis of cases presented in biblical texts, compilations of the "Oral Law" (the *Mishnah*), and commentary on the Torah and *Mishnah* (the *Talmud*). Orthodox Jews are observant of Jewish law and tradition and accept their rabbi as a religious authority and interpreter of Jewish law. For Jews of the Conservative denomination, there is wide variation in the level of observance of Jewish law. For Jews of the Reform denomination, Jewish law is only a guide and is nonbinding.[156] Thus, regarding autonomy, Jewish law recognizes freedom of choice, and Orthodox Jews limit their autonomy by choosing to follow God's law. Autonomy, therefore, is limited to actions that are consistent with Jewish law.

End-of-life medical circumstances, as well as other acutely dire treatment scenarios, may involve decisions related to withholding or withdrawal of treatment and CPR. Additionally, as of 2017, PAS has been legalized in California, Oregon, Washington, Vermont, and Colorado, as well as in the District of Columbia. Jewish law specifically addresses each of these treatment options.

With respect to PAS or medical aid in dying, Judaism teaches that "man's body and his life are not his to give away. The proprietor of all human life is none other than God Himself."[157] Thus, PAS is "opposed in Jewish law and considered as a deliberate hastening of death."[158] The responsibility of the physician does not extend beyond healing and physicians must not provide any intervention that actively determines the time of a patient's death.[159]

Jewish medical ethics distinguishes between withholding and withdrawal of treatment. Treatment may be withheld if the patient's physician determines that treatment will likely not result in remission or cure of the illness, but rather only delays the dying process. In such circumstances, "nature may be allowed to take its course" and the physician's role "may be limited to providing pain relief."[160] However, withdrawal of life-sustaining treatment is generally not permitted by

Jewish law. For example, Jewish law disputes court decisions permitting the withdrawal of ANH from patients in a persistent vegetative state. The inevitable death by dehydration "classifies the removal of hydration as active euthanasia,"[161] which is not permitted. But every case concerned with withdrawal of life-sustaining treatment is unique and patient-specific analysis and decision making is necessary. Only an individualized assessment provided by a rabbi who is an expert in medical aspects of *halacha* can help to determine an appropriate course of action in accordance with Jewish law. Withdrawal of ANH might be permissible "if one is certain that in doing so one is shortening the act of dying and not interrupting life."[162]

Regarding CPR, the medical literature suggests that this procedure has a low success rate. It has been reported that only 14 percent of 294 patients who were resuscitated in a university teaching hospital survived until discharge.[163] In another study, of 503 patients aged seventy and above who received CPR in five Boston healthcare institutions, only nineteen (3.8 percent) survived to hospital discharge.[164] Overall, it is reasonable to conclude that the rate of survival in terminally ill patients may be even lower. For terminally ill patients who survive CPR, the procedure only delays death and "may contribute to increased pain and suffering."[165] Thus, Jewish law permits a patient to refuse such treatment when his condition is irreversible, that is, when the proposed treatment would not cure the illness but would likely only extend the patient's life somewhat.[166] Similarly, physicians may not be required to initiate CPR in medically futile situations, that is, when treatment would not be likely to provide a meaningful benefit or appreciable improvement to the patient as a whole.[167]

Nutrition and hydration support is considered by most rabbis to be basic care rather than a medical intervention.[168] Thus, food and fluids must be provided, including use of ANH for terminally ill patients who are unconscious or who otherwise do not have medical decision-making capacity. However, if a terminally ill patient with capacity refuses food and fluids, "despite our best efforts to convince him to eat, we must respect his wishes."[169] In other cases, the provision of ANH may not provide a meaningful benefit and may cause the patient harm (including infection, retention of fluid, and a need for surgical replacement of the feeding tube). Consultation with a rabbi knowledgeable in these areas will provide guidance for medical decision making in accordance with Jewish law.

Regarding advance directives, from a secular viewpoint, such a document expresses a person's preferences and desires regarding end-of-life decision making. Also, an advance directive specifies a surrogate decision maker or healthcare proxy who will make medical decisions in the case in which the person is unable make those decisions on her own behalf. For Orthodox Jews, advance directives are acceptable provided the instructions in those documents are consistent with Jewish law.[170] Assigning a healthcare proxy or surrogate decision maker is consistent with Jewish law and tradition. However, the rabbi is the final arbiter regarding whether decision making is consistent with Jewish law. Thus, in an advance directive, an Orthodox Jew would be able to designate her rabbi as healthcare proxy in addition to whomever else in her family she deemed appropriate. Also, rather than being predetermined and following expressions of values and preferences as in a secular advance directive, decision making in end-of-life situations is individualized and based on a discussion of the specific clinical circumstances by the patient's physician and the patient's healthcare proxies, that is, the rabbi and the designated family member.[171] For example, the Rabbinical Council of America's Halachic Health Care Proxy enables a person to designate his healthcare proxy as well as identifying an Orthodox rabbi and alternate Orthodox rabbi "whose guidance you want your agent to follow, should any questions

arise as to the requirements of *halacha*."[172] Regarding the specifics of end-of-life decision making, the Halachic Health Care Proxy states the following:

> The issues surrounding end-of-life medical decisions are critical and most complex. ... In order to give them [your healthcare proxy and designated rabbi] guidance, in the event that you are unable to make your own decisions, we ask you to review the following scenarios and discuss with them whether you wish to be treated aggressively with all appropriate life-support interventions, or palliative/comfort care, which may include pain medications, symptom relief, antibiotics and feeding tubes.[173]

Islam

In the Islamic view, the primary obligation of a physician is to provide care and alleviate pain.[174] In terms of end-of-life decision making, there is an obligation to save and prolong life. But there are times "when human beings need to recognize their own limits and entrust nature to take its own course (Qur'ān 39:42)."[175] In Islamic ethics, the biomedical ethical principle of autonomy is not invoked to determine a course of action in end-of-life circumstances. Rather, an individual's welfare and well-being are closely associated with those of his or her family and community. The appropriateness of treatment recommendations "is a joint decision made by all associated with the patient."[176] The matter may be referred to religious leaders who may provide prescriptive rulings.

Regarding PAS, decisions concerning a request by a terminally ill patient to receive assistance in ending his or her life is "beyond a doctor's moral and legal obligations."[177] Qur'ān 3:145 states, "No soul dies without the permission of Allah, and at a term appointed."[178] Also, Qur'ān 3:156 states, "It is Allah who gives life and death, and He sees well all that you do."[179] Thus, the sacred law of Islam (Sharī'ah) does not recognize a patient's right to die voluntarily. Life's term is "fixed by an unalterable divine decree."[180] Qur'ān 39:42 states, "Allah receives the souls at the time of their death, and those that have not yet died, during sleep. Then He withholds those for whom He has ordained death and restores the souls of others till an appointed term."[181] However, based on the principle of istiṣlāḥ (seeking what most benefits the community as a whole, that is, the best interests of all concerned), Muslim jurists have indicated that a collective decision not to prolong the life of a terminally ill patient is possible. Such collective decision making would include the family, the attending physician, and others involved in providing healthcare.

Islamic law permits the withdrawal of life-sustaining treatment that is assessed as futile and disproportionate, based on the advice of the attending physician and the consent of immediate family members. Withdrawing care is permissible when current treatment is no longer curing or relieving suffering, "but merely prolonging a natural and inevitable death."[182] Muslim jurists recognize as legal a competent patient's refusal of treatment in circumstances in which treatment is deemed to be futile or nonbeneficial. Advance directives specifying refusal of treatment in such circumstances are also recognized as legal in Islamic law.[183]

Catholicism

In a March 20, 2004, allocution to the International Congress, "On Life-Sustaining Treatments and Vegetative State: Scientific Advances and Ethical Dilemmas," Pope John Paul II declared that a person in a vegetative state still has the right to basic health care such as nutrition and hydration. The pope stated "the administration of water and food, even when provided by artificial

means, always represents a natural means of preserving life, not a medical act."[184] Considerations regarding a patient's prognosis "cannot ethically justify the cessation or interruption of minimal care for the patient, including nutrition and hydration."[185] Pope John Paul II stated, "it is necessary to promote the taking of positive actions as a stand against pressures to withdraw hydration and nutrition as a way to put an end to the lives of these patients."[186]

This 2004 papal allocution appeared to mandate the continuation of ANH, regardless of a patient's clinical circumstances. But "the allocution's statements have not been repeated by the teaching authority of the church,"[187] indicating this teaching is not authoritative.[188] Later, in a November 12, 2004, statement on palliative care for the dying, Pope John Paul II seemed to affirm the traditional teaching allowing a physician to forgo life-sustaining treatment if it does not offer the hope of a benefit or if it imposes an excessive burden on the patient:

> True compassion, on the contrary, encourages every reasonable effort for the patient's recovery. At the same time, it helps draw the line when it is clear that no further treatment will serve this purpose. The refusal of aggressive treatment is neither a rejection of the patient nor of his or her life. Indeed, the object of the decision on whether to begin or to continue a treatment has nothing to do with the value of the patient's life, but rather with whether such medical intervention is beneficial for the patient. The possible decision either not to start or to halt a treatment will be deemed ethically correct if the treatment is ineffective or obviously disproportionate to the aims of sustaining life or recovering health. Consequently, the decision to forego aggressive treatment is an expression of the respect that is due to the patient at every moment.[189]

Thus, withholding or withdrawing life-sustaining treatment such as ANH may be appropriate, based on an assessment of the benefits and burdens of treatment. Such forgoing of life-sustaining treatment "is not a form of suicide or euthanasia, both of which are prohibited in Catholic teaching."[190] Rather, the purpose of withholding or withdrawing life-sustaining treatment, that is, allowing to die, "is to avoid performing an action that is either futile or overly burdensome."[191]

Advance directives are acceptable and may be implemented in Catholic hospitals if they are in accordance with church teaching.[192] A person may identify a healthcare proxy or surrogate who may make medical decisions on her behalf if she has lost capacity to do so. Decisions by a surrogate "should be faithful to Catholic moral principles and to the person's intentions and values, or if the person's intentions are unknown, to the person's best interests."[193] Overall, the primary criteria for instituting or forgoing life-sustaining treatment are the hope of benefit and the degree of burden.[194] These criteria apply to the use of all medical and surgical interventions, including cardiopulmonary resuscitation and the use of artificial ventilation.

Summary

Effective end-of-life decision making requires preparation and foresight. Writing a clear and precise advance directive is a person's best guarantee for ensuring that one's desires and preferences regarding medical treatment in potentially end-of-life circumstances are implemented. If a person has written an advance directive and subsequently loses the capacity to make medical decisions for oneself, such decision making will likely comply with the patient's wishes and

preferences expressed in that document, unless positive requests are deemed by medical staff and the hospital ethics committee to be medically futile or nonbeneficial. In the absence of an advance directive, the medical team will attempt to identify an appropriate surrogate decision maker among the patient's known family members. In consultation with that surrogate and/or via a family conference, the medical team will utilize the best interests standard to determine a treatment plan that respects the patient's autonomy and adheres to the biomedical ethical principles of beneficence and justice. Conflicts may arise regarding the patient's capacity for medical decision making and the appropriateness or futility of various forms of treatment. Additional family conferences may be required to reach a consensus on the most appropriate way forward. Consultation with the hospital ethics committee enables an in-depth analysis of the case utilizing multiple perspectives and facilitates resolution, always focusing on the predominant consideration of the best interests of the patient.

BOX 8.3

Case Study: Current Perspectives on Withdrawal of Life-Sustaining Treatment

Jahi McMath, a thirteen-year-old child, was declared dead on December 12, 2013, following complications after surgery for sleep apnea.[195] Surgery had included tonsillectomy, adenoidectomy, and removal of superfluous sinus tissue.[196] Following the procedures at Oakland Children's Hospital and Research Center, Oakland, California, Jahi started bleeding from her nose and mouth and suffered cardiopulmonary arrest.[197] She did not regain consciousness, despite aggressive treatment that included CPR and placement of a mechanical ventilator.[198] On December 11, 2013, the chief of neurology at the hospital determined that Jahi "was dead by neurological criteria, and an EEG of her brain showed no electrical activity."[199] On December 12, 2013, a second hospital physician affirmed that the child was dead by neurological criteria.[200]

A diagnosis of brain death requires loss of brainstem function and typically results from a massive intracranial lesion compressing and damaging neurological tissue located in the mesencephalon, pons, and medulla oblongata. Owing to its natural resilience, brainstem function rarely stops completely. But once brainstem function is lost, breathing ceases and the heart stops shortly thereafter.[201] Irreversibility is assessed by absent muscular responses, loss of all brainstem reflexes, and apnea (absence of respiration) following a carbon dioxide challenge.[202] In these circumstances, "recovery does not occur and there is no known effective medical or surgical intervention."[203] Thus, brain death constitutes death of the person.

In 1980 the Uniform Determination of Death Act (UDDA) was developed with the assistance of the American Medical Association and the American Bar Association "to provide a unitary definition of death across the United States that would incorporate the concept of determining death by neurologic criteria."[204] The UDDA has since been adopted "in all 50 states by statute or case law," although in certain states the UDDA has been modified

in various respects.[205] The California Health and Safety Code includes the state's UDDA. Section 7180 states, "An individual who has sustained either (1) irreversible cessation of circulatory and respiratory functions, or (2) irreversible cessation of all functions of the entire brain, including the brain stem, is dead. A determination of death must be made in accordance with accepted medical standards."[206] The New Jersey Declaration of Death Act includes a religious or "conscience" exception, which provides that if a physician has reason to believe that "the individual's personal religious beliefs would be violated by the declaration of death upon the basis of the neurological criteria, then the death of the individual shall be declared ... solely upon the basis of cardio-respiratory criteria."[207] Thus, the New Jersey statute accommodates a religious objection to brain death.[208] In New York, state regulations list the basis for a determination of death, including "irreversible cessation of all functions of the entire brain, including the brain stem." New York regulations require that hospitals establish and implement a written policy regarding determinations of death including "a procedure for the reasonable accommodation of the individual's religious or moral objection to the determination as expressed by the individual, or by the next of kin or other person closest to the individual."[209]

Subsequent to the determination of Jahi's death, the hospital informed her mother and other family members that the ventilator would be removed.[210] However, the family did not believe that Jahi was dead and the hospital agreed to continue mechanical ventilation temporarily. Several days later, in response to a motion filed on behalf of Jahi's mother, the Alameda County Superior Court granted a temporary restraining order preventing the hospital from removing the mechanical ventilator.[211] On January 5, 2014, Jahi was moved out of the hospital and admitted to an undisclosed care facility. The hospital had turned Jahi over to the Alameda County Coroner's Office, which issued a death certificate and the coroner then relinquished custody to Jahi's family.[212] She was then admitted to St. Peter's University Hospital in New Brunswick, New Jersey.[213] At St. Peter's, the chief of pediatric critical care recorded that there was "no hope of brain recovery."[214] Jahi was released from St. Peter's in August 2014 with a discharge diagnosis of brain death. She was moved into an apartment with her mother and family. Following a sworn declaration filed on June 29, 2017, in Alameda County Superior Court that Jahi was no longer brain dead,[215] the Alameda County Superior Court ruled in September 2017 that a jury will decide whether Jahi is dead.[216] The hospital did not respond to the ruling and reissued a statement noting that "Jahi McMath has not undergone a brain death evaluation pursuant to accepted neurologic criteria as set forth in the Guidelines since she was legally declared deceased in December 2013."[217] As of December 2017, the trial had not yet been scheduled.[218]

Ethical Analysis

1. Discuss the appropriateness of continuing to provide medical support for a patient who has been determined to be legally dead.
2. The U.S. Supreme Court has never ruled that a family has the right to insist that a patient be kept "alive" after the state has declared the patient to be dead.[219] Discuss the implications for public policy in the event that an Alameda County jury ultimately decides that Jahi McMath is not dead.

3. Discuss the implications for delivery of healthcare services in end-of-life circumstances if a religious exception to the UDDA were widely adopted by state legislatures.
4. Discuss the impact of widespread adoption of such religious exceptions on the integrity of the medical profession.
5. Discuss recommendations for development of hospital policies regarding working with families who do not accept a determination of death by neurological criteria, including methods of reasonable accommodations for such families.

BOX 8.2

Case Study: Surrogate Requesting Withdrawal of LST

George Patterson, a sixty-seven-year-old man, suffered cardiac arrest while dining at a local restaurant. He was resuscitated in the field and brought to the emergency department, where he was stabilized, regained consciousness, and was being monitored in the coronary care unit (CCU). But during the night his heart stopped again. He required multiple resuscitation attempts, which resulted in several fractured ribs, and he was placed on a ventilator. On admission, his wife, Dolores Patterson, had told the medical team that her husband did not have an advance directive and had never signed any other document that identified her as a healthcare proxy. But when she visited her husband the morning after the second cardiac arrest, she became agitated and expressed great distress. She told the CCU staff that her husband would not want to live this way. She declared they had no right to keep him alive and demanded that the ventilator be removed. CCU staff informed her that her husband was stable and doing well and that he might "wake up" in a day or two. However, these reassurances had no effect and Mrs. Patterson began to raise her voice, warning nearby staff members that she would "see all of you in court." CCU staff immediately contacted the hospital ethicist, who convened a meeting of the hospital biomedical ethics committee later that afternoon.

Ethical Analysis

1. From the perspective of the biomedical ethical principles of beneficence and nonmaleficence, discuss whether Dolores Patterson, even if she had previously been designated as her husband's surrogate decision maker, would be justified in requesting discontinuation of his life-sustaining treatment. Describe additional contextual features (e.g., family harmony, financial circumstances) that might assist in the analysis of this case.
2. From the perspective of the biomedical ethical principle of autonomy, discuss the hospital's responsibilities to George Patterson. As he currently does not have capacity to make his own medical decisions, consider who will speak on his behalf and how his best interests will be upheld.

3. Describe processes by which Dolores Patterson's concerns may be addressed and respect for her husband's dignity as a human being may be sustained.
4. Discuss the overall application of biomedical ethical principles in the analysis and resolution of conflicts between patient/family desires and preferences and recommendations of the medical team.

KEY TERMS

Advance Directive
An advance directive is a legal document in which a person specifies her personal preferences and desires regarding healthcare decision making in circumstances in which she is not able to speak on her own behalf. In an advance directive, a person formalizes what she wants and does not want done in a severe healthcare emergency and identifies the quality of life that is acceptable and not acceptable. An advance directive specifies the author's surrogate decision maker, that is, the person who is legally empowered to make medical decisions on the author's behalf in the case in which she is not able to make such decisions for herself.

Best Interests Standard
The best interests standard is based primarily on the biomedical ethical principle of beneficence. The best interests standard is applicable when a patient does not have the capacity to make medical decisions and an advance directive is not available. In such circumstances, the medical team, in consultation with the hospital ethics committee and the patient's family members or close friends, if available, determines a course of action that is in the patient's best interest, that is, will provide the most good for the patient. At times, it may be determined that further treatment would be medically futile or nonbeneficial and that treatment beyond comfort care measures would not be in the best interests of the patient.

Conscious State
A person who is conscious demonstrates wakefulness (arousal; level of consciousness) and awareness (awareness of the environment and of self; content of consciousness). A person who is conscious is both awake and aware.

Family Conference
A family conference may be convened by the hospital ethics committee, in consultation with the medical team, to meet with the patient's family members in an attempt to achieve consensus regarding medical treatment in the best interests of the patient. Family conferences provide an opportunity to specifically address the concerns of family members. A family conference also enables the medical team to address the family's requests regarding the timing of withdrawal of life-sustaining treatment such as ANH, if such withdrawal is the agreed-upon course of action.

Medical Futility/Nonbeneficial Treatment
Medical futility has both qualitative and quantitative components and is defined as treatment that does not provide appreciable improvement to the patient as a whole. A determination

that treatment is nonbeneficial or medically futile asserts there is no reasonable expectation of achieving the intended physiological outcome of a specific intervention, either on a short-term or long-term basis.

Palliative Care
Palliative care refers to treatment directed toward improving the quality of life of patients with serious illnesses. Palliative care specialists assist chronically ill patients in obtaining appropriate pain control and address psychosocial issues concerning the patient, the patient's caregivers, and family members. Palliative care has a curative intent and a palliative focus. This method of treatment is applicable at any stage of the course of a serious disease and ideally is begun at the time of diagnosis, regardless of the age of the patient.

Palliative Sedation
The National Ethics Committee of the U.S. Veterans Health Administration has defined palliative sedation as "the administration of nonopioid drugs to sedate a terminally ill patient to unconsciousness as an intervention of last resort to treat severe, refractory pain or other clinical symptoms that have not been relieved by aggressive, symptom-specific palliation."[220] The National Hospice and Palliative Care Organization has defined palliative sedation as "the lowering of patient consciousness using medications for the express purpose of limiting patient awareness of suffering that is *intractable* and *intolerable*" [emphasis in original].[221]

Persistent Vegetative State
A persistent vegetative state (PVS) is characterized by complete lack of awareness of the self and environment, accompanied by sleep-wake cycles. A person in a PVS is awake at times, to the extent that he has intervals when he is not sleeping and his eyes are open. But the person in a PVS never demonstrates awareness of himself or his environment. Therefore, a person in a PVS is unconscious. The PVS patient may not require artificial ventilation, as brainstem function may be preserved, but he does require artificial hydration and nutrition for life support.

Substituted Judgment
Substituted judgment is based primarily on the biomedical ethical principle of autonomy. Substituted judgment attempts to uphold a patient's right to make her own medical decisions, even though the patient does not have the capacity at present to make those choices. Thus, as care for the patient proceeds, the patient's surrogate decision maker *substitutes* the decisions the patient would have made if the patient were capable of making those decisions and speaking on her own behalf.

Surrogate Decision Maker or Healthcare Proxy
A surrogate decision maker or healthcare proxy, identified in a patient's advance directive, does not make medical decisions *for* the patient, but rather makes these decisions *on behalf of* the patient. A patient's surrogate does not make choices for medical care based on what the surrogate thinks best, but rather based on instructions contained in the patient's advance directive and the patient's known desires and preferences. Thus, the surrogate decision maker speaks for the patient and expresses judgments that the patient would have made if the patient were capable of medical decision making and speaking for himself. This process is termed *substituted judgment.*

DISCUSSION QUESTIONS

1. Adhering to the preferences specified in a patient's advance directive may be difficult if the document has not been updated recently, that is, within the last two or three years. For example, a family member may insist that the patient had changed his mind and the previously stated preferences are no longer valid. Based on your reading of this chapter, discuss one or two other sets of circumstances that might justify overriding the instructions detailed in a patient's advance directive. Provide an ethical analysis supporting the decision to override the patient's right of autonomy or discuss why such a course of action would not be supported from the perspective of biomedical ethics.
2. Compare and contrast, from the perspective of biomedical ethics, withholding versus withdrawing life-sustaining treatment.
3. Provide an ethical analysis of a decision to withhold life-sustaining treatment in a specific set of clinical circumstances. Next, provide an ethical analysis of a decision to withdraw life-sustaining treatment in a different set of clinical circumstances.
4. Discuss the process of choosing a surrogate decision maker and your surrogate's responsibilities to you and your family. Discuss whether a family member or a friend might be the more effective choice. How do you empower your surrogate decision maker to fulfill her role, that is, act to implement your specified preferences, if the time ever comes when her services are required.

DO-IT-YOURSELF ETHICIST

1. Discuss your analysis of the primary components of medical decision making in potential end-of-life circumstances.
2. As a member of your hospital's biomedical ethics committee, you are evaluating the case of an eighty-two-year-old patient with advanced dementia and congestive heart failure. The patient's prognosis is poor. Recently the patient has been shuttled back and forth between a skilled nursing facility and the hospital, owing to repeated instances of aspiration pneumonia and acute respiratory failure. Surgical placement of a feeding tube has been recommended. From the perspective of biomedical ethics, discuss your analysis of this case and your recommendations for medical treatment.
3. Advance directives are often problematic. Most patients have not written an advance directive or the document available is vague and nonspecific, containing statements such as "I want to die in peace." As a member of your hospital's medical care evaluation committee, you are tasked with identifying solutions to overcome this obstacle to delivery of effective end-of-life care. Propose policies and procedures that might begin to redress various problems posed to effective and appropriate medical decision making at the end of life, with particular focus on the communities served by the hospital.
4. The medical team, hospital biomedical ethics committee, and patient's family are often required to reach a consensus on treatment that is in the best interests of a patient who is not capable of making his own decisions. Today, a family conference has been convened

and you are one of the hospital representatives attending that meeting. As the nurse practitioner who has been working most regularly with the patient,

- How might you assist the patient's surrogate decision maker and family members in evaluating the patient's best interests from the perspective of medical treatment and quality of life?
- What are the key concepts of such best interests that you wish the patient's family members to understand?
- How do you discuss the standards you wish to be applied and the biomedical ethical justifications for those standards?
- How do you discuss the validity of proposed exceptions to those standards?
- How do you avoid overlaying your own values in an attempt to determine the best interests of a particular patient?

REAL-WORLD APPLICATIONS—ETHICS AS A DOCTRINE OF ACTION

As a member of your hospital's biomedical ethics committee, you are asked to speak at a joint meeting of the women's and men's clubs of a local faith organization on the topic of medical futility/nonbeneficial treatment. Create a thirty-minute slide presentation discussing various definitions of nonbeneficial or medically futile treatment, the qualitative and quantitative components of such determinations, considerations involved in assessing the best interests of patients, and methods for achieving consensus on treatment based on the values of the patient, the family, and the community.

REFERENCES

[1]S. Laureys, A. M. Owen, and N. D. Schiff, "Brain Function in Coma, Vegetative State, and Related Disorders," *Lancet Neurology* 3, no. 9 (2004): 537–546.

[2]B. Jennett and F. Plum, "Persistent Vegetative State after Brain Damage. A Syndrome in Search of a Name," *The Lancet* 299, no. 7753 (1972): 734–737.

[3]Multi-Society Task Force on PVS, "Medical Aspects of the Persistent Vegetative State," *New England Journal of Medicine* 330, no. 21 (1994): 1499–1508.

[4]Jennett and Plum, "Persistent Vegetative State after Brain Damage."

[5]Council on Scientific Affairs and the Council on Ethical and Judicial Affairs, "Persistent Vegetative State and the Decision to Withdraw or Withhold Life Support," *JAMA* 263, no. 3 (1990): 426–430.

[6]The Quality Standards Subcommittee of the American Academy of Neurology, "Practice Parameters: Assessment and Management of Patients in the Persistent Vegetative State (Summary Statement)," *Neurology* 45, no. 5 (1995): 1015–1018.

[7]Ibid., 1016.

[8]T. A. Mappes, "Persistent Vegetative State, Prospective Thinking, and Advance Directives," *Kennedy Institute of Ethics Journal* 13, no. 2 (2003): 119–139.

[9]Multi-Society Task Force on PVS, "Medical Aspects of the Persistent Vegetative State. Part 2," *New England Journal of Medicine* 330, no. 22 (1994): 1572–1579.

[10]*In re Quinlan*, 70 N.J. 10 (1976), 355 A. 2d 647, http://law.justia.com/cases/new-jersey/supreme-court/1976/70-n-j-10-0.html.

[11]*Estate of Cruzan*, Estate No. CV384-9P (P. Div. Cir. Ct., Jasper County, Mo., July 27, 1988).

[12]*Cruzan v. Harmon*, 760 S.W. 2d 408 (Mo. 1988), https://scholar.google.com/scholar_case?case=3175542170381519302.

[13]*Cruzan v. Director, Missouri Department of Health*, 497 U.S. 261 (1990), https://www.law.cornell.edu/supremecourt/text/497/261.

[14]Ibid.

[15]*In re Guardianship of Theresa Marie Schiavo, Incapacitated*. Circuit Court for Pinellas County, Florida, Probate Division. File No. 90-2908GD-003, http://abstractappeal.com/schiavo/trialctorder02-00.pdf.

[16]American Academy of Neurology, "Practice Parameters, Assessment, and Management of Patients in the Persistent Vegetative State," *Neurology* 45 (1995): 1015–1018.

[17]Multi-Society Task Force on PVS, "Medical Aspects of the Persistent Vegetative State."

[18]*In re Guardianship of Theresa Marie Schiavo, Incapacitated*. District Court of Appeal of Florida, Second District, No. 2000–1269, January 24, 2001, http://abstractappeal.com/schiavo/2dcaorder01-01.txt.

[19]Chapter 2003-418. House Bill No. 35-E, http://laws.flrules.org/2003/418.

[20]*Bush v. Schiavo*, 885 So. 2d 321 (Fla. 2004), http://ache.org/pubs/hap_companion/Wing/Bush-Schaivo.pdf.

[21]S.686, 109th Congress (2005–2006), https://www.congress.gov/bill/109th-congress/senate-bill/686.

[22]U.S. District Court, Middle District of Florida, Tampa Division, Case No. 8:05-CV-530-T-27TBM, http://www.scotusblog.com/archives/schiavo.TRO-Denial.pdf.

[23]*Schloendorff v. Society of New York Hospital*, 105 N.E. 92 (N.Y. 1914).

[24]*Cruzan v. Director, Missouri Department of Health.*

[25]Ibid., at 337.

[26]*Cruzan v. Harmon*, at 429.

[27]N. Stocchetti and E. R. Zanier, "Chronic Impact of Traumatic Brain Injury on Outcome and Quality of Life: A Narrative Review," *Critical Care* 20 (2016): 148, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4915181/.

[28]H. R. Glick, "The Right-to-Die: State Policymaking and the Elderly," *Journal of Aging Studies* 5, no. 3 (1991): 283–307.

[29]L. Kutner, "Due Process of Euthanasia: e Living Will, A Proposal," *Indiana Law Journal* 44, no. 4 (1969): 539–554.

[30]New York State Department of Health, "Health Care Proxy. Appointing Your Health Care Agent in New York State," https://www.health.ny.gov/publications/1430.pdf.

[31]California Probate Code Section 4700–4701, https://oag.ca.gov/sites/all/files/agweb/pdfs/consumers/ProbateCodeAdvancedHealthCareDirectiveForm-fillable.pdf.

[32]State of West Virginia Combined Medical Power of Attorney and Living Will, http://www.peia.wv.gov/Forms-Downloads/Documents/ppb_plans/members/Advance_Directive_Living_Will.pdf.

[33]AARP, *Advance Directive. Creating a Living Will and Health Care Power of Attorney*, http://www.aarp.org/relationships/caregiving-resource-center/info-11-2010/lfm_living_will_and_health_care_power_of_attorney.html.

[34]AARP, "Advance Directive Forms," http://www.aarp.org/home-family/caregiving/free-printable-advance-directives/.

[35]S. E. Caulfield, "Health Care Facility Ethics Committees. New Issues in the Age of Transparency," *Human Rights* 34, no. 4 (2007): 10–13.

[36]California Secretary of State, Advance Health Care Registry, http://www.sos.ca.gov/registries/advance-health-care-directive-registry/.

[37]California Probate Code Section 4700–4701.

[38]Ibid.

[39]Ibid.

[40]New Jersey Department of Health, *Instruction Directives*, http://www.state.nj.us/health/advancedirective/ad/forums-faqs/.

[41]S. E. Hickman, C. A. Nelson, and N. A. Perrin et al., "A Comparison of Methods to Communicate Treatment Preferences in Nursing Facilities: Traditional Practices versus the Physician Orders for Life-Sustaining Treatment (POLST) Program," *Journal of the American Geriatrics Society* 58, no. 7 (2010): 1241–1248.

[42]B. J. Hammes, B. L. Rooney, J. D. Gundrum et al., "The POLST Program: A Retrospective Review of the Demographics of Use and Outcomes in One Community Where Advance Directives Are Prevalent," *Journal of Palliative Medicine* 15, no. 1 (2012): 77–85.

[43]Ibid., 83.

[44]*Cruzan v. Director, Missouri Department of Health.*

[45]C. P. Sabatino, "The Evolution of Health Care Advance Planning Law and Policy," *Milbank Quarterly* 88, no. 2 (2010): 211–239.

[46]Ibid., 228.

[47]Office of the Press Secretary, *Presidential Memorandum on Hospital Visitation*, April 15, 2010, https://obamawhitehouse.archives.gov/the-press-office/presidential-memorandum-hospital-visitation.

[48]Ibid.

[49]Ibid.

[50]L. Wahlert and A. Fiester, "A False Sense of Security: Lesbian, Gay, Bisexual, and Transgender (LGBT) Surrogate Health Care Decision-Making Rights," *Journal of the American Board of Family Medicine* 26, no. 6 (2013): 802–804.

[51]Ibid., 803.

[52]L. Kcomt and K. M. Gorey, "End-of-Life Preparations among Lesbian, Gay, Bisexual, and Transgender People: Integrative Review of Prevalent Behaviors," *Journal of Social Work in End-of-Life Palliative Care* 13, no. 4 (2017): 284–301.

[53]A. Buchanan and D. W. Brock, "Deciding for Others," *Milbank Quarterly* 64, suppl. 2 (1986): 17–94.

[54]J. W. Berg, P. S. Appelbaum, and T. Grisso, "Constructing Competence: Formulating Standards of Legal Competence to Make Medical Decisions," *Rutgers Law Review* 48, no. 2 (1996): 345–396.

[55]Ibid., 349.

[56]Ibid.

[57]P. S. Appelbaum, "Clinical Practice. Assessment of Patients' Competence to Consent to Treatment," *New England Journal of Medicine* 357, no. 18 (2007): 1834–1840.

[58]A. E. Buchanan and D. W. Brock, *Deciding for Others: The Ethics of Surrogate Decision Making* (New York: Cambridge University Press, 1989).

[59]M. N. Wittink, K. H. Morales, L. A. Meoni et al., "Stability of Preferences for End-of-Life Treatment after 3 Years of Follow-Up: The Johns Hopkins Precursors Study," *Archives of Internal Medicine* 168, no. 19 (2008): 125–130.

[60]C. L. Auriemma, C. A. Nguyen, R. Bronheim et al., "Stability of End-of-Life Preferences: A Systematic Review of the Evidence. *JAMA Internal Medicine* 174, no. 7 (2014): 1085–1092.

[61]*In re Quinlan.*

[62]G. J. Annas, "The Case of Baby Jane Doe. Child Abuse or Unlawful Federal Intervention?" *American Journal of Public Health* 74, no. 7 (1984): 727–729.

[63]United States Court of Appeals, Second Circuit 729 F.2d 144, 19 Ed. Law Rep. 785, http://www.freelawreporter.org/flr3d/f2d/729/729.F2d.144.83-6343.679.html; M. Chambers, "Appeals Court Rebuffs U.S. on Baby Jane Doe Records," *New York Times*, February 24, 1984.

[64]*In re Quinlan.*

[65]Ibid.

[66]S. J. Youngner, D. L. Jackson, C. Coulton et al., "A National Survey of Hospital Ethics Committees," *Critical Care Medicine* 11, no. 11 (1983): 902–905.

[67]J. M. Gibson and T. K. Kushner, "Will the 'Conscience of an Institution' Become Society's Servant? *Hastings Center Report* 16, no. 3 (1986): 9–11.

[68]Caulfield, "Health Care Facility Ethics Committees."

[69]E. Fox, S. Myers, and R. A. Pearlman, "Ethics Consultation in United States Hospitals: A National Survey," *American Journal of Bioethics* 7, no. 2 (2007): 13–25.

[70]M. P. Aulisio and R. M. Arnold, "Role of the Ethics Committee: Helping to Address Value Conflicts or Uncertainties," *Chest* 134, no. 2 (2008): 417–424.

[71]J. J. Fins, "Understanding and Utilizing the Convening Power of Ethics Consultation," *AMA Journal of Ethics* 18, no. 5 (2016): 540–545.

[72]C. A. Rentmeester and C. George, "Legalism, Countertransference, and Clinical Moral Perception," *American Journal of Bioethics* 9, no. 10 (2009): 20–28.

[73]N. R. Flower, A. Muoio, R. Garris et al., *Gather: The Art and Science of Effective Convening* (New York, Rockefeller Foundation, 2013), https://assets.rockefellerfoundation.org/app/uploads/20130626174021/Gather-The-Art-and-Science-of-Effective-Conveing.pdf.

[74]W. H. S. Jones, trans., "Prognostic," in *Hippocrates*, vol. II (Cambridge, MA: Harvard University Press, 1959), 81–82.

[75]Ibid.

[76]L. J. Schneiderman, N. S. Jecker, and A. R. Jonsen, "Medical Futility: Its Meaning and Ethical Implications," *Annals of Internal Medicine* 112, no. 12 (1990): 949–954.

[77]Ibid.

[78]J. F. Drane and J. L. Coulehan, "The Concept of Futility. Patients Do Not Have a Right to Demand Medically Useless Treatment," *Health Progress* 74, no. 10 (1993): 28–32.

[79]P. A. Clark, "Medical Futility: Legal and Ethical Analysis," *AMA Journal of Ethics* 9, no. 5 (2007): 375–383.

[80]Pope John Paul II, *Evangelium Vitae*, chap. III, para. 65, March 25, 1995, http://w2.vatican.va/content/john-paul-ii/en/encyclicals/documents/hf_jp-ii_enc_25031995_evangelium-vitae.html.

[81]AMA Council on Ethical and Judicial Affairs, "Guidelines for the Appropriate Use of Do-Not-Resuscitate Orders," *JAMA* 265, no. 14 (1991): 1868–1871.

[82]G. Rocker and S. Dunbar, "Withholding or Withdrawal of Life Support: The Canadian Critical Care Society Position Paper," *Journal of Palliative Care* 16, suppl. (2000): S53–S62.

[83]President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, *Deciding to Forego Life-Sustaining Treatment: Ethical, Medical, and Legal Issues in Treatment Decisions* (Washington, DC: U.S. Government Printing Office, 1983), 4.

[84]Ibid., 6.

[85]*Matter of Eichner,* Supreme Court, Special Term, Nassau County, 102 Misc.2d 184 (1979), http://www.leagle.com/decision/1979286102Misc2d184_1255/MTR.%20OF%20EICHNER.

[86]President's Commission for the Study of Ethical Problems, *Deciding to Forego Life-Sustaining Treatment*, 76.

[87]J. Stjernswärd, K. M. Foley, and F. D. Ferris, "The Public Health Strategy for Palliative Care," *Journal of Pain Symptom Management* 33, no. 5 (2007): 486–493.

[88]World Health Organization, *Aging and Health*, http://www.who.int/mediacentre/factsheets/fs404/en/.

[89]J. J. Strand, M. M. Kamdar, and E. C. Carey, "Top 10 Things Palliative Care Clinicians Wished Everyone Knew about Palliative Care," *Mayo Clinic Proceedings* 88, no. 8 (2013): 859–865.

[90]S. Deandrea, M. Montanari, L. Moja et al., "Prevalence of Undertreatment in Cancer Pain. A Review of Published Literature," *Annals of Oncology* 19, no. 12 (2008): 1985–1991.

[91]C. D. Blinderman, P. Homel, J. A. Billings et al., "Symptom Distress and Quality of Life in Patients with Advanced Chronic Obstructive Pulmonary Disease," *Journal of Pain Symptom Management* 38, no. 1 (2000): 115–123; S. J. Goodlin, S. Wingate, N. M. Albert et al., "Investigating Pain in Heart Failure Patients: The Pain Assessment, Incidence, and Nature in Heart Failure (PAIN-HF) Study," *Journal of Cardiac Failure* 18, no. 10 (2012): 776–783.

[92]World Health Organization, WHO Definition of Palliative Care, http://www.who.int/cancer/palliative/definition/en/.

[93]Centers for Medicare & Medicaid Services, *Revisions to Appendix PP. Interpretive Guidelines for Long-Term Care Facilities. F tag 309 Quality of Care*, September 27, 2012, https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-12-48.pdf.

[94]S. J. Goodlin, "Palliative Care in Congestive Heart Failure. *Journal of American College of Cardiology* 54, no. 5 (2009): 386–396.

[95]*Code of Federal Regulations*, Title 42, Public Health; Part 418, Hospice Care; §418.22, Certification of terminal illness. (b) (1), https://www.ecfr.gov/cgi-bin/text-idx?rgn=div5;node=42%3A3.0.1.1.5#se42.3.418_120.

[96]I. Boersma, J. Miyasaki, J. Kutner et al., "Palliative Care and Neurology. Time for a Paradigm Shift," *Neurology* 83, no. 6 (2014): 561–567.

[97]R. B. Balaban, "A Physician's Guide to Talking about End-of-Life Care," *Journal of General Internal Medicine* 15, no. 3 (2000): 195–200.

[98]A. A. Wright, B. Zhang, A. Ray et al., "Associations between End-of-Life Discussions, Patient Mental Health, Medical Care Near Death, and Caregiver Bereavement Adjustment," *JAMA* 300, no. 14 (2008): 1665–1673.

[99]R. Schulz and S. R. Beach, "Caregiving as a Risk Factor for Mortality. The Caregiver Health Effects Study," *JAMA* 282, no. 23 (1999): 2215–2219.

[100]L. M. Sebuyira, F. Mwangi-Powell, J. Pereira et al., "The Cape Town Palliative Care Declaration: Home-Grown Solutions for Sub-Saharan Africa," *Journal of Palliative Care* 6, no. 3 (2003): 341–343.

[101]Message of His Holiness Benedict XVI for the Fifteenth World Day of the Sick, December 8, 2006, http://w2.vatican.va/content/benedict-xvi/en/messages/sick/documents/hf_ben-xvi_mes_20061208_world-day-of-the-sick-2007.html.

[102]J. B. Cassel, K. M. Kerr, N. S. Kalman et al., "The Business Case for Palliative Care: Translating Research into Program Development in the U.S.," *Journal of Pain Symptom Management* 50, no. 6 (2015): 741–749.

[103]Thomas of Aquino: *Summa Theologica. Second Part of the Second Part*, Question 64, Article 7: Whether It Is Lawful to Kill a Man in Self-Defense?, trans. Fathers of the English Dominican Province (Cincinnati, OH, Benziger Bros., 1947).

[104]Ibid.

[105]Ibid.

[106]Ibid.

[107]J. T. Mangan, "An Historical Analysis of the Principle of Double Effect," *Theological Studies* 10 (1949):41–61.

[108]Ibid., 43.

[109]*Vacco v. Quill*, 521 U.S. 793, note 11 (1997).

[110]S. A. Fohr, "The Double Effect of Pain Medication: Separating Myth from Reality," *Journal of Palliative Medicine* 1, no. 4 (1998): 315–328.

[111]K. M. Foley, "The Relationship of Pain and Symptom Management to Patient Requests for Physician-Assisted Suicide," *Journal of Pain Symptom Management* 6, no. 5 (1991): 289–297.

[112]R. Gallagher, "Killing the Symptom without Killing the Patient," *Canadian Family Physician* 56, no. 6 (2010): 544–546.

[113]Ibid., 545.

[114]Ibid., 544.

[115]J. Boyle, "Medical Ethics and Double Effect: The Case of Terminal Sedation," *Theoretical Medicine and Bioethics* 25, no. 1 (2004): 51–60.

[116]H. ten Have and J. V. M. Welie, "Palliative Sedation versus Euthanasia: An Ethical Assessment," *Journal of Pain Symptom Management* 47, no. 1 (2014): 123–136.

[117]Assembly Bill No. 15, End of Life Option Act, http://www.leginfo.ca.gov/pub/15-16/bill/asm/ab_0001-0050/abx2_15_bill_20151005_chaptered.htm.

[118]I. Lovett and R. Pérez-Peña, "California Governor Signs Assisted Suicide Bill into Law," *New York Times*, October 5, 2015, https://www.nytimes.com/2015/10/06/us/california-governor-signs-assisted-suicide-bill-into-law.html.

[119]J. Medina, "Who May Die? California Patients and Doctors Wrestle with Assisted Suicide," *New York Times*, June 9, 2016, https://www.nytimes.com/2016/06/10/us/assisted-suicide-california-patients-and-doctors.html.

[120]Ibid. Per §443.1(b), an aid-in-dying drug is "a drug determined and prescribed by a physician for a qualified individual, which the qualified individual may choose to self-administer to bring about his or her death due to a terminal disease."

[121]Coalition for Compassionate Care of California, End of Life Option Act, http://coalitionccc.org/tools-resources/end-of-life-option-act/.

[122]Assembly Bill No. 15, End of Life Option Act, §443.1(a).

[123]Ibid., §443.2(a)(3).

[124]Ibid., §443.1(q).

[125]Ibid. Per §443.1(e), capacity to make medical decisions means that in the opinion of the consulting health professional, "the individual has the ability to understand the nature and consequences of a health care decision, the ability to understand its significant benefits, risks, and alternatives, and the ability to make and communicate an informed decision to health care providers."

[126]Ibid., §443.5(a)(1)(C).

[127]Ibid., §443.2(a)(5).

[128]Oregon Health Authority, Death with Dignity Act, http://www.oregon.gov/oha/ph/ProviderPartnerResources/EvaluationResearch/DeathwithDignityAct/Pages/ors.aspx.

[129]Oregon Health Authority, Oregon Death with Dignity Act: 2017 Data Summary, February 9, 2018, http://www.oregon.gov/oha/ph/providerpartnerresources/evaluationresearch/deathwithdignityact/documents/year20.pdf.

[130]Ibid., 4.

[131]Ibid., 5.

[132]Ibid.

[133]Ibid.

[134]*Washington v. Glucksberg*, 521 U.S. 702 (1997), at 705.

[135]Ibid., at 708.

[136]Ibid., at 731.

[137]Ibid., at 732.

[138]Wash. Rev. Code § 9A.36.060(1) (1994).

[139]*Washington v. Glucksberg*, at 735.

[140]L. O. Gostin and A. E. Roberts, "Physician-Assisted Dying: A Turning Point?" *JAMA* 315, no. 3 (2016): 249–250.

[141]Assembly Bill No. 15, End of Life Option Act, §443.14(e).

[142]Oregon Health Authority, Oregon Death with Dignity Act, 10.

[143]Ibid., 9.

[144]Ibid., 8.

[145]California Department of Public Health, California End of Life Option Act: 2016 Data Report, https://www.cdph.ca.gov/Programs/CHSI/CDPH Document Library/CDPH End of Life Option Act Report -ADA.pdf.

[146]Ibid., 4.

[147]Assembly Bill No. 15, End of Life Option Act, §443.3(c)(1).

[148]L. S. Sulmasy and P. S. Mueller, "Ethics and the Legalization of Physician-Assisted Suicide: An American College of Physicians Position Paper," *Annals of Internal Medicine* 167, no. 8 (2017): 576–578.

[149]Ibid.

[150]T. W. Kirk and M. M. Mahon, "National Hospice and Palliative Care Organization (NHPCO) Position Statement and Commentary on the Use of Palliative Sedation in Imminently Dying Terminally Ill Patients," *Journal of Pain Symptom Management* 39, no. 5 (2010): 914–923.

[151]Ibid., 919.

[152]Ibid., 920.

[153]ten Have and Welie, "Palliative Sedation versus Euthanasia," 129.

[154]B. M. Kinzbrunner, "Jewish Medical Ethics and End-of-Life Care," *Journal of Palliative Medicine* 7, no. 4 (2004): 558–573.

[155]Tanakh, *The Holy Scriptures* (Philadelphia: Jewish Publication Society, 1985), 602–603.

[156]Kinzbrunner, "Jewish Medical Ethics," 564.

[157]J. D. Bleich, "Treatment of the Terminally Ill. I. Preservation of Life," *Tradition* 30, no. 3 (1996): 51–87.

[158]M. D. Tendler and F. Rosner, "Quality and Sanctity of Life in the Talmud and the Midrash," *Tradition* 28, no. 1 (1993): 18–27.

[159]Kinzbrunner, "Jewish Medical Ethics," 565.

[160]Tendler and Rosner, "Quality and Sanctity of Life," 26.

[161]Ibid., 19.

[162]Ibid., 20.

[163]S. E. Bedell, T. L. Delbanco, and E. F. Cook et al., "Survival after Cardiopulmonary Resuscitation in the Hospital," *New England Journal of Medicine* 309, no. 10 (1983): 569–576.

[164]D. J. Murphy, A. M. Murray, B. E. Robinson et al., "Outcomes of Cardiopulmonary Resuscitation in the Elderly," *Annals of Internal Medicine* 111, no. 3 (1989): 199–205.

[165]Kinzbrunner, "Jewish Medical Ethics," 568.

[166]Z. Schostak, "Jewish Ethical Guidelines for Resuscitation and Artificial Nutrition and Hydration of the Dying Elderly," *Journal of Medical Ethics* 20, no. 2 (1994): 93–100.

[167]Ibid., 96.

[168]Kinzbrunner, "Jewish Medical Ethics," 568.

[169]Z. Schostak, "Precedents for Hospice and Surrogate Decision-Making in Jewish Law," *Tradition* 34, no. 2 (2000): 40–57.

[170]Kinzbrunner, "Jewish Medical Ethics," 571.

[171]Ibid.

[172]Rabbinical Council of America, *Halachic Health Care Proxy*, http://www.rabbis.org/pdfs/hcp.pdf.

[173]Ibid.

[174]A. Sachedina, "End-of-Life: The Islamic View," *The Lancet* 366, no. 9487 (2005): 774–779.

[175]Ibid., 776.

[176]Ibid.

[177]Ibid.

[178]*The Majestic Qur'ān* (Chicago: Nawawi Foundation, 2000), 68.

[179]Ibid., 73.

[180]Sachedina, "End-of-Life," 777–778.

[181]*Majestic Qur'ān*, 463.

[182]K. Hedayat, "When the Spirit Leaves: Childhood Death, Grieving, and Bereavement in Islam," *Journal of Palliative Medicine* 9, no. 6 (2006): 1282–1291.

[183]Sachedina, "End-of-Life," 778.

[184]Address of John Paul II to the Participants in the International Congress "On Life-Sustaining Treatments and Vegetative State: Scientific Advances and Ethical Dilemmas," March 20, 2004, https://w2.vatican.va/content/john-paul-ii/en/speeches/2004/march/documents/hf_jp-ii_spe_20040320_congress-fiamc.html.

[185]Ibid.

[186]Ibid.

[187]K. D. O'Rourke, "Artificial Nutrition and Hydration and the Catholic Tradition," *Health Progress* 88, no. 3 (2007): 50–54.

[188]Congregation for the Doctrine of the Faith, *Instruction on the Ecclesial Vocation of the Theologian*, http://www.vatican.va/roman_curia/congregations/cfaith/documents/rc_con_cfaith_doc_19900524_theologian-vocation_en.html.

[189]Address of John Paul II to the Participants in the 19th International Conference of the Pontifical Council for Health Pastoral Care, November 12, 2004, http://w2.vatican.va/content/john-paul-ii/en/speeches/2004/november/documents/hf_jp-ii_spe_20041112_pc-hlthwork.html.

[190]O'Rourke, "Artificial Nutrition and Hydration," 51.

[191]Ibid.

[192]U.S. Conference of Catholic Bishops, *Ethical and Religious Directives for Catholic Health Care*, November 17, 2009, Directive No. 24, http://www.usccb.org/issues-and-action/human-life-and-dignity/health-care/upload/Ethical-Religious-Directives-Catholic-Health-Care-Services-fifth-edition-2009.pdf.

[193]Ibid., Directive No. 25.

[194]D. P. Sulmasy, "End-of-Life Care Revisited," *Health Progress* 87, no. 4 (2006): 50–56.

[195]B. Cary and D. Grady, "At Issue in 2 Wrenching Cases: What to Do After the Brain Dies," *New York Times*, January 9, 2014, https://www.nytimes.com/2014/01/10/health/the-science-behind-brain-death.html.

[196]C. M. Burkle, R. R. Sharp, and E. F. Wijdicks, "Why Brain Death Is Considered Death and Why There Should Be No Confusion," *Neurology* 83, no. 16 (2014): 1464–1469.

[197]K. J. Bender and N. N. Alund, "Judge Grants Restraining Order Keeping Brain Dead Oakland Girl on Ventilator through Monday," *Oakland Tribune*, December 20, 2013, https://www.mercurynews.com/2013/12/20/judge-grants-restraining-order-keeping-brain-dead-oakland-girl-on-ventilator-through-monday/.

[198]J. M. Luce, "The Uncommon Case of Jahi McMath," *Chest* 147, no. 4 (2015): 1144–1151.

[199]Ibid., 1145.

[200]Ibid.

[201]Burkle, Sharp, and Wijdicks, "Why Brain Death Is Considered Death," 1464–1465.

[202]Ibid., 1465.

[203]Ibid.

[204]Luce, "The Uncommon Case of Jahi McMath," 1147.

[205]Burkle, Sharp, and Wijdicks, "Why Brain Death Is Considered Death,"1466.

[206]California Legislative Information, *Health and Safety Code, Chapter 37: Death*, http://leginfo.legislature.ca.gov/faces/codes_displaySection.xhtml?lawCode=HSC&sectionNum=7180.

[207]New Jersey Law Revision Commission, *Final Report Relating to New Jersey Declaration of Death Act*, January 18, 2013, http://www.lawrev.state.nj.us/UDDA/njddaFR011813.pdf.

[208]T. M. Pope, "Brain Death Forsaken: Growing Conflict and New Legal Challenges," *Journal of Legal Medicine* 37, nos. 3–4 (2017): 265–324, 318.

[209]New York Codes, Rules and Regulations: Title 10, Section 400.16, Determination of death, https://regs.health.ny.gov/content/section-40016-determination-death.

[210]Luce, "The Uncommon Case of Jahi McMath," 1145.

[211]H. K. Lee, "Oakland Hospital Must Keep Brain-Dead Girl on Ventilator," *San Francisco Chronicle*, December 21, 2013, https://www.sfgate.com/bayarea/article/Oakland-hospital-must-keep-brain-dead-girl-on-5083153.php.

[212]R. Hurd et al., "Jahi McMath: Brain-Dead Girl Moved to Undisclosed Care Facility," *Oakland Tribune*, January 6, 2014, https://www.mercurynews.com/2014/01/06/jahi-mcmath-brain-dead-girl-moved-to-undisclosed-care-facility/.

[213]R. Aviv, "What Does It Mean to Die?" *The New Yorker*, February 5, 2018, https://www.newyorker.com/magazine/2018/02/05/what-does-it-mean-to-die.

[214]Ibid.

[215]L. Johnson, "Jahi McMath's Family Wins Backing for Argument That She's Alive," *San Francisco Chronicle*, July 24, 2017, https://www.sfchronicle.com/bayarea/article/Jahi-McMath-s-family-wins-backing-for-argument-11319544.php.

[216]J. Lyons, "Alameda County Jury Will Decide If Jahi McMath Is Alive," *San Francisco Chronicle*, September 8, 2017, https://www.sfgate.com/bayarea/article/Judge-Oakland-jury-will-decide-if-Jahi-McMath-is-12180671.php.

[217]Ibid.

[218]Aviv, "What Does It Mean to Die?" 213.

[219]Luce, "The Uncommon Case of Jahi McMath," 1149.

[220]National Ethics Committee, Veterans Health Administration, "The Ethics of Palliative Sedation as a Therapy of Last Resort," *American Journal of Hospital Palliative Care* 23, no. 6 (2006–2007): 483–491, 484.

[221]Kirk and Mahon, "NHPCO Position Statement," 914–915.

Figure Credits

Fig. 8.1: Source: https://pixabay.com/en/tree-nature-wood-winter-kahl-log-3097419/

Fig. 8.2: Source: https://pixabay.com/en/people-adult-woman-man-medicine-3192204/

CHAPTER 9

Healthcare Issues in Contemporary Society—Part 1

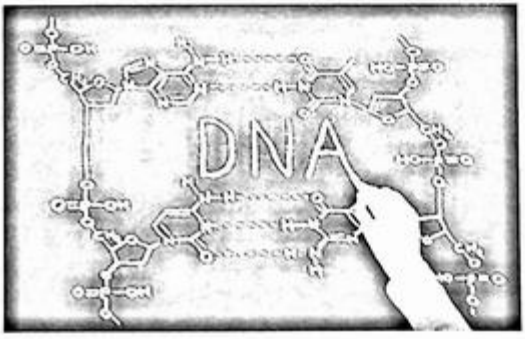
BRIEF HISTORY OF MEDICARE, MEDICAID, AND MANAGED CARE; PATIENT AUTONOMY AND INFORMED CONSENT REVISITED; GENE EDITING AND GENETIC TECHNOLOGIES; AND CONTEMPORARY ISSUES IN HEALTHCARE LAW

Healthcare issues in contemporary society are complex and persistent. New issues arise in response to novel developments in medical research and medical technologies, as well as with conflicts between the availability of healthcare services and the needs of families, communities, and populations for those services. Additional areas of conflict concern ramifications of the biomedical ethical principles of autonomy and beneficence and involve issues related to informed consent; gene editing, genetic technologies, and assisted reproductive technologies; and healthcare provider conflict of interest. These issues will be explored in Chapter 9. Healthcare issues involving electronic health records, healthcare policy and population health, bias in healthcare delivery, and corporate governance will be discussed in Chapter 10.

Brief History of Medicare, Medicaid, and Managed Care

On July 30, 1965, Medicare and Medicaid were enacted as Title XVIII and Title XIX of the Social Security Act,[1] signed into law by President Lyndon B. Johnson. Medicare was established to provide coverage for hospital services, postdischarge extended care, and home health services to almost all Americans aged sixty-five and older.[2] Medicaid was established to provide states with the option to receive federal funds for

FIGURE 9.1 Biomedical breakthroughs require effective public policy



delivering healthcare services to low-income children, their caretaker relatives, and individuals with disabilities.[3]

By July 1, 1966, more than 19 million individuals had enrolled in Medicare. In 1972 Medicare eligibility was extended to include persons under age sixty-five with long-term disabilities and those with end-stage renal disease.[4] As well, in 1972, Medicaid eligibility for elderly, blind, and disabled residents of a state was linked to eligibility for the new Federal Supplemental Security Income program.[5] In 1973, the Health Maintenance Organization Act committed the federal government to a trial period of support for the development of health maintenance organizations (HMOs).[6] HMOs were designed to provide a comprehensive range of healthcare services to subscribers in return for a fixed monthly or annual payment. HMO structure was modeled on prototypes such as the Kaiser Foundation Health Plan in California (established in 1942) and the Health Insurance Plan of Greater New York (established in 1947).[7] In 1972, approximately 7 million Americans (3 percent of the population) were enrolled in HMOs.[8] Per the 1973 legislation, to receive federal assistance HMOs were required to "enroll persons who are broadly representative of the various age, social, and income groups within the areas they serve."[9] HMOs were required to have annual enrollment periods. Further, an HMO "may not refuse to enroll or re-enroll any member for reasons concerning his health status or needs for health services."[10] HMOs were required "to provide medical social services for their members and to actively provide health education services."[11] Such services would assist patients in engaging in self-care activities and in fulfilling their responsibilities for "proper diet, exercise, and use of medications."[12]

In 1983 the Medicare hospice benefit was established as an option "for beneficiaries to receive all-inclusive care to relieve pain and manage symptoms in a home setting rather than an institutional setting."[13] In 1986, Medicaid coverage for pregnant women and infants (up to age one year), at up to 100 percent of the federal poverty level, was established as a state option.[14] In 1997, the Balanced Budget Act created the Children's Health Insurance Program (CHIP). CHIP expanded health insurance coverage for low-income children whose families had too much income to qualify for Medicaid and too little income to afford private insurance.[15] States have the option to provide CHIP services as a separate program, through Medicaid, or in combination. As with Medicaid, state CHIP payments qualify for federal matching payments. In 2003, the Medicare Prescription Drug, Improvement, and Modernization Act created a new optional prescription drug benefit, effective in 2006, and created new coverage for preventive benefits, including initial preventive physical examinations, cardiovascular screening laboratory tests, and diabetes screening tests.[16] The CHIP Reauthorization Act of 2009 was signed into law by President Obama on February 4, 2009.[17] This legislation extended overall funding for CHIP, provided states with significant new funding, and created new state options such as conducting simplified eligibility determinations and providing CHIP assistance to low-income pregnant women.

Prior to the advent of Medicare, 48 percent of Americans age sixty-five and older had no health insurance.[18] As of 2015, that proportion had reduced to 2 percent. In 1966, older Americans paid 56 percent of their healthcare expenses directly out-of-pocket. In 2015, that proportion had reduced to 13 percent.[19] Further, as of 2015, access to healthcare facilitated by Medicare had contributed to a five-year increase in life expectancy at age sixty-five.[20] Medicare covered 55.7 million Americans in 2015 (17 percent of the population) and enrollment was projected to be 81 million in 2030.[21] In 2016, Medicare spending was US$672.1 billion, representing 3.6 percent of the U.S. gross domestic product (GDP). In 2016, Medicaid spending was US$565.5 billion,

representing 3.0 percent of GDP. Together, in 2016, Medicare and Medicaid spending represented 37.5 percent of the US$3.3 trillion total national health expenditure.[22] Importantly, the large majority of Medicare expenditures support treatment for those who are the most unwell and have the most complex care needs. In this context, in 2010, 25 percent of Medicare beneficiaries accounted for 82 percent of Medicare spending.[23]

Medicare compares favorably with private insurance across a broad range of performance measures, including access to care, protection from financial burdens, and overall satisfaction with insurance coverage.[24] Significantly, as of 2011, Medicare administrative costs were approximately 2 percent of program expenditures.[25] Similarly, in 2017, Medicare administrative costs were reported as 2.2 percent, compared with private insurance administrative costs of 12.4 percent.[26] Medicare has required that hospitals, skilled nursing facilities, home health agencies, and dialysis facilities "report data on their processes and outcomes."[27] Current challenges to Medicare include rising costs. Total program spending is anticipated to exceed growth in the total economy as the number of Medicare beneficiaries is increased by retiring baby boomers.[28] A further challenge is the complexity of the current Medicare structure, which include separate plans for hospital care, physician services, and prescription drugs (Part A, Part B, and Part D, respectively). Most beneficiaries purchase supplemental private insurance to cover Medicare "gaps" represented by deductibles and out-of-pocket costs.[29] Also, Medicare coverage for long-term care in a skilled nursing facility (SNF) is limited. In traditional Medicare, there are zero costs to the beneficiary (for each benefit period) for days 1–20 in a SNF. A copayment is required for days 21–100 in a SNF and the beneficiary is responsible for all costs for days 101 and beyond. Supplemental private insurance may provide coverage for these costs.[30] Medicaid may provide funding for long-term care, but only for those who are impoverished and meet state Medicaid requirements regarding income and assets. Overall, Medicare reform measures could include combining the separate plans into a single program with a single premium and a single system of deductibles and copayments.[31] Traditional Medicare could reduce out-of-pocket payments and thus make Medicare gap plans unnecessary. Solutions directed at reforming Medicare coverage for long-term care will likely require new sources of federal funding.[32] Such Medicare reform measures will enable the U.S. healthcare system to continue to provide older Americans with necessary healthcare services "without imposing prohibitive costs on the patients or their families."[33]

In 2010, the Patient Protection and Affordable Care Act (ACA) expanded Medicaid eligibility, as of January 1, 2014, to any American with a family income at or below 133 percent of the federal poverty level (FPL).[34] In practice, the effective threshold level for Medicaid eligibility is 138 percent of the FPL. Medicaid covers a wide range of healthcare and long-term care benefits. Medicaid is the primary payer for long-term services and supports (LTSS),[35] which are required in the treatment of disabling conditions and chronic illnesses. Medicaid enrollees requiring LTSS include working adults with significant disabilities, children who are medically fragile, persons with intellectual and developmental disabilities, and individuals who are severely mentally ill.[36] In 2015, Medicaid spent US$112.8 billion on LTSS, representing more than 20 percent of total Medicaid expenditures.[37] In 2010, approximately 6 percent of Medicaid beneficiaries utilized LTSS, accounting for almost half of all Medicaid spending.[38] Overall, Medicaid beneficiaries tend to be sicker and to have "lower socioeconomic status, poorer nutrition, and fewer community and family resources"[39] compared with persons able to afford private health insurance.

Medicaid enrollment provides previously uninsured persons substantially enhanced access to necessary medical and allied healthcare.[40] For example, major expansions in Medicaid eligibility

in three states in the early 2000s were significantly associated with improved healthcare coverage, access to healthcare services, self-reported health status, and a relative reduction of 6.1 percent in all-cause mortality.[41] As of November 2017, 68.2 million individuals were enrolled in Medicaid and 6.1 million children were enrolled in CHIP. Altogether, nearly 35.7 million children are enrolled in either Medicaid or CHIP, representing more than 50 percent of total Medicaid and CHIP program enrollment.[42] Ongoing enhancements to Medicaid services include state policies promoting community integration and community-based care, as against spending on long-term services delivered via institutional care. Additional enhancements include coordinating care for persons with chronic conditions such as diabetes and developing new models of substance use disorder treatment, maternal and infant healthcare, children's healthcare, and mental healthcare.[43]

Patient Autonomy and Informed Consent Revisited

As discussed in Chapter 3, the legal doctrine of informed consent arose out of court decisions whose concerns were (1) protecting patients from unwarranted intrusions upon their physical persons and (2) the patient's right of self-determination with respect to medical decision making. As well, informed consent is an ethical doctrine, with origins in the Nuremberg Code (1947)[44] and the *Belmont Report* (1978).[45] In the context of ethics, informed consent may be considered as implementing the biomedical ethical principle of autonomy, that is, respect for persons.

But in day-to-day healthcare interactions among providers and patients, the practice of informed consent frequently devolves into one more administrative protocol that must be fulfilled before the provision of actual billable services may begin. Informed consent interactions, such as they are, typically consist of a staff member presenting the patient with a form and requesting her signature. Such procedures have been characterized as empty rituals in which patients are presented with complex information they cannot understand that has minimal impact on their decision making.[46] But formalities or routines devoid of content fail to uphold a patient's right to make her own choices and do not demonstrate respect for that person as an autonomous individual. In this context, it is useful to distinguish ***consent as an event*** from ***consent as a process.***[47]

Consent as an event focuses on fulfilling the legal obligation of providing information that a reasonable person would consider material prior to making a treatment decision and obtaining the patient's signature on the informed consent form. But the event model of informed consent is not concerned with the patient's understanding of the information presented nor with the patient's decision-making process. In the event model, a physician may have fulfilled the letter but not the spirit of her duty to disclose information material to patient decision making. Grounds for a claim for negligence, or even battery, may have been obviated, but this may reasonably represent a secondary consideration. The duty to disclose, underpinning the legal requirement for informed consent, is primarily directed toward upholding the patient's right of self-determination. As the District of Columbia Court of Appeals opined in *Canterbury v. Spence* in 1972, "Respect for the patient's right of self-determination on particular therapy demands a standard set by law for physicians rather than one which physicians may or may not impose upon themselves."[48]

In contrast to consent as an event, *consent as a process* emphasizes the unfolding, evolving characteristics of a patient's understanding of the complex information being presented and the complex health circumstances that have necessitated his participation in treatment decisions.

A process model encourages active patient participation in healthcare decisions. Implicit in such a process model is the opportunity for patients to ask questions, express their concerns, and ensure that their preferences regarding quality of life are addressed. A process model is necessarily iterative and a certain amount of time may be required for a patient to obtain sufficient understanding and make an informed decision. As time is a priority in all patient–physician interactions, training of healthcare providers in the conduct and management of informed consent interactions and conversations[49] will help achieve efficient informed consent processes directed toward upholding patient rights.

The Therapeutic Misconception

Regarding the consent and participation of human subjects in medical research, federal regulations require that institutional review board (IRB) approval must be obtained for all planned protocols.[50] IRB oversight is directed toward ensuring protection of the rights of study participants, including privacy of subjects and confidentiality of the data collected, and identifying and minimizing risks to research subjects.[51] Further, per federal regulations,[52] IRBs shall require that information provided to research subjects as part of informed consent processes is in accordance with the general requirements for informed consent detailed in 45 CFR 46.116.

Individuals who participate as subjects in medical research may choose to do so based on personal altruism; the desire to benefit others in the future, such as family members in the case of an inherited disorder; the possibility of obtaining an intervention that would be unavailable otherwise owing to limitations of supply or substantial costs; or the possibility of obtaining a new and potentially more effective treatment that is, at present, only available in a clinical trial. But if the patient herself has the disease or disorder that is the focus of the research study, she may likely misconstrue the purpose of the study and believe that participation will provide a therapeutic benefit. This misapprehension or misunderstanding has been termed the *therapeutic misconception.*

The therapeutic misconception, originally described in 1982, delineates the belief of patients who choose to participate in medical research studies that "decisions about their care are being made solely with their benefit in mind."[53] This misapprehension may manifest in the patient's belief that the research protocol will advance his own therapeutic interests. The therapeutic misconception persists despite efforts of researchers to effectively communicate the details of a particular study, including randomization, double blinding, and a probabilistic chance of receiving placebo.[54] A research subject's decision to participate in medical research is impacted by a therapeutic misconception when he fails to comprehend that the imperatives of research and of treatment are distinct. The research subject under a therapeutic misconception mistakenly believes that the individualized care and therapeutic intentions from which he would benefit in an ordinary clinical setting will be obtainable in the research study. Thus, the therapeutic misconception occurs when a patient misconstrues the intentions and purposes of medical research and attributes a therapeutic intent to the research project. The patient does not understand "the difference between participating in a clinical trial and receiving ordinary clinical care."[55]

The therapeutic misconception is a common factor in a potential research subject's decision-making process. Depending on how the therapeutic misconception is measured, between 62 and 86 percent of research subjects demonstrate substantial error in comprehending the issues involved in participating in a clinical trial.[56] Research subjects frequently overestimate the likely benefits of participating in a research study,[57] underestimate risks of participation,[58] and conflate

medical research with ordinary treatment. But there are major differences between receiving treatment in a clinical setting and participating as a subject in a research study. In the clinical setting the physician–patient relationship is paramount and the physician's primary allegiance is to the patient's well-being, that is, the physician fulfills the obligation of "personal care."[59] A physician treating a patient will utilize any medication, modality, or procedure that will maximize benefit and improve the patient's outcome. In contrast, in a research trial, it is very unlikely that the specific treatments being studied will be identically beneficial for a particular patient.

Further, the medical researcher has "a commitment to promote the acquisition of scientific knowledge."[60] The research subject's best interests are not the primary consideration for the researcher. A patient who does not respond initially to a low dose of medication may not receive a higher dose, as she typically would if she were being treated by a physician whose principal obligation was to the patient's welfare. A research subject who experiences side effects cannot obtain a lower dose that presumably would decrease the untoward effects of the medication or protocol being studied. Additionally, researchers in a double-blind study are necessarily ignorant of the treatment that research subjects are receiving. Recognition of drug interactions or other side effects or adverse consequences may be delayed. Thus, the formalized nature and inflexibility of an experimental protocol "often lead investigators to forgo individualized treatment decisions."[61] Overall, the purpose of medical research is "to generate data that could lead to improved care for future patients."[62] In other words, the purpose of scientific research is to yield generalizable knowledge that may be of assistance to future generations. Medical research is distinct from medical treatment. Research subjects under a therapeutic misconception fail to recognize that "scientific methodology has other than a therapeutic purpose."[63]

Despite more than thirty-five years of investigation, commentary, and recommendations, the therapeutic misconception remains a common phenomenon among research subjects. It may be reasonably stated that the presence of a therapeutic misconception compromises a potential research subject's decision-making capability. Additionally, researcher inattention or subtle encouragement that benignly or actively perpetuates the therapeutic misconception may restrict or otherwise limit a research subject's right of self-determination and expression of individual autonomy. Such restrictions of the autonomy of potential research subjects, in furtherance of the interests of researchers or even of society as a whole, may be reasonably considered inappropriate violations of those individuals' rights. To provide valid informed consent, a potential research subject must be able to appropriately assess the risks of participation in a research study and the "compromises of personal care built into the design of a clinical trial."[64]

The solution to the therapeutic misconception does not inhere in increasing the amount of information provided in informed consent forms, but rather in teaching prospective research subjects the differences between research and ordinary treatment. For example, emphasis may be placed on the chance nature of group assignment, as opposed to the therapeutic misconception that the research subject will be assigned to the group that is best for her.[65] Further, the research subject's "cognitive frame" that is "personal and focused primarily on their medical problems" may be addressed by clearly explaining clinical trial methodology, explicitly addressing and refuting therapeutic assumptions on the part of the research subject, and avoiding, where possible, the impact of symbols of treatment such as white coats or stethoscopes around the neck of the researcher.[66]

Such necessary modifications of informed consent interactions with potential research subjects may only require minor changes. Introducing a "neutral discloser" to conduct "preconsent

discussions" facilitates teaching prospective study participants about key aspects of the research protocol and how medical research differs from medical treatment. Discussions with a neutral discloser have led to increased understanding by potential research subjects of randomization, double-blinding, and use of placebos.[67] Additional steps include forms prominently displaying the headline, "This medical research project is not expected to benefit you,"[68] emphasizing that study participants have a low likelihood of receiving a health benefit. It may be reasonably stated that the costs of furthering the interest of others, even future generations, should not be borne by research subjects who do not understand "what they themselves are giving up in the process."[69] The principles of biomedical ethics require that measures be taken ongoingly to redress the therapeutic misconception in all medical research undertakings and ensure that the rights of research subjects are upheld.

Informed Consent and the Use of Biospecimens

New challenges to informed consent are presented by the use of biospecimens, previously collected in the course of a patient's medical treatment, in genetic and other medical research. As background, the structure of DNA, the large molecule that stores an organism's genetic code, was identified as a double helix by a British team of researchers and reported in *Nature* in 1953.[70] The information contained in DNA had previously been determined to consist of sequences of ring-shaped nitrogenous base pairs matching a purine (adenine or guanine) with a pyrimidine (thymine or cytosine). Human DNA consists of approximately 3 billion base pairs.[71] Recent estimates of the number of genes (sequences of base pairs that code for specific proteins) in the human genome range from 20,000 to 25,000.[72] An early estimate of 100,000 genes had been described in a 1990 National Institutes of Health report on the Human Genome Project.[73] Human genome sequencing was facilitated by technology including DNA sequencers and synthesizers, protein sequencers and synthesizers, and the polymerase chain reaction[74] (an automated copying process "amplifying" quantities of small segments of DNA), and initial sequencing and analysis of the human genome was published in 2001.[75] Subsequent to publication of the vast data set represented by the human genome, universities, research institutions, and pharmaceutical companies began the ongoing pursuit of useful genetic information that might help identify novel drug targets and other new methods of treatment.

As discussed, the purpose of scientific research is to develop or contribute to generalizable knowledge.[76] But over the course of the past fifty years, as medical research expanded and genetic research progressed, commentators have noted a shift in the practice of medicine from an altruistic pursuit toward a profit-making enterprise, described in 1980 as the medical-industrial complex.[77] Of course, obtaining medical services has always required the payment of fees to individual practitioners and hospitals, but the new phenomenon was characterized as "a large and growing network of private corporations engaged in the business of supplying healthcare services to patients for a profit."[78] Medical research began to be recognized as a venue for generating revenues and profits,[79] with evidence suggesting that "financial ties that intertwine industry, investigators, and academic institutions can influence the research process."[80] The possibility of forging these links and financial ties may be reasonably traced to the Bayh-Dole Act (Public Law 96-517),[81] signed into law in 1980. This legislation, also known as Amendments to the Patent and Trademark Act of 1980, provided universities and other nonprofit organizations the option to retain ownership of inventions arising from federally funded research. As a result, all medical research, via a process of "technology transfer,"[82] could be used as a springboard

to create revenue streams for start-up companies and sponsoring corporations. The act also increased the likelihood of circumstances implicating conflicts of interest.

For example, medical research investigating the genetic causes of diseases such as cancer, cardiovascular disorders, diabetes, and neurological disorders utilizes as basic materials the hundreds of millions of biospecimens derived from routine medical procedures including blood tests, biopsies, and surgeries. In 2000, more than 300 million human tissue samples had been archived in the United States.[83] The total number of such samples had been estimated to increase by more than 20 million per year.[84] The majority had been collected by pathologists on a routine basis, without consideration of the possibility that the samples might be used for research. But the demand for these tissue samples has been increasing each year.[85] Conflicts quickly arose among those whose tissue samples were being used in medical research and others who sought to register patents and derive profits from research on those biospecimens.

In 1990, a key ruling affected the legal right of research participants to profit from use of their previously collected tissue samples. In *Moore v. The Regents of the University of California*,[86] the Supreme Court of California ruled that, effectively, other people may own a patient's body parts but the patient may not. The plaintiff, John Moore, had undergone treatment for hairy cell leukemia at the Medical Center of the University of California at Los Angeles. After hospitalization, "extensive amounts of blood, bone marrow aspirate, and other bodily substances" were withdrawn and the diagnosis was confirmed.[87] Moore returned to UCLA Medical Center several times between November 1976 and September 1983 and additional samples of "blood, blood serum, skin, bone marrow aspirate, and sperm" were withdrawn at each visit.[88] Research on these tissue samples led to the establishment of a cell line from the plaintiff's T lymphocytes, and on January 30, 1981, the regents applied for a patent on the cell line. The patent was issued on March 20, 1984, naming two of the *Moore* defendants "as the inventors of the cell line and the Regents as the assignees of the patent."[89] The plaintiff alleged that his physician "failed to disclose preexisting research and economic interests in the cells before obtaining consent to the medical procedures by which they were extracted."[90] The court stated "so long as a physician discloses research and economic interests that may affect his judgment, the patient is protected from conflicts of interest."[91] Thus, there was a "cause of action for breach of fiduciary duty or lack of informed consent."[92] In other words, Moore's physician had not disclosed the existence of his research activities.[93] As such, informed consent had not been obtained. Moore's physician had failed to fulfill his legal obligation to act in the best interests of his patient.

But, importantly, the *Moore* court did not give the plaintiff a property right in his extracted tissues. Based on the *Moore* decision, a patient's privacy and dignity are protected by a physician's fiduciary duty and informed consent processes, yet interference with those interests does not amount to a conversion of personal property.[94] *Conversion* is a legal term denoting an intentional tort in which one person "takes" another's property by using or substantially changing the property in a way that interfered with the owner's interest in the property. A conversion claim attempts to recover the value of personal property that was altered or damaged by another person's unauthorized use.[95] Further, the court discussed California Health and Safety Code Section 7054.4 and noted, "By restricting how excised cells may be used and requiring their eventual destruction, the statute eliminates so many of the rights ordinarily attached to property that one cannot simply assume that what is left amounts to 'property' or 'ownership' for purposes of conversion law."[96]

The *Moore* court was concerned about the effects of establishing a property interest in body tissues, noting the "conflicting moral, philosophical and even religious values at stake." The ramifications of such a property interest were to be "greatly feared," including "the effect on human dignity of a marketplace in human body parts, the impact on research and development of competitive bidding for such materials, and the exposure of researchers to potentially limitless and uncharted tort liability."[97] Further, a ruling in favor of the plaintiff could "destroy the economic incentive to conduct important medical research."[98] In his concurring opinion, Justice Armand Arabian stated, "Whether, as plaintiff urges, his cells should be treated as property susceptible to conversion is not, in my view, ours to decide."[99] In his concurring and dissenting opinion, Justice Allen Broussard noted, "the majority opinion rests its holding, that a conversion action cannot be maintained, largely on the proposition that a patient generally possesses no right in a body part that has already been removed from his body."[100]

In his dissenting opinion, Justice Stanley Mosk stated, "every individual has a legally protectable property interest in his own body and its products." Justice Mosk described a specter of exploitation that arises "wherever scientists or industrialists claim, as defendants claim here, the right to appropriate and exploit a patient's tissue for their sole economic benefit."[101] Justice Mosk referenced the *Moore* court of appeal opinion that "if this science has become science for profit, then we fail to see any justification for excluding the patient from participation in those profits."[102] Rightly or wrongly decided, *Moore* is a landmark case. However, other jurisdictions have interpreted property interests differently.

Another key case explored how conversion might apply to donations of sperm. In 1993, in *Hecht v. Superior Court of Los Angeles County*, the California Court of Appeals found that sperm is a property to be distributed by the decedent's estate.[103] The *Hecht* court stated, "the decedent's interest in his frozen sperm vials, even if not governed by the general law of personal property, occupies 'an interim category that entitles them to special respect because of their potential for human life' [referencing *Davis v. Davis*[104]], ... Thus, decedent had an interest in his sperm which falls within the broad definition of property in Probate Code section 62."[105] In *York v. Jones*, a U.S. District Court in Virginia ruled that a couple had property rights to an embryo ("pre-zygote") of which they were the progenitors.[106] In *United States v. Arora*, a U.S. District Court in Maryland applied the tort of conversion to misappropriated cell lines (as was claimed by the plaintiff in *Moore*), recognizing that biological material is property capable of being owned.[107] In *Arora*, the court stated, "The fact is that the United States Supreme Court has recognized that a living cell line is a property interest capable of protection [referencing *Diamond v. Chakrabarty*[108]]."

Also, in 2006, *Washington University v. Catalona* addressed the question of ownership of excised or donated biological tissues. In *Catalona*, the Eastern District Court of Missouri found the plaintiff "owns all biological materials including but not limited to blood, tissue, and DNA samples" stored in its biorepository, and the defendants (Dr. Catalona and eight research participants who donated the tissue samples) had no "ownership or proprietary interest in the biological samples" housed in that facility.[109] The *Catalona* trial court had expressed similar concerns to those of the *Moore* majority. Senior District Judge Stephen N. Limbaugh opined, "Medical research can only advance if access to these materials to the scientific community is not thwarted by private agendas."[110] Judge Limbaugh described "the importance of the research protocol to public health" and noted "the integrity and utility of all biorepositories would be seriously threatened" by granting ownership of tissue samples to research participants. He noted

that "selling excised tissue or DNA on e-Bay would become as commonplace as selling your old television on e-Bay."[111]

The *Catalona* decision was appealed to the U.S. Court of Appeals, Eighth Circuit. In 2007, the appeals court affirmed the trial court's ruling that the plaintiff owned the biological materials and neither the defendant "nor any contributing individual has any ownership or proprietary interest in the disputed biological materials."[112] The U.S. Court of Appeals highlighted

> the pivotal inquiry in this dispute: whether individuals who make an informed decision to contribute their biological materials voluntarily to a particular research institution for the purpose of medical research retain an ownership interest. ... Under the facts of this case, the answer is no.[113]

In addition, the trial court had found that the research participants had donated their biological materials to Washington University as *inter vivos* gifts, defined by Missouri law as "a voluntary transfer of property by the owner to another, without any consideration or compensation as an incentive or motive for the transaction."[114] The appeals court agreed that absolute gifts had been made to Washington University. Under terms of the consent documents and research brochures, the research participants were entitled to request that their biological samples no longer be used, and the materials would be destroyed upon request. The *Catalona* court stated that the research subjects "retained no greater interest with regard to their biological materials." The limited rights of the research subjects regarding use of donated tissue samples could not be equated with or interpreted to include the broad privileges or proprietary interests advocated by the defendants."[115]

In summary, research subjects may assert the right that their donated biological materials no longer be used and be destroyed upon request. However, it is not likely that, once their participation in a specific research project has concluded, research subjects will continue to be aware of ongoing use of these biospecimens. In all cases it is possible that, in future, their biological materials will be used for research other than that in which they participated. Further, case law is unsettled regarding a property interest of research subjects in their donated biological materials. Per *Moore*, researchers and research institutions may patent inventions and derive revenues and profits from commercialized ventures based on research on donated biospecimens. It is reasonable to speculate that many persons considering participation as subjects in medical research would not wish that their time and efforts, nor their tissue samples, be used to generate profits for others, especially entities unknown to them at the time of their participation in specified research. As such, respect for persons and considerations of the biomedical ethical principle of autonomy would likely mandate that informed consent documents acknowledge such commercial possibilities, thus enabling an informed choice regarding participation in medical research.

Public Policy Implications

From a broader perspective, public perception of medical research has shifted from an altruistic pursuit of generalizable knowledge that will benefit future generations, to that of a commercial activity whose primary focus is revenue streams, initial public offerings (IPOs), and increasing market share, and may lead to distrust of the medical establishment as a whole and distortion and possibly failure of the physician–patient relationship. Such considerations, including the recognized need to preserve the integrity of the medical research enterprise, led federal policy makers to formulate requirements for enhanced protections of medical research subjects.

In 2011 the Department of Health and Human Services issued an advance notice of proposed rulemaking (ANPRM) regarding how to better protect human medical research subjects, facilitate medical research, and reduce unnecessary burdens and ambiguity for researchers.[116] The ANPRM noted that regulations governing research on human subjects were formulated years ago and have not kept pace with more recent developments such as research involving databases and biological specimen repositories, and the use of advanced technologies including genomics.[117] Revisions to these regulations were to be considered to strengthen protections for human research subjects. In September 2015, a notice of proposed rulemaking (NPRM) was released for public comment.[118] More than 2,100 public comments were submitted,[119] including a report from the National Academies of Sciences, Engineering, and Medicine.[120]

Subsequently, revisions to the Federal Policy for the Protection of Human Subjects, originally promulgated as a Common Rule in 1991 (45 CFR 46),[121] were announced in the *Federal Register* on January 19, 2017. The revised and updated Common Rule, to be known as the "final rule," was to go into effect on January 19, 2018.[122] A key revision in the proposed final rule related to improving informed consent procedures so that potential research subjects would be better informed regarding their participation in a research study. It had been recognized that under previous rules, informed consent forms had become longer and more difficult to understand. The revisions to the Common Rule required providing "essential information that a reasonable person would want to know in order to make an informed decision about whether to participate in research and to provide an opportunity to discuss that information."[123] The presentation in the *Federal Register* acknowledged complaints that consent forms seemed primarily written to protect researchers and research sponsors from legal liability.

The NPRM recommended organizing and presenting information in a manner that would facilitate the potential research subject's understanding and his decision to choose or not choose to participate. Prospective research subjects would receive the most important information in the body of a relatively short consent form and any other information would be included in an appendix or appendices. Key information would no longer be "buried in long and overly complex documents."[124] Thus, the final rule imposed a new requirement at 45 CFR 46.116(a)(5)(i):

> Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of informed consent must be organized and presented in a way that facilitates comprehension.[125]

The core information would include concise explanations of the following:

1. The fact that consent is being sought for research and that participation is voluntary
2. The purposes of the research, the expected duration of the prospective subject's participation, and the procedures to be followed in the research
3. The reasonably foreseeable risks or discomforts to the prospective subject
4. The benefits to the prospective subject or to others that may reasonably be expected from the research
5. Appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the prospective subject[126]

By mandating structural clarity and relative ease of use of informed consent forms, the final rule facilitated the decision-making process of reasonable persons in their consideration of participation as subjects in medical research.

Regarding issues related to use of tissue samples in current and future research, including the privacy of research subjects in their capacity as donors of the biospecimens and the possibility of researchers and research sponsors using the donated tissue samples as a platform for launching commercial enterprises, the final rule mandated inclusion of additional elements of consent. For any research that involved the collection of identifiable private information or identifiable biospecimens, informed consent forms were required to include one of the following statements:

- A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility
- A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies[127]

The final rule provided definitions for *human subject, identifiable private information, identifiable biospecimens,* and *research* at 45 CFR 46.102.[128] A human subject was defined as a living individual about whom an investigator conducting research:

1. Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
2. Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.[129]

Identifiable private information was defined as "private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information."[130] An *identifiable biospecimen* was defined as "a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen."[131] *Research* was defined as "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge."[132]

Additional elements of informed consent were detailed in 45 CFR 46.116(c). When appropriate, potential research subjects shall be provided with the following:

- A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit
- A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions
- And, for research involving biospecimens, whether the research will (if known) or might include *whole genome sequencing* (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen)[133]

The final rule also addressed use of biospecimens that have been previously collected. The discussion of the final rule noted that biospecimens are collected from approximately 30 million people each year and are stored for both clinical and research purposes.[134] Biospecimens from approximately 9 million persons (30 percent) are collected for research purposes. Biospecimens from an additional 6 million persons could potentially be used in research studies conducted in the future. To facilitate secondary use of stored tissue samples, that is, to avoid the necessity for seeking consent or a waiver of consent from up to 15 million individuals annually, the final rule created separate elements of *broad consent* so that potential research subjects could grant, if they chose, "consent for future unspecified research activities."[135] Broad consent, described in 45 CFR 46.116(d), would permit "storage, maintenance, and secondary research use of identifiable private information and identifiable biospecimens."[136] Broad consent would represent an alternative to the requirements for the basic and additional elements of informed consent. Broad consent, if requested, would include the following:

- The basic consent elements listed in 45 CFR 46.116(b) describing (1) the reasonably foreseeable risks or discomforts of participating in the proposed research; (2) any benefits to the subject or others that may be reasonably expected from such participation; (3) the extent to which confidentiality of records identifying the subject will be maintained; and (4) the voluntary nature of participation in the proposed research, including a statement that the subject may discontinue participation at any time "without penalty or loss of benefits to which the subject is otherwise entitled"[137]
- When appropriate, the additional consent elements describing (1) the potential use of the research subject's biospecimens for commercial profit and "whether the subject will or will not share in this commercial profit" and (2) the possibility that research might include whole genome sequencing[138]

Broad consent also required the following:

- A general description of the types of research that may be conducted with the identifiable private information or identifiable biospecimens; this description must include sufficient information such that a reasonable person would expect that the broad consent would permit the types of research conducted
- A description of the identifiable private information or identifiable biospecimens that might be used in research, whether sharing of identifiable private information or identifiable biospecimens might occur, and the types of institutions or researchers that might conduct research with the identifiable private information or identifiable biospecimens
- A description of the period of time that the identifiable private information or identifiable biospecimens may be stored and maintained (which period of time could be indefinite), and a description of the period of time that the identifiable private information or identifiable biospecimens may be used for research purposes (which period of time could be indefinite)
- Unless the subject or legally authorized representative will be provided details about specific research studies, a statement that they will not be informed of the details of any specific research studies that might be conducted using the subject's identifiable

private information or identifiable biospecimens, including the purposes of the research, and that they might have chosen not to consent to some of those specific research studies

- Unless it is known that clinically relevant research results, including individual research results, will be disclosed to the subject in all circumstances, a statement that such results may not be disclosed to the subject
- An explanation of whom to contact for answers to questions about the subject's rights and about storage and use of the subject's identifiable private information or identifiable biospecimens, and whom to contact in the event of a research-related harm[139]

Thus, by providing the possibility of broad consent, the final rule established enhanced protections for both research subjects, researchers, and research institutions. By choosing broad consent, a potential research subject would be

- Acknowledging she has been informed regarding the types of research that may be performed with her tissue samples, the possibility of commercial profit arising from such research, and whether she will participate in this profit.
- Consenting to the storage, maintenance, and use of identifiable private information and identifiable biospecimens for a possibly indefinite period of time.
- Acknowledging that he will not be informed regarding the details of any research studies that might use his stored identifiable private information and identifiable biospecimens, as well as acknowledging that he might have chosen not to consent to some of those research studies.[140]

In effect, by agreeing to broad consent, the research subject waives her putative right to ownership of her tissue samples. As well, broad consent eliminates the expectation of any right to privacy regarding the current and future use of those biospecimens.

The final rule's codification of increased transparency, enhanced ease-of-use of informed consent forms, strengthened requirements for basic consent, and additional elements of consent represented substantial improvements in the informed consent process. These improvements were necessitated by an ever-increasing number of clinical trials, the use of electronic medical records and the persistence of identifiable private information, and privacy concerns associated with the storage of tens of millions of records of identifiable biospecimens and advances in genomics and bioinformatics. The availability of broad consent in the final rule provided potential research subjects a choice and potentially facilitated activities of researchers and research institutions. Overall, the final rule revisions to the Common Rule enhanced protections for human research subjects, reinforced support for the biomedical ethical principles of autonomy and justice, and furthered the activities of the medical research enterprise as a whole.

BOX 9.1

Case Study: Patenting of Human Genes?

In 2013, in *Association for Molecular Pathology v. Myriad Genetics*, the U.S. Supreme Court ruled that "a naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated."[141] Researchers at Myriad Genetics, a medical diagnostics company, had discovered the precise location and sequence of what became known as the BRCA1 and BRCA2 genes, and the company had been awarded patents on these genes in the 1990s.[142] The patents described BRCA1 as "a human breast and ovarian cancer predisposing gene"[143] and BRCA2 as "a human breast cancer predisposing gene."[144] The patents asserted that the inventions related to germline mutations (mutations in an egg or a sperm) in BRCA genes and "their use in the diagnosis of predisposition to breast and ovarian cancer" and somatic mutations in these genes in human breast and ovarian cancer and "their use in the diagnosis and prognosis of human cancers."[145] As well, the patents asserted that the inventions related to screening of the BRCA1 and BRCA2 genes for mutations, which is "useful for diagnosing the predisposition to breast and ovarian cancer."[146] Further, the patents asserted that the inventions related to the therapy of human cancers that have mutations in the BRCA genes, including gene therapy and protein replacement therapy.[147] Overall, as the Court noted, mutations in the BRCA genes may "dramatically increase an individual's risk of developing breast and ovarian cancer."[148]

Thus, the Myriad Genetics patents established the company's interests in all diagnostic testing and treatment procedures related to mutations in the BRCA genes. Myriad Genetics held patents that, if valid, "give it the exclusive right to isolate an individual's BRCA1 and BRCA2 genes (or any strand of fifteen or more nucleotides within the genes)."[149] In the view of Myriad Genetics, manipulation of BRCA DNA by others would trigger its "right to exclude others from making" its patented composition of matter under the Patent Act.[150] In consequence, Myriad Genetics had filed "patent infringement suits against other entities that performed BRCA testing."[151] But several plaintiffs filed suit against the U.S. Patent and Trademark Office (USPTO) in *Association for Molecular Pathology v. USPTO*,[152] in which the U.S. District Court for the Southern District of New York granted summary judgment to the plaintiffs based on the court's conclusion that Myriad's claims "were invalid because they covered products of nature."[153] The district court had noted that "Supreme Court precedent has established that products of nature do not constitute patentable subject matter absent a change that results in the creation of a fundamentally new product."[154] The appeal to the federal circuit ultimately reached the Supreme Court.

In *Association for Molecular Pathology v. Myriad Genetics*, the Supreme Court noted that regarding Section 101 of the Patent Act, the Court has "long held that this provision contains an important implicit exception: Laws of nature, natural phenomena, and abstract ideas are not patentable" (referencing the Court's decision in *Mayo Collaborative Services v. Prometheus Laboratories* in 2012[155]). At issue was whether the Myriad Genetics patents claimed any "new and useful composition of matter" or instead claimed naturally occurring

phenomena. The Court noted that the "location and order of the nucleotides existed in nature before Myriad found them"[156] and stated that Myriad Genetics did not *create* anything. Further, separating the BRCA genes from their surrounding genetic material "is not an act of invention."[157] Thus, the discovery by itself does not render the BRCA genes "new compositions of matter."[158] The Court noted that, had Myriad Genetics created a novel method of manipulating genes, "it could possibly have sought a method patent."[159] But the processes used by the company to isolate DNA "were well understood by geneticists at the time of Myriad's patents."[160] Further, the case did not involve "patents on new *applications* of knowledge about the BRCA1 and BRCA2 genes" [emphasis in original].[161] Overall, the Court held that "genes and the information they encode are not patent eligible under §101 simply because they have been isolated from the surrounding genetic material."[162] On June 13, 2013, *The New York Times* summarized the Court's unanimous 9–0 ruling and reported that "human genes may not be patented."[163]

Ethical Analysis

1. Compare and contrast the rulings in *Moore v. The Regents of the University of California* and *Association for Molecular Pathology v. Myriad Genetics* with respect to the impact of each case on the biotechnology and medical device industries.
2. Describe the meaning of "composition of nature" as specified in 35 U.S. Code §101.[164]
3. Describe possible circumstances, if any, in which issuing a patent for a "product of nature" would be appropriate.
4. Discuss the implications of each case in the context of the biomedical ethical principle of autonomy.
5. Discuss the implications of each case in the context of the biomedical ethical principle of justice.

Gene Editing and Genetic Technologies: Benefit or Risk?

As discussed in Chapter 3, the advent of the CRISPR-Cas9 system[165] and other gene editing technologies made possible a wide range of opportunities, almost without limitation, to manipulate the genome of a living organism. Human gene editing was of especial concern. Regulatory guidance was needed, as scientists, medical ethicists, religious leaders, and legislators were all agreed that gene editing research could lead to great harm as well possible benefit. In 2017, the National Academies of Science, Engineering, and Medicine published its report on human gene editing,[166] including principles for governance of this burgeoning field and detailed recommendations for implementing these principles. Consideration was given to research involving editing the genomes of somatic (nonreproductive) cells and possible research involving editing the human germline, that is, the genomes of sperm and egg cells. Of note, as of 2017, the U.S. Food and Drug Administration (FDA) prohibited use of federal funds to review "research in which a human embryo is intentionally created or modified to

include a heritable genetic modification."[167] Further, Title V of the Consolidated Appropriations Act, 2016, stated that federal funds may not be used for "the creation of a human embryo or embryos for research purposes."[168]

In 2013, CRISPR-Cas9 assemblies were used to induce breaks in double-stranded DNA at specific sites, demonstrating the possibility of programmable gene editing and the introduction of site-specific genetic changes in any cell, including human cells.[169] Since then, a steadily increasing number of research papers have appeared in peer-reviewed journals describing new applications of gene editing methods. For example, in January 2016, a research team reported modification of the germline of *Anopheles gambiae* mosquitos (the main vector for malaria) to include sequences that would disrupt specific genes and cause female sterility.[170] The purpose of the research was to develop genetic methods to suppress *An. gambiae* populations to levels that do not support malaria transmission. On August 5, 2016, the FDA published a final environmental assessment and a finding of no significant impact regarding a proposed field trial of the release of genetically modified *Aedes aegypti* mosquitos in the Florida Keys.[171] *Ae. aegypti* is known to transmit human viral diseases such as Zika, dengue, and yellow fever. CRISPR-Cas9 methods have created targeted genome modifications in zebrafish, salamanders, mice, rats, pigs, and monkeys for use in research in experimental biology and biomedicine.[172]

Although prohibited by the FDA and federal law, research on human embryos quickly followed the spate of CRISPR-Cas9 demonstrations in other species. In August 2017, an international team of researchers, funded in part by Oregon Health and Science University and several foundations, reported using CRISPR-Cas9 constructs to correct the *MYBPC3* mutation in affected human embryos.[173] The *MYBPC3* gene participates in the formation of striated muscle such as the myocardium (heart muscle).[174] The *MYBPC3* mutation causes hypertrophic cardiomyopathy (HCM), a disorder in which the myocardium becomes abnormally thick, making it more difficult for the heart to pump blood. HCM affects approximately one in 500 people and may cause sudden heart failure. The techniques used in the *MYBPC3* study improved upon prior attempts at gene editing in human embryos, by avoiding mosaicism (in which some cells continued to carry the mutation) and achieving a high yield of embryos carrying a normal *MYBPC3* gene and without evidence of mutations introduced by the genetic manipulation process (off-target mutations). The improved CRISPR-Cas9 methods could be used to target inherited mutations causing breast and ovarian cancer such as those located in the *BRCA* gene, as well as Huntington's disease, Tay Sachs disease, cystic fibrosis, or any of the more than 10,000 genetic disorders.[175] But society needs to consider closely whether we wish to be responsible for directly altering the human genome.

Ethical concerns abound when considering the implications and possible consequences of use of genome modifying techniques. Depending on the problem being addressed, substantial benefit could be obtained by various human populations. However, it is not unreasonable to assert that human activities affect all biomes and all living organisms. Further, as discussed in Chapter 3, complex systems are highly sensitive to small perturbations. We cannot possibly calculate the long-term effects of introducing any modification to any organism's genetic sequence, regardless of the apparent good that is obtained. We do this tinkering and manipulating because we can, but merely having the capability to do a thing does not imply that we should do it. As we gain these new powers, it becomes critically important for us to deliberate and assess the moral rightness of our potential actions.

The Possibility of Precision Medicine

In his state of the union address on January 20, 2015, President Barack Obama noted the possibility of "a new era of medicine—one that delivers the right treatment at the right time" and announced the launch of a new Precision Medicine Initiative.[176] The Precision Medicine Initiative is intended to leverage advances in genomics as well as emerging methods for managing and analyzing large data sets to accelerate biomedical discoveries.[177] The initial components of the Precision Medicine Initiative are (1) developing a voluntary national research cohort of a million or more Americans who will "contribute their health data to improve health outcomes, fuel the development of new treatments, and catalyze a new era of data-based and more precise medical treatment" (the *All of Us* Research Program[178]) and (2) scaled-up efforts by the National Cancer Institute to "identify genomic drivers in cancer and apply that knowledge in the development of more effective approaches to cancer treatment."[179] Data from large numbers of people are needed to identify genetic markers that may be predictive of a treatment response.[180]

The goal of precision medicine has been described as the identification of a subset of patients with a common biological basis of disease, often defined by genomics, who are most likely to benefit from a specific drug.[181] Precision medicine is not the creation of a drug or medical device that is unique to a specific patient. Rather, precision medicine represents tailoring medical treatment to the individual characteristics of each patient, based on "the ability to classify individuals into subpopulations that differ in their susceptibility to a particular disease ... or in their response to a specific treatment."[182]

The pharmacological treatment of cystic fibrosis with ivacaftor is an example of precision medicine. Ivacaftor targets the protein encoded by a mutation in the cystic fibrosis transmembrane regulatory gene (CFTR).[183] Ivacaftor increases the activity of the defective cell membrane channel regulatory protein and impacts the function of those transmembrane channels,[184] with possible decreased pulmonary airway obstruction and improved lung function.[185] Ivacaftor is effective in a subset of cystic fibrosis patients with a specific configuration of the affected transmembrane channel, and thus exemplifies a precision medicine framework that targets a drug to a precise subclass of patients.[186]

A goal of precision medicine is to use information "about the genes, proteins, and other features of a person's cancer to diagnose or treat their particular disease."[187] For example, the methodology of pharmacogenetics attempts to use a patient's genome to ascertain and prescribe the most effective, safest drug for that person.[188] But randomized controlled trials are needed before primary care physicians are able to employ precision medicine at the level of the individual patient.[189] Randomized comparisons "are the only way to reliably estimate the effects of tested therapies on clinical outcomes."[190] Randomization assists in removing selection bias and provides an internal control for efficacy and safety.[191] As well, randomization aids in the direct comparison between the experimental therapy and the existing standard of care. Overall, a primary as-yet-unanswered question regarding precision medicine relates to the demonstration of improvement in morbidity and mortality associated with specific diseases.[192]

Assisted Reproductive Technologies: Postmortem Sperm Retrieval

Postmortem sperm retrieval (PMSR)[193] is the medical practice of obtaining sperm for later use with assisted reproductive technologies.[194] To ensure viability, sperm should be retrieved within twenty-four to thirty-six hours of death.[195] After retrieval, sperm are typically frozen and stored

at a sperm bank for future use.[196] PMSR was first reported in 1980 in the case of a thirty-year-old man who had suffered a fatal brain injury in a motor vehicle accident.[197] The first baby born as a result of posthumous conception was reported in 1999.[198] Overall, requests for PMSR have been reported as increasing.[199] For example, PMSR requests increased by 60 percent in the interval from 1997 to 2002.[200]

Regarding legality of the procedure, in the United Kingdom, per the Human Fertilisation and Embryology Act of 1990, "a person's gametes must not be kept in storage unless there is an effective consent by that person to their storage and they are stored in accordance with the consent."[201] In New Zealand, the National Ethics Committee on Assisted Human Reproduction has stated that "collection of sperm from a comatose or recently deceased person without that person's prior written consent is ethically unacceptable."[202] Thus, in these countries, PMSR would not be permissible in the absence of prior consent of the decedent. In December 2016, in a case involving postmortem sperm retrieval, Israel's Supreme Court ruled that the right to procreate also applies to posthumous fertilization, but only the spouse of the deceased is entitled to decide on implementation of this right.[203] Subsequently, in August 2017, Israel's Supreme Court approved the decision of a district court that the process of procreation utilizing a decedent's sperm could not be initiated by the parents of the deceased.[204] In the United States, as of 2016, there was no federal law or state law that directly addressed PMSR.[205]

In the absence of federal and state legislation in the United States, certain healthcare institutions and professional associations have created guidelines for PMSR. In New York, the Weill Cornell Medicine (WCM) Guidelines for PMSR states the institution only considers requests for sperm retrieval from the decedent's wife. The request should establish "convincing evidence that the man would have wanted to conceive children this way, and evaluation of the request should also be supported by unanimous agreement among available members of the immediate family."[206] The WCM Guidelines specifies that the decedent's wife is "considered the only person for whom the sperm could be used for procreation."[207] Regarding a decision to use retrieved sperm, the WCM Guidelines strongly recommends a one-year quarantine period after sperm retrieval, with psychological counseling and reassessment of decision making prior to attempting assisted reproduction.[208] The Ethics Committee of the American Society for Reproductive Medicine has stated that healthcare institutions are not obligated to participate in PMSR and should develop written policies "regarding the specific circumstances in which they will or will not participate in such activities."[209] The American Bar Association formally adopted the Model Act Governing Assisted Reproductive Technology (Model Act) on February 11, 2008.[210] The Model Act specifies that gametes shall not be collected from deceased individuals or from preserved tissues unless written consent was obtained prior to death.[211]

Thus, overall, PMSR entails numerous biomedical issues and poses numerous biomedical ethical challenges. These ethical concerns relate to the legality of PMSR, requirement for prior consent of the decedent, requests by persons such as a family member or same-sex partner for sperm retrieval or use of retrieved sperm in assisted reproductive technologies, rights and responsibilities of healthcare institutions and providers, and the rights of a child conceived via PMSR.[212] As with other novel biomedical technologies, engagement of the public in policy discussions at the state and federal level will help ensure that social, cultural, and religious norms are considered and included as appropriate legislation is developed concerning new arenas of healthcare delivery.

Healthcare Fraud and Abuse, Provider Self-Referral, and Provider Conflict of Interest

HIPAA defines healthcare fraud as knowingly and willingly executing, or attempting to execute, a scheme or deception "to defraud any health care benefit program; or to obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by ... any health care benefit program."[213] As well, healthcare fraud may be described as an intentional attempt to wrongfully collect money relating to healthcare services.[214] Abuse is similar to fraud, but the investigator is not able to establish that the act "was committed knowingly, willfully, and intentionally."[215] Abuse may be described as "actions which are inconsistent with acceptable business and medical practices."[216]

The financial losses associated with healthcare fraud and abuse have been estimated to be billions of dollars annually. For example, in its 2010–2011 Financial Crimes Report, the Federal Bureau of Investigation stated that fraudulent billings to public and private healthcare programs represented between 3 and 10 percent of total healthcare expenditures.[217] In consequence of the impact of fraud on all those participating in the healthcare delivery system, especially patients and their families, and on the national economy, federal legislation has incorporated "new prohibitions and ever-stronger penalties for those who engage in fraudulent activities."[218] Such federal legislation includes the Medicare and Medicaid Anti-Kickback Statute, the False Claims Act, and the Stark Law and emendations, directed toward healthcare provider self-referral and conflict of interest. These laws variously impose civil penalties, criminal penalties, and exclusion from federal healthcare programs on persons and entities that engage in certain types of misconduct.[219]

Medicare and Medicaid Anti-Kickback Statute

Specific penalties for fraudulent acts and false reporting involving Medicare and Medicaid programs were established in Public Law 92-603 (Social Security Amendments of 1972).[220] Public Law 92-603 §242(b) stated the following:

> Whoever furnishes items or services to an individual for which payment is or may be made under this title and who solicits, offers, or receives any—
>
> (1) kickback or bribe in connection with the furnishing of such items or services or the making or receipt of such payment, or
>
> (2) rebate of any fee or charge for referring any such individual to another person for the furnishing of such items or services,
>
> shall be guilty of a misdemeanor and upon conviction thereof shall be fined not more than $10,000 or imprisoned for not more than one year, or both.[221]

These provisions regarding Medicare and similar provisions regarding Medicaid were codified as §1877 and §1909 of the Social Security Act, respectively.[222] Subsequently, the Medicare and Medicaid anti-kickback provisions were combined into Section 1128B of the Social Security Act

(42 U.S. Code §1320a-7b), as specified in Public Law 100-93 (Medicare and Medicaid Patient and Program Protection Act of 1987).[223] These provisions, known as the Medicare and Medicaid Anti-Kickback Statute, state the following:

> Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—
>
> (A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
>
> (B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under Federal health care program,
>
> shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.
>
> Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—
>
> (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
>
> (B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,
>
> shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.[224]

Thus, the Medicare and Medicaid Anti-Kickback Statute prohibits both the solicitation or receipt of remuneration, and the offer or payment of remuneration, for patient referrals and transactions associated with goods and services reimbursable by a federal healthcare program. Importantly, the Office of Inspector General (OIG) of the Department of Health and Human Services established "safe harbors," that is, various business and payment practices that would not be treated as criminal offenses under Section 1128B of the Social Security Act.[225] Per 42 CFR §1001.952, safe harbors include certain types of investment interest, personal services and management contracts, referral services, group purchasing organizations, referral arrangements for specialty services, ambulatory surgical centers, and cooperative hospital service organizations.[226] Business arrangements must fulfill numerous criteria, as specified in 42 CFR §1001.952, to obtain protection within safe harbor designations. Overall,

safe harbor regulations continue to be revised and updated. For example, on December 7, 2016, OIG promulgated a final rule adding two new safe harbors and updating existing safe harbor regulations, with an effective date of January 6, 2017.[227] Updates included expanding the scope of the cost-sharing waiver safe harbor to all federal healthcare programs and to amounts owed to a pharmacy.[228] The final rule added a safe harbor for local transportation and shuttle services. This provision protects free or discounted local transportation made available by an "eligible entity," for transportation "both to a provider or supplier of services and back to a patient's home."[229] The final rule noted that "Congress intended the safe harbors to evolve with changes in the health care system ... this final rule balances additional flexibility for industry stakeholders to provide efficient, well-coordinated, patient-centered care with protections against fraud and abuse risks."[230]

False Claims Act

The False Claims Act (FCA)[231] was enacted in 1863 in response to fraud schemes perpetrated by suppliers of goods to the Union Army during the Civil War.[232] The FCA prohibits knowingly submitting false claims to the government and imposes civil penalties on persons violating the law. As well, the FCA provides for private persons to "file suit for violations of the FCA on behalf of the government." Such a suit is known as a *qui tam action*, and the person bringing the action is referred to as a *relator* (that is, a whistleblower).[233] In a successful *qui tam* action, the whistleblower could receive between 15 and 30 percent of the monetary proceeds that are recovered by the government.[234] For example, the Department of Justice obtained more than US$3.7 billion in settlements and judgments from civil cases involving fraud and false claims against the government in the fiscal year ending September 30, 2017, of which US$2.4 billion involved the healthcare industry.[235]

The FCA is a law of general applicability and is invoked frequently in a healthcare context.[236] As such, the FCA is implicated when an "improper claim for payment is submitted to a federal healthcare program."[237] Healthcare program false claims may arise in terms of billing, such as "billing for services not rendered, billing for unnecessary medical services, double billing for the same service or equipment, or billing for services at a higher rate than provided," that is, *upcoding*.[238] (Upcoding is billing using a higher level code to receive inflated reimbursement.) As well, the FCA is implicated by referral arrangements in which claims for goods or services provided are in violation of the Medicare and Medicaid Anti-Kickback Statute.[239]

Stark Law: Healthcare Provider Self-Referral

Healthcare provider self-referral involves referral to entities with which the provider has a financial relationship. The prospect of financial gain may impact a healthcare provider's judgment regarding the medical necessity of recommended treatment. As well, self-referral encourages overutilization of services.[240] To counter these practices, the Ethics in Patient Referrals Act of 1988 (the "Stark Law") was introduced in the House of Representatives, where it received no further action.[241] Elements of the Stark Law were included in the Physician Self-Referral Law (42 U.S. Code §1395nn; Section 1877 of the Social Security Act: Limitation of Certain Physician Referrals), enacted as part of Public Law 101-239 (Omnibus Budget Reconciliation Act of 1989).[242] Of note, prior to enactment of Section 1877, a number of studies had "consistently

found that physicians who had ownership or investment interests in entities to which they referred ordered more services than physicians without those financial relationships ... . This correlation between financial ties and increased utilization was the impetus for section 1877 of the Act."[243]

The Physician Self-Referral Law, or Stark Law, as subsequently amended, generally prohibits a physician from "making referrals for certain designated health services (DHS) payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship."[244] DHS include clinical laboratory services, radiology and other imaging services, durable medical equipment and supplies, inpatient and outpatient hospital services, and outpatient prescription drugs. The "Phase III" final rule was issued in 2007,[245] updating 42 CFR 411, "Exclusions from Medicare and Limitations on Medicare Payment."[246]

The Medicare and Medicaid Anti-Kickback Statute, the False Claims Act, the Stark Law, and their numerous exceptions create a complex regulatory environment that is designed to assist, but may also hinder, effective functioning of the healthcare system. In a 2015 report to Congress, the Centers for Medicare and Medicaid Services had stated that "the fraud and abuse laws may serve as an impediment to robust, innovative programs that align providers by using financial incentives to achieve quality standards, generate cost savings, and reduce waste."[247] For example, restrictions on financial relationships may adversely inhibit appropriate referral choices, including "efforts to financially incentivize providers to coordinate patient care."[248] In consequence, risk-averse healthcare institutions and providers may forgo opportunities to create novel and efficient patient-centered care arrangements such as participation in the Medicare Shared Savings Program (MSSP).[249] The MSSP offers healthcare providers, suppliers, and institutions the opportunity to create an accountable care organization (ACO). An ACO "agrees to be held accountable for the quality, cost, and experience of care of an assigned Medicare fee-for-service beneficiary population."[250] ACO participants are eligible to receive financial bonuses if they meet quality and cost-effectiveness benchmarks. But arrangements in which primary care physicians, specialists, other healthcare providers, and hospitals work together "to change patient referral practices, in return for potential financial gain, directly implicate the fraud laws." In response to this conundrum, the Office of Inspector General promulgated Final Waivers in Connection with the Shared Savings Program (effective October 29, 2015), which waived application of certain provisions of the Medicare and Medicaid Anti-Kickback Statute and the Physician Self-Referral Law to ACOs formed in connection with the MSSP.[251] Certain provisions of the fraud and abuse laws were waived "so that the laws do not unduly impede the development and operation of beneficial ACOs, while also ensuring that ACO arrangements are not misused for fraudulent or abusive purposes that harm patients or federal health care programs."[252]

Healthcare Provider Conflict of Interest

Healthcare provider *conflict of interest* arises whenever circumstances, owing to inducement or coercion, predispose him or her to act other than in a patient's best interest.[253] Such conflicts of interest might involve prescribing a pharmaceutical or medical device that is not considered first line or is more costly than equivalent recommendations, referral for unnecessary diagnostic testing, or performing unnecessary procedures. Also, a conflict of interest might arise owing to "pay for performance" standards that result in avoidance of treating the sickest patients, who might negatively impact a provider's or institution's successful outcome rates. Conflicts of

interest always abrogate the biomedical ethical principles of beneficence, nonmaleficence, and justice. Autonomy may be violated as well, whenever patient decision making is compromised by the receipt of incomplete or less-than-accurate information regarding proposed treatment.

Conflicts of interest are built in to a healthcare system where profits derive from utilization of services. The temptation to perform additional services is perpetually present in a fee-for-service system. The rise of commercialism in healthcare has been dated to the 1970s, with the advent of new sources of payment such as the Medicare and Medicaid programs and the rapid expansion of private, employer-based insurance.[254] The focus on revenues had been abetted by the pharmaceutical and medical device industries in the form of gift giving, support of continuing medical education (CME) programs, and underwriting of clinical practice guidelines.[255] Gift giving, a direct form of influence, has been consistently demonstrated to cause attitudinal and behavioral changes in the recipient in favor of the benefactor or gift giver.[256] The investment of the pharmaceutical industry in CME had been substantial, peaking at US$1.2 billion per year by 2007.[257] Such support blurred the line between education and marketing. In April 2007, a report by the U.S. Senate Committee on Finance stated the committee had become aware that "pharmaceutical companies were routinely using educational grants to help build market share for their newer and more lucrative products."[258] The committee noted evidence of numerous cases in which "companies had too much influence over the content of supposedly independent educational programs."[259] Subsequently, commercial support for CME began to decline. In 2009, an Institute of Medicine report recommended development of a new system of funding accredited CME that would be free of industry influence.[260] By 2010, 80 percent of accredited CME activities did not receive any such funding.[261] By 2015, only 11 percent of accredited CME activities received commercial support, accounting for 17 percent of physician interactions and 19 percent of other learner interactions.[262]

Regarding clinical practice guidelines (CPG), these recommendations have the potential to influence treatment patterns of large numbers of physicians. Thus, industry underwriting of CPG could project treatment recommendations associated with an inherent conflict of interest to an entire sector of the medical community.[263] One study reported that eighty-seven of one hundred CPG authors had some form of interaction with the pharmaceutical industry, representing the considerable extent of such relationships.[264] Fifty-eight authors had received research support and sixty-four had received speaker honorariums. The mean number of companies with whom CPG authors had relationships was 10.5.[265] In response, numerous medical specialty organizations have "developed and instituted strict policies governing conflicts of interest among members of guideline development committees."[266] For example, the American College of Chest Physicians Conflict of Interest Policy on Guidelines/Consensus Statements states the organization "must limit the potential for bias through careful vetting, evaluation, and management of the financial relationships and intellectual activities of each potential participant" in the creation of evidence-based guidelines and consensus statements.[267] All potential panelists must submit complete disclosure, including personal potential conflicts of interest for a three-year period. All conflicts of interest will be published with the final guideline/consensus statement.[268]

Overall, for a healthcare provider–patient relationship to function appropriately, the patient must be certain the practitioner is acting in the patient's best interests and making recommendations that will promote those interests. The seed of doubt introduced by the possibility of provider conflict of interest will threaten the integrity of the entire relationship. Healthcare providers must be forthright in disclosure of any such potential conflicts. Patients must maintain awareness of the potential for provider conflicts of interest and take action, if needed, to protect their own health and welfare.

Antitrust Legislation

National priorities in healthcare include improving efficiency in delivering healthcare services, ensuring access to coverage, and promoting public health. Antitrust laws "prohibiting private anticompetitive organization and conduct" help society attain these objectives.[269] Key antitrust statutes include the Sherman Antitrust Act of 1890,[270] the Clayton Antitrust Act of 1914,[271] and the Hart-Scott-Rodino Antitrust Improvements Act of 1976.[272]

The Sherman Act states that "Every contract, combination ... , or conspiracy, in restraint of trade or commerce ... , is declared to be illegal."[273] A violation of Section 1 of the Sherman Act requires proof of an agreement between the parties and that the conduct referred to unreasonably interfered with trade.[274] Corporations or persons found violating the Sherman Act shall be deemed guilty of a felony, with fines of up to US$100,000,000 or US$1,000,000 respectively, imprisonment of up to ten years, or both. Section 2 of the Sherman Act is directed toward unilateral conduct of an entity that seeks to maintain or obtain monopoly power and engage in predatory pricing and exclusionary activities.[275] To violate Section 2 of the Sherman Act, an entity must have a market share of 60 to 70 percent or more and have engaged in anticompetitive activity.[276] Importantly, distinguishing harmful predation from procompetitive discounting of prices may be difficult and runs the risk of erroneous condemnation. Optimally, application of Section 2 of the Sherman Act would effectively condemn "only harmful predation while providing clear and sound guidance to firms, competition authorities, potential private plaintiffs, and courts."[277]

Section 7 of the Clayton Antitrust Act prohibits mergers and acquisitions "where in any line of commerce ... the effect of such acquisition may be substantially to lessen competition, or to tend to create a monopoly."[278] The Hart-Scott-Rodino Antitrust Improvements Act (HSR) requires prior notification to federal antitrust enforcement agencies regarding "transactions that exceed a certain size and which are not otherwise exempt under the statute."[279] HSR is typically implicated in mergers and acquisitions involving insurance companies, hospitals, and pharmaceutical companies.

Antitrust enforcement of joint conduct of entities under Section 1 of the Sherman Act, unilateral conduct of an entity under Section 2 of the Sherman Act, and mergers and acquisitions under Section 7 of the Clayton Act is directed toward the effects of the transaction or conduct at issue on the competitive process.[280] For example, guidance from the Department of Justice (DOJ) and the Federal Trade Commission (FTC) note that most hospital mergers and acquisitions do not present competitive concerns.[281] The DOJ and FTC have issued statements of antitrust enforcement policies regarding hospital mergers, hospital joint ventures, hospital participation in exchanges of price and cost information, healthcare providers' joint purchasing arrangements, and physician network joint ventures.[282] Of note, as assessed by the Robert Wood Johnson Foundation Synthesis Project, increases in hospital market concentration (less competitive markets) lead to increases in the price of hospital care and have not led to improved quality.[283]

Since 2006, the FTC has successfully brought suit to stop several hospital mergers. For example, *ProMedica Health System v. Federal Trade Commission* was an antitrust case involving a proposed merger between two of the four hospital systems in Lucas County, Ohio.[284] The parties to the merger were ProMedica, the county's dominant hospital provider, and St. Luke's, an independent community hospital. The two entities merged in August 2010, giving ProMedica a greater than 50 percent share of the market for primary and secondary services and a greater than 80 percent share in the market for obstetric services. Five months later, the FTC challenged the merger

under Section 7 of the Clayton Act. An administrative law judge and later the FTC found that the merger would adversely affect competition. The FTC ordered ProMedica to divest St. Luke's and ProMedica petitioned for review. The United States Court of Appeals, Sixth Circuit, agreed with the FTC's assessment of the law and its analysis of the merger's competitive effects, and denied the ProMedica petition.[285] The court noted that the two aspects of the case, that is, "the strong correlation between market share and price, and the degree to which this merger would further concentrate markets that are already highly concentrated," converged in a manner that fully supported "the Commission's application of a presumption of illegality."[286] Thus, the FTC was "correct to presume the merger substantially anticompetitive."[287] Subsequently, ProMedica petitioned the Supreme Court to overturn the court of appeals decision. On May 4, 2015, the Supreme Court denied the hospital system's petition and allowed the Sixth Circuit Court's ruling to stand.[288]

Additional mergers and acquisitions have been proposed since the *ProMedica* rulings. On July 3, 2015, Aetna announced it had agreed to acquire Humana for US$37 billion in cash and stock. The deal would have merged two of the biggest healthcare insurers in the United States. The new entity would have estimated operating revenues of US$115 billion in 2015 and serve more than 33 million people.[289] Aetna stated the acquisition "will significantly advance our strategy of more effectively serving members in a rapidly changing health care industry."[290] The Aetna-Humana combination was largely focused on the private market for Medicare Advantage plans, in which Medicare benefits are offered by private companies approved by Medicare.[291] But the Department of Justice, eight states, and the District of Columbia filed an antitrust challenge to the merger. Consumer advocates and government officials argued that the private market was already concentrated and "individuals would suffer from lack of choice and competition in certain markets."[292] On January 23, 2017, the U.S. District Court for the District of Columbia concluded that the merger would likely substantially lessen competition in the market for Medicare Advantage as well as individual insurance plans sold on state exchanges.[293] The court noted that "federal regulation would likely be insufficient to prevent the merged firm from raising prices or reducing benefits."[294] Further, the court was "unpersuaded that the efficiencies generated by the merger will be sufficient to mitigate the anticompetitive effects for consumers in the challenged markets."[295] In consequence, the court enjoined (prohibited) the proposed merger of Aetna and Humana.

Shortly thereafter, on February 8, 2017, the U.S. District Court for the District of Columbia enjoined the proposed US$48 billion merger of Anthem and Cigna, two large healthcare insurance companies.[296] The court stated the merger would likely result in higher prices and have other anticompetitive effects. For example, the proposed merger would "eliminate the two firms' vigorous competition against each other for national accounts, reduce the number of national carriers available to respond to solicitations in the future, and diminish the prospects for innovation in the market."[297] Subsequent to the ruling, the Department of Justice stated "This merger would have stifled competition, harming consumers by increasing health insurance prices and slowing innovation aimed at lowering the costs of healthcare."[298]

Almost ten months later, on December 3, 2017, CVS Health announced an agreement to buy Aetna for approximately US$69 billion.[299] CVS Health services include 10,000 retail pharmacy and clinic locations and pharmacy benefits management. The combination uniting CVS Health and Aetna "reflects the increasingly blurred lines between the traditionally separate spheres of a rapidly changing industry."[300] The companies asserted the merger would transform the CVS stores into "community-based sites of care that would be far less expensive for patients."[301] But

the proposed vertical merger (combining companies in two different industries), would unite management of pharmacy benefits, which includes negotiating rebates, managing distribution of pharmaceuticals, and overseeing patient compliance, with one of the largest healthcare insurers in the United States. Skeptics to the proposed combination noted that "CVS Health and Aetna were already industry behemoths that had had ample opportunity to improve conditions for patients" and it was unlikely that consumers would see much benefit.[302]

Similarly, on March 8, 2018, Cigna announced a US$52 billion agreement to buy Express Scripts, the largest U.S. pharmacy benefits manager.[303] Express Scripts oversees prescription plans for more than 80 million Americans. Cigna stated the agreement furthers its strategy to "improve the affordability and value to the consumer in a more personalized way."[304] Healthcare insurance companies have indicated the need to "integrate the delivery of care and pharmacy benefits into their own operations in order to tackle high medical costs."[305] However, Consumers Union has noted that such vertical integration "could result in restricted choices throughout the marketplace, ultimately leading to higher costs and potentially poorer coverage and care for consumers."[306]

Overall, these agreements likely represented a strategic response to the rapidly transforming landscape of healthcare delivery, including hospitals coordinating more closely with primary care physicians and other healthcare providers, increasing numbers of urgent care clinics, the possible entrance of online retailers into the pharmacy business, and the rise of telemedicine, including the possibility of technology companies offering medical care via cell phone.[307] Additional possible motives for consolidation include economies of scale, negotiating power against large healthcare institutions, and continued dominance in local markets.[308] As of late March 2018, the Department of Justice and the FTC had not yet responded to possible antitrust implications of the agreements between CVS Health and Aetna and Cigna and Express Scripts.

Professional License and Certificate Abuse

State professional licensing boards license and discipline physicians, nurses, dentists, physical therapists, occupational therapists, psychologists, and other healthcare practitioners. Disciplinary action may be filed against a practitioner for gross negligence, repeated negligent acts, and incompetence, as well as for sexual misconduct, substance abuse, filing false claims, and engaging in kickback schemes.[309] For example, physician gross negligence may include not performing basic diagnostic tests, not recognizing or acting on symptoms presented by a patient, and not referring a patient to a specialist when appropriate.[310] A finding of incompetence may be based on a physician's continued use of a procedure that is unnecessary or obsolete.[311] As well, a physical therapist may forfeit her or his license based on grounds of patient abuse, medication violation, and poor documentation or record-keeping.[312]

Use of social media by healthcare practitioners has also come under the scrutiny of professional licensing boards. For example, a study of state medical boards reported that greater than 75 percent were likely or very likely to investigate a physician who may have violated online professionalism by allegedly citing misleading information regarding clinical outcomes, using patient images without consent, or misrepresenting credentials.[313]

Professional licensing boards themselves may engage in anticompetitive behavior by favoring their own license holders over potential rivals and by prohibiting or restricting "new forms of

practice organization, marketing, and service delivery."[314] For example, in *North Carolina State Board of Dental Examiners v. Federal Trade Commission*,[315] the FTC had filed an administrative complaint against the board, which had "issued at least 47 official cease-and-desist letters to nondentist teeth whitening service providers and product manufacturers, often warning that the unlicensed practice of dentistry is a crime."[316] The FTC alleged that the board's action constituted an anticompetitive and unfair method of competition under the Federal Trade Commission Act. An administrative law judge then determined that the board "had unreasonably restrained trade in violation of antitrust law."[317] The U.S. Court of Appeals for the Fourth Circuit had affirmed the FTC in all respects.[318] Subsequently, the U.S. Supreme Court affirmed the judgment of the Fourth Circuit Court of Appeals, holding that "When a controlling number of the decision makers on a

BOX 9.2

Case Study: Advances in Medical Technologies

Imagine that in the not-too-distant future, gene-editing technologies and precision medicine technologies have been applied successfully to the treatment of various human diseases and disorders. Patients with Alzheimer's disease, breast and colon cancer, hypertension, and diabetes have all benefited from these treatments. But vociferous and insistent demonstrations have been staged outside the halls of Congress, in state capitols, at biomedical industry conferences, and on the grounds of biotechnology industrial parks.

Participants in these demonstrations represent the vast majority of people who cannot afford the exorbitantly high costs of gene-editing and precision medicine treatments. In the several years since critical breakthroughs were announced, demonstrations have continued to increase in frequency and property damages and even personal injuries have continued to escalate. Experts in ethical and legal issues in healthcare have persistently and consistently highlighted the widening inequities of healthcare delivery in these new frontiers of care. Public officials at every level of government call for calm and patience, but legislative action regarding access to and affordability of genetics-based treatments remains elusive.

Ethical Analysis

1. Given the premise that public policy is best formulated in advance of an anticipated problem, discuss legislative solutions that could address potential inequities in access and affordability as related to gene-editing and precision medicine treatments.
2. Apply the biomedical ethical principles of beneficence and justice to the advent of gene-editing and precision medicine technologies. Discuss additional ethical concerns beyond those of equitable distribution of benefits.
3. Discuss ethical constraints, if any, regarding technological innovations in the arena of human health and disease. For example, if human DNA can be modified, how can we control the downstream effects of our genetic interventions, that is, the effects on future generations? As well, does a boundary exist beyond which human beings cease to be humans as such and are transformed into a novel species?

state licensing board are active participants in the occupation the board regulates, the board can invoke state-action immunity only if it is subject to active supervision by the state."[319] Thus, state licensing boards composed of market participants "do not enjoy automatic immunity from antitrust laws."[320] Overall, the Court stated that "The Sherman Act protects competition while also respecting federalism. It does not authorize the States to abandon markets to the unsupervised control of active market participants."[321] Following the Supreme Court ruling, there has been an increase in new claims against state licensing boards brought by private plaintiffs.[322] States will need to actively supervise professional licensing boards and ensure that they are accountable to state government.[323]

KEY TERMS

Conflict of Interest
A conflict of interest arises in circumstances in which an individual has competing interests or loyalties. In the context of healthcare and healthcare delivery, a physician conflict of interest ensues whenever events, owing to inducement or coercion, predispose him or her to act other than in a patient's best interest.[324]

Consent as an Event
Consent as an event focuses on the legal obligation of providing information that a reasonable person would consider material prior to making a treatment decision and obtaining the patient's signature on the informed consent form.

Consent as a Process
Consent as a process focuses on a patient's evolving understanding of the complex information being presented. A process model encourages active patient participation in healthcare decisions. The patient has an opportunity to ask questions, express her concerns, and ensure that her preferences regarding quality of life are addressed.

Conversion
Conversion is a legal term denoting an intentional tort (wrongful act leading to civil legal liability) in which one person uses or substantially changes another person's property, essentially "taking" that person's property, in a way that interfered with the owner's interest in the property. A conversion claim attempts to recover the value of personal property that was altered or damaged by another person's unauthorized use.[325]

Genome
A genome is an organism's complete set of DNA. The human genome is comprised of approximately 3 billion base pairs, each representing a "letter" or datum of information. The human genome is estimated to contain between 20,000 and 25,000 genes, each of which contains the instructions for building a specific protein or set of proteins.[326]

Genomics
Genomics is the study of genes and their functions. Genomics attempts to identify the combined influence of genes and their interrelationships on the growth and development of organisms.[327]

Qui Tam Action
In a *qui tam* action, a private individual, termed a *relator,* brings an action on behalf of the government. The government is considered the real plaintiff. If the government prevails in the lawsuit, then the relator receives a share of the award. *Qui tam* is shortened from *qui tam pro domino rege quam pro se ipso in hac parte sequitur,* that is, "who as well for the king as for himself sues in this matter."[328]

Therapeutic Misconception
Patients with a therapeutic misconception likely misapprehend the purpose of a research study and believe that participation will provide a therapeutic benefit. Under this misapprehension, patients believe that the research protocol will advance their own therapeutic interests and that "decisions about their care are being made solely with their benefit in mind."[329]

Whole Genome Sequencing
Whole genome sequencing is sequencing of a human germline or somatic specimen with the intent to generate the genome or exome (coding) sequence of that specimen.[330] Whole genome sequencing poses numerous biomedical ethical concerns, as the technology may be used to identify an individual from whom the biospecimen was derived. Whole genome sequencing may identify genetic markers of disease, with the potential for violation of an individual's privacy with respect to protected health information. As well, whole genome sequencing provides information regarding probable DNA sequences of close relatives.[331]

DISCUSSION QUESTIONS

1A. Describe a specific medical research study and the measures you would employ to counter the therapeutic misconceptions of potential research subjects.
1B. Discuss whether the presence of therapeutic misconceptions impacts the internal validity of a medical research study, that is, the extent to which no other variables other than the ones being studied contributed to the result.
2A. You are one of the California Supreme Court justices deciding *Moore v. The Regents of the University of California.* Describe your main comment as presented in your concurring or dissenting opinion.
2B. Compare and contrast the rulings in *Moore* and *Myriad Genetics* from the perspectives of the biomedical ethical principles of autonomy, beneficence, and justice.

DO-IT-YOURSELF ETHICIST

- Numerous ethical pitfalls exist for healthcare providers who recruit patients as potential research subjects.
- Create a list of three ethically problematic scenarios that such a provider might cause or encounter.
- Create a self-inventory for providers detailing several methods to aid in identifying and avoiding these ethical dilemmas.

- Create a factsheet for patients who are considering participation in medical research, alerting them to potential conflicts of interest on the part of the requesting provider and including information intended to counter various therapeutic misconceptions.

REAL-WORLD APPLICATIONS—ETHICS AS A DOCTRINE OF ACTION

1. In *Griswold v. Connecticut*,[332] Justice William O. Douglas famously (or infamously) described emanations and penumbras associated with the Bill of Rights. These metaphorical emissions of light and related shadowy regions may offer protections that represent conceptual extensions of the Bill of Rights. As your healthcare organization's public advocate, write a 750-word policy paper investigating the potential existence of a right to healthcare, with specific reference to Medicare and Medicaid, including discussions supporting and denying the existence of such a right.
2. Gene editing research continues to accomplish new breakthroughs. As a senior-level ethics advisor to the FDA, you have been tasked to assist in the process of updating federal regulations. Write a 750-word policy assessment discussing ethical issues associated with genome manipulation of various living organisms and the potential benefits and harms of various applications of such research.

REFERENCES

[1]Centers for Medicare and Medicaid Services, *Medicare & Medicaid Milestones: 1937–2015*, July 2015, https://www.cms.gov/About-CMS/Agency-Information/History/Downloads/Medicare-and-Medicaid-Milestones-1937-2015.pdf.

[2]Ibid., 2.

[3]Ibid.

[4]Ibid., 2–3.

[5]Ibid., 3.

[6]Mueller MS: Notes and Brief Reports. Health Maintenance Organization Act of 1973. Social Security Bulletin, March 1974, 35–39, https://www.ssa.gov/policy/docs/ssb/v37n3/v37n3p35.pdf.

[7]Ibid., 35.

[8]Ibid.

[9]Ibid., 37.

[10]Ibid.

[11]Ibid.

[12]Ibid.

[13]Centers for Medicare and Medicaid Services, *Medicare & Medicaid Milestones: 1937–2015*, 4.

[14]Ibid.

[15]The Commonwealth Fund, *The State Children's Health Insurance Program: Past, Present, and Future*, http://www.commonwealthfund.org/publications/fund-reports/2007/feb/the-state-childrens-health-insurance-program--past--present--and-future.

[16]Public Law 108-173, December 8, 2003, Medicare Prescription Drug, Improvement, and Modernization Act of 2003, https://www.congress.gov/108/plaws/publ173/PLAW-108publ173.pdf.

[17]Public Law 111-3, February 4, 2009, Children's Health Insurance Program Reauthorization Act, https://www.congress.gov/111/plaws/publ3/PLAW-111publ3.pdf.

[18]K. Davis, C. Schoen, and F. Bandeali, *Medicare. 50 Years of Ensuring Coverage and Care* (Washington, DC: Commonwealth Fund, 2015), 7, http://www.commonwealthfund.org/~/media/files/publications/fund-report/2015/apr/1812_davis_medicare_50_years_coverage_care.pdf.

[19]Ibid.

[20]Ibid.

[21]The Commonwealth Fund, *Medicare's Numbers Game*, April 30, 2015, http://www.commonwealthfund.

org/interactives-and-data/infographics/2015/apr/medicare-numbers.

[22]Centers for Medicare and Medicaid Services, NHE Fact Sheet. Historical NHE, 2016, last modified on December 6, 2017, https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/nationalhealthexpenddata/nhe-fact-sheet.html.

[23]Davis, Schoen, and Bandeali, *Medicare. 50 Years of Ensuring Coverage and Care*, 15.

[24]Ibid., 22.

[25]L. Potetz, J. Cubanski, and T. Neuman, *Medicare Spending and Financing. A Primer* (Menlo Park, CA: Henry J. Kaiser Family Foundation, 2011), 5, https://kaiserfamilyfoundation.files.wordpress.com/2013/01/7731-03.pdf.

[26]S. Woolhandler and D. U. Himmelstein, "Single-Payer Reform: The Only Way to Fulfill the President's Pledge of More Coverage, Better Benefits, and Lower Costs," *Annals of Internal Medicine* 166, no. 8 (2017): 587–588.

[27]D. Blumenthal, K. Davis, and S. Guterman, "Medicare at 50. Origins and Evolution," *New England Journal of Medicine* 372, no. 5 (2015): 479–486.

[28]Ibid., 485.

[29]Ibid.

[30]*Your Medicare Coverage*, https://www.medicare.gov/coverage/skilled-nursing-facility-care.html, retrieved on February 8, 2018.

[31]D. Blumenthal, K. Davis, and S. Guterman, "Medicare at 50. Moving Forward," *New England Journal of Medicine* 372, no. 7 (2015): 671–677.

[32]Ibid., 676.

[33]Ibid.

[34]Public Law 111-148, March 23, 2010, Patient Protection and Affordable Care Act, Subtitle A, Section 2001, https://www.gpo.gov/fdsys/pkg/PLAW-111publ148/pdf/PLAW-111publ148.pdf.

[35]J. K. Iglehart and B. D. Sommers, "Medicaid at 50. From Welfare Program to Nation's Largest Health Insurer," *New England Journal of Medicine* 372, no. 22 (2015): 2152–2159.

[36]Medicaid and CHIP Payment and Access Commission (MACPAC), "Medicaid's Role in Providing Assistance with Long-Term Services and Supports," in *June 2014 Report to the Congress on Medicaid and CHIP*, chap. 2, 38, https://www.macpac.gov/wp-content/uploads/2015/01/Medicaids_Role_in_Providing_Assistance_with_Long-Term_Services_and_Supports.pdf.

[37]Long Term Services and Supports, Medicaid.gov, https://www.medicaid.gov/medicaid/ltss/index.html.

[38]MACPAC, "Medicaid's Role in Providing Assistance," 38.

[39]A. Frakt, A. E. Carroll, H. A. Pollack et al., "Our Flawed but Beneficial Medicaid Program," *New England Journal of Medicine* 364, no. 16 (2011): e31.

[40]Iglehart and Sommers, "Medicaid at 50," 2157.

[41]B. D. Sommers, K. Baicker, and A. M. Epstein, "Mortality and Access to Care among Adults after State Medicaid Expansions," *New England Journal of Medicine* 367, no. 11 (2012): 1025–1034.

[42]November 2017 Medicaid and CHIP Enrollment Data Highlights, Medicaid.gov, https://www.medicaid.gov/medicaid/program-information/medicaid-and-chip-enrollment-data/report-highlights/index.html.

[43]Centers for Medicare and Medicaid Services, *Medicaid & CHIP. Strengthening Coverage, Improving Health*, January 2017, https://www.medicaid.gov/medicaid/program-information/downloads/accomplishments-report.pdf.

[44]"The Nuremberg Code," in *Doctors of Infamy: The Story of the Nazi Medical Crimes*, eds. A. Mitscherlich and F. Mielke (New York: Schuman, 1949), xxiii–xxv. Also, the Nuremberg Code may be located online on the National Institutes of Health website, https://history.nih.gov/research/downloads/nuremberg.pdf.

[45]National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *The Belmont Report. Ethical Principles and Guidelines for the Protection of Human Subjects of Research*, DHEW Publication No. (OS) 78-0012 (Washington, DC: Government Printing Office, 1978), 4, https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/.

[46]C. W. Lidz, P. S. Appelbaum, and A. Meisel, "Two Models of Implementing Informed Consent," *Archives of Internal Medicine* 148, no. 6 (1988): 1385–1389.

[47]Ibid.

[48]*Canterbury v. Spence*, 464 F.2d 772 (D.C. Cir. 1972), at 784.

[49]J. A. Erlen, "Informed Consent: Revisiting the Issues," *Orthopaedic Nursing* 29, no. 4 (2010): 276–280.

[50]45 CFR 46.109, IRB review of research, https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/.

[51]Ibid., 45 CFR 46.111, Criteria for IRB approval of research.

[52]Ibid., 45 CFR 46.109(b).

[53]P. S. Appelbaum, L. H. Roth, and C. Lidz, "The Therapeutic Misconception: Informed Consent in Psychiatric Research," *International Journal of Law and Psychiatry* 5, nos. 3–4 (1982): 319–329.

[54]Ibid., 328.

[55]C. W. Lidz, K. Albert, and P. Appelbaum, "Why Is Therapeutic Misconception So Prevalent?" *Cambridge Quarterly of Healthcare Ethics* 24, no. 2 (2015): 231–241.

[56]C. W. Lidz, "The Therapeutic Misconception and Our Models of Competency and Informed Consent," *Behavioral Sciences and the Law* 24, no. 4 (2006): 535–546.

[57]C. K. Daugherty, D. M. Banik, L. Janish et al., "Quantitative Analysis of Ethical Issues in Phase I Trials: A Survey Interview Study of 144 Advanced Cancer Patients," *IRB* 22, no. 3 (2000): 6–14.

[58]S. Joffe, E. F. Cook, P. D. Cleary et al., "Quality of Informed Consent in Cancer Clinical Trials. A Cross-Sectional Survey," *The Lancet* 358, no. 9295 (2001): 1772–1777.

[59]C. Fried, *Medical Experimentation. Personal Integrity and Social Policy*, new ed. (New York: Oxford University Press, 2016).

[60]A. Schafer, "The Ethics of the Randomized Clinical Trial," *New England Journal of Medicine* 307, no. 12 (1982): 719–724.

[61]P. S. Appelbaum, L. H. Roth, C. W. Lidz, et al., "False Hopes and Best Data: Consent to Research and the Therapeutic Misconception," *Hastings Center Report* 17, no. 2 (1987): 20–24.

[62]R. Dresser, "The Ubiquity and Utility of the Therapeutic Misconception," *Social Philosophy and Policy* 19, no. 2 (2002): 271–294.

[63]Appelbaum, Roth, and Lidz, "False Hopes and Best Data", 21.

[64]Lidz, "The Therapeutic Misconception," 540.

[65]Appelbaum, Roth, and Lidz, "False Hopes and Best Data", 23.

[66]Lidz, Albert, Appelbaum, "Why Is Therapeutic Misconception So Prevalent?", 232.

[67]Appelbaum, Roth, and Lidz, "False Hopes and Best Data", 23.

[68]J. Moreno, A. L. Caplan, P. R. Wolpe et al., "Updating Protections for Human Subjects Involved in Research," *JAMA* 280, no. 22 (1998): 1951–1958.

[69]Dresser, "Ubiquity and Utility", 294.

[70]J. D. Watson and F. H. C. Crick, "A Structure for Deoxyribose Nucleic Acid," *Nature* 171, no. 4356 (1953): 737–738; M. H. F. Wilkins, A. R. Stokes and H. R. Wilson, "Molecular Structure of Deoxypentose Nucleic Acids," *Nature* 171, no. 4356 (1953): 738–740; R. Franklin and R. G. Gosling, "Molecular Configuration in Sodium Thymonucleate," *Nature* 171, no. 4356 (1953): 740–741.

[71]L. Rowen, G. Mahairas, and L. Hood, "Sequencing the Human Genome," *Science* 278, no. 5338 (1997): 605–607.

[72]M. Pertea and S. L. Salzberg, "Between a Chicken and a Grape: Estimating the Number of Human Genes. *Genome Biology* 11, no. 5 (2010): 206, https://link.springer.com/article/10.1186/gb-2010-11-5-206.

[73]U.S. Department of Health and Human Services/U.S. Department of Energy, *Understanding Our Genetic Inheritance. The U.S. Human Genome Project: The First Five Years, Fiscal Years 1991–1995*. NIH Publication No. 90-1590, April 1990, http://web.ornl.gov/sci/techresources/Human_Genome/project/5yrplan/index.shtml.

[74]K. B. Mullis, "Target Amplification for DNA Analysis by the Polymerase Chain Reaction," *Annales de Biologie Clinique* (Paris) 48, no. 8 (1990): 579–582.

[75]International Human Genome Sequencing Consortium: Initial Sequencing and Analysis of the Human Genome," *Nature* 409, no. 6822 (2001): 860–921; J. C. Venter, M. D. Adams, E. M. Myers et al., "The Sequence of the Human Genome," *Science* 291, no. 5507 (2001): 1304–1351.

[76]*Federal Register* 82, no. 12: 7149–7274, January 19, 2017, https://www.gpo.gov/fdsys/pkg/FR-2017-01-19/pdf/2017-01058.pdf, 7260.

[77]A. S. Relman, "The New Medical-Industrial Complex," *New England Journal of Medicine* 303, no. 17 (1980): 963–970.

[78]Ibid.

[79]B. Capps, "Can a Good Tree Bring Forth Evil Fruit? The Funding of Medical Research by Industry," *British Medical Bulletin* 118, no. 1 (2016): 5–15.

[80]J. E. Bekelman, Y. Li, and C. P. Gross, "Scope and Impact of Financial Conflicts of Interest in Biomedical Research: A Systematic Review," *JAMA* 289, no. 4 (2003): 454–465.

[81]Public Law 96-517, December 12, 1980, https://nifa.usda.gov/sites/default/files/resource/Pub.%20L.%2096-517%2C%20December%2012%2C%201980.pdf.

[82]C. S. Hayter and J. H. Rooksby, "A Legal Perspective on University Technology Transfer," *Journal of Technology Transfer* 41, no. 2 (2016): 270–289.

[83]C. Macilwain, "U.S. Survey Reveals Location of Human Tissue Samples," *Nature* 403, no. 6768 (2000): 352.

[84]E. Eiseman and S. B. Haga, *Handbook of Human Tissue Sources: A National Resource of Human Tissue Samples* (San Francisco: RAND Corporation, 1999).

[85]Centers for Medicare and Medicaid Services, *Medicaid & CHIP*.

[86]*Moore v. The Regents of the University of California*, 51 Cal.3d 120 (1990), 793 P.2d 479, 271 Cal. Rptr. 146.

[87]Ibid., at 125.

[88]Ibid., at 126.

[89]Ibid., at 127.

[90]Ibid., at 125.

[91]Ibid., at 147.

[92]Ibid.

[93]Ibid., at 132.

[94]Ibid., at 154.

[95]D. D. Dobbs, P. T. Hayden, and E. M. Bublick, *Hornbook on Torts*, 2nd ed. (St. Paul, MN: West Academic, 2016), 107–109, 114.

[96]*Moore v. The Regents of the University of California*, at 163.

[97]Ibid., at 149.

[98]Ibid., at 145.

[99]Ibid., at 149.

[100]Ibid., at 151.

[101]Ibid., at 174.

[102]Ibid., at 176.

[103]*Hecht v. The Superior Court of Los Angeles County*, 16 Cal. App. 4th 836 (1993), 20 Cal. Rptr.2d 275.

[104]*Davis v. Davis*, 842 S.W.2d 588 (Tenn. 1992).

[105]*Hecht v. The Superior Court of Los Angeles County*, at 846.

[106]*York v. Jones*, 717 F. Supp. 421, 427 (E.D. Va. 1989).

[107]*United States v. Arora*, 860 F. Supp. 1091, 1098-99 (D. Md. 1994).

[108]*Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

[109]*Washington University v. Catalona*, 437 F. Supp.2d 985, 1002 (E.D. Mo. 2006).

[110]Ibid.

[111]Ibid.

[112]*Washington University v. Catalona*, 490 F.3d 667 (2007).

[113]Ibid., at 673.

[114]Ibid., at 674.

[115]Ibid., at 675.

[116]*Federal Register* 76, no. 143: 44512–44531, July 26, 2011, https://www.gpo.gov/fdsys/pkg/FR-2011-07-26/pdf/2011-18792.pdf.

[117]Ibid., 44512.

[118]*Federal Register* 80, no. 173: 53933–5406 1, September 8, 2015, at 53933, https://www.gpo.gov/fdsys/pkg/FR-2015-09-08/pdf/FR-2015-09-08.pdf.

[119]J. Menikoff, J. Kaneshiro, and I. Pritchard, "The Common Rule, Updated," *New England Journal of Medicine* 376, no. 7 (2017): 613–615.

[120]National Academies of Sciences, Engineering, and Medicine, *Optimizing the Nation's Investment in Academic Research: A New Regulatory Framework for the 21st Century* (Washington, DC: National Academies Press, 2016), https://www.nap.edu/catalog/21824/optimizing-the-nations-investment-in-academic-research-a-new-regulatory.

[121]U.S. Department of Health and Human Services, Office for Human Research Protections, *Federal Policy for the Protection of Human Subjects ("Common Rule")*, https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html.

[122]*Federal Register* 82(12): 7273. On January 17, 2018, the Office for Human Research Protections announced a delay in the new Final Rule effective date and general compliance date to July 19, 2018, https://www.hhs.gov/ohrp/interim-final-rule-common-rule.html.

[123]*Federal Register* 82(12): 7211.

[124]Ibid.

[125]Ibid., 7265.

[126]Ibid., 7214.

[127]Ibid., 7247.

[128]Ibid., 7260.

[129]Ibid.

[130]Ibid.

[131]Ibid.

[132]Ibid.

[133]Ibid., 7266.

[134]Ibid., 7252.

[135]Ibid.

[136]Ibid., 7266.

[137]Ibid.

[138]Ibid.

[139]Ibid., 7266–7267.

[140]Ibid., 7266.

[141]*Association for Molecular Pathology v. Myriad Genetics*, 133 S. Ct. 2107, 186 L. Ed. 2d 124 (2013).

[142]U.S. Patent 5,837,492, November 17, 1998, https://patentimages.storage.googleapis.com/d2/f6/68/c6cc678ef4e2f0/US5837492.pdf; U.S. Patent 5,747,282, May 5, 1998, https://patentimages.storage.googleapis.com/ea/54/59/c2b7ed13fd4994/US5747282.pdf; U.S. Patent 5,693,473, December 2, 1997, https://patentimages.storage.googleapis.com/7b/af/58/d6ff48b517f948/US5693473.pdf.

[143]U.S. Patent 5,747,282, May 5, 1998.

[144]U.S. Patent 5,837,492, November 17, 1998.

[145]U.S. Patent 5,747,282, May 5, 1998.

[146]Ibid.

[147]Ibid.

[148]*Association for Molecular Pathology v. Myriad Genetics.*

[149]Ibid.

[150]Ibid.; 35 U.S. Code §101 states that "Whoever invents or discovers any new and useful … composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." https://www.gpo.gov/fdsys/pkg/USCODE-2011-title35/pdf/USCODE-2011-title35-partII-chap10-sec101.pdf.

[151]*Association for Molecular Pathology v. Myriad Genetics.*

[152]*Association for Molecular Pathology v. United States Patent and Trademark Office*, 702 F. Supp. 2d 181 (S.D.N.Y. 2010).

[153]*Association for Molecular Pathology v. Myriad Genetics.*

[154]*Association for Molecular Pathology v. United States Patent and Trademark Office*, at 222.

[155]*Mayo Collaborative Services v. Prometheus Laboratories*, 132 S. Ct. 1289, 182 L. Ed. 2d 321 (2012).

[156]*Association for Molecular Pathology v. Myriad Genetics.*

[157]Ibid.

[158]Ibid.

[159]Ibid.

[160]Ibid.

[161]Ibid.

[162]Ibid.

[163]A. Liptak, "Justices, 9–0, Bar Patenting Human Genes," *New York Times*, June 13, 2013, http://www.nytimes.com/2013/06/14/us/supreme-court-rules-human-genes-may-not-be-patented.html.

[164]35 U.S. Code §101.

[165]A. Bolotin, B. Quinquis, A. Sorokin et al. "Clustered Regularly Interspaced Short Palindrome Repeats (CRISPRs) Have Spacers of Extrachromosomal Origin," *Microbiology* 151, Pt. 8 (2005): 2551–2561; F. J. M. Mojica, C. Díez-Villaseñor, J. García-Martínez et al., "Intervening Sequences of Regularly Spaced Prokaryotic Repeats Derive from Foreign Genetic Elements," *Journal of Molecular Evolution* 60, no. 2 (2005): 174–182.

[166]National Academies of Science, Engineering, and Medicine, *Human Genome Editing: Science, Ethics, and Governance* (Washington, DC: National Academies Press, 2017).

[167]Consolidated Appropriations Act, 2016 (Public Law 114-113), December 18, 2015, Sec. 749, https://www.gpo.gov/fdsys/pkg/PLAW-114publ113/pdf/PLAW-114publ113.pdf.

[168]Ibid., Sec. 508.

[169]M. Jinek, A. East, A. Cheng et al., "RNA-Programmed Genome Editing in Human Cells," *eLife* 2 (2013): e00471, doi:10.7554/eLife.00471.

[170]A. Hammond, R. Galizi, K. Kyrou et al., "A CRISPR-Cas9 Gene Drive System Targeting Female Reproduction in the Malaria Mosquito Vector *Anopheles gambiae*," *Nature Biotechnology* 34, no. 1 (2016): 78–85.

[171]U.S. Food and Drug Administration (FDA), *FDA Releases Final Environmental Assessment for Genetically Engineered Mosquito*, August 5, 2016, https://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm490246.htm.

[172]J. A. Doudna and E. Charpentier, "The New Frontier of Genome Engineering with CRISPR-Cas9," *Science* 346, no. 6213 (2014): 1077, http://science.sciencemag.org/content/346/6213/1258096.

[173]H. Ma, N. Marti-Gutierrez, S-W. Park et al., "Correction of a Pathogenic Gene Mutation in Human Embryos," *Nature* 548, no. 7668 (2017): 413–419.

[174]National Center for Biotechnology Information, *MYBPC3 Myosin Binding Protein C, Cardiac [Homo sapiens (human)]*, https://www.ncbi.nlm.nih.gov/gene/4607.

[175]World Health Organization, *Genes and Human Disease*, http://www.who.int/genomics/public/geneticdiseases/en/index2.html.

[176]The White House, Office of the Press Secretary, "Remarks by the President in State of the Union Address," January 20, 2015, https://obamawhitehouse.archives.gov/the-press-office/2015/01/20/remarks-president-state-union-address-january-20-2015.

[177]The White House, Office of the Press Secretary, *Fact Sheet: President Obama's Precision Medicine Initiative*, January 30, 2015, https://obamawhitehouse.archives.gov/the-press-office/2015/01/30/fact-sheet-president-obama-s-precision-medicine-initiative.

[178]National Institutes of Health, *About the All of Us Research Program*, https://allofus.nih.gov/about/about-all-us-research-program.

[179]White House, "President Obama's Precision Medicine Initiative."

[180]M. J. Khoury and J. P. Evans, "A Public Health Perspective on a National Precision Medicine Cohort Balancing Long-Term Knowledge Generation with Early Health Benefit," *JAMA* 313, no. 21 (2015): 2117–2118.

[181]Committee on a Framework for Developing a New Taxonomy of Disease, Board on Life Sciences, National Research Council, *Toward Precision Medicine: Building a Knowledge Network for Biomedical Research and a New Taxonomy of Disease* (Washington, DC: National Academies Press, 2011, 37).

[182]Ibid., 125.

[183]M. E. Condren and M. D. Bradshaw, "Ivacaftor: A Novel Gene-Based Therapeutic Approach for Cystic Fibrosis," *Journal of Pediatric Pharmacology and Therapeutics* 18, no. 1 (2013): 8–13.

[184]B. W. Ramsey, J. Davies, N. G. McElvaney et al., "A CFTR Potentiator in Patients with Cystic Fibrosis and the G551D Mutation," *New England Journal of Medicine* 365, no. 18 (2011): 1663–1672.

[185]Condren and Bradshaw, "Ivacaftor."

[186]E. A. Ashley, "The Precision Medicine Initiative: A New National Effort," *JAMA* 313, no. 21 (2015): 2119–2120.

[187]National Cancer Institute, *NCI-Sponsored Trials in Precision Medicine. What Is "Precision Medicine,"* https://dctd.cancer.gov/majorinitiatives/NCI-sponsored_trials_in_precision_medicine.htm.

[188]R. Hodson, "Precision Medicine," *Nature* 537, no. 7619 (2016): S49.

[189]V. Prasad, "Is 'Precision Medicine' Ready to Use in Primary Care Practice?" *American Family Physician* 96, no. 12 (2017): 769–770.

[190]E. D. Saad, X. Paoletti, T. Burzykowski et al., "Precision Medicine Needs Randomized Clinical Trials," *Nature Reviews Clinical Oncology* 14, no. 5 (2017): 317–323.

[191]Ibid.

[192]M. J. Joyner and N. Paneth, "Seven Questions for Personalized Medicine," *JAMA* 314, no. 10 (2015): 999–1000.

[193]K. K. Ahuja, J. Mamiso, and G. Emmerson et al., "Pregnancy Following Intracytoplasmic Sperm Injection Treatment with Dead Husband's Spermatozoa: Ethical and Policy Considerations," *Human Reproduction* 12, no. 6 (1997): 1360–1363; J. B. Evans, "Post-Mortem Semen Retrieval: A Normative Prescription for Legislation in the United States," *Concordia Law Review* 1, no. 1 (2106): 133–160.

[194]Ibid. Although postmortem retrieval of ovarian tissue is technologically feasible, reports of requests for such procedures had been rare as of 2016.

[195]S. M. Bahm, K. Karkazis, and D. Magnus, "A Content Analysis of Posthumous Sperm Procurement Protocols with Considerations for Developing an institutional Policy," *Fertility and Sterility* 100, no. 3 (2013): 839–843.

[196]Ibid., 839.

[197]C. M. Rothman, "A Method for Obtaining Viable Sperm in the Postmortem State," *Fertility and Sterility* 34, no. 5 (1980): 512.

[198]C. Strong, J. R. Gingrich, and W. H. Kutteh, "Ethics of Postmortem Sperm Retrieval. Ethics of Sperm Retrieval after Death or Persistent Vegetative State," *Human Reproduction* 15, no. 4 (2000): 739–745.

[199]R. P. Smith and L. I. Lipshultz, "A Call for Institutional Policies on Postmortem Sperm Retrieval," *Fertility and Sterility* 100, no. 3 (2013): 656–657.

[200]J. M. Hurwitz and F. R. Batzer, "Posthumous Sperm Procurement. Demands and Concerns," *Obstetrical and Gynecological Survey* 59, no. 12 (2004): 806–808.

[201]Human Fertilisation and Embryology Act of 1990, Chapter 37. Schedule 3: Consents to Use of Gametes or Embryos, 38, https://www.legislation.gov.uk/ukpga/1990/37/pdfs/ukpga_19900037_en.pdf.

[202]National Ethics Committee on Assisted Human Reproduction, *Guidelines for the Storage, Use, and Disposal of Sperm from a Deceased Man* (Wellington, New Zealand: Ministry of Health, 2000), https://acart.health.govt.nz/system/files/documents/publications/acart-guidelines-storage-use-disposal-sperm-deceased.pdf.

[203]A. Westreich, "The Debate over Postmortem Sperm Retrieval of Fallen Soldiers," *Jerusalem Post*, November 22, 2017, http://www.jpost.com/Israel-News/The-debate-over-postmortem-sperm-retrieval-of-fallen-soldiers-514994.

[204]Ibid.

[205]Evans, "Post-Mortem Semen Retrieval," 152.

[206]Weill Cornell Medicine Urology, *Postmortem Sperm Retrieval (PMSR)*, https://urology.weillcornell.org/Postmortem-Sperm-Retrieval.

[207]Ibid.

[208]Ibid.

[209]Ethics Committee of the American Society for Reproductive Medicine, "Posthumous Collection and Use of Reproductive Tissue: A Committee Opinion," *Fertility and Sterility* 99, no. 7 (2013): 1842–1845.

[210]C. P. Kindregan and S. H. Snyder, "Clarifying the Law of ART: The New American Bar Association Model Act Governing Assisted Reproductive Technology," *Family Law Quarterly* 42, no. 2 (2008): 203–229.

[211]American Bar Association Model Act Governing Assisted Reproductive Technology, February 2008, https://www.americanbar.org/content/dam/aba/publishing/family_law_quarterly/family_flq_artmodelact.authcheckdam.pdf.

[212]Evans, "Post-Mortem Semen Retrieval," 136.

[213]18 U.S. Code §1347, Health Care Fraud, https://www.law.cornell.edu/uscode/text/18/1347.

[214]J. A. Staman, "Health Care Fraud and Abuse Laws Affecting Medicare and Medicaid: An Overview," Congressional Research Service Report for Congress, September 8, 2014, RS22743, https://fas.org/sgp/crs/misc/RS22743.pdf.

[215]W. J. Rudman, "Healthcare Fraud and Abuse," Perspectives in Health Information Management 6, fall (2009): 1g.

[216]Staman, "Health Care Fraud and Abuse Laws," 1.

[217]Federal Bureau of Investigation, *Financial Crimes Report to the Public: Fiscal Years 2010–2011* (Washington, DC: U.S. Department of Justice, 2011), 16, https://www.fbi.gov/file-repository/stats-services-publications-financial-crimes-report-2010-2011-financial-crimes-report-2010-2011.pdf/view.

[218]J. H. Krause, "Integration, Fragmentation, and Human Nature: The Role of the Fraud and Abuse Laws in a Changing Healthcare System," in *The Oxford Handbook of U.S. Health Law*, eds., I. G. Cohen, A. K. Hoffman, and W. M. Sage (New York, Oxford University Press, 2017), 852–872.

[219]Staman, "Health Care Fraud and Abuse Laws," 1–2.

[220]Public Law 92-603, October 30, 1972, Social Security Amendments of 1972, https://www.gpo.gov/fdsys/pkg/STATUTE-86/pdf/STATUTE-86-Pg1329.pdf.

[221]Ibid., 86 Stat. 1419.

[222]Ibid., 86 Stat. 1419–1420.

[223]Public Law 100-93, August 18, 1987, Medicare and Medicaid Patient and Program Protection Act of 1987, https://www.gpo.gov/fdsys/pkg/STATUTE-101/pdf/STATUTE-101-Pg680.pdf.

[224]42 U.S. Code *§1320a-7b, Criminal Penalties for Acts Involving Federal Health Programs*, https://www.ssa.gov/OP_Home/ssact/title11/1128B.htm.

[225]42 CFR Part 1001. Final Rule, effective July 29, 1991, https://oig.hhs.gov/fraud/docs/safeharborregulations/072991.htm.

[226]42 CFR §1001.952, Exceptions, https://www.law.cornell.edu/cfr/text/42/1001.952.

[227]*Federal Register* 81, no. 235: 88368–88409, December 7, 2016, https://www.gpo.gov/fdsys/pkg/FR-2016-12-07/pdf/2016-28297.pdf.

[228]Ibid., 88371.

[229]Ibid., 88379.

[230]Ibid., 88370.

[231]31 U.S. Code *§3729, False Claims*, https://www.law.cornell.edu/uscode/text/31/3729.

[232]U.S. Department of Justice, *The False Claims Act: A Primer*, https://www.justice.gov/sites/default/files/civil/legacy/2011/04/22/C-FRAUDS_FCA_Primer.pdf.

[233]Ibid.

[234]Staman, "Health Care Fraud and Abuse Laws," 9.

[235]U.S. Department of Justice, *Justice Department Recovers Over $3.7 Billion from False Claims Act Cases in Fiscal Year 2017*, December 21, 2017, https://www.justice.gov/opa/pr/justice-department-recovers-over-37-billion-false-claims-act-cases-fiscal-year-2017.

[236]Staman, "Health Care Fraud and Abuse Laws," 8.

[237]Krause, "Integration, Fragmentation, and Human Nature," 862.

[238]Staman, "Health Care Fraud and Abuse Laws," 9.

[239]Krause, "Integration, Fragmentation, and Human Nature," 862.

[240]R. M. Kirkner, "The Enduring Temptation of Physician Self-Referral," *Managed Care* 20, no. 10 (2011): 48–56.

[241]S. R. Hirschtick and A. R. Chenen, "The Ethics in Patient Referrals Act of 1989: What Will It Mean to Physicians?" *Medical Staff Counselor* 3, no. 3 (1989): 9–13.

[242]Public Law 101-239, December 19, 1989, Omnibus Budget Reconciliation Act of 1989, 103 STAT. 2236, https://www.gpo.gov/fdsys/pkg/STATUTE-103/pdf/STATUTE-103-Pg2106.pdf.

[243]*Federal Register* 66, no. 3: 705–1012, January 4, 2001, 859, https://www.gpo.gov/fdsys/pkg/FR-2001-01-04/pdf/FR-2001-01-04.pdf.

[244]Centers for Medicare and Medicaid Services, Physician Self-Referral, https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/index.html, last modified 1/5/2015.

[245]*Federal Register* 72, no. 171: 51012–51099, September 5, 2007 https://www.gpo.gov/fdsys/pkg/FR-2007-09-05/pdf/07-4252.pdf.

[246]Ibid., 51079–51098.

[247]Centers for Medicare and Medicaid Services, *Report to Congress: Fraud and Abuse Laws Regarding Gainsharing or Similar Arrangements between Physicians and Hospitals, 2015*, https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/Report-to-Congress-2015.pdf.

[248]Krause, "Integration, Fragmentation, and Human Nature," 863.

[249]Centers for Medicare and Medicaid Services, *Shared Savings Program*, https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/index.html.

[250]Centers for Medicare and Medicaid Services, *Shared Savings Program: About the Program*, https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/about.html.

[251]Office of Inspector General, *Medicare Program; Final Waivers in Connection with the Shared Savings Program*, https://www.federalregister.gov/documents/2015/10/29/2015-27599/medicare-program-final-waivers-in-connection-with-the-shared-savings-program.

[252]*Federal Register* 80, no. 209: 66413–66780, October 29, 2015, 66727, https://www.gpo.gov/fdsys/pkg/FR-2015-10-29/pdf/FR-2015-10-29.pdf.

[253]M. R. Tonelli, "Conflict of Interest in Clinical Practice," *Chest* 132, no. 2 (2007): 664–670.

[254]A. S. Relman, "The Problem of Commercialism in Medicine," *Cambridge Quarterly of Healthcare Ethics* 16, no. 4 (2007): 375–376.

[255]Tonelli, "Conflict of Interest in Clinical Practice," 666–667.

[256]A. Wazana, "Physicians and the Pharmaceutical Industry: Is a Gift Ever Just a Gift?" *JAMA* 283, no. 3 (2000): 373–380; J. P. Orlowski and L. Wateska, "The Effects of Pharmaceutical Firm Enticements on Physician Prescribing Patterns. There's No Such Thing as a Free Lunch," *Chest* 102, no. 1 (1992): 270–273.

[257]M. A. Steinman, C. S. Landefeld, and R. B. Baron, "Industry Support of CME: Are We at the Tipping Point?" *New England Journal of Medicine* 366, no. 12 (2012): 1069–1071.

[258]Staff of the Committee on Finance, U.S. Senate: Committee Staff Report to the Chairman and Ranking Member, *Use of Educational Grants by Pharmaceutical Manufacturers* (Washington, DC: U.S. Government Printing Office, 2007), https://www.finance.senate.gov/imo/media/doc/Prt110-21.pdf.

[259]Ibid., 2.

[260]Institute of Medicine, *Conflict of Interest in Medical Research, Education, and Practice*, eds. B. Lo and M. J. Field (Washington, DC: National Academies Press, 2009), 161, https://www.nap.edu/catalog/12598/conflict-of-interest-in-medical-research-education-and-practice.

[261]Accreditation Council for Continuing Medical Education, *2010 Annual Report Data Addendum: Analysis of Commercial Support Distribution and Long-Term CME Trends*, 8, http://www.accme.org/sites/default/files/null/606_2010_Annual_Report_Addendum_20120702.pdf.

[262]Accreditation Council for Continuing Medical Education, *2015 Annual Report*, 22, http://www.accme.org/sites/default/files/630_20160719_2015_Annual_Report.pdf.

[263]Tonelli, "Conflict of Interest in Clinical Practice," 667.

[264]N. K. Choudhry, H. T. Stelfox, and A. S. Detsky, "Relationships between Authors of Clinical Practice Guidelines and the Pharmaceutical Industry," *JAMA* 287, no. 5 (2002): 612–617.

[265]Ibid., 614.

[266]Tonelli, "Conflict of Interest in Clinical Practice," 667.

[267]American College of Chest Physicians, *Conflict of Interest Policy on Guidelines/Consensus Statements*, June 2017, http://www.chestnet.org/Guidelines-and-Resources/About-CHEST-Guidelines/—Guideline-Development.

[268]Ibid.

[269]W. M. Sage, "Antitrust Enforcement and the Future of Healthcare Competition," in *The Oxford Handbook of U.S. Health Law*, eds. I. G. Cohen, A. K. Hoffman, and W. M. Sage (New York: Oxford University Press, 2017), 606–636.

[270]Sherman Antitrust Act of 1890, 15 U.S. Code §§1-7, https://www.justice.gov/atr/file/761131/download.

[271]Clayton Antitrust Act of 1914, 15 U.S. Code §§12-27, https://www.justice.gov/atr/file/761131/download.

[272]Hart-Scott-Rodino Antitrust Improvements Act of 1976, U.S. Code §18a, https://www.law.cornell.edu/uscode/text/15/18a.

[273]15 U.S. Code §1, Trusts, etc., in restraint of trade illegal; penalty, https://www.law.cornell.edu/uscode/text/15/1.

[274]Choudhry, Stelfox, and Detsky, "Relationships between Authors of Clinical Practice Guidelines and the Pharmaceutical Industry," 608.

[275]U.S. Department of Justice, Competition and Monopoly, Single-Firm Conduct under Section 2 of the Sherman Act: Chapter 4, https://www.justice.gov/atr/competition-and-monopoly-single-firm-conduct-under-section-2-sherman-act-chapter-4.

[276]Sage, "Antitrust Enforcement," 608.

[277]U.S. Department of Justice, "Competition and Monopoly."

[278]U.S. Code §18, Acquisition by One Corporation of Stock of Another, https://www.law.cornell.edu/uscode/text/15/18.

[279]Sage, "Antitrust Enforcement," 608.

[280]Ibid., 609.

[281]U.S. Department of Justice, *Statements of Antitrust Enforcement Policy in Health Care*, https://www.justice.gov/atr/statements-antitrust-enforcement-policy-health-care.

[282]Ibid.

[283]Robert Wood Johnson Foundation, *Synthesis Project. Update June 2012*, https://www.rwjf.org/content/dam/farm/reports/issue_briefs/2012/rwjf73261.

[284]*ProMedica Health System v. Federal Trade Commission*, 749 F.3d 559 (2014).

[285]Ibid.

[286]Ibid.

[287]Ibid.

[288]M. Harris, "ProMedica System Must Sell Off St. Luke's Hospital," *Toledo Blade*, May 5, 2015, http://www.toledoblade.com/business/2015/05/05/ProMedica-must-sell-off-St-Luke-s-nbsp.html.

[289]C. Bray and R. Abelson, "Aetna Agrees to Acquire Humana for $37 Billion in Cash and Stock," *New York Times*, July 3, 2015, https://www.nytimes.com/2015/07/04/business/dealbook/aetna-agrees-to-acquire-humana-for-37-billion-in-cash-and-stock.html.

[290]Ibid.

[291]Medicare.gov, *How Do Medicare Advantage Plans Work?* https://www.medicare.gov/sign-up-change-plans/medicare-health-plans/medicare-advantage-plans/how-medicare-advantage-plans-work.html.

[292]R. Abelson and L. Picker, "Judge Blocks Aetna's $37 Billion Deal for Humana," *New York Times*, January 23, 2017, https://www.nytimes.com/2017/01/23/business/dealbook/aetna-humana-deal-blocked.html.

[293]*United States of America, et al., v. Aetna Inc., et al.*, Civil Action No. 16-1494, filed January 23, 2017, 155–156, https://www.justice.gov/opa/press-release/file/930361/download.

[294]Ibid., 156.

[295]Ibid.

[296]M. J. de la Merced and L. Picker, "Judge, Citing Harm to Customers, Blocks $48 Billion Anthem-Cigna Merger," *New York Times*, February 8, 2017, https://www.nytimes.com/2017/02/08/business/dealbook/anthems-blue-cross-cigna-deal.html.

[297]*United States of America, et al., v. Anthem Inc., et al.*, Civil Action No. 16-1493, February 8, 2017, 3, https://www.justice.gov/atr/case-document/file/940946/download.

[298]U.S. Department of Justice, "U.S. District Court Blocks Anthem's Acquisition of Cigna," February 8, 2017, https://www.justice.gov/opa/pr/us-district-court-blocks-anthem-s-acquisition-cigna.

[299]M. J. de la Merced and R. Abelson, "CVS to Buy Aetna for $69 Billion in a Deal That May Reshape the Health Industry," *New York Times*, December 3, 2017, https://www.nytimes.com/2017/12/03/business/dealbook/cvs-is-said-to-agree-to-buy-aetna-reshaping-health-care-industry.html.

[300]Ibid.

[301]Ibid.

[302]R. Abelson and K. Thomas, "CVS and Aetna Say Merger Will Improve Your Health Care. Can They Deliver?" *New York Times*, December 4, 2017, https://www.nytimes.com/2017/12/04/health/cvs-aetna-merger.html.

[303]K. Thomas, R. Abelson, C. Bray, "Cigna to Buy Express Scripts in $52 Billion Health Care Deal," *New York Times*, March 8, 2018, https://www.nytimes.com/2018/03/08/business/dealbook/cigna-express-scripts.html.

[304]Ibid.

[305]Ibid.

[306]Ibid.

[307]Abelson and Thomas, "CVS and Aetna Say Merger Will Improve Your Health Care,"

[308]Sage, "Antitrust Enforcement," 619.

[309]Medical Board of California, *Information and Services for Consumers*, rev. March 2009, http://www.mbc.ca.gov/Publications/Brochures/consumer_info_english-web.pdf.

[310]Ibid.

[311]Ibid.

[312]Federation of State Boards of Physical Therapy, *Ten Easy Ways to Lose Your License*, https://www.fsbpt.org/Licensees/EthicalConduct/TenEasyWaystoLoseYourLicense.aspx.

[313]S. R. Greysen, D. Johnson, T. Kind et al., "Online Professionalism Investigations by State Medical Boards: First, Do No Harm," *Annals of Internal Medicine* 158, no. 2 (2013): 124–130.

[314]Sage, "Antitrust Enforcement," 627.

[315]*North Carolina State Board of Dental Examiners v. Federal Trade Commission*, 135 S. Ct. 1101 (2015), https://www.supremecourt.gov/opinions/14pdf/13-534_19m2.pdf.

[316]Ibid., 1.

[317]Ibid.

[318]*North Carolina State Board of Dental Examiners v. FTC*, 717 F.3d 359 (4th Cir. 2013).

[319]SCOTUSblog, "North Carolina Board of Dental Examiners v. Federal Trade Commission," http://www.scotusblog.com/case-files/cases/north-carolina-board-of-dental-examiners-v-federal-trade-commission/.

[320]E. M. Fraser, SCOTUSblog, "Opinion Analysis: No Antitrust Immunity for Professional Licensing Boards," February 25, 2015, http://www.scotusblog.com/2015/02/opinion-analysis-no-antitrust-immunity-for-professional-licensing-boards/.

[321]*North Carolina State Board of Dental Examiners v. Federal Trade Commission*, 18.

[322]Sage, "Antitrust Enforcement," 627.

[323]Ibid., 628.

[324]Tonelli, "Conflict of Interest in Clinical Practice."

[325]Dobbs, Hayden, and Bublick, *Hornbook on Torts*, 107–109, 114.

[326]National Human Genome Research Institute, *A Brief Guide to Genomics*, https://www.genome.gov/18016863/a-brief-guide-to-genomics/.

[327]World Health Organization (WHO), *WHO definitions of genetics and genomics*, http://www.who.int/genomics/geneticsVSgenomics/en/.

[328]B. A. Garner, ed., *Black's Law Dictionary*, 10th ed. (St. Paul, MN, West, 2014), 1444.

[329]Appelbaum, Roth, and Lidz, "Therapeutic Misconception," 321.

[330]*Federal Register* 82(12): 7256.

[331]R. H. Sijmons, I. M. Van Langen, and J. G. Sijmons, "A Clinical Perspective on Ethical Issues in Genetic Testing," *Accountability in Research* 18, no. 3 (2011): 148–162.

[332]*Griswold v. Connecticut*, 381 U.S. 479 (1965)

Figure Credit

Fig. 9.1: Copyright © 2013 Depositphotos/Maridav.

CHAPTER 10

Healthcare Issues in Contemporary Society—Part 2

ELECTRONIC HEALTH RECORDS, HEALTHCARE POLICY AND POPULATION HEALTH, BIAS IN HEALTHCARE DELIVERY, AND CORPORATE GOVERNANCE

As Part 1 of an exploration of healthcare issues in contemporary society, Chapter 9 discussed ramifications of the biomedical ethical principles of autonomy and beneficence including issues related to informed consent, gene editing and genetic technologies, and physician conflict of interest. Chapter 10 continues the discussion of contemporary healthcare issues and includes concerns associated with the biomedical ethical principles of nonmaleficence and justice. These concerns involve the areas of electronic health records, healthcare policy and population health, and bias in healthcare delivery. As well, Chapter 10 discusses the impact of the Sarbanes-Oxley Act of 2002 on governance standards, financial accountability, and transparency of nonprofit organizations including nonprofit healthcare institutions.

Electronic Health Records and the HIPAA Security and Privacy Rules

FIGURE 10.1 Electronic health records must adhere to HIPAA privacy and security rules

Today's electronic health records (EHRs) have their origin in the Institute of Medicine's 1991 report (revised in 1997), the "Computer-Based Record: An Essential Technology for Health Care."[1] The intention of the computer-based patient record (CPR) was to harness the information management capabilities of healthcare to improve care of individual patients and populations and reduce waste via continuous quality improvement. The CPR was viewed as "essential to the full

maturation of the scientific basis of health care."[2] In July 2003, an Institute of Medicine (IOM) Letter Report[3] responded to a May 2003 request of the U.S. Department of Health and Human Services (HHS) to provide guidance on the care-related capabilities of what was now termed an electronic health record (EHR) system. The IOM Letter Report identified eight core functionalities for an EHR:

- Health information and data
- Results management
- Order entry/management
- Decision support
- Electronic communication and connectivity
- Patient support
- Administrative processes
- Reporting and population health management[4]

Effective design and deployment of EHRs was intended to enhance and optimize the delivery of healthcare services from intake through discharge and beyond. EHRs would create a repository for all patient data, including chart notes; laboratory, imaging, and diagnostic testing reports; and medications. These data would be available relatively instantaneously to a patient's multiple providers, with the intention of reducing duplication of services, prescription errors, and drug interactions. Healthcare facility workflow would be improved by simplifying medication order entry, reducing medication dose and frequency errors, eliminating lost orders, and generating related orders automatically. Regarding decision support, EHR systems designs have the capability of providing assistance in clinical decision making and treatment recommendations, including delivery of general clinical knowledge and guidance in evidence-based best practices for managing patients with specific disease states. Decision support contributes to quality improvement by assisting in the avoidance of errors and adverse events.

Patient support includes patient education materials delivered via mobile platforms, including video formatting, medication alerts, and telemedicine systems delivering real-time transmission of home monitoring data, as for patients with diabetes, asthma or chronic obstructive pulmonary disease, or Alzheimer's disease. EHRs provide patients with detailed after-care instructions and self-care guidelines, including information regarding compliance with medications, self-care measures, and timely scheduling and follow-up.

EHRs provide support to fulfill institutional reporting requirements to local, state, and federal agencies regarding patient safety, other aspects of quality of care, and public health considerations. Regarding population health management, EHR support to public health agencies includes information on levels and distribution of diseases, incidence and prevalence estimates of acute and chronic diseases and disorders, syndrome surveillance, and immunization monitoring.[5]

Overall, the goals of EHRs are to provide uniformity and consistency, improve coordination of care, and foster patient participation in care. EHR systems, optimally, are designed to improve patient safety; support the delivery of effective patient care; facilitate management of chronic conditions; and improve efficiency of healthcare institutions, that is, avoid and eliminate waste of equipment, supplies, and human resources.[6]

Possibly the greatest disadvantages of EHRs compared with paper records are the potential threats to patient privacy and security breaches. The right to privacy, as such, is not enumerated in the U.S. Constitution or Bill of Rights. The possibility of such a right was publicized in 1890 in a widely influential article, "The Right to Privacy."[7] The authors, attorneys Samuel D. Warren and the future Supreme Court Justice Louis D. Brandeis, stated that the scope of the right to life had broadened to include the "right to be let alone." "The Right to Privacy" noted that "Instantaneous photographs and newspaper enterprise have invaded the sacred precincts of private and domestic life."[8] Further, the press was "overstepping in every direction the obvious bounds of propriety and decency."[9] The authors asserted that existing law afforded a principle that could be invoked to protect the privacy of an individual. Decades later, in 1928, in his dissenting opinion in *Olmstead v. U.S.*, Justice Brandeis stated the following:

> The makers of our Constitution undertook to secure conditions favorable to the pursuit of happiness .... They conferred, as against the Government, the right to be let alone—the most comprehensive of rights and the right most valued by civilized men. To protect that right, every unjustifiable intrusion by the Government upon the privacy of the individual, whatever the means employed, must be deemed a violation of the Fourth Amendment.[10]

In 1961, *Mapp v. Ohio* referred to the Fourth Amendment's right of privacy and stated the right to privacy was "no less important than any other right carefully and particularly reserved to the people."[11] Shortly thereafter, in 1965, the right to privacy was established explicitly in *Griswold v. Connecticut*.[12] In *Griswold*, Justice William O. Douglas referenced *Gitlow v. New York*, which had described "the fundamental personal rights and 'liberties' protected by the due process clause of the Fourteenth Amendment from impairment by the States."[13] Justice Douglas noted that the Court stated many years ago that the due process clause protects those liberties that are "so rooted in the traditions and conscience of our people as to be ranked as fundamental."[14] He then opined,

> the First Amendment has a penumbra where privacy is protected from governmental intrusion. ... specific guarantees in the Bill of Rights have penumbras, formed by emanations from those guarantees that help give them life and substance. ... the right of privacy which presses for recognition here is a legitimate one.[15]

Justice Douglas's *penumbras* could be construed as protections located within an outer region of shadow or a surrounding area[16] with reference to the constitutional amendments. *Emanations* could be understood as virtues or powers emitted or evolved[17] from the source represented by those constitutional amendments. Such methods of interpreting the Constitution have been disputed by succeeding jurists. For example, in his dissent in *Chicago v. Morales*, Justice Antonin Scalia declared that "The entire practice of using the Due Process Clause to add judicially favored rights ... is in my view judicial usurpation."[18] But the right to privacy, established in *Griswold*, has persisted.

The advent of EHRs represented a characteristically modern threat to the integrity of personal privacy and necessitated the creation of new protections in this domain. The Health Insurance Portability and Accountability Act (HIPAA) was enacted on August 21, 1996, (Public Law 104–191) with the intentions, among others, of improving portability and continuity of health insurance coverage in group and individual markets and improving access to long-term care

services and coverage.[19] HIPAA Subtitle F, "Administrative Simplification," was directed toward improving Medicare, Medicaid, and the efficiency and effectiveness of the healthcare system by "encouraging the development of a health information system through the establishment of standards and requirements for the electronic transmission of certain health information."[20] Section 262 included definitions for *healthcare provider, health plan, healthcare clearinghouse,* and *individually identifiable health information.*

Also through HIPAA, HHS was directed to adopt security standards for health information, including administrative, technical, and physical safeguards (1) to ensure integrity and confidentiality of the information and (2) to protect against threats or hazards to the security or integrity of the information and unauthorized uses or disclosures of the information.[21] Section 264 required HHS to prepare and submit to several congressional committees "detailed recommendations on standards with respect to the privacy of individually identifiable health information."[22] Those recommendations were to address the rights of individuals, procedures to be established to exercise those rights, and the uses and disclosures of such information. Overall, the Administrative Simplification provisions required HHS to publicize standards for the electronic exchange, privacy, and security of health information.

The final version of the HIPAA Security Rule was promulgated in the *Federal Register* on February 20, 2003, with an effective date of April 21, 2003.[23] The Security Rule is located at 45 CFR Part 160 and Subparts A and C of Part 164. The Security Rule "establishes national standards to protect individuals' electronic personal health information that is created, received, used, or maintained by a covered entity."[24] The standards and requirements specified in these regulations applied to health plans, healthcare clearinghouses, and healthcare providers who transmit any health information in electronic form (*covered entities,* 45 CFR 160.102[25]).

The *Security Rule* provided definitions for confidentiality and security in 45 CFR 164.304.[26] *Confidentiality* meant that "data or information is not made available or disclosed to unauthorized persons or processes." Security encompassed "all of the administrative, physical, and technical safeguards in an information system." Covered entities are required to fulfill numerous security standards, including the following general requirements:

1. Ensure the confidentiality, integrity, and availability of all electronic protected health information the covered entity creates, receives, maintains, or transmits.
2. Protect against any reasonably anticipated threats or hazards to the security or integrity of such information.
3. Protect against any reasonably anticipated uses or disclosures of such information that are not permitted or required.
4. Ensure compliance with these regulations by its workforce.[27]

The Security Rule requires covered entities to implement administrative safeguards, including policies and procedures to prevent, detect, contain, and correct security violations. These protocols must include the following:

1. Risk analysis, that is, accurate and thorough assessment of the potential risks and vulnerabilities to the confidentiality, integrity, and availability of electronic protected health information held by the covered entity.

2. Risk management, that is, implementation of security measures sufficient to reduce risks and vulnerabilities to a reasonable and appropriate level to comply with the general requirements of the HIPAA Security Rule.
3. A sanction policy that applies appropriate sanctions against workforce members who fail to comply with the security policies and procedures of the covered entity.
4. Information system activity review, that is, implementation of procedures to regularly review records of information system activity, such as audit logs, access reports, and security incident tracking reports.[28]

Additionally, in 45 CFR 164.310 and 164.312,[29] the Security Rule delineated physical safeguards and technical safeguards to limit access to electronic information systems. Physical safeguards include procedures regarding the following:

- Recovery of lost data
- Protection against unauthorized physical access, tampering, and theft
- Access control and validation procedures
- Maintenance of records
- Workstation use

Technical safeguards include procedures regarding the following:

- Unique user identification
- Emergency access procedures
- Automatic logoff
- Encryption and decryption
- Data integrity, that is, protection of electronic health information from improper alteration or destruction

The final version of the HIPAA Privacy Rule was promulgated in the *Federal Register* on December 28, 2000, with an effective date of February 26, 2001.[30] The final regulation and its modifications are contained in 45 CFR Part 160 and Subparts A and E of Part 164. As with the Security Rule, the Privacy Rule applies to covered entities, that is, health plans, healthcare clearinghouses, and healthcare providers, who transmit any health information in electronic form.[31] The Privacy Rule protects all *individually identifiable health information* held or transmitted by a covered entity.[32] *Health information* is any information created or received by a covered entity, public health authority, employer, school or university, or life insurer that relates to the following:

- The individual's past, present, or future physical or mental health or condition
- The provision of health care to the individual
- The past, present, or future payment for the provision of health care to the individual[33]

Individually identifiable health information is a subset of health information collected from an individual that includes many common identifiers such as name, address, birth date, and Social Security number, and "with respect to which there is a reasonable basis to believe the information can be used to identify the individual."[34] *Protected health information* (PHI) means

individually identifiable health information that is "transmitted by electronic media, maintained in ... electronic media, or transmitted or maintained in any other form."[35]

The *Privacy Rule* defines and limits the circumstances in which an individual's PHI may be used or disclosed by covered entities. A covered entity may not use or disclose PHI except as (1) permitted or required by the Privacy Rule or (2) as authorized in writing by the individual who is the subject of the protected health information.[36]

The Privacy Rule requires that each covered entity, with certain exceptions, must provide a notice of its privacy practices regarding protected health information.[37] Per the Privacy Rule, an individual has a right to adequate notice of the uses and disclosures of PHI that may be made by the covered entity, the individual's rights, and the covered entity's legal duties with respect to PHI. The notice must be written in plain language and must contain the following prominently displayed statement:

> **This notice describes how medical information about you may be used and disclosed and how you can get access to this information. Please review it carefully.**[38]

A covered healthcare provider that has a direct treatment relationship with an individual must provide the notice no later than the date of the first service delivery or, in emergency circumstances, as soon as reasonably practicable.[39]

The Privacy Rule requires covered entities to implement administrative, physical, and technical safeguards to protect the privacy of individually identifiable health information.[40] As described above, these safeguards were further enumerated in the Security Rule. As well, under the Privacy Rule, a covered entity is responsible for fulfilling all of an individual's rights, including the rights of access, amendment, and accounting. Regarding right of access, an individual has the right to inspect and obtain a copy of PHI about the individual in a designated record set. Exceptions include psychotherapy notes and information compiled in reasonable anticipation of a civil, criminal, or administrative action or proceeding.[41] The Privacy Rule notes that "An individual has the right to have a covered entity amend protected health information or a record about the individual in a designated record set for as long as the protected health information is maintained in that record set."[42] Additionally, an individual has the right to receive an accounting of disclosures of PHI made by a covered entity for six years prior to the date of the request. Various exceptions include disclosures (1) to carry out treatment, payment, and certain healthcare operations; (2) for national security or intelligence purposes; and (3) to correctional institutions or law enforcement officials.[43]

Importantly, when a patient has been assessed to lack capacity for medical decision making, the Privacy Rule permits a patient's medical team at a covered entity to discuss her care with a family member, other relative, or close personal friend if the medical team has determined that doing so would be in the best interests of the patient. Per the Privacy Rule at 45 CFR 164.510(b), a covered entity may "disclose to a family member, other relative, or a close personal friend of the individual ... the protected health information directly relevant to such person's involvement with the individual's care."[44]

Thus, HIPAA enumerated and enshrined privacy and security requirements that protected an individual's identifiable health information and defined specific rights of an individual related to protected health information. But not all of the new methodologies and practices that widespread use of EHR systems have introduced into physician–patient interactions are beneficial.

As well, the humans who use these systems necessarily have human failings, make errors, and frequently violate rules for privacy and security, intentionally or otherwise. Problematically, EHR systems may be compromised or manipulated for nefarious intent. As a result, healthcare institutions and healthcare providers must continually evaluate and improve their procedures and practices, and information system developers must continually upgrade EHR systems to facilitate ease-of-use and enhance the robustness of system security.[45]

For example, many EHR systems have an inefficient and poorly constructed user interface that does not match clinical workflow. Data entry is time-consuming. Many EHR systems produce an inordinate number of electronic messages and alerts. Too often, EHR systems require healthcare providers to perform tasks that could be more appropriately and efficiently done by support personnel such as clerks and transcriptionists. Further, user interface features "allow rapid inclusion of standard phrases and even boilerplate paragraphs."[46] Inclusion of such prepackaged materials, some or much of which may not be relevant to the case at hand, may introduce inaccurate or extraneous content into the patient record. Use of copy-and-paste functions facilitates the perpetuation of elements of the patient's history and prior evaluations that are out-of-date, create additional record bloat, and result in medication errors, inappropriate requests for diagnostic testing, mistakes in diagnosis, and unnecessary treatment that may harm the patient.

Problematically, use of an EHR system disrupts communication between physicians and patients and interferes with face-to-face patient care. Use of EHRs alters how clinicians think about the patient and the healthcare encounter.[47] Prior to the advent of EHRs, a clinician's interaction with a patient was directed toward creating a patient narrative, based on a detailed history, signs and symptoms, a problem-focused physical examination, and special testing. These elements, in association with the clinician's experience and diagnostic expertise, would be combined to create a prose description of the patient's clinical circumstances. This narrative report was the unifying component of the patient's medical record. But this mode of physician–patient interaction required direct communication with and observation of the patient. Focus on the EHR diverts the clinician's attention to the laptop or mobile device screen, with the potential for loss of significant information that could only be obtained via heightened attention to the patient.

Additional problems in EHR functionality derive from a lack of uniformity in software design. Records created on proprietary systems cannot be read on other systems. Thus, a primary function of EHRs, that is, real-time transferability of patient records and ease of access among multiple users, is only possible within a single institution (provided the institution's various departments are using the same EHR platform) or between institutions that utilize the same EHR software.[48]

On July 28, 2010, to address multiple issues of efficiency, portability, interoperability, and security of EHRs, HHS issued a final rule. The 2010 final rule established an initial set of required capabilities, standards, and implementation specifications that certified electronic health record technology (CEHRT) would need to provide to facilitate the achievement of meaningful use "under the Medicare and Medicaid EHR Incentive Programs."[49] Previously, the American Recovery and Reinvestment Act (ARRA) of 2009 (Public Law 111-5) had been enacted on February 17, 2009.[50] The Health Information Technology for Economic and Clinical Health (HITECH) Act[51] was a component of the ARRA and amended the Public Health Service Act. The HITECH Act established "Title XXX—Health Information Technology and Quality" to improve "health

care quality, safety, and efficiency" via the promotion of health information technology and the electronic exchange of health information. Title XXX of the HITECH Act included a definition of CEHRT.[52] CEHRT meant a qualified EHR such as those used in ambulatory and inpatient settings that met established standards. As well, Title IV of the HITECH ACT established Medicare Incentives and Medicaid Incentives for use of EHRs by eligible professionals and hospitals.[53] As of July 28, 2010, per 45 CFR 170, CEHRT systems would meet *content exchange standards, vocabulary standards* for representing electronic health information (EHI), and *security standards* including encryption and decryption of EHI; include general certification criteria such as drug-drug and drug-allergy interaction checks; maintain up-to-date problem lists; and incorporate and display laboratory and other test results in a structured format.[54]

On September 4, 2012, in a final rule, HHS adopted certification criteria that CEHRT would need to include to support the achievement of *meaningful use*.[55] Later, on March 30, 2015, stage 3 meaningful use criteria for eligible professionals, eligible hospitals, and critical access hospitals for 2018 and subsequent years were specified as 42 CFR Part 495, Section 495.7.[56]

Per the September 4, 2012, final rule, base EHRs were defined as records that, among additional criteria,

- Include patient demographic and clinical health information, such as medical history and problem lists
- Provide clinical decision support, including physician order entry; exchange of electronic health information and integration of such information from other sources; and protection of the confidentiality, integrity, and availability of health information stored and exchanged
- Meet certification criteria regarding specific clinical quality measures[57]

The 2014 edition of electronic health record certification criteria, reported in the *Federal Register* on September 4, 2012, and specified in 45 CFR 170.314,[58] included extensive clinical requirements and security protocols. As of 2017, the Centers for Medicare and Medicaid Services stated that "all providers must attest to objectives and measures using EHR technology certified to the 2014 edition." If available, providers may also attest using EHR technology certified to the 2015 edition, or a combination of the two.[59] The 2015 edition EHR certification criteria were reported in the *Federal Register* on October 16, 2015,[60] specified in 45 CFR 170.315,[61] and became effective on January 14, 2016. The 2015 edition supported the establishment of an interoperable nationwide health information infrastructure, with a focus on reducing health information developer and provider burden. The 2015 edition adopted "new and updated vocabulary and content standards for the structured recording and exchange of health information."[62] Additionally, the 2015 edition adopted measures to improve patient safety and increase the reliability and transparency of certified health information technology. The Office of the National Coordinator for Health Information Technology has developed an online interactive tool based on the 2015 edition certification criteria.[63]

Thus, EHR design and user interfaces continue to be upgraded, and federal regulations related to certification of EHR technology continue to be revised and enhanced. But privacy and security challenges are pervasive and increasing in complexity. Patient privacy is threatened by "inside attacks" in which legitimate users of an EHR hijack patient data for personal financial gain or other criminal enterprises. EHRs are subject to security breaches from outside the system, as

most of these record collections are web-based. Additionally, even appropriate use of EHRs could violate patient privacy, as a patient might not want certain portions of his medical record, such as mental health history, to be shared with other providers.[64] Solutions to the latter challenge to patient privacy include the software capability to sequester sections of the medical record and restrict access based on patient preferences.

As of 2017, security breaches to government, corporate, and healthcare institution databases and information systems were increasing in frequency and the consequences of such attacks were increasing in severity. A 2016 report noted that nearly 90 percent of the ninety-one healthcare organizations represented in the study had had a data breach within the past two years.[65] In a 2016 survey of U.S. hospitals, more than 50 percent of the sixty-one responses reported a "ransomware" attack in the last year.[66] (With ransomware, a hacked database is encrypted by the attacker and the "key" to unlock the data is provided upon payment of a ransom.) In 2017, England's National Health Service suffered a ransomware attack that caused some hospitals to stop accepting patients, doctor's offices to shut down, and critical surgeries to be canceled.[67] Other healthcare organizations attacked by ransomware in 2017 included the Heritage Valley Health System in Pennsylvania.[68]

The risk of these threats to public health may be reduced by implementing best-practice security measures including data encryption, antivirus software, software updates, and two-factor authentication.[69] Risk analyses, as mandated by HIPAA, should be performed routinely. Regular employee training and education programs are essential in updating and enhancing an organization's EHR privacy and security protocols. Robust EHR systems anticipate security breaches and maintain up-to-date protocols in an "arms race" to combat the ever-increasing complexity and power of cyberattacks.

Health Disparities/Health Inequities

In addition to biomedical research, healthcare policy and advocacy is an arena for ethical investigation and assessment. As discussed in Chapter 3, the National Institutes of Health defines health disparities as "gaps in the quality of health and health care that mirror differences in socioeconomic status, racial and ethnic background, and education level."[70] *Healthy People 2020* defines health disparities as

> a particular type of health difference that is closely linked with social, economic, and/or environmental disadvantage. Health disparities adversely affect groups of people who have systematically experienced greater obstacles to health based on their racial or ethnic group; religion; socioeconomic status; gender; age; mental health; cognitive, sensory, or physical disability; sexual orientation or gender identity; geographic location; or other characteristics historically linked to discrimination or exclusion.[71]

The term "health disparity" was coined in the United States around 1990[72] and represents differences among socioeconomic groups in the areas of availability, access, and quality of healthcare; health status; and health outcomes.[73] In efforts to improve health and reduce the incidence and prevalence of disease, the global scientific community has conducted extensive research and translated research into evidence-based guides for public health practice.[74] In the United

States, these guides include *The Guide to Community Preventive Services*[75] and the Institute of Medicine's *Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care*.[76] An international example is the World Health Organization's *Action Plan for the Global Strategy for the Prevention and Control of Noncommunicable Diseases*.[77]

But health disparities persist, in the United States and around the world, indicating the complex and multifactorial basis of their origins. For example, in the United States, from 2011 through 2014, the age-adjusted percentage of all men and women over age twenty with hypertension was 30.4. In contrast, the comparable rate for non-Hispanic black men was 42.4 percent and the comparable rate for non-Hispanic black women was 44.0 percent.[78] From 2011 through 2014, the percentage of all children and adolescents aged two to nineteen with obesity was 17.0 percent. The comparable rate for Hispanic or Latino children and adolescents in the same age group was 21.9 percent, with the comparable rate for non-Hispanic black or African American children and adolescents being 19.5 percent.[79] Obesity has been defined as a body mass index at or above the sex- and age-specific 95th percentile of the Centers for Disease Control growth charts.[80] Regarding infant mortality, the rate in the U.S. decreased from 7.04 infant deaths per 1,000 live births in 1999 to 5.96 in 2013. However, for non-Hispanic black mothers, the infant mortality rate was 11.11 in 2013. For American Indians or Alaska Natives, the infant mortality rate was 7.72 in 2013.[81] From 1980 through 2014, for both males and females, life expectancy at birth in the United States was longest for white persons and shortest for black persons. In 2014, life expectancy at birth was 76.5 years for non-Hispanic white males and 72.0 years for non-Hispanic black males. In 2014, life expectancy at birth was 81.1 years for non-Hispanic white females and 78.1 years for non-Hispanic black females.[82] Importantly, most Americans across all ethnic and racial groups continue to be unaware of the existence of health disparities in any context.[83]

In order to sharpen the focus and improve the outcomes of public policy initiatives directed toward redressing these issues, it is useful to identify the differences among the terms *disparity, inequality,* and *inequity.* Disparity is defined as (1) difference, dissimilarity, incongruity, or an instance of this and (2) inequality or an instance of inequality.[84] Inequality is defined as a lack of equality among persons or things; superiority or inferiority as related to some condition; and "inconsistency of people or distribution of things; unfairness; inequity."[85] Inequity is defined as "lack of equity of justice; unfairness."[86] Thus, recognition of a *health disparity* represents acknowledgment of the existence of a difference in outcomes, or even the existence of an inequality. In contrast, recognition of a health inequity represents acknowledgment of unfairness and, possibly, injustice. Health inequities are "differences in health which are not only unnecessary and avoidable but, in addition, are considered unfair and unjust."[87] Although disparity may be defined as inequality and inequality may be defined as inequity, the term *health inequity* directly emphasizes the condition of lack of equity or lack of justice, with the implicit requirement or need to rectify such injustice. Importantly, what is unequal is not necessarily unjust or inequitable. Public policy development and implementation, as well as civic and community participation and follow-through, may be more comprehensive, consistent, and effective when the policies are directed toward issues of health inequities rather than those of health disparities. For example, public policy in the United Kingdom declares that all health differences between worse-off and better-off socioeconomic groups represent health inequities.[88]

As noted, health inequities among racial, ethnic, and socioeconomic groups persist despite decades of research and numerous public policy initiatives. These injustices may begin to be

addressed by implementing a social determinants approach and emphasizing translation of research efficacy into community effectiveness.[89] Most often, public policy begins with a focus on improving access to and affordability of healthcare services, as with the Patient Protection and Affordable Care Act (ACA) of 2010.[90] However, regarding redress of health inequities, availability of healthcare is not sufficient, as its effects are likely to be constrained "relative to the impacts of social and physical environments."[91] These social determinants of health include early childhood environments; education; housing; economic and work environments;[92] unequal distribution of income, goods, and services; and opportunities of leading a flourishing life.[93]

Thus, improving the health and well-being of individuals, families, and communities depends not only on the provision of healthcare services, but also on enhanced understanding of the complexity of interactions represented by the social determinants of health and implementation of actions directed toward creating more equitable conditions and circumstances of life. Problematically, there is a lack of ability to clearly identify the specific social determinants of health that are associated with a particular inequality and to quantify the magnitude of those determinants.[94] Limitations to formulating effective public policies include the following:

- Lack of specific knowledge regarding how to avoid a disparity
- Which social determinants of health are susceptible to intervention
- How to implement changes based on what is known

One way forward focuses on extensive evidence of fundamental and pervasive links between education and income levels and access to resources and opportunities that shape and determine health.[95] Substantial progress toward redressing health inequities may likely be obtained via the determinants of income and education.

Development of robust public policies that will effectively reduce and eliminate health disparities and health inequities is ideally based on wide-ranging social sciences and medical research. An integrated approach includes health assessments, social and economic factors, the physical environment including housing and land use, community support networks, and access to health services. Health disparities may be assessed in the overlapping contexts of population, geography, disease, and risk factors.[96] Overall, research is required that not only uncovers potential connections but also facilitates solutions that can be implemented in actual communities, towns, and cities.

Historically, investigators have assumed that "effectiveness research naturally and logically follows from successful efficacy research."[97] However, in practice, community health research is targeted toward real-world outcomes. Efficacy studies involve standardized programs delivered uniformly to homogeneous, narrowly targeted research subjects. Efficacy trials assess whether a "program does more good than harm when delivered under optimum conditions."[98] In contrast, effectiveness studies test whether a "program does more good than harm when delivered under real-world conditions."[99] Thus, efficacy research and effectiveness research are disparate enterprises. The traditional model of translating research into practice, that is, "progressing from efficacy studies to effectiveness trials to dissemination projects,"[100] is flawed or incomplete when applied to public policy development.

One approach is the RE-AIM evaluation framework, which prioritizes public health issues.[101] The acronym RE-AIM stands for reach, efficacy or effectiveness, adoption, implementation, and maintenance:

- *Reach* refers to participation rate and the representativeness of study participants.
- *Adoption* refers to the representativeness of community settings or organizations that will conduct the program or intervention.
- *Maintenance* refers to the persistence of behavioral change at the individual level and "the extent to which a treatment or practice becomes institutionalized in an organization."[102]

The model balances emphasis on *internal validity* (efficacy studies) and *external validity* (effectiveness studies). The RE-AIM framework assists researchers in accounting for contextual factors or moderating factors, such as race/ethnicity, socioeconomic status, and type of setting, thus incorporating features of effectiveness studies into efficacy studies. By blending considerations of both internal validity and external validity, the RE-AIM model assists researchers and public policy planners to "select samples, interventions, settings, and agents" that will enhance the likelihood that findings of initial, more controlled studies will be reproduced in later, more widespread studies.[103]

Innovative research methods include *community-based participatory research* (CBPR),[104] which creates a partnership between university and institutional researchers and community members. CBPR is intended to foster development of interventions and protocols that will yield measurable benefit in terms of reducing health disparities and health inequities. Initial successes based on such strategic partnerships have been obtained in the United States and around the globe in countries such as England,[105] Uganda,[106] and Ecuador.[107] In England, the Department of Health 2008 report indicated achievement of almost all policy commitments established in 2003. The 2008 report declared a new target of reducing inequalities in health outcomes by 10 percent by 2010 with respect to infant mortality and life expectancy. The 2016 estimated infant mortality rate in the United Kingdom was 4.3 per 1,000 live births,[108] reduced from 5.0 in 2005.[109] The 2016 estimated life expectancy in the United Kingdom was 80.7 years,[110] improved from 77.1 years in 2005.[111] In Uganda, in the remote and impoverished district of Kitgum, a multisectoral framework of national, district, and subcounty institutions acted to reduce cases of acute childhood malnutrition and stunting in the one-year period from 2005 to 2006. In Ecuador, in the municipality of Cotacachi, the activities of an intersector health council resulted in the elimination of maternal and child mortality in 2004, 2005, and 2006. In 2005 Cotacachi declared itself free from illiteracy, the multisectoral agencies having taught more than 6,000 illiterate people to read in approximately two years.

Overall, use of the social determinants approach to reducing and eliminating health disparities will require government leadership, innovative research protocols whose goal is to translate efficacy into effectiveness, and broad-based community participation. Ongoing ethical commitment to achieving health equity and continuing partnerships among communities, researchers, and governments will assist in establishing improved local, national, and global health and greater achievement of human flourishing.

Health Disparities/Health Inequities and LGBT Populations

Lesbian, gay, bisexual, and transgender (LBGT) persons experience unique health disparities and health inequities. In 2011, the IOM published *The Health of Lesbian, Gay, Bisexual, and Transgender People: Building a Foundation for Better Understanding.* The IOM report focused on the health of sexual-minority populations and assessed current levels of scientific knowledge regarding the health status of LGBT populations.[112] The IOM report emphasized the need to collect more national data to "fully understand the health needs of U.S. LGBT populations."[113]

The report noted that LGBT persons have been subject to discrimination within the healthcare system[114] As well, LGBT individuals are disproportionately affected by stigmatization and victimization.[115] In 2012, HHS published the HHS LGBT Issues Coordinating Committee 2012 Report.[116] The HHS report noted that research suggests that LGBT individuals and families may face significant disparities in access to healthcare and health coverage. HHS objectives in 2012 included informing the National Institutes of Health and the broader research community "about important areas in which to advance biomedical research on LGBT health."[117]

However, despite these initiatives, healthcare practitioners, healthcare service providers, and medical researchers report a lack of knowledge regarding health disparities and health inequities that impact LBGT populations.[118] Healthy People 2020 identified numerous health disparities affecting LBGT persons,[119] including the following:

- A higher prevalence of HIV infection, mental health issues, and suicide among transgender people
- LGBT populations have high rates of tobacco, alcohol, and other drug use
- Lesbians are less likely to obtain preventive services for cancer
- Lesbians and bisexual females are more likely to be overweight or obese
- LGBT youth are more likely to be homeless
- LGBT youth are two to three times more likely to attempt suicide
- Elderly LGBT individuals encounter additional barriers to health owing to isolation and a lack of social services and culturally competent providers

Health inequities impacting LGBT persons include lack of health insurance, fear of discrimination from providers, insufficient availability of healthcare providers with appropriate training in the health needs of LGBT individuals,[120] and decreased access to quality preventive care.[121]

To begin to redress health disparities and health inequities experienced by LGBT individuals, the IOM report recommended that the National Institutes of Health implement "a research agenda designed to advance knowledge and understanding of LGBT health."[122] Priority research areas included demographic research, health inequities, and transgender-specific health needs.[123] The IOM recommended that data on sexual orientation and gender identity be collected in federally funded surveys administered by HHS. As well, data on sexual orientation and gender identity should be collected in EHRs.[124] In terms of healthcare practice, providers are encouraged to use gender neutral language when discussing a patient's personal relationships. Further, healthcare practitioners should provide statements regarding equal treatment for all patients and include partners (per the patient's instructions) in treatment planning.[125] Standardized intake forms should include additional identifiers for sexual orientation, gender identity, and alternative family units.[126] Additionally, professional education of physicians, nurses, and allied healthcare providers should include specific training regarding how to better serve LGBT patients and how to redress health disparities and health inequities that affect LGBT persons.[127]

Bias in Healthcare Delivery

Bias (or prejudice) may be defined as an unjustified negative attitude toward another based on that person's group membership.[128] Health disparities/health inequities among members of racial/ethnic minorities, those in lower socioeconomic groups, and LGBT persons may often be perpetuated by

bias in healthcare delivery.[129] As well, health disparities/health inequities exist in a "broader historical and contemporary context of social and economic inequality, prejudice, and systematic bias."[130]

Thus, healthcare providers, as all other persons, are likely influenced in their racial and ethnic attitudes by pervasive social trends.[131] Despite the explicit commitment to deliver care equally, some studies suggest that implicit stereotyping and bias on the part of healthcare providers can impact their judgment and behavior when they interact with stigmatized patients.[132] For example, evidence of implicit (unconscious) race bias among physicians was first formally documented in 2007.[133] Utilizing clinical vignettes of a "50-year-old male patient presenting to the emergency department with chest pain and an electrocardiogram suggestive of anterior myocardial infarction," physicians' implicit biases were strongly associated with treatment choices regarding thrombolysis (use of medication to dissolve clots formed in blood vessels). Specifically, as the degree of antiblack bias on a race preference *Implicit Association Test* (IAT)[134] increased, "recommendations for thrombolysis for black patients decreased."[135] As well, implicit bias against blacks (as measured by the race preference IAT) was "positively correlated with likelihood of recommending thrombolysis for white patients."[136] More recently, an assessment of the literature worldwide demonstrated that more than two-thirds of studies reviewed found evidence of racism among healthcare providers.[137] For example, eleven vignette-based studies found that "race influences the medical decision making of healthcare practitioners, whereas eight studies found no association."[138] Recommendations for redress included a "systematic approach to monitoring racism among healthcare providers" and concurrent implementation of evidence-based antiracism approaches that counter stereotypes, build empathy and perspective taking, develop personal responsibility, and "promote intergroup contact and intercultural understanding within healthcare settings."[139]

Importantly, members of racial/ethnic minorities report greater dissatisfaction with their healthcare providers, particularly when the providers are not of the same ethnicity/race, and perceive significantly more bias in healthcare delivery compared with whites.[140] Compared with whites, members of racial/ethnic minorities, including Hispanic Americans, African Americans, and Asian Americans, reported greater difficulty in communicating with their healthcare providers, were approximately fourteen times as likely to believe they would receive better healthcare if they were of a different race or ethnicity, and were more likely to feel treated with disrespect during a healthcare visit.[141]

As well, regarding LGBT persons, sexual minority status is "a marker of elevated risk for mental, physical, and sexual health problems."[142] The health of LGBT individuals may be compromised by chronic stress associated with minority status, legal barriers to health insurance, providers who receive minimal training in culturally competent care of LGBT persons, and experiences and expectations of discrimination within the healthcare system.[143] As an example of healthcare provider bias, research has demonstrated that "implicit preferences for heterosexual over lesbian and gay people are pervasive among a majority of health care providers."[144] Further, implicit stereotyping of LGBT older adults persists in the healthcare delivery system, and "these biases contribute to health disparities."[145] Such nonconscious stereotyping may manifest in acts of victimization and discrimination, as when "a transgender patient is denied care or when a hospital fails to allow a same-sex life partner to be at the patient's bedside in the intensive care unit."[146] Overall, for all individuals, such experiences of bias encountered in the delivery of healthcare services are likely to influence subsequent interactions with the healthcare community and may lead even to the avoidance of needed care.[147]

Recommendations for remedying bias include increasing the proportion of underrepresented U.S. racial and ethnic minorities among healthcare professionals and promoting consistency and equity of care through use of evidence-based guidelines.[148] Most professional educational interventions utilize a two-step approach that includes (1) making students aware of their implicit biases and (2) providing instruction in strategies "to either reduce the activation of implicit associations, or control how those associations influence judgment and behavior."[149] Strategies employed include bias awareness strategies, control strategies, and perspective-taking strategies. For example, control strategies are directed toward controlling automatic responses to members of minority groups and utilizing affirming egalitarian goals, seeking common-group identities, and relating to the patient as an individual via counterstereotyping.[150] As well, bias reduction should be promoted at the institutional level by utilizing positive intergroup contact across group boundaries, that is, across provider–patient and student-faculty boundaries.[151] The ultimate goal of training students and healthcare professionals to reduce implicit bias "is to reverse the disparities in care that many stigmatized patient groups receive."[152]

Universal Healthcare and a Right to Healthcare

Whether healthcare is a right or a commodity has remained an open question in the United States, the only industrialized nation that, as of 2017, did not have universal health insurance coverage.[153] A right to health, which is distinct from a right to healthcare, may be located in the World Health Organization (WHO) Constitution, signed on July 22, 1946, by representatives of sixty-one countries, including the United States.[154] The WHO Constitution declared the following:

> The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition ... . Governments have a responsibility for the health of their peoples which can be fulfilled only by the provision of adequate health and social measures.[155]

It may be reasonably stated that the WHO constitution does not propose a right to health as such. But (as discussed in Chapter 7) the WHO constitution's asserted obligation or duty of a government regarding the health of its peoples (a term more inclusive than "citizens") implies the existence of a corresponding right.[156] A right to health could be declared but would be aspirational rather than practical, as "health" is necessarily a complex phenomenon and based on a wide variety of independent variables. Further, an individual's health status is not fixed over time and an assertion of a "right" to all of those states becomes problematic. A right to health, as a *positive* right, would obligate the government (the *debtor*) to provide the circumstances, including the services, that would facilitate attainment of health. But as health is a quality and healthy states vary from person to person and within individuals over time, the duties inherent in a right to health would not be fixed or even specifiable on a continual basis. Thus, the "right" itself may not be a legitimate right as characterized by well-accepted rights frameworks.[157]

A *right to healthcare*, in contrast to a right to health, could be quantified and operationalized. A right to healthcare would necessitate equal access to appropriate services and would mandate the achievement of equity in health states.[158] Equal access to healthcare services would require

establishing a minimum standard for everyone. Thus, nations with universal healthcare systems operationalize a right to healthcare by making an identical "basket of services" available to all people. Provision of a minimum standard of services represents an entitlement without financial or other considerations. The minimum standard is comprehensive and includes preventive and public health services as well as medical care. The scope is society-wide, including both individuals and populations, that is, communities, cities, and states.[159]

Examples of universal healthcare systems include Britain's National Health Service (NHS) and Canada Medicare. The NHS launched on July 5, 1948, and was grounded in three core principles: meeting the needs of everyone, being free at the point of delivery, and being based on clinical need rather than ability to pay.[160] By fulfilling these core principles, the NHS was intended to address inequities in healthcare and inequities in health states across society.[161] As of 2016, the NHS in England was dealing with more than 1 million patients every thirty-six hours, covered everything, and employed more than 1.5 million people.[162] In a 2017 international comparison of healthcare systems, the Commonwealth Fund rated the United Kingdom's NHS first overall among eleven high-income countries, including the United States, Australia, Canada, Sweden, France, and Germany.[163]

The NHS ranked first in care process, which rates performance in the areas of prevention, safety, coordination of care, and patient engagement. As well, the NHS ranked first in equity, denoting relatively small differences among lower- and higher-income adults regarding access, affordability, and timeliness of care. Of note, the NHS ranked tenth in healthcare outcomes. For example, five-year breast cancer relative survival rate was 81 percent, compared with the top rate of 89 percent obtained in Norway, Sweden, and the United States. Five-year colon cancer relative survival rate was 56 percent in the U.K., compared with the top rate of 69 percent obtained in Australia.[164] But "over the past decade the U.K. saw a larger decline in mortality amenable to healthcare (i.e., a greater improvement in the measure) than the other countries studied."[165] The U.K. had made a major investment in the NHS, increasing healthcare spending from 6.7 percent of gross domestic product (GDP) to 9.9 percent of GDP in 2015,[166] as part of efforts to place primary care at the center of NHS modernization and support a comprehensive program of quality improvement.[167]

In Canada, Medicare refers to the nation's publicly funded healthcare system, which is based on thirteen provincial and territorial health insurance plans rather than a single national plan.[168] The legislative origins of Canadian Medicare are located in the Hospital Insurance and Diagnostic Services Act of 1957 (HIDSA),[169] which established universal hospital coverage by means of implementing national standards and cost-share transfers from the federal government to the provinces, and the Medical Care Act of 1966 (MCA),[170] which established universal medical care insurance, again implementing national standards and cost-share transfers. Per the 1966 legislation, a medical care insurance plan of a province was required to furnish insured services "upon uniform terms and conditions to all insurable residents of the province." The number of insurable residents of the province who were entitled under the plan to insured services was to be "not less than 90% of the total number of insurable residents of the province." This minimum was to be expanded to 95 percent on July 1, 1970. Further, the plan must not impose any minimum period of residence or any waiting period greater than three months "before persons who are or become residents of the province are eligible for or entitled to insured services."[171] Overall, the phrase "uniform terms and conditions" established the universality of healthcare insurance in Canada.

Subsequently, in 1977, the shared-cost format was replaced by block funding from the Canadian federal government to the provinces. This change resulted in a proliferation of direct patient charges, including user charges and extra-billing.[172] In response to these infringements on universal coverage, Health and Welfare Canada issued a document in 1983 stating the following:

> The Government of Canada believes that a civilized and wealthy nation, such as ours, should not make the sick bear the financial burden of health care. Everyone benefits from the security and peace of mind that come with having prepaid insurance .... The costs of care should be borne by society as a whole. That is why the Government of Canada wishes to reaffirm in a new Canada Health Act our commitment to the essential principle of universal health insurance.[173]

The Canada Health Act (CHA) was passed on April 1, 1984, combining and updating the HIDSA and MCA. The CHA incorporated restrictions specifically added to deter direct patient charges and "provide citizens of all provinces with access to health care regardless of ability to pay."[174] By doing so, the CHA established the requirement of accessibility in addition to the "four existing criteria of public administration, comprehensiveness, portability, and universality."[175]

Thus, Britain's NHS and Medicare in Canada are two examples of universal healthcare implemented via single-payer systems. In Britain, the single payer is the national government, which establishes the budget for NHS England. Funding for the NHS comes directly from taxation. In Canada, the single payers are the thirteen healthcare insurance plans administered by the provinces and territories. The federal government provides healthcare funding to the provinces and territories via the Canada Health Transfer.[176] Other universal healthcare systems, such as those implemented in Germany and the Netherlands, utilize multipayer formats. In Germany, health insurance is required for all citizens and permanent residents. Coverage is provided by competing not-for-profit, nongovernmental health insurance funds in the statutory health insurance system (SHI) or by private health insurance. Funding for the SHI derives from compulsory contributions. As of 2015, the uniform contribution rate was 14.6 percent of gross wages.[177] In the Netherlands, the national government partly finances the health insurance basic benefit package via general taxation and payroll levies, as well as the compulsory health insurance system for long-term care, for which municipalities and health insurers are primarily responsible. In addition to statutory coverage, 84 percent of the population (as of 2015) purchases supplementary insurance covering benefits such as dental care, physiotherapy, and the full cost of copayments for pharmaceuticals.[178] Overall, a variety of universal healthcare systems have been implemented among the Organisation for Economic Co-operation and Development member countries.[179]

Other nations not typically considered affluent, including Ghana and Rwanda, are moving toward the goal of universal healthcare coverage. Ghana had passed mandatory national health insurance legislation (Act 650) in 2003 and launched nationwide implementation in 2004.[180] As of 2012, the general government expenditure on healthcare was 5.2 percent of the nation's GDP and encompassed 57 percent of all healthcare expenses. Private expenditures on healthcare were 43 percent of the total.[181] The Ghana National Health Insurance Scheme (NHIS) system is a "pro-poor policy and offers a generous benefit package," but many poor people have difficulty paying registration fees and premiums. As a result, as of 2012, the NHIS still was utilized more by higher-income groups.[182]

In Rwanda, in 1999, the government introduced a pilot community-based health insurance (CBHI) program in several districts and extended the program to all thirty districts in 2005.[183]

In 2010, the government implemented a CBHI contribution policy[184] based on socioeconomic stratification, revising the prior regressive structure in which all households had paid equal premiums.[185] Rwanda's CBHI is structured on community ownership and management. Membership is voluntary and renewable annually. The expansion of CBHI, in association with malaria and HIV programs and community health and quality assurance programs, led to improvement in assisted delivery rates from 39 percent in 2000 to 52 percent in 2008 and a reduction in infant mortality rate from 139 per 1000 live births in 2005 to 62 in 2008.[186] (The 2016 estimate was 56.8.[187]) Under age five mortality rate declined from 152 per 1,000 population in 2005 to 103 in 2008.[188] (The rate in 2015 was approximately 42.[189]) As of 2017, Rwanda's near-universal healthcare system, financed by tax revenue, foreign aid, and voluntary premiums stratified by income, covered more than 90 percent of the population.[190]

Achieving universal healthcare in the United States will require broad public support. As of mid-2017, a Kaiser Health Tracking poll reported that 53 percent of Americans favored a single-payer system in which a single government plan would provide health insurance.[191] Additional public support would help to counter opposition from insurers, the medical care industry, and large segments of organized medicine.[192] Further, implementing a single-payer model, as in "Medicare for All," would require adopting large-scale tax increases.[193] As of 2017, adoption of a national single-payer healthcare system did not seem likely in the immediate future, and states were considering their own approaches. As against federal inaction, individual states such as New York and California were considering single-payer legislation. Examples of such legislation include A05062 ("New York Health Act"),[194] which passed the New York state assembly on June 1, 2016, and SB-562 ("The Healthy California Act"),[195] which passed the California senate on June 1, 2017. As of mid-2018, neither bill had made any further legislative progress.

However, worldwide, universal healthcare is recognized as a social good.[196] Importantly, as demonstrated by the social gradient of health,[197] short- and long-term improvement across a range of health indicators requires not only access, affordability, and delivery of healthcare services, but also public policies directed toward the social determinants of health. If the WHO constitution[198] could be utilized as a foundation for public policy, creating a moral context for action in the healthcare arena, then policies regarding healthcare would include "social measures" targeting inequities in income, housing, early childhood development, education, neighborhood construction and the built environment, and the work environment. Such a comprehensive approach would improve individual health, population health, and global economic health.[199]

Legislation Impacting Nonprofit Healthcare Institutions: The Sarbanes-Oxley Act of 2002

The American Competitiveness and Corporate Accountability Act of 2002 (Sarbanes-Oxley Act; Public Law 107-204),[200] was passed by Congress on July 30, 2002, in large part as a legislative response to the corporate and accounting scandals of Enron, Arthur Andersen, WorldCom, and others in 2001 and 2002.[201] The Sarbanes-Oxley Act (SOX) was designed to regulate corporate oversight of for-profit entities.[202] SOX requires the chief executive officer (CEO) and chief financial officer (CFO) to attest personally to the validity of financial statements. As well,

SOX requires independence of audit committee members and that the "extent and effectiveness of internal controls on financial reporting are provided to the public."[203] These requirements apply to for-profit, publicly traded organizations. SOX provisions requiring whistleblower protection and describing penalties for unlawful document destruction apply to nonprofit organizations as well as for-profit entities. Overall, SOX served as a "wake-up call to the entire nonprofit community."[204]

SOX provisions were intended to restrict the ability of senior corporate officers to "claim ignorance of accounting irregularities and internal control problems" in their organizations.[205] Regarding nonprofit healthcare institutions, claims have been raised concerning aggressive billing and collection practices that violate the institution's charity obligations, inadequate provision of charity care, and excessive executive compensation.[206] In consequence, nonprofit healthcare institutions would benefit from heightened scrutiny of board activities and corporate governance, as well as improved integrity and transparency of financial statements. Voluntary compliance with SOX provisions has been widely advocated for nonprofit healthcare institutions.[207] SOX compliance aids in streamlining communication and decision making regarding financial matters, developing an enterprise-wide risk management program, and investing in information technology upgrades to create more efficient business processes and practices.[208]

Regarding a for-profit organization's audit committee, SOX requires that each committee member be a member of the board of directors and be independent, that is, not a part of the management team and not receiving any compensation from the organization for service on the audit committee. Per SOX, an audit is "an examination of the financial statements of any issuer by an independent public accounting firm."[209] An organization's audit committee is established by and among the board of directors for the purpose of overseeing the accounting and financial reporting processes and overseeing the audits of the financial statements of the organization.[210] It is a best practice for nonprofit healthcare institutions to implement protocols to ensure the independence of the audit committee per SOX provisions.[211] The audit committee provides oversight to ensure that audit reports are "received, monitored, and disseminated appropriately."[212] The auditing firm should be prevented from providing nonauditing services such as bookkeeping, investment advice, and legal services. Such a provision precludes a conflict of interest between the auditing firm and the client healthcare institution.[213] Importantly, although not required by law, a nonprofit healthcare institution's CEO and CFO should certify the appropriateness of financial statements and sign off on these documents. This internal best practice establishes good faith, creates transparency, and increases public confidence in the activities of the organization.

SOX requires that for-profit organizations disclose whether the entity has adopted a code of ethics for senior financial officers.[214] If the organization has not adopted such a code, it is required to disclose the reasons for nonadoption. SOX defines a code of ethics as standards that are necessary to promote the following:

1. Honest and ethical conduct, including the ethical handling of actual or apparent conflicts of interest between personal and professional relationships.
2. Full, fair, accurate, timely, and understandable disclosure in the periodic reports required to be filed by the issuer.
3. Compliance with applicable governmental rules and regulations."[215] For both publicly traded companies and nonprofit healthcare organizations, a code of ethics helps ensure greater accountability for board members and managers.[216]

BOX 10.1

Case Study: Health Disparities/Health Inequities

In scenario A, Daisy, a fifteen-year-old girl, has sustained a left ankle injury during a Saturday morning high school soccer match. Her parents, who were attending the match, drive her to the local hospital, a large suburban complex associated with the state university system. Daisy is seen in the emergency department, and x-rays show a bony abnormality. Follow-up computed tomography (CT) demonstrates a fracture of the tibia with mild displacement. Closed reduction of the displaced fracture is performed using general anesthesia. Daisy does well following the procedure and is placed in a cast. Later, she begins a course of physical therapy and learns how to perform cross-training exercises. Ultimately, premature closure of her tibial growth plate has been prevented and she achieves full function. Daisy is able to return to soccer team activities four months after her injury.

In scenario B, Daisy has sustained a left ankle injury during a Saturday morning high school soccer match. Her coach phones Daisy's mother, a cafeteria worker at a skilled nursing facility. Thirty minutes later Daisy's mother arrives. Two of Daisy's friends help her into her mother's car, and mother and daughter drive off in search of an urgent care center. They wait more than two hours to be seen by a harried physician's assistant, and then wait another thirty minutes for x-rays to be taken. CT is not performed. A pediatric orthopedist is not available and closed reduction is not done. Daisy does receive a cast and crutches. She is given a prescription for physical therapy, but Daisy knows this will not happen as her mother works and is not available to drive Daisy to appointments. Daisy makes a slow, painful recovery. Three months later she concludes that her ankle function is not the same as prior to her injury. She arranges with a friend to be driven to urgent care, where follow-up x-rays show premature closure of the tibial growth plate. Daisy never returns to sports. Five years later she is told during an employment physical examination that her left leg is one-quarter of an inch shorter than her right leg.

Ethical Analysis

1. Compare and contrast the outcomes in scenario A and scenario B in the context of health disparities and health inequities.
2. Discuss the possible long-term impacts of Daisy's outcomes in scenario B on Daisy herself, her community, and society as a whole.
3. From the perspective of the biomedical ethical principle of justice, discuss whether scenario B Daisy has a right to obtain a similar level of healthcare services as those obtained by scenario A Daisy. Discuss the social determinants of health that need to be addressed to achieve greater healthcare equity in scenario B.

The SOX whistleblower provisions apply to both for-profit and nonprofit organizations. Section 1514A provides whistleblower protection for employees of publicly traded companies. No officer or employee of such a company may "discharge, demote, suspend, threaten, harass, or in

any other manner discriminate against an employee in the terms and conditions of employment because of any lawful act done by the employee ... to provide information, cause information to be provided, or otherwise assist in an investigation regarding any conduct ... relating to fraud against shareholders."[217] Regarding retaliation against informants, Section 1107 states that "Whoever knowingly, with the intent to retaliate, takes any action harmful to any person, including interference with the lawful employment or livelihood of any person, for providing to a law enforcement officer any truthful information relating to the commission or possible commission of any Federal offense, shall be fined under this title or imprisoned not more than 10 years, or both."[218] In the context of whistleblower protection, nonprofit healthcare institutions may protect themselves by eliminating "careless and irresponsible accounting practice," conducting internal audits that disclose weaknesses and install processes "that are not vulnerable to fraud and abuse," and institute written policies that misconduct is not tolerated with vigorous enforcement by executive staff and the board.[219] As well, nonprofit healthcare institutions must develop procedures for handling employee complaints, including establishing anonymous and confidential mechanisms that encourage employees to report any inappropriate practices within the organization's financial management.[220]

Regarding unlawful document destruction, SOX establishes criminal penalties for altering documents. Sections 1519 and 1520 describe fines and possible imprisonment for (1) destruction, alteration, or falsification of records in federal investigations and bankruptcy and (2) destruction of corporate audit records.[221] Therefore, document destruction in nonprofit healthcare institutions must be monitored, justifiable, and administered with care.[222] Financial records, contracts, other major transactions, and employment files should be archived based on guidelines established by the nonprofit entity.[223] Further, nonprofit healthcare institutions should have a "written, mandatory document retention and periodic destruction policy. Such a policy also helps limit accidental or innocent destruction."[224]

Overall, there is a relationship between good governance and organizational effectiveness.[225] Thus, compliance with SOX specifications contributes to the success of nonprofit healthcare institutions.[226] Voluntary adoption of SOX provisions by nonprofit healthcare institutions will strengthen governance, increase transparency and accountability, and enhance the credibility of the organization's financial reporting.[227]

KEY TERMS

External Validity
External validity refers to a researcher's ability to generalize the findings of an experiment, that is, the ability to apply the findings to other groups, environments, and circumstances. External validity refers to how well theories and data developed and obtained in one setting apply to different settings, specifically, other target populations or across populations. Attempts to control threats to internal validity may jeopardize external validity, in that by stringently controlling a variable the study results may no longer be generalizable.

Health Information
Health information is any information created or received by various sources that relates to an individual's "past, present, or future physical or mental health or condition; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual."[228]

HIPAA Privacy Rule
The HIPAA Privacy Rule protects all individually identifiable health information held or transmitted by a covered entity.[229]

HIPAA Security Rule
The HIPAA Security Rule established "national standards to protect individuals' electronic personal health information that is created, received, used, or maintained by a covered entity."[230] The Security Rule provided definitions for confidentiality and security.

Identifiable Private Information
Identifiable private information is "private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information."[231]

Implicit Association Test
The implicit association test (IAT) measures differential association of two target concepts with an attribute.[232] The IAT is sensitive to consciously disavowed evaluative differences such as "automatic expressions of race-related stereotypes and attitudes that are consciously disavowed by the subjects who display them."[233] The IAT is widely used to measure bias that may not be consciously recognized.[234] Since the introduction of the IAT, implicit measures generally have had a broad impact on behavioral research.[235]

Individually Identifiable Health Information
Individually identifiable health information is a subset of an individual's health information that includes many common identifiers such as the person's name, address, birth date, and Social Security Number, and "with respect to which there is a reasonable basis to believe the information can be used to identify the individual."[236]

Internal Validity
Internal validity assesses whether a research study was done properly. A study is internally valid based on the extent to which a researcher is able to state that no other variables other than the one being studied caused the result. A study's internal validity is associated with the procedures and operations used to conduct the study, including the study design, the composition of groups, and how the variables are measured. For example, "internal validity is compromised when one treatment group differs systematically from another group on an important variable."[237] The degree of internal validity assists in establishing a causal link between an intervention and the outcomes. As internal validity is based on control of extraneous variables, it is difficult to achieve outside of laboratory conditions.

Meaningful Use
Meaningful use criteria must be met by eligible professionals, eligible hospitals, and critical access hospitals to quality for Medicare and Medicaid EHR incentive payments. On March 30, 2015, eight objectives for meaningful use were proposed as part of the stage 3 final rule.[238] These objectives were designed to

- Align with national health care quality improvement efforts.
- Promote interoperability and health information exchange.
- Focus on the three-part aim of reducing cost, improving access, and improving quality.[239]

Meaningful use demonstrates "use of certified EHR technology in a meaningful manner."[240] Examples of meaningful use include (1) maintaining up-to-date problem lists of current and active diagnoses, recorded in structured data[241] and (2) recording demographics.[242]

Protected Health Information

Protected health information means individually identifiable health information that is "transmitted by electronic media, maintained in electronic media, or transmitted or maintained in any other form or medium."[243]

Right to Healthcare

A right to healthcare, if established, would require equal access to appropriate services and would mandate the achievement of equity in health states.[244] A right to healthcare may be considered to be implied by the existence of universal healthcare systems around the world.

DISCUSSION QUESTIONS

1A. Discuss two benefits of the use of EHRs, one related to the care of an individual patient and one related to population health. How does the use of EHRs facilitate obtaining these benefits?

1B. Describe a method by which a healthcare provider could both effectively interact with a patient and fulfill the requirements imposed by the healthcare institution's EHR system.

2A. Describe one advantage and one disadvantage of universal healthcare systems as implemented, for example, in the United Kingdom and Canada. Support your statements with references from the peer-reviewed literature.

2B. Discuss whether universal healthcare should be implemented in the United States. What are the obstacles to such implementation and how might they be overcome?

DO-IT-YOURSELF ETHICIST

1A. Design a ten-question survey instrument to identify the existence of a health inequity in your community or workplace.

1B. Presuming the existence of a specific health inequity, discuss three action steps to begin to redress this issue. How will you implement these protocols?

2. You are a senior-level manager accountable for your healthcare organization's community outreach programs. Create a twenty-slide presentation (to be delivered to community groups) detailing methods by which community health issues and concerns may be identified and how community partnerships may be established to develop solutions to these problems.

REAL-WORLD APPLICATIONS—THICS AS A DOCTRINE OF ACTION

1. You are the end-user ombudsperson at a health information technology company. Create a ten-point checklist for EHR system developers, incorporating specific concerns of physician end-users regarding ease-of-use, workflow, error-checking, patient management, portability, security, and other areas of need in a robust EHR system.

REFERENCES

[1]Institute of Medicine, *The Computer-Based Record: An Essential Technology for Health Care*, rev. ed. (Washington, DC: National Academy Press, 1997), https://www.nap.edu/catalog/5306/the-computer-based-patient-record-an-essential-technology-for-health.

[2]Ibid., xi.

[3]Institute of Medicine, *Key Capabilities of an Electronic Health Record System: Letter Report* (Washington, DC: National Academy Press, 2003), https://www.nap.edu/catalog/10781/key-capabilities-of-an-electronic-health-record-system-letter-report.

[4]Ibid., 7.

[5]D. J. Friedman, R. G. Parrish and D. A. Ross, "Electronic Health Records and US Public Health: Current Realities and Future Promise," *American Journal of Public Health* 103, no. 9 (2013): 1560–1567.

[6]Institute of Medicine, *Key Capabilities of an Electronic Health Record System*, 5–6.

[7]S. D. Warren and L. D. Brandeis, "The Right to Privacy," *Harvard Law Review* 4, no. 5 (1890): 193–220.

[8]Ibid., 195.

[9]Ibid., 196.

[10]*Olmstead v. U.S.*, 277 U.S. 438, 478 (1928).

[11]*Mapp v. Ohio*, 367 U.S. 643, 655, 656 (1961).

[12]*Griswold v. Connecticut*, 381 U.S. 479 (1965).

[13]*Gitlow v. New York*, 268 U.S. 652, 666 (1925).

[14]*Griswold v. Connecticut*, at 487.

[15]Ibid., at 483, 484, 485.

[16]L. Brown, ed., *The New Shorter Oxford English Dictionary on Historical Principles*, thumb index ed. (New York: Oxford University Press, 1993), 2152.

[17]Ibid., 802.

[18]*City of Chicago v. Morales*, 527 U.S. 41, 85 (1999).

[19]Health Insurance Portability and Accountability Act (Public Law 104-191), https://www.gpo.gov/fdsys/pkg/PLAW-104publ191/pdf/PLAW-104publ191.pdf.

[20]Ibid., Section 261.

[21]Ibid., 110 Stat. 2026.

[22]Ibid., 110 Stat. 2033.

[23]*Federal Register* 68, no. 34: 8334–8381, February 20, 2003, https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/administrative/securityrule/securityrulepdf.pdf.

[24]U. S. Department of Health and Human Services, *The Security Rule*, https://www.hhs.gov/hipaa/for-professionals/security/index.html.

[25]45 CFR 160.102, https://www.gpo.gov/fdsys/pkg/CFR-2007-title45-vol1/pdf/CFR-2007-title45-vol1-sec160-102.pdf.

[26]*Federal Register* 68, no. 34: 8376.

[27]45 CFR 164.306, https://www.gpo.gov/fdsys/pkg/CFR-2007-title45-vol1/pdf/CFR-2007-title45-vol1-sec164-306.pdf.

[28]45 CFR 164.308, https://www.gpo.gov/fdsys/pkg/CFR-2007-title45-vol1/pdf/CFR-2007-title45-vol1-sec164-308.pdf.

[29]*Federal Register* 68, no. 34: 8378–8379.

[30]*Federal Register* 65, no. 250: 82462–82829, December 28, 2000, https://www.gpo.gov/fdsys/pkg/FR-2000-12-28/pdf/00-32678.pdf.

[31]45 CFR 160.103.

[32]*Federal Register* 65, no. 250: 82488.

[33]45 CFR 160.103, https://www.gpo.gov/fdsys/pkg/CFR-2007-title45-vol1/pdf/CFR-2007-title45-vol1-sec160-103.pdf.

[34]*Federal Register* 65, no. 250: 82804.

[35]45 CFR 160.103.

[36]45 CFR 164.502, https://www.gpo.gov/fdsys/pkg/CFR-2007-title45-vol1/pdf/CFR-2007-title45-vol1-sec164-502.pdf.

[37]45 CFR 164.520, https://www.gpo.gov/fdsys/pkg/CFR-2007-title45-vol1/pdf/CFR-2007-title45-vol1-sec164-520.pdf.

[38]Ibid.

[39]Ibid.

[40]45 CFR 164.530(c), https://www.gpo.gov/fdsys/pkg/CFR-2007-title45-vol1/pdf/CFR-2007-title45-vol1-sec164-530.pdf.

[41]45 CFR 164.524, https://www.gpo.gov/fdsys/pkg/CFR-2007-title45-vol1/pdf/CFR-2007-title45-vol1-sec164-524.pdf.

[42]45 CFR 164.526, https://www.gpo.gov/fdsys/pkg/CFR-2007-title45-vol1/pdf/CFR-2007-title45-vol1-sec164-526.pdf.

[43]*Federal Register* 65, no. 250: 82826.

[44]45 CFR 164.510, https://www.gpo.gov/fdsys/pkg/CFR-2007-title45-vol1/pdf/CFR-2007-title45-vol1-sec164-510.pdf.

[45]M. W. Friedberg, P. G. Chen, K. R. Van Busum et al., *Factors Affecting Physician Professional Satisfaction and Their Implications for Patient Care, Health Systems, and Health Policy* (Santa Monica, CA, RAND Corporation, 2013), 33–47.

[46]J. J. Cimino, "Improving the Electronic Health Record: Getting What We Wished for," *JAMA* 309, no. 10 (2013): 991–992.

[47]D. A. Moros, "The Electronic Medical Record and the Loss of Narrative," *Cambridge Quarterly of Healthcare Ethics* 26, no. 2 (2017): 328–331.

[48]R. D. Kush, E. Helton, F. W. Rockhold et al., "Electronic Health Records, Medical Research, and the Tower of Babel," *New England Journal of Medicine* 358, no. 16 (2008): 1738–1740.

[49]*Federal Register* 75, no. 144: 44590–44654, July 28, 2010, https://www.gpo.gov/fdsys/pkg/FR-2010-07-28/pdf/2010-17210.pdf.

[50]American Recovery and Reinvestment Act of 2009, February 17, 2009, https://www.gpo.gov/fdsys/pkg/PLAW-111publ5/pdf/PLAW-111publ5.pdf.

[51]Ibid., Title XIII ("Health Information Technology"; "HITECH Act").

[52]Ibid., Title XXX ("Health Information Technology and Quality"), Sec. 3000.

[53]Ibid., Title IV ("Medicare and Medicaid Health Information Technology"), Sec. 4101–4201.

[54]45 CFR 170, https://www.gpo.gov/fdsys/pkg/CFR-2011-title45-vol1/pdf/CFR-2011-title45-vol1-part170.pdf.

[55]*Federal Register* 77, no. 171: 54163–54292, September 4, 2012, https://www.gpo.gov/fdsys/pkg/FR-2012-09-04/pdf/2012-20982.pdf.

[56]*Federal Register* 80, no. 60: 16732–16804, March 30, 2015, 16797, https://www.gpo.gov/fdsys/pkg/FR-2015-03-30/pdf/2015-06685.pdf.

[57]*Federal Register* 77, no. 171: 54283.

[58]Ibid., 54287–54291.

[59]Centers for Medicare and Medicaid Services, *Certified Electronic Health Record Technology*, https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Certification.html.

[60]*Federal Register* 80, no. 200: 62602-62759, October 16, 2015, https://www.gpo.gov/fdsys/pkg/FR-2015-10-16/pdf/2015-25597.pdf.

[61]Ibid., 62747.

[62]Ibid., 62602.

[63]Office of the National Coordinator for Health Information Technology, *Understanding Certified Health IT*, https://www.healthit.gov/sites/default/files/understanding-certified-health-it-2.pdf.

[64]A. Shenoy and J. M. Appel, "Safeguarding Confidentiality in Electronic Health Records," *Cambridge Quarterly of Healthcare Ethics* 26, no. 2 (2017): 337–341.

[65]Ponemon Institute, *Sixth Annual Benchmark Study on Privacy and Security of Healthcare Data*, May 2016, https://www.ponemon.org/blog/sixth-annual-benchmark-study-on-privacy-security-of-healthcare-data-1.

[66]Healthcare IT News, *More Than Half of Hospitals Hit with Ransomware in Last 12 Months*, April 7, 2016, http://www.healthcareitnews.com/news/more-half-hospitals-hit-ransomware-last-12-months.

[67]S. Erlanger, D. Bilefsky, and S. Chan, "U.K. Health Service Ignored Warnings for Months," *New York Times*, May 12, 2017, https://www.nytimes.com/2017/05/12/world/europe/nhs-cyberattack-warnings.html.

[68]N. Perlroth, M. Scott, and S. Frenkel, "Cyberattack Hits Ukraine Then Spreads Internationally," *New York Times*, June 27, 2017, https://www.nytimes.com/2017/06/27/technology/ransomware-hackers.html.

[69]W. J. Gordon, A. Fairhall, and A. Landman, "Threats to Information Security—Public Health Implications," *New England Journal of Medicine* 377, no. 8 (2017): 707–709.

[70]National Institute of Allergy and Infectious Diseases, *Minority Health*, https://www.niaid.nih.gov/research/minority-health.

[71]HealthyPeople.gov, *Healthy People 2020, Disparities*, https://www.healthypeople.gov/2020/about/foundation-health-measures/Disparities.

[72]P. Braveman, "What Are Health Disparities and Health Equity? We Need to Be Clear," *Public Health Reports* 129, suppl. 2 (2014): 5–8.

[73]O. Carter-Pokras and C. Baquet, "What Is a "Health Disparity" *Public Health Reports* 117, no. 5 (2002): 426–434.

[74]H. K. Koh, S. C. Oppenheimer, S. B. Massin-Short et al., "Translating Research Evidence into Practice to Reduce Health Disparities: A Social Determinants Approach," *American Journal of Public Health* 100, suppl. 1 (2010): S72–S80.

[75]Task Force on Community Preventive Services, *The Guide to Community Preventive Services: What Works to Promote Health?*, eds. S. Zaza. P. A. Briss, and K. W. Harris (New York: Oxford University Press, 2005).

[76]B. D. Smedley, A. Y. Stith, and A. R. Nelson, eds., *Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care* (Washington, DC: National Academies Press, 2003).

[77]World Health Organization (WHO), *2008–2013 Action Plan for the Global Strategy for the Prevention and Control of Noncommunicable Diseases* (Geneva: WHO, 2008), http://www.who.int/nmh/publications/9789241597418/en/.

[78]Centers for Disease Control and Prevention, National Center for Health Statistics: Health, United States, 2015, with Special Feature on Racial and Ethnic Health Disparities. DHHS Publication No. 2016-1232. Washington, D.C., Department of Health and Human Services, 2016, pp. 43 and 61 — https://www.cdc.gov/nchs/data/hus/hus15.pdf

[79]Ibid., 26, 43.

[80]Centers for Disease Control and Prevention, *Clinical Growth Charts*, https://www.cdc.gov/growthcharts/clinical_charts.htm.

[81]Centers for Disease Control and Prevention, *Health, United States, 2015*, 23, 39.

[82]Ibid., 22.

[83]Institute of Medicine, How *Far Have We Come in Reducing Health Disparities? Progress Since 2000. Workshop Summary*, ed. K. M. Anderson (Washington, DC: National Academies Press, 2012), https://www.nap.edu/catalog/13383/how-far-have-we-come-in-reducing-health-disparities-progress.

[84]Brown, *New Shorter Oxford English Dictionary on Historical Principles*, 697.

[85]Ibid., 1357.

[86]Ibid.

[87]M. Whitehead, "The Concepts and Principles of Equity and Health," *Health Promotion International* 6, no. 3 (1991): 217–228.

[88]PAHO/WHO, Division of Health and Human Development, *Principles and Basic Concepts of Equity and Health. 1999*, http://www1.paho.org/english/hdp/hdd/pahowho.pdf.

[89]Koh et al., "Translating Research Evidence into Practice," S74.

[90]Patient Protection and Affordable Care Act (Public Law 111-148, March 23, 2010), https://www.gpo.gov/fdsys/pkg/PLAW-111publ148/pdf/PLAW-111publ148.pdf.

[91]P. A. Braveman, C. Cubbin, S. Egerter et al., "Socioeconomic Disparities in Health in the United States: What the Patterns Tell Us," *American Journal of Public Health* 100, suppl. 1 (2010): S186–S196.

[92]Institute of Medicine, *A Framework for Educating Health Professionals to Address the Social Determinants of Health* (Washington, DC: National Academies Press, 2016), 59, https://www.nap.edu/catalog/21923/a-framework-for-educating-health-professionals-to-address-the-social-determinants-of-health.

[93]World Health Organization Commission on the Social Determinants of Health, *Closing the Gap in a Generation. Health Equity through Action on the Social Determinants of Health* (Geneva: WHO, 2008, 9, http://apps.who.int/iris/bitstream/10665/43943/1/9789241563703_eng.pdf.

[94]Koh et al., "Translating Research Evidence into Practice."

[95]Braveman et al., "Socioeconomic Disparities in Health," S193.

[96]Koh et al., "Translating Research Evidence into Practice," S73.

[97]R. E. Glasgow, E. Lichtenstein, and A. C. Marcus, "Why Don't We See More Translation of Health Promotion Research to Practice? Rethinking the Efficacy-to-Effectiveness Transition," *American Journal of Public Health* 93, no. 8 (2003): 1261–1267.

[98]B. R. Flay, "Efficacy and Effectiveness Trials (and Other Phases of Research) in the Development of Health Promotion Programs," *Preventive Medicine* 15, no. 5 (1986): 451–474,

[99]Ibid.

[100]Glasgow, Lichtenstein, and Marcus, "Why Don't We See More Translation of Health Promotion Research to Practice?" 1262.

[101]R. E. Glasgow, T. M. Vogt, and S. M. Boles, "Evaluating the Public Health Impact of Health Promotion Interventions: The RE-AIM Framework," *American Journal of Public Health* 89, no. 9 (1999): 1322–1327.

[102]Glasgow, Lichtenstein, and Marcus, "Why Don't We See More Translation of Health Promotion Research to Practice?" 1263.

[103]Ibid., 1264.

[104]B. A. Israel, A. J. Schulz, E. A. Parker et al., "Review of Community-Based Research: Assessing Partnership Approaches to Improve Public Health," *Annual Review of Public Health* 19, no. 1 (1998): 173–202; L. Cacari-Stone, N. Wallerstein, A. P. Garcia et al., "The Promise of Community-Based Participatory Research for Health Equity: A Conceptual Model for Bridging Evidence with Policy," *American Journal of Public Health* 104, no. 9 (2014): 1615–1623.

[105]Department of Health, *Health Inequalities: Progress and Next Steps* (London: Department of Health, 2008), http://webarchive.nationalarchives.gov.uk/20130123194028/http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_085307.

[106]R. Mutambi, R. Hasunira, and V. Oringa, *Intersectoral Action on Health in a Conflict Situation. A Case Study of Kitgum District, Northern Uganda* (Geneva: WHO, 2007), http://www.who.int/social_determinants/resources/isa_conflict_uga.pdf.

[107]L. M. Vega, *Innovative Intersector Practices for Health and Equity. The Case of Cotacachi Ecuador* (Geneva: WHO, 2007), http://www.who.int/social_determinants/resources/isa_cotacachi_ecu.pdf.

[108]Central Intelligence Agency, *The World Factbook, 2017*, https://www.cia.gov/library/publications/the-world-factbook/rankorder/2091rank.html.

[109]Office for National Health Statistics, *Childhood, Infant and Perinatal Mortality in England and Wales: 2012*, https://www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/deaths/bulletins/childhoodinfantandperinatalmortalityinenglandandwales/2014-01-30.

[110]Central Intelligence Agency, *The World Factbook, 2017*, https://www.cia.gov/library/publications/the-world-factbook/rankorder/2102rank.html.

[111]Office for National Health Statistics, "National Life Tables, UK: 2013–2015," https://www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/lifeexpectancies/bulletins/nationallifetablesunitedkingdom/20132015.

[112]Institute of Medicine, *The Health of Lesbian, Gay, Bisexual, and Transgender People: Building a Foundation for Better Understanding* (Washington, DC: National Academies Press, 2011), http://www.nationalacademies.org/hmd/Reports/2011/The-Health-of-Lesbian-Gay-Bisexual-and-Transgender-People.aspx.

[113]Ibid., 132.

[114]Ibid., 75.

[115]J. W. Buckey and C. N. Browning, "Factors Affecting the LGBT Population When Choosing a Surrogate Decision Maker," *Journal of Social Services Research* 39, no. 2 (2013): 233–252.

[116]U.S. Department of Health and Human Services, *HHS LGBT Issues Coordinating Committee 2012 Report*, https://www.hhs.gov/programs/topic-sites/lgbt/enhanced-resources/reports/health-objectives-2012/index.html.

[117]Ibid.

[118]Buckey and Browning, "Factors Affecting the LGBT Population," 246.

[119]Healthy People 2020, *Lesbian, Gay, Bisexual, and Transgender Health*, https://www.healthypeople.gov/2020/topics-objectives/topic/lesbian-gay-bisexual-and-transgender-health.

[120]Institute of Medicine, *The Health of LGBT People*, 297.

[121]L. Mollon, "The Forgotten Minorities: Health Disparities of the Lesbian, Gay, Bisexual, and Transgendered Communities," *Journal of Health Care for the Poor and Underserved* 23, no. 1 (2012): 1–6.

[122]Institute of Medicine, *The Health of LGBT People*, 6.

[123]Ibid.

[124]Ibid., 9.

[125]K. A. Bonvicini and M. J. Perlin, "The Same but Different: Clinician-Patient Communication with Gay and Lesbian Patients," *Patient Education and Counseling* 51, no. 2 (2001): 115–22.

[126]Mollon, "The Forgotten Minorities," 4–5.

[127]Ibid., 5.

[128]B. D. Smedley, A. Y. Stith, and A. R. Nelson, eds., *Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care* (Washington, DC: National Academies Press, 2003), 10.

[129]E. N. Chapman, A. Kaatz, and M. Carnes, "Physicians and Implicit Bias: How Doctors May Unwittingly Perpetuate Health Care Disparities," *Journal of General Internal Medicine* 28, no. 11 (2013): 1504–1510.

[130]R. L. Johnson, S. Saha, J. J. Arbelaez et al., "Racial and Ethnic Differences in Patient Perceptions of Bias and Cultural Competence in Health Care," *Journal of General Internal Medicine* 19 (2004): 101–110.

[131]Smedley, Stith, and Nelson, *Unequal Treatment*, 490.

[132]C. A. Zestcott, I. V. Blair, and J. Stone, "Examining the Presence, Consequences, and Reduction of Implicit Bias in Health Care: A Narrative Review," *Group Process and Intergroup Relations* 19, no. 4 (2016): 528–542, 529.

[133]A. R. Green, D. R. Carney, D. J. Pallin et al., "Implicit Bias among Physicians and Its Prediction of Thrombolysis Decisions for Black and White Patients," *Journal of General Internal Medicine* 22, no. 9 (2007): 1231–1238.

[134]A. G. Greenwald, D. E. McGhee, and J. L. K. Schwartz, "Measuring Individual Differences in Implicit Social Cognition: The Implicit Association Test," *Journal of Personality and Social Psychology* 74, no. 6 (1998): 1464–1480.

[135]Green et al., "Implicit Bias among Physicians," 1235.

[136]Ibid., 1237.

[137]Y. Paradies, M. Truong, and N. Priest, "A Systematic Review of the Extent and Measurement of healthcare provider racism," *Journal of General Internal Medicine* 29, no. 2 (2014): 364–387.

[138]Ibid., 383.

[139]Ibid.

[140]Zestcott, Blair, and Stone, "Examining the Presence, Consequences, and Reduction of Implicit Bias in Health Care," 529.

[141]K. S. Collins, D. L. Hughes, M. M. Doty et al., *Diverse Communities, Common Concerns: Assessing Health Care Quality for Minority Americans. Findings from the Commonwealth Fund 2001 Health Care Quality Survey* (Washington, DC: Commonwealth Fund, 2002), http://www.commonwealthfund.org/publications/fund-reports/2002/mar/diverse-communities—common-concerns—assessing-health-care-quality-for-minority-americans.

[142]J. A. Sabin, R. G. Riskind, and B. A. Nosek, "Health Care Providers' Implicit and Explicit Attitudes Toward Lesbian Women and Gay Men," *American Journal of Public Health* 105, no. 9 (2015): 1831–1841.

[143]Ibid., 1831.

[144]Ibid., 1840.

[145]M. B. Foglia and K. J. Fredriksen-Goldsen, "Health Disparities among LGBT Older Adults and the Role of Nonconscious Bias," *Hastings Center Report* 44, no. 5 (2014): S40–S44.

[146]Ibid., S42.

[147]Ibid., S43.

[148]Smedley, Stith, and Nelson, *Unequal Treatment*, 20.

[149]Zestcott, Blair, and Stone, "Examining the Presence, Consequences, and Reduction of Implicit Bias in Health Care," 535.

[150]Ibid.

[151]Ibid., 536.

[152]Ibid., 537.

[153]E. C. Schneider, D. O. Sarnak, D. Squires et al., *Mirror, Mirror 2017: International Comparison Reflects Flaws and Opportunities for Better U.S. Health Care* (Washington, DC: The Commonwealth Fund, 2017), http://www.commonwealthfund.org/interactives/2017/july/mirror-mirror/.

[154]World Health Organization (WHO), "Constitution of the World Health Organization," in *Summary Report on Proceedings, Minutes, and Final Acts of the International Health Conference Held in New York from 19 June to 2 July 1946* (New York: WHO, 1948), http://apps.who.int/iris/bitstream/10665/85573/1/Official_record2_eng.pdf.

[155]Ibid., 100.

[156]W. N. Hohfeld, *Fundamental Legal Conceptions as Applied in Judicial Reasoning, and Other Legal Essays* (New Haven, CT: Yale University Press, 1919), 38.

[157]Ibid., 65–72.

[158]M. Susser, "Health as a Human Right: An Epidemiologist's Perspective on the Public Health," *American Journal of Public Health* 83, no. 3 (1993): 418–426.

[159]Ibid., 420.

[160]National Health Service (NHS), Principles and values that guide the NHS, http://www.nhs.uk/NHSEngland/thenhs/about/Pages/nhscoreprinciples.aspx.

[161]Susser, "Health as a Human Right," 420.

[162]National Health Service (NHS), *About the National Health Service (NHS)*, http://www.nhs.uk/NHSEngland/thenhs/about/Pages/overview.aspx.

[163]Schneider et al., *Mirror, Mirror 2017*.

[164]Ibid., 24.

[165]Ibid., 9.

[166]Office of National Statistics, *UK Health Accounts: 2015*, https://www.ons.gov.uk/

peoplepopulationandcommunity/healthandsocialcare/healthcaresystem/bulletins/ukhealthaccounts/2015.

[167]T. Doran and M. Roland, "Lessons from Major Initiatives to Improve Primary Care in the United Kingdom," *Health Affairs* 29, no. 5 (2010): 1023–1029.

[168]Government of Canada, Canada's Health Care System, https://www.canada.ca/en/health-canada/services/canada-health-care-system.html.

[169]J. G. Turner. "The Hospital Insurance and Diagnostic Services Act: Its Impact on Hospital Administration," *Canadian Medical Association Journal* 78, no. 1 (1958): 768–770.

[170]Department of Medical Economics, The Canadian Medical Association, "The Medical Care Act: Bill C-227," *Canadian Medical Association Journal* 95, no. 21 (1966): 1107–1108.

[171]Ibid., 1108.

[172]O. Madore, *The Canada Health Act: Overview and Options*, CIR 94-4E. Library of Parliament, Canada, Parliamentary Information and Research Service, revised May 16, 2005, https://lop.parl.ca/content/lop/researchpublications/944-e.pdf.

[173]Ibid., 5.

[174]Ibid.

[175]G. P. Marchildon, "The Three Dimensions of Universal Medicare in Canada," *Canadian Public Administration* 57, no. 3 (2014): 362–382.

[176]Department of Finance, Canada, *Canada Health Transfer*, https://www.fin.gc.ca/fedprov/cht-eng.asp.

[177]E. Mossialos, M. Wenzl, R. Osborn et al., *2015 International Profiles of Health Care Systems* (Washington, DC: The Commonwealth Fund, 2016), 69, http://www.commonwealthfund.org/~/media/files/publications/fund-report/2016/jan/1857_mossialos_intl_profiles_2015_v7.pdf.

[178]Ibid., 115.

[179]Organisation for Economic Co-operation and Development, *Members and Partners*, http://www.oecd.org/about/membersandpartners/#d.en.194378.

[180]A. Fusheini, "The Politico-Economic Challenges of Ghana's National Health Insurance Scheme Implementation," *International Journal of Health Policy Management* 5, no. 9 (2016): 543–552.

[181]B. Garshong and J. Akazili, *Universal Health Coverage Assessment: Ghana*, Global Network for Health Equity, July 2015, http://gnhe.org/blog/wp-content/uploads/2015/05/GNHE-UHC-assessment_Ghana1.pdf.

[182]Ibid., 11.

[183]Ministry of Health, *Annual Report: Community Based Health Insurance* (Kigali: Government of Rwanda, 2012), 8, http://www.moh.gov.rw/fileadmin/templates/Docs/CBHI-Annual-Report-2011-2012f-3__1_.pdf.

[184]Ministry of Health, *Rwanda Community Based Health Insurance Policy* (Kigali: Government of Rwanda, 2010), https://images.indiegogo.com/medias/1274880/files/20140301080253-mutual_policy.pdf.

[185]Ministry of Health, *Annual Report*, 9.

[186]Ministry of Health, *Rwanda Community Based Health Insurance Policy*, 6.

[187]Central Intelligence Agency, *The World Factbook, 2016*, https://www.cia.gov/library/publications/the-world-factbook/rankorder/2091rank.html.

[188]Ministry of Health, *Rwanda Community Based Health Insurance Policy*, 6.

[189]The World Bank, *Mortality Rate, Under-5 (per 1,000 Live Births)*, https://data.worldbank.org/indicator/SH.DYN.MORT?locations=RW.

[190]E. Porter, "In Health Care, Republicans Could Learn from Rwanda," *New York Times*, July 7, 2017, https://www.nytimes.com/2017/07/18/business/economy/senate-obamacare-rwanda.html.

[191]Kaiser Family Foundation, *Polling: Data Note: Modestly Strong but Malleable Support for Single-Payer Health Care*, July 5, 2017, http://www.kff.org/health-reform/poll-finding/data-note-modestly-strong-but-malleable-support-for-single-payer-health-care/.

[192]J. Oberlander, "The Virtues and Vices of Single-Payer Health Care," *New England Journal of Medicine* 374, no. 15 (2016): 1401–1403.

[193]Ibid.

[194]New York State Assembly, A05062 Summary, http://assembly.state.ny.us/leg/?default_fld=&bn=A05062&term=2015&Summary=Y&Actions=Y&Votes=Y&Text=Y.

[195]California Legislative Information, SB-562. The Healthy California Act, https://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=201720180SB562.

[196]J. Rodin and D. de Ferranti, "Universal Health Coverage: The Third Global Health Transition?" *The Lancet* 380, no. 9845 (2012): 861–862.

[197]M. G. Marmot, R. Fuhrer, S. L. Ettner et al., "Contribution of Psychosocial Factors to Socioeconomic Differences in Health," *Milbank Quarterly* 76, no. 3 (1998): 403–448.

[198]WHO, "Constitution of the World Health Organization."

[199]J. Frenk and D. de Ferranti, "Universal Health Coverage: Good Health, Good Economics," *The Lancet* 380, no. 9845 (2012): 863–864.

[200]Public Law 107-204, July 30, 2002, https://www.gpo.gov/fdsys/pkg/PLAW-107publ204/pdf/PLAW-107publ204.pdf.

[201]A. Fass, "One Year Later, The Impact of Sarbanes-Oxley," *Forbes*, July 22, 2003, https://www.forbes.com/2003/07/22/cz_af_0722sarbanes.html.

[202]P. R. Loubeau and A. S. Griffith, "Some Empirical Evidence of Sarbanes-Oxley Implementation in the Hospital Sector," *Coastal Business Journal* 11, no. 1 (2012): 39–47.

[203]M. B. Royo and D. B. Nash, "Sarbanes-Oxley and Not-for-Profit Hospitals: Current Issues and Future Prospects," *American Journal of Medical Quality* 23, no. 1 (2008): 70–72.

[204]BoardSource, *The Sarbanes-Oxley Act and Implications for Nonprofit Organizations. GuideStar*, March 1, 2003, https://trust.guidestar.org/the-sarbanes-oxley-act-and-implications-for-non-profit-organizations.

[205]Loubeau and Griffith, "Some Empirical Evidence of Sarbanes-Oxley," 39.

[206]Ibid.

[207]E. Giniat and J. Saporito, "Sarbanes-Oxley Impetus for Enterprise Risk Management," *Healthcare Financial Management* 61, no. 8 (2007): 64–70.

[208]Ibid., 70, referencing Standard & Poor's December 7, 2005, report, "U.S. Not-for-Profit Health Care Sector Explores the Benefits of Sarbanes–Oxley Compliance."

[209]Public Law 107-204, 116 Stat. 747.

[210]Ibid.

[211]BoardSource, *The Sarbanes-Oxley Act*.

[212]Loubeau and Griffith, "Some Empirical Evidence of Sarbanes-Oxley," 43.

[213]Ibid.

[214]Public Law 107-204, Section 406, 116 Stat. 789.

[215]Ibid., 116 Stat. 789–790.

[216]Loubeau and Griffith, "Some Empirical Evidence of Sarbanes-Oxley," 44.

[217]Public Law 107-204, Section 1514A, 116 Stat. 802–803.

[218]Ibid., Section 1107, 116 Stat. 810.

[219]BoardSource, *The Sarbanes-Oxley Act*.

[220]Ibid.

[221]Public Law 107-204, Sections 1519 and 1520, 116 Stat. 800.

[222]BoardSource, *The Sarbanes-Oxley Act*.

[223]Ibid.

[224]Ibid.

[225]R. Cohen, "Sarbanes-Oxley: Ten Years Later," *Nonprofit Quarterly*, December 30, 2012, https://nonprofitquarterly.org/2012/12/30/sarbanes-oxley-ten-years-later/.

[226]Loubeau and Griffith, "Some Empirical Evidence of Sarbanes-Oxley," 41.

[227]Ibid., 45.

[228]45 CFR 160.103.

[229]*Federal Register* 65, no. 250: 82488.

[230]U. S. Department of Health and Human Services, *The Security Rule*.

[231]*Federal Register* 82, no. 12: 7149–7274, January 19, 2017, https://www.gpo.gov/fdsys/pkg/FR-2017-01-19/pdf/2017-01058.pdf, 7260.

[232]Greenwald, McGhee, and Schwartz, "Measuring Individual Differences in Implicit Social Cognition," 1464.

[233]Ibid., 1473.

[234]Green et al., "Implicit Bias among Physicians," 1231.

[235]B. A. Nosek, Y. Bar-Anan, N. Sriram, et al., "Understanding and Using the Brief Implicit Association Test: Recommended Scoring Procedures," *PLoS One*, December 8, 2014, doi:10.1371/journal.pone.0110938.

[236]*Federal Register* 65, no. 250: 82804.

[237]J. P. Leighton, "Internal Validity," in *Encyclopedia of Research Design*, ed. N. J. Salkind (Oaks, CA, Sage Publications, 2010).

[238]*Federal Register* 80, no. 60: 16734.

[239]Ibid.

[240]*Federal Register* 75, no. 144: 44591.

[241]Ibid., 44603.

[242]Ibid., 44627.

[243]45 CFR 160.103.

[244]Susser, "Health as a Human Right," 420.

Figure Credit

Fig. 10.1: Copyright © 2015 Depositphotos/Pandpstock001.

CHAPTER 11

Global Challenges and the Future of Healthcare

Case Study: Ebola Virus Disease Epidemic

On September 25, 2014, a forty-two-year-old Liberian citizen sought medical care at Texas Health Presbyterian Hospital in Dallas, Texas.[1] Although Thomas Eric Duncan reported his travel from Liberia and demonstrated Ebola-like symptoms, he was prescribed antibiotics and sent home.[2] His condition deteriorated and three days later he returned to the hospital, where he was admitted and placed in isolation. Mr. Duncan subsequently tested positive for Ebola virus disease (EVD), ten days after his arrival in the United States on September 20.[3] He died on October 8.[4] It had been determined that Mr. Duncan contracted EVD on September 15, when he shared a taxi with a pregnant neighbor who was convulsing and then helped carry her as she was unable to walk. The neighbor died hours later of Ebola infection.[5] On October 12, in Dallas, a nurse who had treated him tested positive for EVD. On October 14, another nurse on the treatment team was confirmed to have EVD.[6] Following treatment, both nurses were declared free of Ebola virus.[7]

On October 23, 2014, in New York City, a doctor who had recently returned from treating Ebola patients in Guinea, in West Africa, was taken to Bellevue Hospital Center and placed in isolation. Craig Spencer tested positive for Ebola virus and then his fiancée and two friends with whom he had recent contact were also quarantined. Dr. Spencer had developed a fever on the morning of October 23, but

FIGURE 11.1 All children require accessible and affordable healthcare

on the day before he had traveled by subway, visited a bowling alley, and returned home by taxi. At a news conference on the night of October 23, city officials stated that as it was likely that Dr. Spencer had not been symptomatic when he traveled around the city, he had not posed a health risk to the public. Dr. Spencer had been working with Doctors Without Borders in Guinea. He completed his work on October 12 and arrived in New York City on October 17. Since returning, he had been taking his temperature twice a day to monitor his health and detect the onset of fever.[8] Dr. Spencer was released from Bellevue Hospital Center on November 11, after nineteen days of treatment. By then, no other person with whom he had contact had become ill.[9]

It is useful to compare and contrast the management and outcomes of the Ebola virus disease cases in Dallas and New York City. In Dallas, according to medical records, Mr. Duncan had had a high fever (103°) when he presented to the emergency department at Texas Health Presbyterian Hospital on September 25, 2014. Although Mr. Duncan had reported severe pain and stated he had recently arrived from Africa, he was sent home by emergency department staff rather than being admitted.[10] Mr. Duncan's delayed diagnosis led to several public health lapses. He was transported by emergency medical services (EMS) personnel who were not wearing appropriate protective equipment. The transporting ambulance continued to be used for forty-eight hours prior to being decontaminated. The four people with whom Mr. Duncan had shared an apartment were required to remain there by the Dallas County health department, "even though the apartment had not been decontaminated," exposing these individuals to unnecessary risk.[11] Subsequently, the residents were moved to another location. Health officials traced known contacts and identified forty-eight individuals, including five schoolchildren, but it was only after a nurse tested positive for EVD, on October 12, that surveillance was extended to the approximately 50 healthcare workers who had participated in Mr. Duncan's treatment.[12] In consequence, a second nurse tested positive on October 14. Mr. Duncan himself died on October 8, possibly as the outcome of the several days' delay in receiving appropriate treatment.

In contrast, in New York City, when Dr. Spencer found he had developed a fever he alerted the staff of Doctors Without Borders. The Doctors Without Borders staff called the city's health department, which then called the Fire Department. EMS personnel, in full protective gear, rushed to Dr. Spencer's apartment and transported him to Bellevue Hospital Center.[13] Subsequent to Dr. Spencer's phone call, the entire process took approximately 2 hours. Dr. Spencer was placed in a special isolation unit and attended by a designated critical care team. Team members wore "personal protective equipment with undergarment air ventilation systems."[14] In the New York City region, hospitals and emergency workers had been preparing for the appearance of EVD for months. The city's health department had been mobilized and several additional supporting agencies had been fully engaged. Approximately 100 healthcare workers had been involved in Dr. Spencer's treatment, but no one with whom he had come in contact had become ill.[15] Overall, preparation and planning are critical in the response to a local diagnosis of an emerging infectious disease such as EVD. Best practices include the following:

- Accurately identifying patients with Ebola at presentation to minimize potential exposures
- Rapidly identifying contacts of Ebola patients and evaluating their level of exposure risk
- Monitoring potentially large numbers of community and healthcare contacts
- Updating infection control practices and conducting large-scale training sessions

- Developing protocols to safely transport suspected Ebola patients to hospitals and safely evaluate these patients within a hospital
- Designating facilities to care for patients with confirmed Ebola[16]

These four cases of EVD in the United States, including the first cases of Ebola virus transmission within the United States, derived from the "deadliest Ebola outbreak in history," which likely began in December 2013 in the village of Meliandou in Guinea, in West Africa.[17] But Ebola was virtually unknown in the region and the cluster of deaths was attributed to a variant of cholera. Within twelve weeks there were almost fifty suspected cases and twenty-nine deaths. On March 21, 2014, initial testing on blood samples obtained from patients in Guinea demonstrated a filovirus, which can cause hemorrhagic fevers such as Ebola and Marburg virus disease. In March 2014, a few people had died or been sick with Ebola-like symptoms in Sierra Leone as well. More than two months later, in late May, Sierra Leone recorded its first confirmed cases of EVD. By December 2014, there had been almost 2,500 suspected, probable, and confirmed cases of Ebola virus disease in Guinea.[18] Sierra Leone had documented approximately 9,400 reported Ebola infections and there had been almost 8,000 reported cases in Liberia's second-wave outbreak. Overall, in West Africa, by December 2014, one year after the likely origination of the outbreak in Guinea, there were more than 20,000 suspected, probable, and confirmed Ebola cases and 7,800 deaths.[19] As of April 2016, there had been more than 28,000 cases of EVD and more than 11,300 people had died in West Africa from Ebola infection.[20]

Of note, on March 23, 2014, a World Health Organization (WHO) spokesperson had posted to Twitter that "There has never been an #Ebola outbreak larger than a couple of hundred cases." Two days later, the WHO spokesperson posted that "Ebola has always remained a very localised event."[21] In contrast, a March 31 news release from Doctors Without Borders stated that "We are facing an epidemic of a magnitude never before seen in terms of the distribution of cases in the country."[22] In the event, the early WHO assessment was wrong. More than two years later, researchers reported that a genetic mutation may have enhanced the ability of the Ebola virus to invade human cells. The mutation, known as GP-A82V, was first observed in viral samples collected from a patient in Guinea on March 31, 2014.[23] Ebola viruses carrying the GP-A82V mutation then spread quickly across Guinea, Sierra Leone, and Liberia. The mutated version was more deadly and infected patients were "significantly more likely to die."[24] Thus, the perspective of those treating the disease at the local level proved to be more accurate than the perspective based on transmission data of the earlier, nonmutated virus. Overall, what came to be described as the 2013–2016 EVD epidemic in West Africa was "a costly lesson in addressing an infectious disease outbreak in the absence of preparedness of both the exposed population and the international community."[25]

Emerging Infectious Diseases

Ebola virus disease is the prototypical emerging infectious disease. Infectious diseases such as EVD, cholera, Rift Valley fever, and schistosomiasis are endemic worldwide and many of these disorders maintain a broad reservoir of agents with the potential for rapid dissemination.[26] In 2015, lower respiratory diseases remained the third most frequent cause of death around the world. Diarrheal diseases were the eighth and tuberculosis was the ninth most frequent cause

of death globally.[27] However, in 2015, in low-income countries, lower respiratory diseases were the number one cause of death and diarrheal diseases were the second most frequent cause of death. In 2015, in low-income countries, HIV/AIDS was the fifth, tuberculosis the sixth, and malaria the seventh most frequent cause of death.[28] Despite more than a century of progress in combatting these disorders, infectious diseases continue to cause extensive human suffering, interfere with and inhibit social and economic development, and contribute to global instability.[29]

Emerging infectious diseases may be categorized as *newly emerging* and *reemerging* disorders. Newly emerging infectious diseases are those recognized in the human host for the first time and are newly appearing in the population. Reemerging infectious diseases have historically infected humans, but are rapidly increasing in incidence or geographic range.[30] Reemerging infectious diseases may appear in new locations, reappear after apparent control or elimination, or appear in drug-resistant forms.[31] Infectious diseases emerge via a two-step process: (1) introduction of the infectious agent into a new host population and (2) establishment and dissemination within the new host population.[32] Many emerging infectious diseases are *zoonoses*, that is, they emerged from animal populations to infect and spread among humans.[33] Zoonoses include some of the most challenging illnesses healthcare systems are confronting at present, such as human immunodeficiency virus (HIV), Ebola virus, H5N1 and H1N1 influenza viruses, and the SARS coronavirus.[34] Emerging infectious diseases transmitted by vectors such as mosquitos include malaria, West Nile virus infection, dengue fever, and Japanese encephalitis.

Human factors contributing to emergence of infectious diseases include migration, urbanization, increased air travel, increased vehicular traffic across regions, and dam building. For example, population movement from rural areas to cities may spread a previously localized infection.[35] Cities that serve as transportation hubs provide numerous additional routes for widespread dissemination of an emerging infectious disease. The spread of HIV, cholera, and dengue infections has been facilitated by these urban gateways.[36] Infections transmitted by mosquitos and other arthropods such as snails are often accelerated by expansion of standing water. Examples include Japanese encephalitis, a mosquito-borne disease whose incidence is closely associated with rice production and flooding irrigation. Outbreaks of Rift Valley fever, a mosquito-borne viral disease, in sub-Saharan Africa have been associated with dam-building projects that cause flooding. The altered ecological conditions and interactions between animals and humans facilitate transmission of Rift Valley fever.[37] The spread of schistosomiasis, caused by a parasitic worm whose intermediate hosts are certain freshwater snails, is similarly facilitated by flooding and overflow of freshwater in great lakes and rivers.[38] As well, the emergence of antibiotic-resistant bacteria such as MRSA (methicillin-resistant *Staphylococcus aureus*) is associated with "overuse of antibiotics in animals and inappropriate use in humans."[39] Overall, the circumstances of modern life "ensure that the factors responsible for disease emergence are more prevalent than ever before."[40] Yet, when planning and undertaking projects that are not specifically medical, the impacts of those projects on the environment and on population health are often not considered until after the fact.

Infectious pathogens demonstrate extraordinary adaptability in their capacity to replicate and undergo mutational change. These capabilities consistently provide temporary evolutionary advantages as against environmental factors, the human immune response, and antimicrobial drugs. Thus, as "infectious pathogens are evolutionarily dynamic," they possess the potential for "unpredictable and explosive global impact."[41] Animals, the environment, and insect vectors provide reservoirs for infectious pathogens and enable these microbes to become pervasive with the potential for future outbreaks.[42]

Therefore, countering the ever-changing threat of emerging infectious diseases necessarily entails effective public health measures. In the best case, countermeasures observe what has been termed the fundamental maxim of public health: "The health of the individual is best ensured by maintaining or improving the health of the entire community."[43] Essential public health services include the following:

- Assessment—monitoring health status, and investigating and diagnosing health hazards in the community
- Policy development—informing and educating people regarding health issues, and developing policies and plans that support individual and community health efforts
- Assurance of quality health services—enforcing laws and regulations, and evaluating accessibility, quality, and effectiveness of personal and population-based health services[44]

Strong public health fundamentals include ongoing surveillance of infectious diseases, laboratory detection, and epidemiologic investigation, including descriptive and analytical studies of the distribution and determinants of specific infectious diseases.[45] In order for surveillance to be effective, it must be specific, that is, associated with known agents of disease transmission and precise laboratory testing. Prevention and control programs are supported by applied research and public health infrastructure.[46] For example, as the accuracy of sequencing viral genomes improves and sequencing instruments become more portable, "real-time viral surveillance and molecular epidemiology will be routinely deployed on the front lines of infectious disease outbreaks."[47] As an example of a collaborative, transdisciplinary approach, the One Health global initiative links human health, animal health, and environmental health experts in efforts to develop and implement new approaches to prevention and control of zoonotic and vector-borne diseases.[48] One Health aims to foster collaborative relationships, improve communication between sectors, and coordinate disease surveillance activities. As well, One Health aims to develop uniform communications to the public regarding the interconnections between people, plants, animals, and our shared environment, and prevention and control of emerging infectious diseases. Overall, given their endemic characteristics, eradication of any of these disorders is unlikely. Preparation, readiness, international cooperation, and rapid response are the keys to effectively combatting the ongoing threat of emerging infectious diseases.

International Readiness and Response

The 2013–2016 Ebola epidemic in West Africa raised significant concerns in the international public health community and in federal legislatures regarding emergency preparedness. Enhanced risk factors include extensive international travel and commerce, which places health and healthcare in a global context. The WHO International Health Regulations (2005) were designed to prevent the international spread of disease. The WHO International Health Regulations require states to develop, strengthen, and maintain "the capacity to respond promptly and effectively to public health risks and public health emergencies of international concern."[49] In the United States, the Pandemic and All-Hazards Preparedness Act of 2006 had been reauthorized in 2013 as Public Law No. 113-5.[50] The purpose of the law was to advance national health security by authorizing funding for public health and medical preparedness programs

and supporting research and development of potential medical countermeasures.[51] For example, the Hospital Preparedness Program established goals of medical readiness, medical response coordination, continuity of healthcare service delivery, and the capability of transitioning to contingency and crisis medical surge response.[52] However, it may be reasonably stated that preparedness efforts in themselves are insufficient. Preparedness "depends on the core strength of health systems."[53] As was originally demonstrated in 2003 by the global outbreak of severe acute respiratory syndrome (SARS), which spread over the course of several months from Asia to more than two dozen countries in North America, South America, and Europe and infected more than 8,000 people worldwide,[54] international borders do not provide barriers to infectious diseases. Internationally, improvements are required in the capabilities and capacities of domestic healthcare systems.

But to enhance the welfare and well-being of communities, cities, nations, and global populations, it is necessary to expand the focus on healthcare systems to include the social determinants of health. The United Nations Millennium Development Goals (MDG) included efforts to eradicate extreme poverty and hunger, achieve universal primary education, reduce child mortality, improve maternal health, combat infectious diseases, ensure environmental sustainability, and promote gender equality and empower women. The MDG final report was published in 2015.[55] Results of fifteen years of worldwide efforts included the following:

- Reducing extreme poverty. In 1990, nearly half of the population in the developing world lived on less than US$1.25 per day. By 2015, that proportion had decreased to 14 percent.
- Reducing hunger. The proportion of undernourished people in developing countries declined from 23 percent in 1990–1992 to 13 percent in 2014–2016.
- Expanding literacy. The literacy rate among young people aged fifteen to twenty-four increased worldwide from 83 to 91 percent between 1990 and 2015.
- Reducing child mortality. The global mortality rate for children under age five declined more than 50 percent, decreasing from 90 to 43 deaths per 1,000 live births between 1990 and 2015.
- Improving maternal health. Since 1990, the maternal mortality ratio (deaths per 100,000 live births) decreased from 380 to 210, representing a 45 percent reduction. Worldwide, in 2014, more than 71 percent of births were assisted by skilled health personnel, representing a 59 percent improvement compared to rates in 1990.
- Combatting infectious diseases. New HIV infections declined by approximately 40 percent between 2000 and 2013, from an estimated 3.5 million to 2.1 million cases. Between 2004 and 2014, more than 900 million insecticide-treated mosquito nets were delivered to malaria-endemic countries in sub-Saharan Africa. By 2015, the global malaria incidence rate had declined by an estimated 37 percent and the global malaria mortality rate had dropped by 58 percent.
- Improving access to clean water and sanitation. By 2015, 91 percent of the global population was using an improved drinking water source, compared with 76 percent in 1990. Worldwide, 2.1 billion people had gained access to improved sanitation.[56]

Despite significant achievements toward accomplishing the MDG, progress has been uneven across countries and regions and hundreds of millions of people are being left behind. For

example, as of 2015, approximately 800 million people continue to live in extreme poverty and suffer from hunger. More than 160 million children under age five were of inadequate height owing to lack of sufficient food. In developing countries, the maternal mortality rate was fourteen times higher than in developed regions. In 2015, more than 2.4 billion people were still using unimproved sanitation facilities. More than 880 million people were living in slum-like conditions in cities in the developing world.[57]

To continue worldwide efforts toward ending poverty, improving living conditions, and improving global health, on September 25, 2015, the United Nations General Assembly adopted the 2030 Agenda for Sustainable Development,[58] which included the seventeen Sustainable Development Goals (SDGs).[59] The SDGs include the following:

- No poverty
- Zero hunger
- Quality education
- Gender equality
- Clean water and sanitation
- Affordable and clean energy
- Reduced inequalities
- Sustainable cities and communities
- Responsible consumption and production
- Climate action[60]

Actions taken by individuals and families, as well as actions taken by city, state, and national governments and by nongovernmental organizations (NGOs), will help achieve the SDGs. For example, the United Nations "Lazy Person's Guide to Saving the World" lists the following:

- Things you can do from your couch, including saving electricity and using online bank statements and utility bills
- Things you can do at home, including plugging air leaks in windows and doors; recycling paper, plastic, and glass; and composting
- Things you can do outside your house, including shopping locally; walking, biking, and taking public transportation; and maintaining your car[61]

From the perspective of the four principles of biomedical ethics explored in this book, it is reasonable to conclude that people, communities, and nations should take actions to help each other. From a purely pragmatic perspective, a society becomes more resilient and stronger over time as its individual members become stronger. As Henry David Thoreau stated more than 150 years ago, in his invited talk and essay posthumously titled *Civil Disobedience*, "Action from principle, the perception and the performance of right, changes things and relations."[62] Thus, systematic attention to and redress of the social determinants of health, that is, public policy initiatives based on biomedical ethical principles, will impact societies on a global basis. (As discussed above regarding the 2013–2016 Ebola virus disease epidemic in West Africa, a lack of attention in even a single geographic region may pose a global risk.) Mutually beneficial engagement will benefit the entirety of humankind.

Clean Water and Sanitation and Maternal and Newborn Health

The Sustainable Development Goals Report 2017 stated that in 2015, 5.2 billion people (71 percent of the global population) used a "safely managed" drinking water service, that is, an improved water source located on premises, free of contamination and available as needed.[63] In 2015, 2.9 billion people (39 percent of the global population) used a "safely managed" sanitation service, that is, an improved sanitation facility with treatment and disposal of wastewater.[64] Improved drinking water sources include a household connection, public standpipe, protected dug well, and protected spring.[65] Improved sanitation facilities include connection to a public sewer, connection to a septic system, and a pour-flush latrine.[66] But the converse of these statistics is that, in 2015, 2.2 billion people did not have access to onsite safe drinking water and 4.4 billion people did not have access to safe sanitation.

In 2015, in fourteen countries in Latin America and the Caribbean, greater than 75 percent of the population, on average, had *hygiene coverage*. But in thirty-four countries in sub-Saharan Africa, less than 20 percent of the population, on average, had a soap-and-water facility at home.[67] Lack of safely managed drinking water and safely managed sanitation facilities are associated with serious health risks, including diarrhea, infection with intestinal parasites, and malnutrition.[68] Further, improved water, sanitation, and hygiene (WASH) is an essential intervention that impacts maternal and child morbidity and mortality globally. As of 2015, 500,000 newborns—approximately the population of a medium-size U.S. city—died annually within the first month of life owing to lack of clean water and inadequate sanitation.[69]

Optimizing maternal and newborn health (MNH) remains a global challenge.[70] For example, in 2015 the overall maternal mortality ratio (MMR) was 239 per 100,000 live births in low- and middle-income countries compared to 12 per 100,000 live births in developed countries. Developing regions accounted for approximately 99 percent (302,000) of the estimated global maternal deaths in 2015. Approximately 66 percent of the estimated global maternal deaths in 2015 occurred in sub-Saharan Africa.[71] Based on worldwide health outcomes data, strategies for reducing maternal mortality include the following:

- Addressing inequities in access to and quality of maternal and newborn healthcare
- Ensuring universal health coverage for comprehensive maternal and newborn healthcare
- Addressing all causes of maternal mortality and morbidity[72]

Overall strategies toward improving MNH include the following:

- Community-based health insurance programs[73]
- Expanded access to maternity services
- Expanded access to modern family planning methods
- Increased school attendance and literacy rates among women and girls[74]
- Expanded emergency obstetric care services
- Training of midwives[75]

As of 2017, newborn deaths accounted for 45 percent of deaths of children under age five globally, up from 40 percent in 1990.[76] Globally, in 2016, 2.6 million newborns died (7,000 per day), representing a neonatal mortality rate of 19 per 1,000 live births. Disparities in child

survival exist across countries and regions. For example, in sub-Saharan Africa, about one child in thirty-six dies in the first month. In high-income countries worldwide, the neonatal mortality ratio is 1 in 333. Most deaths for children under age five are caused by infectious diseases such as malaria and pneumonia, diarrhea, and neonatal complications that are all readily preventable or treatable with appropriate resources and infrastructure.[77] Malnutrition is a factor in almost half the cases, and unsafe water, sanitation, and hygiene are additional significant contributing factors.[78]

Improvements in maternal and newborn health are directly associated with improved WASH. WASH can prevent or limit transmission of infectious disease via multiple routes.[79] For example, as demonstrated by a systematic review and meta-analysis in 2011, clean birth and postnatal care practices reduced neonatal mortality from sepsis and tetanus. In one study, postnatal maternal hand washing resulted in a 44 percent reduction in all-cause mortality.[80] Thus, to effectively impact maternal and newborn health, WASH is needed in home environments and healthcare facilities. In support of these goals, in 2008 WHO published the Essential Environmental Health Standards in Health Care.[81] The WHO standards included guidelines and methods of assessing their implementation in the following areas:

- Water quality
- Sufficient water quantity
- Water facilities and access to water
- Wastewater disposal
- Healthcare waste disposal
- Food storage and preparation
- Building design, construction, and management
- Control of vector-borne disease
- Hygiene promotion[82]

Internationally, WASH facility monitoring is required within healthcare delivery environments. WASH indicators associated with obstetric and newborn care include the following:

- Water filters or other methods to ensure availability of potable water to patients and staff
- A functioning water supply
- Availability of disinfectants and antiseptics such as chlorhexidine[83]

It is possible to achieve substantial improvement in maternal and newborn health, even in dire circumstances and within resource-constrained environments. For example, in postwar Sierra Leone, the Bo District Hospital lacked adequate water and lighting. The postcaesarean section wound sepsis rate was 60 percent. UNICEF and other development partners assisted in erecting water storage facilities at the hospital and supplied a generator for the operating theater. Staff were trained in WASH principles and wound care. Within three months the postcaesarean section wound sepsis rate dropped to less than 10 percent. Antibiotic usage decreased dramatically. As the community became aware that services in the maternity unit had improved, the admission delivery rate doubled within six months. Subsequently, the development interventions were replicated in eight additional district hospitals in Sierra Leone.[84]

We may consider the profound impact of this simple, low-cost intervention: worldwide, improved water, sanitation, and hygiene is essential for human flourishing and economic prosperity. On July 28, 2010, the United Nations General Assembly adopted Resolution 64/292, "The human right to water and sanitation."[85] In Resolution 64/292, the General Assembly recognized the right to safe and clean drinking water and sanitation as a human right that is essential for the realization of all human rights. Achieving universal access to safe drinking water, sanitation, and hygiene is central to reducing poverty and inequalities; improving education, employment, and health; and supporting the rights of women and children.[86] In 2000, the Associated Press reported that providing universal access to water and sanitation would cost US$10 billion per year.[87] This cost was described as "the same as Europe spends on ice cream and half of what the United States spends each year on pet food." Even if, at present, the costs tripled to US$30 billion per year, such a sum could be reasonably contrasted to the 2016 U.S. gross domestic product of US$18.6 trillion[88] and 2016 U.S. budgetary spending of US$3.9 trillion.[89] An international commitment to provide the necessary funds would support attainment of the SDGs.

Undernutrition and Poverty

The seventeen SDGs of the 2030 Agenda for Sustainable Development include ending poverty in all its forms everywhere (SDG 1: No poverty) and ending hunger, achieving food security, improving nutrition, and promoting sustainable agriculture (SDG 2: Zero hunger).[90] As of 2013, 767 million people worldwide were living in extreme poverty, that is, on less than US$1.90 per day.[91] As of 2016, 13 percent of the world's population was undernourished. Child *stunting*, that is, low height for age, affected 27.8 percent of children under age five.[92] National statistics are even more dire in certain regions. For example, in the Democratic Republic of Congo, approximately 43 percent of children under age five are stunted. In Papua New Guinea, approximately 41.5 percent of children are affected by stunting.[93] In 2017, 20 million people were at risk of starvation, including 4.5 million people in northeast Nigeria.[94] Poverty and *undernutrition* are intricately interrelated. Children growing up in extreme poverty obtain inadequate nutrition, lack early stimulation and learning, and are exposed to significant stress. The consequences include stunted development, low levels of skills required for life and work, and limited productivity as adults.[95] Death is the most serious consequence of an inadequate food supply, and children are the most vulnerable.[96] For example, as of 2016, the child mortality rate was 13.7 percent in Somalia and 9.3 percent in South Sudan.[97] The consequences of undernutrition, including fetal growth restriction, suboptimal breastfeeding, *wasting*, and stunting, result in increased risk of death from diarrhea, pneumonia, and other infectious diseases.[98] Overall, undernutrition causes approximately 3.1 million child deaths annually worldwide.[99]

Significant progress toward reducing global poverty and undernutrition has been obtained since 1999. For example, in 1999, 1.7 billion people worldwide were living in extreme poverty, representing 28 percent of the 1999 global population. The global rate of extreme poverty had declined to 11 percent by 2013 (767 million people).[100] In 2000, 18.2 percent of the global population were undernourished (approximately 1.1 billion people). In 2016, approximately 960 million people worldwide obtained insufficient nutrition (13 percent).[101] In support of these efforts, in 2012, the World Health Assembly (WHA) Resolution 65.6 endorsed a *Comprehensive*

implementation plan on maternal, infant and young child nutrition.[102] The plan specified six global nutrition targets to be achieved by 2025:

1. 40 percent reduction in stunting in children under age five
2. Ensuring no increase in childhood overweight
3. 50 percent reduction in the rate of anemia in women of reproductive age
4. 30 percent reduction in the incidence of low birth weight
5. Achieving a 50 percent rate of exclusive breastfeeding in the first six months of life
6. Achieving rates of childhood wasting of less than 5 percent

The WHA global nutrition targets were subsequently integrated into SDG 2.[103] As well, on April 1, 2016, the United Nations General Assembly declared 2016–2025 the "Decade of Action on Nutrition."[104] The resolution endorsed the Rome Declaration on Nutrition[105] and the Framework for Action[106] approved by the Second International Conference on Nutrition in November 2014. The Framework for Action effectively adopted the 2025 targets specified in WHA Resolution 65.6.[107]

Global nutrition interventions are also needed for marginalized populations including adolescents and young adults.[108] In 2014, the United Nations Population Fund estimated there were 1.8 billion young people between the ages of ten and twenty-four worldwide.[109] But many children living in developing nations and in low-resource environments in industrialized nations enter the adolescent period stunted, underweight, or otherwise malnourished.[110] The consequences include increased rates of death from infectious disease in childhood, diminished learning capacity in childhood, and increased occurrence of noncommunicable diseases in adulthood.[111] Obtaining adequate nutrition in adolescence may represent an opportunity to correct childhood nutritional inadequacies and inadequate growth.[112] Obtaining sufficient nutrition is especially important for adolescent girls in the context of maternal health. For example, the health and nutritional status of adolescent girls before and during pregnancy affect fetal growth and newborn health. Adolescent undernutrition and ill health are critical determinants of adverse fetal/neonatal outcomes, including stillbirths, preterm births, small for gestational age births, and neonatal mortality.[113]

Malnutrition most commonly refers to undernutrition, but may also refer to overnutrition. In the United States, in 2013–2014, more than one-third of adults (37.7 percent) and 17 percent of youth aged two to nineteen were obese.[114] Thus, in the reported time frame, the prevalence of obesity more than doubled following the transition from youth to adulthood. Comparative data demonstrate that in the U.S., in 1999–2000, 30.5 percent of adults and 13.9 percent of youth were obese. In 2016, key facts included the following:

- Worldwide, more than 1.9 billion adults (eighteen years old and older) were overweight. Of these, more than 650 million were obese.
- Worldwide, 39 percent of adults were overweight and 13 percent were obese.
- Worldwide, more than 340 million children and adolescents aged five to nineteen were overweight or obese
- Worldwide, 41 million children under age five were overweight or obese[115]

Overall, a "double burden of malnutrition" has been described in developing countries where "problems of nutritional deficiencies coexist with problems of nutritional excess."[116]

Problematically, overweight and obesity are associated with increased risk for cardiovascular disease, hypertension, abnormal glucose metabolism, and diabetes.

A perspective ranging across a person's lifetime facilitates an understanding of the benefits and effects of nutritional interventions. Nutrition-specific interventions and programs focus on the following:

- Adolescent health and preconception nutrition
- Maternal dietary and vitamin/mineral (micronutrient) supplementation
- Breastfeeding support
- Dietary supplementation for children
- Disease prevention and management[117]

By improving *food security*, reducing the burden of infectious diseases, and improving access to and use of health services, nutritional interventions and programs

- Decrease childhood morbidity and mortality
- Increase cognitive and motor development in childhood
- Increase learning capability and school performance
- Increase adult stature
- Decrease incidence and prevalence of obesity
- Decrease incidence and prevalence of other noncommunicable diseases
- Increase work capacity and productivity[118]

A focus on adolescent health provides a key entry point to improving the health of women and children, with beneficial effects on all segments of society, especially as an estimated 10 million girls younger than age eighteen are married each year.[119] Community platforms provide an opportunity to obtain broad coverage by utilizing communication and outreach strategies to reach poor and difficult to access populations at the local level.[120] Community health worker programs and community-based nutrition programs integrate nutritional and therapeutic interventions, linking nutrition with maternal, newborn, and child health.[121] Worldwide, nearly 1 million deaths of children younger than age five could be prevented if specific core nutrition interventions could be scaled up.[122] The cost of scaling up to 90 percent coverage of at-risk populations was estimated in 2013 to be US$9.6 billion per year, that is, a cost of approximately US$370 per life-year saved.[123] Specific interventions include the following:

- Family planning
- Delayed age of first pregnancy
- Preconception care
- Multiple micronutrient supplementation
- Early initiation of breastfeeding
- Early management of severe acute malnutrition
- Obesity prevention
- Malaria prevention
- WASH[124]

Overall, fundamental issues should be targeted, including food security; education, especially female literacy; and improving sanitation and other living conditions.[125] Successful community-based programs require a continuum of community participation, comprehensive planning and implementation strategies, and capacity building and training at multiple levels. Collaboration with NGOs and civil organizations such as teaching institutions is essential for long-term sustainability.[126]

U.S. Opioid Epidemic

Since 2000, more than 300,000 Americans have died owing to an opioid overdose.[127] Overall, since 2000, the rate of overdose deaths involving opioids has increased 200 percent.[128] In 2015, more than 33,000 Americans died from a drug overdose involving prescription or illicit opioids,[129] exceeding the more than 28,600 such deaths recorded in 2014.[130] Important contributors to the opioid epidemic are semisynthetic prescription opioid pain medications such as oxycodone and hydrocodone, which are "frequently used for nonmedical purposes and are implicated in many opioid overdose deaths."[131] The majority of heroin users report that their opioid use disorder began with prescription opioids.[132]

Long-term opioid use often begins with the prescription of opioid medications to treat acute pain. Persistent opioid use has been demonstrated among patients who had not taken opioids previously (opioid-naive patients) who were treated for "short-term conditions that did not require long-term pain management."[133] Many patients frequently receive their first opioid treatment in the emergency department (ED) setting.[134] Of note, from 2001 to 2010, the percentage of overall ED visits in the United States in which opioid pain medication was prescribed increased from 20.8 to 31.0 percent.[135] As well, in 2012, U.S. healthcare practitioners "wrote more than 200 million prescriptions for opioids, double the number in 1998 and 10 million more than in 2008."[136] A 2017 report noted that in a sample of more than 1.2 million patients who had received an initial prescription for opioid medication during the interval 2006–2015, the rate of long-term opioid use (continued use of opioids one year later) was 6.0 percent for patients with at least one day of opioid treatment and 13.5 percent for patients whose first episode of use was for greater than eight days. The rate of long-term use was 29.9 percent when the first episode of use was for greater than thirty-one days.[137] Overall, more patients are "experiencing an inexorable progression from initial opioid use to frequent use, highly frequent use, or an opioid use disorder."[138]

But a study reported in 2017 demonstrated that, for patients presenting to the ED, "there were no statistically significant or clinically important differences in pain reduction at two hours among single-dose treatment with ibuprofen and acetaminophen or with three different opioid and acetaminophen combination analgesics."[139] Ibuprofen and acetaminophen have different mechanisms of action and the combination "apparently provides additive analgesic effects while reducing the short-term risk for adverse effects."[140] The 2017 report presented evidence that nonopioid pain medication can provide comparable pain reduction to that obtained via opioid medication for selected patients in the ED setting.[141] Further, a study completed in December 2016 and reported in 2018 demonstrated that, for patients with chronic back pain or hip and knee osteoarthritis pain, "treatment with opioids was not superior to treatment with nonopioid medications for improving pain-related function over twelve months."[142] Study results did not

support initiation of opioid therapy for such patients. The 2018 report noted that owing to "the risk for serious harms without sufficient evidence for benefits, current guidelines discourage opioid prescribing for chronic pain."[143]

Responses to the opioid epidemic have been undertaken by federal agencies, professional journals, and the courts. For example, in March 2016, the Centers for Disease Control and Prevention responded to the U.S. opioid epidemic with an opioid prescribing guideline.[144] The CDC guideline stated the following:

- Nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred for chronic pain.
- Before starting opioid therapy for chronic pain, clinicians should establish treatment goals with all patients, including realistic goals for pain and function, and should consider how therapy will be discontinued if benefits do not outweigh risks.
- When opioids are started, clinicians should prescribe the lowest effective dosage.
- When opioids are used for chronic pain, clinicians should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than seven days will rarely be needed.[145]

An April 2016 editorial in *JAMA* noted the persistence of substantial deficiencies in physician education and training regarding addiction, despite an increase in continuing education courses on safe prescribing.[146] Previously, an October 2015 *JAMA* editorial noted that reducing the incidence of patients using opioids for the first time is a "logical way to reduce the prevalence of opioid use disorders."[147] The authors stated that "an important step is to start at the beginning and keep opioid-naive patients opioid naive."[148]

More than 400 federal lawsuits responding to the U.S. opioid epidemic have been brought by cities, counties, and Native American tribes against "makers of the prescription painkillers, companies that distribute them, and pharmacy chains that sell them."[149] On December 7, 2017, the U.S. Judicial Panel on Multidistrict Litigation ordered transfer of sixty-four actions to be centralized and litigated in the Northern District of Ohio. The cases concern "the alleged improper marketing of and inappropriate distribution of various prescription opiate medications into cities, states and towns across the country."[150] The theories under which the parties are suing include "public nuisance laws; fraud, racketeering and corruption; and violations of federal and state laws on controlled substances."[151] Litigation may "help alleviate the opioid epidemic by changing industry practices and building public awareness." Settlement agreements may include commitments on the part of defendants to modify marketing and distribution practices. As well, increasing numbers of lawsuits helps build the case for greater federal regulation.[152] Overall, as the CDC guideline has noted, "Clinicians should consider the circumstances and unique needs of each patient when providing care."[153]

The Future of Healthcare

As national and global populations continue to expand, pressures will correspondingly increase on national healthcare systems to provide essential and timely services. As has been discussed in the preceding chapters, to maximize population health, national healthcare systems must

FIGURE 11.2 Healthcare equity is necessary for the well-being of children around the world

ongoingly address the social determinants of health and persistent health disparities/health inequities. Further, it is reasonable to assert that a fundamental right to healthcare provides the basis for equitable delivery of healthcare services around the world, including in the United States that, as of 2017, remained the only country in the industrialized world that did not provide universal healthcare.[154]

As discussed in Chapter 4, the social determinants of health are the circumstances and environments in which people grow, live, work, and age that impact "a wide range of health, functioning, and quality-of-life outcomes and risks."[155] As discussed in Chapter 3, health disparities are "gaps in the quality of health and health care that mirror differences in socioeconomic status, racial and ethnic background, and education level."[156] Health inequities are "differences in health which are not only unnecessary and avoidable but, in addition, are considered unfair and unjust."[157] Overall, health outcomes are linked to genetics; the physical environment, including the built environment and the availability of green space; availability of nutritious food; individual biological and behavioral responses; access to affordable health care; social supports; and the work environment.[158] Beyond individual choices, collaboration from all segments of society, including families and communities, regional, state, and national governments, international organizations such as WHO and UNICEF, and other NGOs, is required to efficiently and effectively address the multiple intersecting factors that determine health and well-being. Systematic, consistent approaches are needed to strengthen individual, family, and community (local, national, and global) health.[159]

For example, the "3 by 5 Initiative,"[160] launched by WHO and the Joint United Nations Programme on HIV/AIDS (UNAIDS) in 2003, planned to provide antiretroviral treatment (ART) to 3 million people living with AIDS in developing regions by the end of 2005.[161] Although "3 by 5" did not reach its target, 1.3 million people were provided ART, tripling the previous number

who had been receiving treatment. The program prevented an estimated 250,000 to 350,000 AIDS-related deaths.[162] By the end of 2005, more than eighteen countries reported having met the "3 by 5" target of providing ART to at least 50 percent of those needing treatment.[163] In 2006, WHO defined health system strengthening as building capacity in the areas of "policy, funding, human resources, service management and information and monitoring systems,"[164] that is, the critical components of healthcare systems. The "3 by 5" program encouraged countries to establish ambitious national treatment targets and undertake policy reforms to expand access to healthcare and improve the capacity of healthcare systems.[165] Overall, "3 by 5" demonstrated the feasibility of cooperation among multiple community, regional, national, and international agencies to attain meaningful success in the global health arena. At present, SDG 3 is "Ensure healthy lives and promote well-being for all at all ages." SDG Target 3.3 is "By 2030, end the epidemics of AIDS, tuberculosis, malaria and neglected tropical diseases and combat hepatitis, water-borne diseases and other communicable diseases."[166]

Achieving SDG 3 and, especially, SDG Target 3.3 will depend significantly on addressing and remediating healthcare system infrastructure, with specific focus on the maldistribution of healthcare workers around the world. This global maldistribution, in terms of geography and resources and with respect to region, nation, and community, impacts social justice and health disparities/health inequities.[167] In 2013, WHO noted there was a global shortage of 7.2 million healthcare workers. WHO estimated the worldwide shortage would increase to 12.9 million by 2035.[168] WHO identified the basic threshold as twenty-three skilled health professionals (midwives, nurses, and physicians) per 10,000 population. But, as of 2013, eighty-three countries had not met this minimum requirement.[169]

Overall, distribution of the global healthcare workforce and distribution of global financial resources for healthcare are unequal and inequitable. For example, in 2007, the United States and Canada accounted for 14 percent of the world's population, but possessed 37 percent of the global healthcare workforce and spent approximately 50 percent of the world's financial resources for healthcare. In contrast, sub-Saharan Africa accounted for 11 percent of the global population, but was home to only 3 percent of the global healthcare workforce and spent less than 1 percent of the world's financial resources for healthcare.[170] Ample evidence has demonstrated a positive correlation between healthcare worker concentration and delivery of quality healthcare, especially in the areas of primary care, immunization coverage, and newborn, child, and maternal survival.[171] Addressing the maldistribution of global healthcare workers requires training new midwives, nurses, and physicians, as well as retaining current skilled healthcare professionals. This worldwide undertaking requires "global responsibility, political will, financial commitment and public-private partnership" to fulfill country-led and country-specific interventions.[172]

The global maldistribution of healthcare workers results in part from substantial disparities in health education worldwide.[173] These inequities may begin to be redressed by redesigning professional health education. Toward this end, the Commission on Education of Health Professionals for the 21st Century was established in January 2010.[174] The commission asserted that health impacts pressing global issues including "socioeconomic development, national and human security, and the global movement for human rights."[175] Thus, good health is a condition of development, security, and rights. A key outcome of the proposed educational redesign is for healthcare professionals to be able to mobilize knowledge and engage in critical reasoning and ethical conduct, with the intention of participating in "patient and population-centered

health systems as members of locally responsive and globally connected teams."[176] The ultimate purpose is to assure universal coverage of comprehensive services that are "essential to advance opportunity for health equity within and between countries."[177]

The commission declared that healthcare professionals would be trained in programs that incorporated "global flows of educational content, teaching resources, and innovations."[178] For example, twinning programs, such as that established in 1989 by Moi University School of Medicine in Kenya and the Indiana University School of Medicine, exemplify the capabilities of medical schools to foster international exchange, share resources, and engage in collaborative activities and programs.[179] By the mid-1990s, the success of this alliance resulted in the formation of AMPATH (Academic Model Providing Access to Healthcare), which included a consortium of North American universities led by Indiana University.[180] AMPATH is engaged in "the delivery of health-promoting services to individuals and populations in low-income environments." In collaboration with the Kenyan Ministry of Health, AMPATH builds health systems in the public sector that strengthen sustainable healthcare services, develop human capacity through training and education, and work toward eliminating health disparities.[181]

Subsequent to the release of the commission's report in 2010, the National Academies of Sciences, Engineering, and Medicine established the Global Forum on Innovation in Health Professional Education, and in 2015 the Global Forum held a workshop titled "Envisioning the Future of Health Professional Education."[182] The workshop addressed, among additional critical issues, an "increasing gap between what future health care professionals are being taught and what the health care delivery system and the social and local environments currently look like."[183] Building a global healthcare workforce will require addressing core competencies including cultural competency, community dimensions of practice, and leadership and systems thinking.[184] Implementation of global healthcare strategies will be facilitated by leveraging technology to deliver healthcare where it is most needed, investing in community-based health education and promotion, and "prioritizing prevention and community-oriented health delivery rather than highly subspecialized health care interventions."[185] Overall, an increasing educational focus on the social determinants of health is required, which includes "health literacy, lifestyle choices, and cultural diversity."[186]

As well, the Millennium Project *State of the Future V. 19.0* report lists fifteen global challenges, including democratization, status of women, population and resources, health issues, sustainable development and climate change, clean water, energy, and global ethics.[187] The Millennium Project notes these challenges are "transnational in nature and transinstitutional in solution."[188] Collaborative action is required among governments, universities, international organizations, and communities around to world to address these shared challenges creatively and effectively.

Summary

As Henry David Thoreau stated in *A Week on the Concord and Merrimack Rivers*, "Your scheme must be the frame-work of the universe; all other schemes will soon be ruins."[189] Health is an inherently global concept. In 2010, WHO stated that "Rights concepts and standards provide an instrument for turning diffuse social demand into focused legal and political claims."[190] The universal right to healthcare requires broad actions toward redressing the social determinants

of health, which will encompass eliminating health disparities/health inequalities and advancing toward health equity.[191] The overall goal is ensuring universal access to the highest attainable standard of health, a human right recognized in the International Covenant on Economic, Social and Cultural Rights (Article 12),[192] adopted by the United Nations General Assembly on December 16, 1966, and entered into force on January 3, 1976. Based on available data, it may be reasonably asserted that the health of individuals, families, and communities is interconnected with the overall health of regions within a nation, nations themselves, international regions, and the global community. Thus, consistent access to healthcare underlies solutions to all major global health problems.

BOX 11.1

Case Study: Global Healthcare Public Policy

Imagine that in the near future, the global community has been wracked by successive crises including economic upheaval, severe food and water shortages, and attacks on human dignity. In response, nationwide grassroots movements of young people have elected members of congress and parliament who support restoring leadership throughout the world in the areas of health, freedom, and human rights. Groundswells invoking liberty and justice are sweeping Europe, Africa, South America, Oceania, and the United States.

Prompted by this worldwide atmosphere of new hope, the United Nations is convening a World Congress of Present and Future Human Flourishing. Conference sessions will focus on the right to healthcare, health disparities/health inequities, emerging infectious diseases, food and water security, and mechanisms for global environmental and climate governance.

Ethical Analysis

1. Discuss the role of the principles of biomedical ethics in helping to establish a robust global healthcare community capable of providing services to all those in need.
2. Apply the biomedical ethical principles of beneficence and justice to the design of international readiness and response efforts in relation to the threat of global infectious diseases.
3. Analyze the persistence of global undernutrition and poverty from the perspective of the biomedical ethical principles of autonomy and justice. Describe two global public policy solutions to meaningfully influence these social determinants of health.
4. Analyze the importance of helping to ensure optimal maternal and newborn health from the perspective of the biomedical ethical principles of autonomy and justice. Describe two global public policy solutions to meaningfully impact these social determinants of health.

KEY TERMS

Food Security
Food security refers to circumstances in which "all people, at all times, have physical, social and economic access to sufficient, safe and nutritious food that meets their dietary needs and food preferences for an active and healthy life."[193] The four food security dimensions are food availability, economic and physical access to food, food utilization, and stability over time.[194]

Health Disparities
The National Institutes of Health defines health disparities as "gaps in the quality of health and health care that mirror differences in socioeconomic status, racial and ethnic background, and education level."[195] *Healthy People 2020* defines health disparities as "a particular type of health difference that is closely linked with social, economic, and/or environmental disadvantage."[196] Overall, health disparity represents differences among socioeconomic groups in the areas of availability, access, and quality of healthcare; health status; and health outcomes.[197] Health disparities are associated with inequalities in access to healthcare, affordability of healthcare, and outcomes of healthcare services. Health disparities are associated with inequalities in the incidence and prevalence of infectious, chronic, and environmental diseases.

Health Inequities
Inequity is defined as "lack of equity of justice; unfairness."[198] Health inequities are "differences in health which are not only unnecessary and avoidable but, in addition, are considered unfair and unjust."[199] WHO defines health inequities as systematic differences in the health status and health outcomes of different population groups.[200] For example, in the United States, African Americans represent approximately 13 percent of the population, but account for almost 50 percent of all new HIV infections.[201] As well, maternal mortality is a key indicator of health inequity. Approximately 99 percent of annual maternal deaths occur in developing countries. Women in Chad, for example, have a lifetime risk of maternal death of 1 in 16. In contrast, women in Sweden have a lifetime risk of maternal death of less than 1 in 10,000.[202] Recognition of a health inequity represents acknowledgment of unfairness and, possibly, injustice. The term *health inequity* directly emphasizes the condition of lack of equity or lack of justice, with the implicit requirement or need to rectify such injustice.

Hygiene Coverage
Hygiene coverage is defined as "the availability of a handwashing facility with soap and water on premises."[203] Hygiene coverage is an essential component of improved water, sanitation, and hygiene (WASH). Sustainable Development Goal (SDG) 6 ("Ensure availability and sustainable management of water and sanitation for all") includes SDG 6.2.1, "Proportion of population using safely managed sanitation services, including a handwashing facility with soap and water."[204] Thus, the global goal for hygiene coverage is universal access by 2030.[205] The profound consequences of poor access to WASH include the global burden of diarrheal disease, a leading cause of child mortality worldwide[206] and a likely important determinant of child undernutrition.[207] Inadequate WASH is associated with increased maternal mortality, transmission of a range of tropical diseases, and respiratory infections.[208] As an example of the gap that needs to be bridged,

the prevalence of handwashing with soap at critical times such as before eating was estimated to be 14 percent in sub-Saharan Africa. In 2014, an estimated 19 percent of people worldwide wash their hands with soap after contact with human waste.[209]

Malnutrition
Malnutrition represents a low weight-for-age ratio. Moderate malnutrition is defined as weight-for-age between −2 and −3 standard deviations below the median weight-for-age of a reference population.[210]

Stunting
Stunting represents a low height-for-age ratio. Moderate stunting is defined as height-for-age between −2 and −3 standard deviations below the median height-for-age of a reference population.[211]

Undernutrition
Undernutrition includes being underweight for one's age (malnourished), being too thin for one's height (wasted), being too short for one's age (stunted), and deficient in vitamins and minerals (micronutrient malnutrition).[212]

Wasting
Wasting represents a low weight-for-height ratio. Moderate wasting is defined as weight-for-height between −2 and −3 standard deviations below the median weight-for-height of a reference population.[213]

Zoonosis
A zoonosis is an emerging infectious disease in humans caused by a naturally occurring virus of another animal species,[214] including mammals, birds, reptiles, and fish. The "zoonotic pool" characterizes introductions of viruses from other species. Zoonoses include Ebola virus disease, Zika virus disease, SARS, dengue fever, and plague.[215]

DISCUSSION QUESTIONS

1A. Discuss two key public health measures that target the threat of emerging infectious diseases.
1B. What resources are needed to implement and sustain these measures?
1C. How may these measures be implemented on an international basis?
2A. Describe two specific impacts of WASH (improved water, sanitation, and hygiene) programs on international health.
2B. Discuss the moral foundations of a "human right to water and sanitation" (declared by United Nations General Assembly Resolution 64/292 on July 28, 2010[216]).
3A. Discuss the implications of the concept of food security in the context of global health.
3B. Discuss the role of developed nations in helping to establish and maintain food security in developing regions.

4A. Describe how education of healthcare professionals impacts the delivery of healthcare services in the community and around the world.
4B. Discuss two capabilities/competencies required of today's healthcare professionals in addition to those related to their professional specialization.
4C. Discuss how these additional capabilities/competencies assist in the long-term process of optimizing global health.

DO-IT-YOURSELF ETHICIST

1. As a government public health official specializing in human rights, you have been invited to address a WHO subcommittee whose focus is emerging infectious diseases. Discuss how combatting an emerging infectious disease may affect the rights of specific individuals. Analyze potential conflicts between the rights of individuals and the welfare of society, and discuss how these moral conflicts may be resolved.
2. You are a healthcare professional specializing in maternal and child health. Your community health center has invited you to speak on key issues in maternal and newborn nutrition. Create a twenty-slide presentation including a discussion of prenatal nutrition; the impact of malnutrition, stunting, and wasting; and the importance of targeting adolescent health.

REAL-WORLD APPLICATIONS—ETHICS AS A DOCTRINE OF ACTION

1. You are a healthcare professional and a member of your state's congressional delegation, serving on the Budget Committee of the House of Representatives. Write a 500-word Op-Ed article or blog post for submission to a national newspaper regarding a new federal budget line item providing funds in support of the United Nations 2030 Agenda for Sustainable Development and the Sustainable Development Goals.[217] Support your arguments by referencing biomedical ethical principles and discuss the role of the United States in efforts to promote global health.
2. As a public health professional and medical school faculty member, you have been tasked to design a new program to reduce the incidence and prevalence of chronic diseases such as type 2 diabetes and hypertension in your community. Write a 500-word proposal including discussions of (1) how the successes of the WHO "3 by 5 Initiative"[218] may be leveraged to support the implementation of your institution's community program and (2) how the program might be scaled up to deliver services at the city and state levels.
3. Your healthcare institution has launched a twelve-month pilot program to target the social determinants of health in your community. As a member of the steering committee, you are responsible for engaging local businesses in providing financial and volunteer support. Create a twenty-slide presentation highlighting the impact of the social determinants of health[219] on community welfare and the likely long-term socioeconomic benefits of the new program in terms of enhanced productivity, creativity, and human flourishing.

REFERENCES

[1]M. Fernandez and N. Onishi, "U.S. Patient Aided Ebola Victim in Liberia," *New York Times*, October 1, 2014, https://www.nytimes.com/2014/10/02/us/after-ebola-case-in-dallas-health-officials-seek-those-who-had-contact-with-patient.html.

[2]L. O. Gostin, "Is the United States Prepared for Ebola?" *JAMA* 312, no. 23 (2014): 2497–2498.

[3]D. Grady, "Ebola Is Diagnosed in Texas, First Case Found in the U.S." *New York Times*, September 30, 2014, https://www.nytimes.com/2014/10/01/health/airline-passenger-with-ebola-is-under-treatment-in-dallas.html.

[4]M. Fernandez and D. Philipps, "Death of Thomas Eric Duncan in Dallas Fuels Alarm Over Ebola," *New York Times*, October 8, 2014, https://www.nytimes.com/2014/10/09/us/ebola-us-thomas-eric-duncan.html.

[5]N. Onishi, "U.S. Patient Aided Pregnant Liberian, Then Took Ill," *New York Times*, October 1, 2014, https://www.nytimes.com/2014/10/02/world/africa/ebola-victim-texas-thomas-eric-duncan.html.

[6]Gostin, "Is the United States Prepared for Ebola?"

[7]M. Paulson, "Nina Pham, Free of Ebola, Makes White House Detour on Way Home," *New York Times*, October 24, 2014, https://www.nytimes.com/2014/10/25/us/nina-pham-free-of-ebola-virus.html; A. Blinder, "Amber Joy Vinson, Dallas Nurse Treated for Ebola, Is Released from Hospital," *New York Times*, October 28, 2014, https://www.nytimes.com/2014/10/29/us/ebola-outbreak-dallas-nurse-amber-joy-vinson.html.

[8]M. Santora, "Doctor in New York City Is Sick with Ebola," *New York Times*, October 23, 2014, https://www.nytimes.com/2014/10/24/nyregion/craig-spencer-is-tested-for-ebola-virus-at-bellevue-hospital-in-new-york-city.html.

[9]A. Hartocollis and M. Santora, "Plenty of Hugs as Craig Spencer, Recovered New York Ebola Patient, Goes Home," *New York Times*, November 11, 2014, https://www.nytimes.com/2014/11/12/nyregion/craig-spencer-new-york-ebola-patient-bellevue.html.

[10]M. Fernandez and K. Sack, "Ebola Patient Sent Home Despite Fever, Records Show," *New York Times*, October 10, 2014, https://www.nytimes.com/2014/10/11/us/thomas-duncan-had-a-fever-of-103-er-records-show.html.

[11]Gostin, "Is the United States Prepared for Ebola?"

[12]Ibid.

[13]Santora, "Doctor in New York City."

[14]Ibid.

[15]Hartocollis and Santora, "Plenty of Hugs."

[16]M. S. Chevalier, W. Chung, J. Smith et al., "Ebola Virus Disease Cluster in the United States, Dallas County, Texas, 2014," *CDC Morbidity and Mortality Weekly Report*, November 14, 2014, https://www.cdc.gov/mmwr/pdf/wk/mm63e1114a5.pdf.

[17]K. Sack, S. Fink, P. Belluck et al., "How Ebola Roared Back," *New York Times*, December 29, 2014, https://www.nytimes.com/2014/12/30/health/how-ebola-roared-back.html.

[18]Centers for Disease Control and Prevention, *2014 Ebola Outbreak in West Africa, Epidemic Curves*, updated December 27, 2017, https://www.cdc.gov/vhf/ebola/history/2014-2016-outbreak/cumulative-cases-graphs.html.

[19]Centers for Disease Control and Prevention, *2014 Ebola Outbreak in West Africa, Case Counts*, updated December 27, 2017, https://www.cdc.gov/vhf/ebola/history/2014-2016-outbreak/case-counts.html

[20]Centers for Disease Control and Prevention, *2014 Ebola Outbreak in West Africa, Epidemic Curves.*

[21]Sack et al., "How Ebola Roared Back,"

[22]S. Samb, "Scale of Guinea's Ebola Epidemic Unprecedented: Aid Agency," Reuters, March 31, 2014, http://in.reuters.com/article/us-guinea-ebola/scale-of-guineas-ebola-epidemic-unprecedented-aid-agency-idINBREA2U10E20140331.

[23]W. E. Diehl, A. E. Lin, N. D. Grubaugh et al., "Ebola Virus Glycoprotein with Increased Infectivity Dominated the 2013–2016 Epidemic," *Cell* 167, no. 4 (2016): 1088–1098.

[24]C. Zimmer, "Ebola Evolved into Deadlier Enemy During the African Epidemic," *New York Times*, November 3, 2016.

[25]G. Dudas, L. M. Carvalho1, T. Bedford et al., "Virus Genomes Reveal Factors That Spread and Sustained the Ebola Epidemic," *Nature* 544, no. 7650 (2017): 309–315.

[26]D. Satcher, "Emerging Infections: Getting Ahead of the Curve," *Emerging Infectious Diseases* 1, no. 1 (1995): 1–6, https://dx.doi.org/10.3201/eid0101.950101.

[27]World Health Organization, *The Top 10 Causes of Death*, Updated January 2017, http://www.who.int/mediacentre/factsheets/fs310/en/.

[28]World Health Organization, *The Top 10 Causes of Death: Leading Causes of Death by Economy Income Group*, http://www.who.int/mediacentre/factsheets/fs310/en/index1.html.

[29]D. M. Morens and A. S. Fauci, "Emerging Infectious Diseases: Threats to Human Health and Global Stability," *PLoS Pathogens* 9, no. 7 (2013): e1003467, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3701702/.

[30]S. S. Morse, "Factors in the Emergence of Infectious Diseases," *Emerging Infectious Diseases*1, no. 1 (1995): 7–15, https://dx.doi.org/10.3201/eid0101.950102.

[31]A. S. Fauci and D. M. Morens, "The Perpetual Challenge of Infectious Diseases," *New England Journal of Medicine* 366, no. 5 (2012): 454–461, http://www.nejm.org/doi/pdf/10.1056/NEJMra1108296.

[32]S. S. Morse, "Emerging Viruses: Defining the Rules for Viral Traffic," *Perspectives in Biology and Medicine* 34, no. 3 (1991): 387–409.

[33]Centers for Disease Control and Prevention (CDC), *A CDC Framework for Preventing Infectious Diseases: Sustaining the Essentials and Innovating for the Future* (Atlanta, GA: CDC, 2011), 7, https://www.cdc.gov/oid/docs/ID-Framework.pdf.

[34]Ibid. 7.

[35]Morse, "Factors in the Emergence of Infectious Diseases," 9.

[36]Ibid.

[37]Centers for Disease Control and Prevention, *Rift Valley Fever*, last updated October 19, 2016, https://www.cdc.gov/vhf/rvf/index.html.

[38]X. H. Wu, S. Q. Zhang, X. J. Xu et al., "Effect of Floods on the Transmission of Schistosomiasis in the Yangtze River Valley, People's Republic of China," *Parasitology International* 57, no. 3 (2008): 271–276.

[39]Fauci and Morens, "The Perpetual Challenge of Infectious Diseases." 459.

[40]Morse, "Factors in the Emergence of Infectious Diseases," 13.

[41]Fauci and Morens, "The Perpetual Challenge of Infectious Diseases," 455.

[42]Ibid.

[43]Satcher, "Emerging Infections," 3.

[44]Institute of Medicine of the National Academies, *The Future of the Public's Health in the 21st Century* (Washington, DC: National Academies Press, 200), 99, https://www.nap.edu/catalog/10548/the-future-of-the-publics-health-in-the-21st-century.

[45]Centers for Disease Control and Prevention, *CDC Framework for Preventing Infectious Diseases*, 3.

[46]Centers for Disease Control and Prevention, "Addressing Emerging Infectious Disease Threats: A Prevention Strategy for the United States," *Morbidity and Mortality Weekly Report* 43, no. RR-5, April 15, 1994, https://www.cdc.gov/mmwr/PDF/rr/rr4305.pdf.

[47]Dudas et al., "Virus Genomes Reveal Factors," (referencing J. Quick, N. J. Loman, S. Duraffour et al., "Real-Time, Portable Genome Sequencing for Ebola Surveillance," Nature 530, no. 7589 (2016): 228–232.

[48]Centers for Disease Control and Prevention, *One Health Basics*, last updated August 4, 2017, https://www.cdc.gov/onehealth/basics/index.html.

[49]World Health Organization (WHO), *International Health Regulations (2005)*, 2nd ed. (Geneva: WHO, 2008), http://apps.who.int/iris/bitstream/10665/43883/1/9789241580410_eng.pdf.

[50]Pandemic and All-Hazards Preparedness Reauthorization Act of 2013, https://www.gpo.gov/fdsys/pkg/PLAW-113publ5/pdf/PLAW-113publ5.pdf.

[51]U.S. Department of Health and Human Services, Public Health Emergency. Pandemic and All-Hazards Preparedness Reauthorization Act, https://www.phe.gov/Preparedness/legal/pahpa/Pages/pahpra.aspx.

[52]Office of the Assistant Secretary for Preparedness and Response, *2017–2022 Hospital Preparedness Program. Performance Measures and Implementation Guideline*, https://www.phe.gov/Preparedness/planning/hpp/reports/Documents/hpp-pmi-guidance-2017.pdf.

[53]Gostin, "Is the United States Prepared for Ebola?"

[54]Centers for Disease Control and Prevention, *SARS Basic Fact Sheet*, last updated July 2, 2012, https://www.cdc.gov/sars/about/fs-sars.html.

[55]United Nations, *The Millennium Development Goals Report 2015*, http://www.un.org/millenniumgoals/2015_MDG_Report/pdf/MDG%202015%20rev%20(July%201).pdf.

[56]Ibid., 4–7.

[57]Ibid., 8–9.

[58]United Nations General Assembly, Resolution 70/1. Transforming Our World: the 2030 Agenda for Sustainable Development, https://sustainabledevelopment.un.org/post2015/transformingourworld and http://www.un.org/ga/search/view_doc.asp?symbol=A/RES/70/1&Lang=E.

[59]United Nations, *Sustainable Development Goals*, http://www.un.org/sustainabledevelopment/sustainable-development-goals/.

[60]Ibid.

[61]United Nations, *Lazy Person's Guide to Saving the World*, http://www.un.org/sustainabledevelopment/takeaction/.

[62]E. H. Witherell, ed., *Henry David Thoreau. Collected Essays and Poems* (New York: Library of America, 2001), 210.

[63]United Nations, *The Sustainable Development Goals Report 2017* (New York: United Nations Publications, 2017), 30, https://unstats.un.org/sdgs/files/report/2017/TheSustainableDevelopmentGoalsReport2017.pdf.

[64]Ibid.

[65]UNICEF/World Health Organization (WHO), *Progress on Drinking Water and Sanitation. 2012 Update* (New York/Geneva: UNICEF/WHO, 2012), 33.

[66]Ibid.

[67]United Nations: *Sustainable Development Goals Report 2017*, 30.

[68]Ibid., 31.

[69]L. C. Callister, "WASH: Highlighting Global Water, Sanitation, and Hygiene Initiatives. *MCN American Journal of Maternal/Child Nursing* 40, no. 6 (2015): 398.

[70]World Health Organization (WHO), *Every Newborn: An Action Plan to End Preventable Deaths* (Geneva: WHO, 2014), http://apps.who.int/iris/bitstream/10665/127938/1/9789241507448_eng.pdf.

[71]World Health Organization (WHO), UNICEF, UNFPA, World Bank Group, and UNPD: *Trends in Maternal Mortality: 1990 to 2015* (Geneva: WHO, 2015), 16, http://apps.who.int/iris/bitstream/10665/194254/1/9789241565141_eng.pdf.

[72]Ibid., 25.

[73]H. Worley, *Rwanda's Success in Improving Maternal Health 2015* (Washington, DC: Population Reference Bureau, 2015), http://www.prb.org/Publications/Articles/2015/rwanda-maternal-health.aspx.

[74]Nepal Ministry of Health and Population, *Success Factors for Women's and Children's Health* (Geneva: WHO, 2015), 16, http://www.who.int/pmnch/knowledge/publications/nepal_country_report.pdf.

[75]W. Van Lerberghe, Z. Matthews, E. Achadi et al., "Country Experience with Strengthening of Health Systems and Deployment of Midwives in Countries with High Maternal Mortality," *The Lancet* 384, no. 9949 (2014): 1215–1225.

[76]World Health Organization (WHO), *Reaching the Every Newborn National 2020 Milestones*. (Geneva: WHO, 2017), 2, http://apps.who.int/iris/bitstream/10665/255719/1/9789241512619-eng.pdf?ua=1.

[77]World Health Organization, UNICEF, World Bank Group, and UNDP, *Levels and Trends in Child Mortality Report, 2017* (Geneva: WHO, 2017), 1–2, https://www.unicef.org/publications/files/Child_Mortality_Report_2017.pdf.

[78]Ibid., 2.

[79]Y. Velleman, E. Mason, W. Graham et al., "From Joint Thinking to Joint Action: A Call to Action on Improving Water, Sanitation, and Hygiene for Maternal and Newborn Health," *PLoS Medicine* 11, no. 12 (2014): e1001771, http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1001771.

[80]H. Blencowe, S. Cousens, L. C. Mullany et al., "Clean Birth and Postnatal Care Practices to Reduce Neonatal Deaths from Sepsis and Tetanus: A Systematic Review and Delphi Estimation of Mortality Effect," *BMC Public Health* 11, suppl. 3 (2011): S11, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3231884/.

[81]J. Adams, J. Bartram and Y. Chartier, eds., *Essential Environmental Health Standards in Health Care* (Geneva: WHO, 2008), http://www.who.int/water_sanitation_health/hygiene/settings/ehs_health_care.pdf.pdf.

[82]Ibid., 11.

[83]Velleman et al., "From Joint Thinking to Joint Action," 5.

[84]Ibid., 6.

[85]United Nations General Assembly, Resolution 64/292. The Human Right to Water and Sanitation, http://www.un.org/es/comun/docs/?symbol=A/RES/64/292&lang=E.

[86]Water Supply and Sanitation Collaborative Council, *WSSCC Launches Its Strategic Plan for 2017–2020*, http://wsscc.org/2017/03/08/wsscc-launches-strategic-plan-2017-2020/?q=/page/3/&_sf_s=strategy.

[87]Associated Press, "Price of Safe Water for All: $10 Billion and the Will to Provide It," November 23, 2000, http://www.nytimes.com/2000/11/23/world/price-of-safe-water-for-all-10-billion-and-the-will-to-provide-it.html.

[88]World Bank, *World Development Indicators Database. Gross Domestic Product 2016*, April 17, 2017, http://databank.worldbank.org/data/download/GDP.pdf.

[89]Congressional Budget Office, *The Federal Budget in 2016: An Infographic*, February 8, 2017, https://www.cbo.gov/publication/52408.

[90]United Nations, *The Sustainable Development Goals Report* 2017, 3–4.

[91]Ibid., 12.

[92]2017 Global Hunger Index, *The Inequalities of Hunger* (Washington, DC: International Food Policy Research Institute, 2017), 5, https://doj19z5hov92o.cloudfront.net/sites/default/files/resource/2017/10/global_hunger_index_2017.pdf.

[93]Ibid., 19.

[94]Ibid., 3.

[95]*Ending Extreme Poverty: A Focus on Children* (Washington, DC: UNICEF and World Bank Group, 2016), 2, https://www.unicef.org/publications/files/Ending_Extreme_Poverty_A_Focus_on_Children_Oct_2016.pdf.

[96]2017 Global Hunger Index, *The Inequalities of Hunger*, 8.

[97]Ibid., 18.

[98]R. E. Black, C. G. Victoria, S. P. Walker et al., "2013. Maternal and Child Undernutrition and Overweight in Low-Income and Middle-Income Countries, *The Lancet* 382 (2013): 427–451.

[99]Ibid., 427.

[100]United Nations, *The Sustainable Development Goals Report* 2017, 3.

[101]2017 Global Hunger Index, *The Inequalities of Hunger*, 5.

[102]World Health Organization, *Global Targets 2025: To Improve Maternal, Infant and Young Child Nutrition*, http://www.who.int/nutrition/global-target-2025/en/.

[103]Z. A. Bhutta, "Global Child Nutrition and the Sustainable Development Goals," *Lancet Child and Adolescent Health*, https://doi.org/10.1016/S2352-4642(17)30119-0.

[104]World Health Organization (WHO), *General Assembly Proclaims the Decade of Action on Nutrition*, http://www.who.int/nutrition/GA_decade_action/en/.

[105]Second International Conference on Nutrition, *Rome Declaration on Nutrition*, Rome, Italy, November 19–21, 2014, http://www.fao.org/3/a-ml542e.pdf.

[106]Second International Conference on Nutrition, *Framework for Action*. Rome, Italy, November 19–21, 2014, http://www.fao.org/3/a-mm215e.pdf.

[107]Ibid., 1–2.

[108]Bhutta, "Global Child Nutrition."

[109]UNFPA State of World Population 2014, *The Power of 1.8 Billion. Adolescents, Youth and the Transformation of the Future*, http://www.unfpa.org/sites/default/files/pub-pdf/EN-SWOP14-Report_FINAL-web.pdf.

[110]N. Akseer, S. Al-Gashm, S. Mehta et al., "Global and Regional Trends in the Nutritional Status of Young People: A Critical and Neglected Age Group," *Annals of the New York Academy of Science* 1393, no. 1 (2017): 3–20.

[111]Black et al., "Maternal and Child Undernutrition," 443.

[112]Akseer et al., "Global and Regional Trends," 4.

[113]Z. A. Bhutta, Z. S. Lassi, G. Bergeron et al., "Delivering an Action Agenda for Nutrition Interventions Addressing Adolescent Girls and Young Women: Priorities for Implementation and Research," *Annals of the New York Academy of Science* 1393, no. 1 (2017): 61–71.

[114]C. L. Ogden, M. D. Carroll, C. D. Fryar et al., "Prevalence of Obesity Among Adults and Youth: United States, 2011–2014," Centers for Disease Control and Prevention, National Center for Health Statistics Data Brief No. 219, November 2015, https://www.cdc.gov/nchs/data/databriefs/db219.pdf.

[115]World Health Organization (WHO), *Obesity and Overweight. Fact Sheet*, updated October 2017, http://www.who.int/mediacentre/factsheets/fs311/en/.

[116]C. Chaparro and C. Lutter, *Underweight, Short Stature and Overweight in Adolescents and Young Women in Latin America and the Caribbean* (Washington, DC: Pan American Health Organization, 2011), http://www.paho.org/hq/index.php?option=com_docman&%C2%A0option=com_%C2%A0docman&task=doc_view&gid=15146&Itemid=3482&lang=pt.

[117]Black et al., "Maternal and Child Undernutrition," 428.

[118]Ibid.

[119]The Partnership for Maternal, Newborn and Child Health, *PMNCH Knowledge Summary #22. Reaching Child Brides* (Geneva: WHO, 2017), http://www.who.int/pmnch/knowledge/publications/summaries/ks22/en/.

[120]Z. A. Bhutta, J. K. Das, A. Rizvi et al., "Evidence-Based Interventions for Improvement of Maternal and Child Nutrition: What Can Be Done and at What Cost?" *The Lancet* 382, no. 9890 (2013): 452–477.

[121]Ibid., 472.

[122]Ibid., 453.

[123]Ibid., 472.

[124]Ibid., 454.

[125]Bhutta, "Global Child Nutrition."

[126]E. V. Shantha1 and R. Shrimpton, "Community Based Nutrition Programs. Critical Design Elements and Research Needs," *World Nutrition* 8, no. 1 (2017): 41–51.

[127]Centers for Disease Control and Prevention, *New Data Show Continuing Opioid Epidemic in the United States*, December 16, 2016, https://www.cdc.gov/media/releases/2016/p1216-continuing-opioid-epidemic.html.

[128]R. A. Rudd, N. Aleshire, J. E. Zibbell et al., "Increases in Drug and Opioid Overdose Deaths—United States, 2000–2014," *Morbidity and Mortality Weekly Report* 64, no. 50–51 (2016): 1378–1382.

[129]Centers for Disease Control and Prevention, *New Data Show Continuing Opioid Epidemic.*

[130]Rudd et al., "Increases in Drug and Opioid Overdose Deaths."

[131]D. N. Kyriacou, "Opioid vs. Nonopioid Acute Pain Management in the Emergency Department," *JAMA* 318, no. 17 (2017): 1655–1656.

[132]R. J. Bonnie, M. A. Ford, and J. K. Phillips, eds., *Pain Management and the Opioid Epidemic: Balancing Societal and Individual Benefits and Risks of Prescription Opioid Use* (Washington, DC: National Academies Press, 2017), 6, http://nationalacademies.org/hmd/Reports/2017/pain-management-and-the-opioid-epidemic.aspx.

[133]Kyriacou, "Opioid vs. Nonopioid Acute Pain Management," 1655.

[134]Ibid.

[135]M. Mazer-Amirshahi, P. M. Mullins, I. Rasooly et al., "Rising Opioid Prescribing in Adult U.S. Emergency Department Visits: 2001–2010," *Academic Emerging Medicine* 21, no. 3 (2014): 236–243.

[136]Y. Olsen, "The CDC Guideline on Opioid Prescribing: Rising to the Challenge," *JAMA* 315, no. 15 (2016): 1577–1579.

[137]A. Shah, C. J. Hayes, and B. C. Martin, "Characteristics of Initial Prescription Episodes and Likelihood of Long-Term Opioid Use—United States, 2006–2015," *Morbidity and Mortality Weekly Report* 66, no. 10 (2017): 265–269.

[138]L. S. Nelson, D. N. Juurlink, and J. Perrone, "Addressing the Opioid Epidemic," *JAMA* 314, no. 14 (2015): 1453–1454.

[139]A. K. Chang, P. E. Bijur, D. Esses et al., "Effect of a Single Dose of Oral Opioid and Nonopioid Analgesics on Acute Extremity Pain in the Emergency Department: A Randomized Clinical Trial," *JAMA* 318, no. 17 (2017): 1661–1667.

[140]Kyriacou, "Opioid vs. Nonopioid Acute Pain Management," 1656.

[141]Ibid.

[142]E. E. Krebs, A. Gravely, S. Nugent et al., "Effect of Opioid vs Nonopioid Medications on Pain-Related Function in Patients with Chronic Back Pain or Hip or Knee Osteoarthritis Pain: The SPACE Randomized Clinical Trial," *JAMA* 319, no. 9 (2018): 872–882.

[143]Ibid.

[144]D. Dowell, T. M. Haegerich and R. Chou, "CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016," *Morbidity and Mortality Weekly Report* 65, no. 1 (2016): 1–49.

[145]Ibid.

[146]Olsen, "CDC Guideline on Opioid Prescribing," 1578.

[147]Nelson, Juurlink, and Perrone, "Addressing the Opioid Epidemic," 1454.

[148]Ibid.

[149]J. Hoffman, "Can This Judge Solve the Opioid Crisis?" *New York Times*, March 5, 2018, https://www.nytimes.com/2018/03/05/health/opioid-crisis-judge-lawsuits.html.

[150]United States Judicial Panel on Multidistrict Litigation, Transfer Order, December 5, 2017, http://www.jpml.uscourts.gov/sites/jpml/files/MDL-2804-Initial-Transfer-11-17.pdf.

[151]Hoffman, "Can This Judge Solve the Opioid Crisis?" 150.

[152]R. L. Haffajee and M. M. Mello, "Drug Companies' Liability for the Opioid Epidemic," *New England Journal of Medicine* 377, no. 24 (2017): 2301–2305.

[153]Dowell, Haegerich, and Chou, "CDC Guideline for Prescribing Opioids, 2.

[154]E. C. Schneider, D. O. Sarnak, D. Squires et al., *Mirror, Mirror 2017: International Comparison Reflects Flaws and Opportunities for Better U.S. Health Care* (Washington, DC: The Commonwealth Fund, July 2017), http://www.commonwealthfund.org/interactives/2017/july/mirror-mirror/.

[155]Office of Disease Prevention and Health Promotion, *Healthy People 2020. Social Determinants of Health*, last updated November 17, 2017, https://www.healthypeople.gov/2020/topics-objectives/topic/social-determinants-of-health.

[156]National Institute of Allergy and Infectious Diseases, *Minority Health*, https://www.niaid.nih.gov/research/minority-health.

[157]M. Whitehead, "The Concepts and Principles of Equity and Health," *Health Promotion International* 6, no. 3 (1991): 217–228.

[158]O. Solar and A. Irwin, *A Conceptual Framework for Action on the Social Determinants of Health. Social Determinants of Health Discussion Paper 2 (Policy and Practice)* (Geneva: WHO, 2010), 13, http://www.who.int/sdhconference/resources/ConceptualframeworkforactiononSDH_eng.pdf.

[159]Association of Public Health Nurses, *The Public Health Nurse's Role in Achieving Health Equity. Eliminating Inequalities in Health*, Position Paper, December 13, 2015, http://phnurse.org/resources/APHN%20Health%20Equity%20Paper-%20Version%20%2012-3-15%20(2).pdf.

[160]World Health Organization (WHO), *The 3 by 5 Initiative*, http://www.who.int/3by5/en/.

[161]World Health Organization (WHO): *World Health Organization and UNAIDS Unveil Plan to Get 3 Million AIDS Patients on Treatment by 2005* (Geneva: WHO, 2003), http://data.unaids.org/cosponsors/who/pr_who_3by5_01dec03_en.pdf.

[162]World Health Organization (WHO), *UNAIDS: Progress on Global Access to HIV Antiretroviral Therapy: A Report on 3 by 5 and Beyond* (Geneva: WHO, 2006), http://www.who.int/hiv/fullreport_en_highres.pdf.

[163]Ibid., 7.

[164]Ibid., 9.

[165]Ibid., 10.

[166]World Health Organization (WHO): *Sustainable Development Goal 3: Health*, http://www.who.int/topics/sustainable-development-goals/targets/en/.

[167]C. Edmonson, C. McCarthy, S. Trent-Adams et al., "Emerging Global Health Issues: A Nurse's Role. *Online Journal of Issues in Nursing* 22, no. 1 (2017): 2, http://www.nursingworld.org/MainMenuCategories/ANAMarketplace/ANAPeriodicals/OJIN/TableofContents/Vol-22-2017/No1-Jan-2017/Emerging-Global-Health-Issues.html.

[168]World Health Organization (WHO), *Global health workforce shortage to reach 12.9 million in coming decades*, Recife, Brazil, November 11, 2013, http://www.who.int/mediacentre/news/releases/2013/health-workforce-shortage/en/.

[169]World Health Organization (WHO), *A Universal Truth: No Health without a Workforce* (Geneva: WHO, 2014), http://www.who.int/workforcealliance/knowledge/resources/GHWA-a_universal_truth_report.pdf.

[170]S. C. E. Anyangwe and C. Mtonga, "Inequities in the Global Health Workforce: The Greatest Impediment to Health in Sub-Saharan Africa," *International Journal of Environmental Research and Public Health* 4, no. 2 (2007): 93–100, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3728573/.

[171]Ibid., 97.

[172]Ibid., 93.

[173]A. Barnett-Vanes and T. Kedia, "Anyangwe: Equitable Access for Global Health Internships: Insights and Strategies at WHO Headquarters," *Lancet Global Health* 2, no. 5 (2014): e257-9, doi:10.1016/S2214-109X(14)70211-6.

[174]J. Frenk, L. Chen, Z. A. Bhutta et al., "Health Professionals for a New Century: Transforming Education to Strengthen Health Systems in an Interdependent World," *Lancet* 376, no. 9756 (2010): 1923–1958, http://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736(10)61854-5.pdf.

[175]Ibid., 1927.

[176]Ibid., 1924.

[177]Ibid.

[178]Ibid.

[179]Indiana University and Moi University School of Medicine Partnership, *2016–2017 Orientation Guidebook*, http://www.ampathkenya.org/media/90379/2016_orientation_manual_v4.060916.pdf.

[180]Ibid.

[181]Ibid.

[182]P. A. Cuff, *Envisioning the Future of Health Professional Education: Workshop Summary* (Washington, DC: National Academies Press, 2016), https://www.nap.edu/catalog/21796/envisioning-the-future-of-health-professional-education-workshop-summary.

[183]Ibid.

[184]Ibid., 79.

[185]Ibid., 82–83.

[186]Ibid., 81.

[187]J. C. Glenn and E. Florescu, *Millennium Project Team: State of the Future V. 19.0. Executive Summary* (Washington, DC: The Millennium Project, 2017), http://www.millennium-project.org/state-of-the-future-version-19-0/.

[188]Ibid., 8.

[189]C. F. Hovde, W. L. Howarth, and E. H. Witherell, eds., *The Writings of Henry David Thoreau. A Week on the Concord and Merrimack Rivers* (Princeton, NJ: Princeton University Press, 1980), 70.

[190]Solar and Irwin, "A Conceptual Framework for Action," 13.

[191]Ibid., 14.

[192]Office of the United Nations High Commissioner for Human Rights, *International Covenant on Economic, Social and Cultural Rights*, http://www.ohchr.org/Documents/ProfessionalInterest/cescr.pdf.

[193]The State of Food Security and Nutrition in the World 2017, *Building resilience for peace and food security*, (Rome: FAO, IFAD, UNICEF, WFP and WHO, 2017), 107, http://www.fao.org/3/a-I7695e.pdf.

[194]Ibid.

[195]National Institute of Allergy and Infectious Diseases, *Minority Health*, https://www.niaid.nih.gov/research/minority-health.

[196]HealthyPeople.gov, *Healthy People 2020. Disparities*, https://www.healthypeople.gov/2020/about/foundation-health-measures/Disparities.

[197]O. Carter-Pokras and C. Baquet, "What Is a "Health Disparity"? *Public Health Reports* 117, no. 5 (2002): 426–434.

[198]L. Brown (ed.). *The New Shorter Oxford English Dictionary on Historical Principles*, thumb index ed. (New York: Oxford University Press, 1993), 1357.

[199]M. Whitehead. "The Concepts and Principles of Equity and Health." *Health Promotion International* 6, no. 3 (1991): 217–228.

[200]World Health Organization (WHO), *10 Facts on Health Inequities and Their Causes*, updated April 2017, http://www.who.int/features/factfiles/health_inequities/en/.

[201]Ibid.

[202]Ibid.

[203]United Nations, *The Sustainable Development Goals Report* 2017, 30.

[204]United Nations, *SDG Indicators. Metadata Repository*, last updated July 17, 2017, https://unstats.un.org/sdgs/metadata/.

[205]United Nations General Assembly, Resolution 70/1.

[206]L. Liu, H. J. Johnson, S. Cousens et al., "Global, Regional, and National Causes of Child Mortality: An Updated Systematic Analysis for 2010 with Time Trends Since 2000," *The Lancet* 379, no. 9832 (2012): 2151–2161, http://can-mnch.ca/wp-content/uploads/2012/06/1.-LiuetalLancetCHERG2012.pdf.

[207]W. Checkley, G. Buckley, and R. H. Gilman, "Multi-Country Analysis of the Effects of Diarrhoea on Childhood Stunting," *International Journal of Epidemiology* 37, no. 4 (2008): 816–830, https://academic.oup.com/ije/article/37/4/816/736863.

[208]R. Roche, R. Bain, and O. Cumming, "A Long Way to Go—Estimates of Combined Water, Sanitation and Hygiene Coverage for 25 sub-Saharan African Countries," *PLoS One* 12, no. 2 (2017): e0171783, doi:10.1371/journal.pone.0171783, http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0171783#pone.0171783.

[209]M. C. Freeman, M. E. Stocks, O. Cumming et al., "Hygiene and Health: Systematic Review of handwashing Practices Worldwide and Update of Health Effects," *Tropical Medicine and International Health* 19, no. 8 (2014): 906–916, http://onlinelibrary.wiley.com/doi/10.1111/tmi.12339/full.

[210]UNICEF, *Nutrition. Definitions of the Indicators*, https://www.unicef.org/infobycountry/stats_popup2.html.

[211]Ibid.

[212]UNICEF, *Progress for Children. Nutrition, Survival and Development*, https://www.unicef.org/progressforchildren/2006n4/index_undernutrition.html.

[213]UNICEF, *Nutrition. Definitions of the Indicators.*

[214]S. S. Morse, "Examining the Origins of Emerging Viruses," in *Emerging Viruses*, ed. S. S. Morse (New York: Oxford University Press, 1993), 15.

[215]World Health Organization, *Zoonoses*, http://www.who.int/zoonoses/diseases/en/.

[216]United Nations General Assembly, Resolution 64/292.

[217]United Nations General Assembly, Resolution 70/1; United Nations, *Sustainable Development Goals.*

[218]World Health Organization, *The 3 by 5 Initiative.*

[219]Solar and Irwin, "A Conceptual Framework for Action."

Figure Credits

Fig. 11.1: Copyright © Mirage3 (CC by 2.0) at https://depositphotos.com/20212555/stock-photo-african-kids-all-sisters-smiling.html.

Fig. 11.2: Copyright © 2011 Depositphotos/Monkeybusiness.

Index

M

N

ETHICAL AND LEGAL ISSUES IN HEALTHCARE

Ethical and Legal Issues in Healthcare is a definitive resource for healthcare students and professionals in nursing, medicine, and the allied health sciences, providing a comprehensive overview and exploration of today's ethical and legal landscape in healthcare delivery.

The textbook presents, discusses, and analyzes the history of healthcare ethics, key concepts and intellectual traditions, the four principles of biomedical ethics, the history of legal systems, tort law and negligence, landmark court decisions and legislation in the context of healthcare ethics, and issues related to HIPAA, informed consent, patient rights and responsibilities, and end-of-life decision-making. Later chapters investigate healthcare issues in contemporary society, including the Medicare and Medicaid systems, health disparities/health inequities, bioethics, healthcare delivery, corporate governance, electronic health records, and gene editing and genetic technologies. The textbook concludes with an examination of global challenges and the future of healthcare.

Each chapter of *Ethical and Legal Issues in Healthcare* features real-world applications including case studies, discussion questions, "do-it-yourself ethicist" exercises, and "ethics as a doctrine of action" exercises. Overall, *Ethical and Legal Issues in Healthcare* provides healthcare students and professionals with the critical information needed to navigate the myriad ethical and legal issues that inform and influence modern healthcare.

David Lemberg, M.S., D.C., is associate faculty professor in the School of Health and Human Services at National University. He is a bioethicist and serves as a community member on the Biomedical Ethics Committee of a large medical center in the greater San Diego area. Dr. Lemberg received his M.S. degree in bioethics from Albany Medical College and his D.C. degree from New York Chiropractic College. He maintained a private practice in New York City for more than 20 years. Dr. Lemberg has provided expert commentary for articles in *The New York Times*, *The Translational Scientist*, and *Popular Science*.

cognella ACADEMIC PUBLISHING

ISBN 978-1-5165-2170-8

9 781516 521708 90000

SKU 82060-1A