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CHAPTER 2

Contemporary Ethical Dilemmas



No right is held more sacred, or is more carefully guarded, 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 unquestioned authority of law.

—*Union Pac. Ry. Co. v. Botsford*

► LEARNING OBJECTIVES

Upon completion of this chapter, the reader will be able to:

- Describe various historical events that have had an impact on the resolution of ethical dilemmas.
- Describe common ethical dilemmas and the various ethical issues that have in many instances divided many segments of the population. Topics include abortion; sterilization; artificial insemination; surrogacy; organ donations; research, experimentation, and clinical trials; human genetics, stem cell research; and AIDS.

► INTRODUCTION

An *ethical dilemma* arises in situations where a choice must be made between unpleasant alternatives. It can occur whenever a choice involves giving up something good and suffering something bad, no matter what course of action is taken. Ethical dilemmas often require caregivers to make decisions that may break some ethical norm or contradict some ethical value. For example, should I choose to continue a pregnancy knowing that an unborn child will be born with severe disabilities, or should I choose abortion with the goal of preventing pain for both parent and child? Should I adhere to my spouse's wishes not to be placed on a respirator, or should I choose life support technology, disregarding her wishes and right to self-determination? Should I encourage my daughter—the victim of a gang rape—to have an abortion, or should I advocate that she do no harm to the unborn child? Such dilemmas give rise to conflicting answers.

There is a wide range of ethical and legal issues impacting the healthcare system. This chapter focuses on some of the more common ethical and legal dilemmas facing the providers of health care. In reviewing this chapter, the reader should apply court decisions and the ethical theories, principles, and values previously discussed.

► NOTEWORTHY HISTORICAL EVENTS



I was created at the end of the Renaissance, watched pirates rule the oceans as Ivan the Terrible ruled Russia, and witnessed the arrest of Galileo for believing the earth revolved around the sun.

—I Am History

The historical events presented in this section describe some of the many milestones that have had a significant impact on healthcare ethics.

68,000–58,000 BC

Neanderthal Burial Sites

Evidence of belief in an afterlife was found in Neanderthal burial sites, where various implements and supplies were buried with the deceased.

According to anthropologist F. Clark Howell the flexed position of the body, and discoveries of other sites where stone slabs were placed over the Neanderthal graves, along with food

and tools, suggests that Neanderthal man believed in life after death. Their concept of the afterlife must not have been that much different than the life they experienced on earth; they provided the dead with food, tools, and other everyday items, much like the Egyptians did for their journey to the next life.¹

AD 1932–1972

Tuskegee Study of Syphilis

The Tuskegee Study of Syphilis, involving African American men, was designed to analyze the natural progression of untreated syphilis. The study was conducted from 1932 through the early 1970s. The participants were not told during the study that there was a cure for syphilis at the time of the study. It is reported that some of the participants in the study had syphilis and others were intentionally given syphilis during the study. The participants believed that they were receiving adequate care and unknowingly suffered unnecessarily. The Tuskegee syphilis study used disadvantaged black men to investigate the untreated course of a disease, one that is by no means confined to that population. We know now that the selection of research subjects must be closely monitored to ensure that specific classes of individuals (e.g., terminally ill patients, welfare patients, racial and ethnic minorities, or persons confined to institutions) are not selected for research studies because of their easy availability, compromised position, or manipulability. Rather, they must be selected for reasons directly related to the research being conducted.

1933–1945

The Holocaust

The Holocaust was one of the most violent events in human history. Over 6 million Jews were murdered as well as millions of people from other cultural groups, including Slavs, homosexuals, and Gypsies.

Doctors have always been thought of as the saviors of mankind, the healers, and caretakers of our utter existence. Even ancient civilizations revered the medicine men as having special power to protect life. The trust of a physician is sacred. This is why the practice of medicine by the doctors of the Third Reich is egregious, outrageous, and shocking. The Nazi doctors violated the trust placed in them by humanity. The most painful truth is for the most part the doctors escaped their crimes against Humanity and lived a life, unlike their victims.²

1946***Military Tribunal for War Crimes***

In 1946, the Military Tribunal for War Crimes began criminal proceedings against 23 German physicians and administrators for war crimes and crimes against humanity. As a direct result of these proceedings, the Nuremberg Code was established, which made it clear that the voluntary and informed consent of human subjects is essential to research and that benefits of research must outweigh risks to human subjects involved.³

1949***WMA International Code of Medical Ethics***

The World Medical Association International Code of Medical Ethics was adopted in October 1949 after it was learned that the Nazis conducted numerous inhumane experiments on prisoners in concentration camps. Prisoners were exposed to cholera, diphtheria, malaria, mustard gas, yellow fever, and typhus and forced to participate in other horrendous experiments, ultimately claiming thousands of lives. This exploitation of unwilling prisoners as research subjects was condemned as a particularly flagrant injustice. The code has been amended several times since its initial adoption—first in August 1968, then in October 1983, and most recently in October 2006 at the 57th WMA General Assembly, Pilanesberg, South Africa.⁴

1954***Guidelines on Human Experimentation***

The National Institutes of Health published guidelines on human experimentation following the first kidney transplant⁵ conducted in 1954. The transplantation of human organs has generated numerous ethical issues (e.g., the harvesting and selling of organs, who should have first access to freely donated human organs, how death is defined).

1960s***Cardiopulmonary Resuscitation Raises Ethical Dilemmas***

Cardiopulmonary resuscitation was developed, leading to numerous ongoing ethical dilemmas because it involves the prolonging of life beyond what would reasonably be expected. Should limited resources, for example, be spent on those who have been determined to be in a comatose vegetative state without hope of recovery? Or, should limited resources be spent on preventative medicine, aimed at improving the quality of life?

1964***WMA Guidelines for Conducting Biomedical Research***

The World Medical Association established guidelines for medical doctors conducting biomedical research involving human subjects.⁶ The WMA's Declaration of Helsinki laid the foundation for advanced clinical practices today.⁷

1968***Harvard Ad Hoc Committee on Brain Death***

The Harvard Ad Hoc Committee on Brain Death published the following criteria to aid in determining a permanently nonfunctioning brain, a condition it referred to as “irreversible coma,” now known as brain death:

1. Patient shows total unawareness to external stimuli and unresponsiveness to painful stimuli.
2. No movements or breathing; all spontaneous muscular movement, spontaneous respiration, and response to stimuli are absent.
3. No reflexes; fixed, dilated pupils; no eye movement even when hit or turned, or when ice water is placed in the ear; no response to noxious stimuli; no tendon reflexes.

In addition to these criteria, the report recommended adding the presence of a flat electroencephalogram.⁸

1970***Patient as a Person***

The Patient as a Person by Paul Ramsey discusses the question of *paternalism*. As physicians are faced with many options for saving lives, transplanting organs, and furthering research, they also must wrestle with new and troubling choices, for example, who should receive scarce resources (e.g., organ transplants), how to determine when life ends, and what limits should be placed on care for the dying.

1971***Kennedy Institute of Ethics***

The Joseph P. and Rose F. Kennedy Institute of Ethics was established at Georgetown University in 1971 by a generous grant from the Joseph P. Kennedy Jr. Foundation. Today it is the world's oldest and most

comprehensive academic bioethics center. The institute and its library serve as an unequaled resource for those who research and study ethics, as well as those who debate and make public policy. The Kennedy Institute is home to scholars who engage in research, teaching, and public service on issues that include protection of research subjects, reproductive and feminist bioethics, end-of-life care, healthcare justice, intellectual disability, cloning, gene therapy, eugenics, and other major bioethical issues. Institute scholars figure prominently among the pioneers of the discipline. They are extending the boundaries of the field to incorporate emerging issues of racial and gender equality, international justice and peace, and other policies affecting the world's most vulnerable populations.⁹

1972

Informed Consent

Informed consent in the *Canterbury v. Spence*¹⁰ case set the *reasonable man standard*, requiring informed consent for treatment. Patients must be informed of the risks, benefits, and alternatives associated with recommended treatments. The court found that Dr. Spence negligently failed to disclose a risk of serious disability inherent in the operation and that the Washington Hospital Center provided negligent postoperative care.¹¹ The U.S. Court of Appeals Justice Spottswood W. Robinson III described what led up to the Court's decision remanding the case to the District Court, which had previously ruled in favor of the appellees:

The record we review tells a depressing tale. A youth troubled only by back pain submitted to an operation without being informed of a risk of paralysis incidental thereto. A day after the operation he fell from his hospital bed after having been left without assistance while voiding. A few hours after the fall, the lower half of his body was paralyzed, and he had to be operated on again. Despite extensive medical care, he has never been what he was before. Instead of the back pain, even years later, he hobbled about on crutches, a victim of paralysis of the bowels and urinary incontinence. In a very real sense, this lawsuit is an understandable search for reasons.¹² . . . In the case before us, appellant's evidentiary presentation on negligence survived the claims of legal insufficiency, and appellees should have been put to their proof.

1973

Women's Right to Abortion

The *Roe v. Wade*¹³ abortion case gave strength to a woman's right to privacy in the context of matters relating to her own body, including how a pregnancy would end.

1974

National Research Act (NRA) of 1974

Because of publicity from the Tuskegee Syphilis Study, the National Research Act (NRA) of 1974 was passed. The NRA created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. One of the commission's charges was to identify the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects and to develop guidelines to ensure that such research is conducted in accordance with those principles.¹⁴

The commission was directed to consider the following:¹⁵

1. The boundaries between biomedical and behavioral research and the accepted and routine practice of medicine
2. The role of assessment of risk-benefit criteria in determining the appropriateness of research involving human subjects
3. Appropriate guidelines for the selection of human subjects for participation in such research
4. The nature and definition of informed consent in various research settings

1976

Substituted Judgment— Karen Ann Quinlan

The New Jersey Supreme Court in the *Matter of Karen Ann Quinlan*¹⁶ rendered a unanimous decision providing for the appointment of Joseph Quinlan as personal guardian of his daughter, Karen Ann Quinlan, a young woman in a persistent vegetative state who was being kept alive on a respirator against her parents' wishes. A conflict arose when hospital officials refused to remove the respirator, concerned that they would be charged with homicide if they complied. The record was remanded to the trial court to implement without further testimonial hearing:

To appoint Joseph Quinlan as guardian of the person of Karen Quinlan with full power to

make decisions with regard to the identity of her treating physicians.

We repeat for the sake of emphasis and clarity that upon the concurrence of the guardian and family of Karen, should the responsible attending physicians conclude that there is no reasonable possibility of Karen's ever emerging from her present comatose condition to a cognitive, sapient state and that the life-support apparatus now being administered to Karen should be discontinued, they shall consult with the hospital "Ethics Committee" or like body of the institution in which Karen is then hospitalized. If that consultative body agrees 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 and said action shall be without any civil or criminal liability therefor, on the part of any participant, whether guardian, physician, hospital or others.

By the above ruling we do not intend to be understood as implying that a proceeding for judicial declaratory relief is necessarily required for the implementation of comparable decisions in the field of medical practice.

First Living Will Legislation Enacted

In California, the first living will legislation was enacted, permitting a person to sign a declaration stating that if there is no hope of recovery, no heroic measures need to be taken to prolong life. This provision is now available in every state.

1978

Commission for the Study of Ethical Problems

The President's Commission for the Study of Ethical Problems in Medicine includes studies regarding the ethical and legal issues of informed consent for research participants; the matter of defining death, including the advisability of developing a uniform definition of death; the voluntary testing, counseling, and information and education programs with respect to genetic diseases and conditions, taking into account the essential equality of all human beings, born and unborn; the differences in the availability of health services, as determined by the income or residence of the persons receiving the services; current procedures and mechanisms designed to safeguard the privacy

of human subjects of behavioral and biomedical research, to ensure the confidentiality of individually identifiable patient records and to ensure appropriate access of patients to information; and such other matters relating to medicine or biomedical or behavioral research as the president may designate for study by the commission.¹⁷

1980

Hemlock Society

The Hemlock Society was an organization formed to advocate for physician-assisted dying for the terminally ill, mentally competent patient suffering with incurable illnesses.

Controversial in death as in life, the Hemlock Society USA as a name died suddenly on June 13, 2003, in a boardroom in Denver, Colorado. It was 23 years old. Public relations experts and political strategists—leaning heavily on focus groups—were on hand to usher in the death knell. Months of agonizing debate had preceded the decision because no one could think of a better name!¹⁸

1983

First Durable Power of Attorney Legislation

California enacted the first durable power of attorney legislation permitting an advance directive to be made describing the kind of health care that one would desire when facing death by designating an agent to act on the patient's behalf. Currently, the California Advance Health Care Directive Form reads in part:

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. This form lets you do either or both of these things. It also lets you express your wishes regarding donation of organs and the designation of your primary physician. If you use this form, you may complete or modify all or any part of it. You are free to use a different form.¹⁹

Compassion and Choices

The Hemlock Society evolved into "End-of-Life Choices," which in 2005 merged with "Compassion in Dying" to form "Compassion & Choices."²⁰

Despite sophisticated medical advances—and sometimes because of them—too many people suffer painful, drawn-out deaths against their wishes. At Compassion & Choices, we are fighting to broaden end-of-life options and place control back in the hands of people. We have advocated the right to refuse unwanted medical treatment . . . legitimized the use of advance directives . . . and secured people’s right to receive the full measure of pain medication needed for relief.

Beginning with Oregon’s Death with Dignity Act in 1997, we have been instrumental to the passage of every medical aid-in-dying law in the nation. These laws allow terminally ill adults to request medication to die gently if they choose.²¹

1987

Unethical Experiments on Children

The Willowbrook State School on Staten Island, New York, was a state institution for children with intellectual disability from 1947 until 1987. Infectious disease expert Paul Offit, in his history of the work of vaccine pioneer Maurice Hilleman, recounted how the school’s residents were abused in the name of research:

In an effort to control outbreaks of hepatitis, the medical staff at Willowbrook consulted Saul Krugman [an award-winning U.S. pediatrician whose studies of hepatitis, rubella, and measles resulted in the development of vaccinations for these debilitating diseases]. . . . One of his studies involved feeding live hepatitis virus to sixty healthy children. Krugman watched as their skin and eyes turned yellow and their livers got bigger. He watched them vomit and refuse to eat. All the children fed hepatitis virus became ill, some severely. Krugman reasoned that it was justifiable to inoculate retarded children at Willowbrook with hepatitis virus because most of them [90%] would get hepatitis anyway. But by purposefully giving the children hepatitis, Krugman increased that chance to 100 percent.²²

Offit calls the Willowbrook studies “the most unethical medical experiments ever performed on children in the United States”²³—a far more damning assessment than the contemporaneous judgment of medical ethicist Henry Beecher, who in a 1966 *New England*

Journal of Medicine article cited Willowbrook as being merely “ethically dubious.”²⁴ The Willowbrook studies represented a shift in how experimentation on children and individuals not capable of informed consent was perceived.²⁵

1990

Patient Self-Determination Act

The Patient Self-Determination Act of 1990²⁶ was enacted to ensure that patients are informed of their rights to execute advance directives and accept or refuse medical care. The act was intended to reinforce a person’s constitutional right to make his or her own healthcare decisions. The act requires that federally funded healthcare organizations explain to patients their right to complete an advance directive.

Nancy Cruzan Feeding Tube Removed

The Supreme Court ruled that the parents of Nancy Cruzan, a 32-year old woman who had been unconscious since a 1983 car accident, could have her feeding tube removed.²⁷ The court determined the Missouri Department of Health was permitted to require clear and convincing evidence of the wishes of a patient regarding provision of artificial nutrition and hydration.²⁸ Thus affirming the right of Americans to refuse unwanted medical treatment and their right to appoint a healthcare proxy.

Kevorkian Illegally Assists Terminally Ill Patients in Suicide

Dr. Jack Kevorkian assisted terminally ill patients in suicide outside the boundaries of law. He used a suicide machine to assist Janet Adkins, a 54-year-old woman with Alzheimer’s disease, in ending her life at her request.²⁹

Timothy Quill and Prescription for Death

Timothy Quill, a primary care physician, published an article describing how he had prescribed a lethal dose of sedatives to end the life of a young woman whose suffering from leukemia had become unbearable.³⁰

Final Exit and Freedom of Speech

Derek Humphry’s popular text *Final Exit: The Practicalities of Self-Deliverance and Assisted Suicide for the Dying* was published. Although there were calls for it to be banned, it was not possible under the First Amendment to the U.S. Constitution:

Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof; or abridging the freedom of speech, or of the press; or the right of the people peaceably to assemble, and to petition the Government for a redress of grievances.³¹

Radiation Experiments: Human Subjects Unaware

From the 1930s until as recently as the 1990s, the United States government conducted human radiation experiments on uninformed and unconsenting individuals, including pregnant women, school-age children, disabled children, and a range of other individuals. In all of these cases, the *subjects had no knowledge of what was going on and did not consent*. Some of the victims were actively deceived by the research program's staff (over 800 pregnant women were told they were ingesting "vitamin cocktails"). The government covered up most of these radiation mishaps until 1993, when President Bill Clinton ordered a change of policy. The president's Advisory Committee on Human Radiation Experiments investigated and issued a controversial 1995 report that stated that "wrongs were committed" but held no one accountable.³²

1993

Patient's Wishes Honored

In the case of *DeGrella v. Elston*, the Kentucky Supreme Court ruled on an incompetent's right to die. The decision determined that a patient's wishes will be honored if the attending physician, the hospital, or nursing home ethics committee where a patient resides and the legal guardian or next of kin all agree upon and document the patient's wishes and the patient's condition. If no one disputes their decision, no court order is required to proceed to carry out the patient's wishes. Future criminal sanctions or civil liability turn not on the existence or absence of a court order, but on the facts of the case. No liability attaches to a decision to refuse or withdraw treatment if the necessary facts are established and carefully documented by the parties involved. In contrast, the court cannot absolve the parties from liability where the facts do not exist to support the action taken.³³

1994

Oregon—Physician Assisted Suicide Legal

Oregon's Death with Dignity Act,³⁴ involving physician-assisted suicide, became a legal medical option for terminally ill patients in Oregon. The Oregon Death with Dignity Act allows terminally ill Oregon residents to

obtain from their physicians and use prescriptions for self-administered, lethal medications.

Michigan—Physician Assisted Suicide Illegal

The Supreme Court of Michigan ruled on December 13, 1994, that assisted suicide is illegal in the state of Michigan.³⁵ The ruling overturned several lower court decisions. The court determined that there is no constitutional right to aid in carrying out a suicide in Michigan. Jack Kevorkian, a physician, assisted terminally ill patients in suicide outside the boundaries of the law. He claims to have assisted 130 patients.

1996

Health Insurance Portability and Accountability Act

The Health Insurance Portability and Accountability Act (Public Law 104191) was enacted to protect the privacy, confidentiality, and security of patient information.

Dolly the Sheep Cloned

Ian Wilmut, Keith Campbell, and colleagues at the Roslin Institute, University of Edinburgh, and the biotechnology company PPL Therapeutics near Edinburgh in Scotland successfully cloned Dolly the sheep.³⁶

Several clones had been produced in the lab before Dolly, including frogs, mice, and cows, which had all been cloned from the DNA from embryos. Dolly was remarkable in being the first mammal to be cloned from an adult cell. This was a major scientific achievement as it demonstrated that the DNA from adult cells, despite having specialised as one particular type of cell, can be used to create an entire organism.³⁷

Fourteenth Amendment and Terminally Ill

The Second and Ninth U.S. Circuit Courts of Appeals ruled that there is a constitutional right under the Fourteenth Amendment for a terminally ill person to receive help from a physician when dying.

1997

Physician-Assisted Suicide

Physician-assisted suicide, through referendum, became a legal medical option within narrowly prescribed circumstances for terminally ill Oregon residents.

Kevorkian Charged with Murder

Kevorkian was charged with murder in five cases of physician-assisted suicide and was acquitted.

Supreme Court—States May Enact Assisted Suicide Laws

The Supreme Court ruled that it is up to the individual states to enact laws regarding medically assisted death.

1998

Oregon Voters Reaffirm Death with Dignity Act

Oregon voters reaffirm their support for the Death with Dignity Act by a 60% majority.

Kevorkian Administers Lethal Injection

Kevorkian administered a lethal injection to Thomas Youk, a 52-year-old man with Lou Gehrig's disease, on national television.

Ballot Physician-Assisted Suicide Defeated

Michigan voters defeated a ballot measure that would legalize physician-assisted suicide.

1999

Kevorkian Convicted of Second-Degree Murder

Kevorkian was convicted of second-degree murder for Youk's death and sentenced 10 to 20 years in prison.

Patients Receive Lethal Doses of Medication

Twenty-three terminally ill patients were reported as having received lethal doses of medication since passage of Oregon's Death with Dignity Act.

2000

Seven Myths About End-of-Life Care

Legal myths about end-of-life care may prevent doctors and patients and families from providing adequate comfort measures to dying patients, according to an article published in the November 15, 2000, issue of the *Journal of the American Medical Association*.³⁸

2001

President's Council on Bioethics

President George W. Bush created the President's Council on Bioethics. The council was charged with advising the president on bioethical issues that may emerge as a consequence of advances in biomedical science and technology.

Assisted Suicide Act Challenged

U.S. Attorney General John Ashcroft abrogated former Attorney General Janet Reno's mandate allowing physician-assisted suicide. Instead, he decided that physician-assisted suicide was a violation of the federal Controlled Substance Act.³⁹ In *State of Oregon v. Ashcroft*, CV01-1647 (D-Oregon), the judge allowed Oregon's law to remain in effect.

Oregon: Assisted Suicide Cases

Since 1991, the number of physician-assisted suicide cases totaled 129. On April 17, U.S. District Court Judge Robert Jones upheld Oregon's Death with Dignity Act.

2002

Attorney General Appeals District Court's Ruling

Attorney General John Ashcroft filed an appeal, asking the Ninth U.S. Circuit Court of Appeals to lift the District Court's ruling.⁴⁰

2003

Human Genome System Fully Sequenced

The human genome system became fully sequenced, allowing molecular genetics and medical research to accelerate at an unprecedented rate. The ethical implications of human genome research are as immense as the undertaking of the totality of the research that was conducted to map the human genome system (e.g., cloning of humans).⁴¹

Oregon: Assisted Suicide Cases

Forty-two residents of the state of Oregon ingested medications under provisions of the Death with Dignity Act.

2004***Death with Dignity Act Upheld***

The Ninth U.S. Circuit Court of Appeals upheld Oregon's Death with Dignity Act, blocking the attempt by the U.S. Justice Department, under Attorney General Ashcroft, to use the federal Controlled Substances Act to prevent doctors in the state from prescribing drugs to assist the suicide of their patients. The Ashcroft directive interfered with Oregon's authority to regulate medical care within its borders and therefore altered the usual constitutional balance between the state and federal governments.⁴²

2005

The United Nations Educational, Scientific, and Cultural Organization released the second edition to the 2005 *Human Cloning, Ethical Issues* publication.⁴³

Hospital Allowed to Remove Life Support Contrary to Wishes of the Legal Guardian

A Texas hospital was allowed to remove life support contrary to the requests of the mother. The patient was eventually accepted at a nursing facility, where he died of natural causes.⁴⁴

In Houston, Texas, in 2004, Wanda Hudson gave birth to a son with a fatal form of congenital dwarfism. The father was unknown. Ms. Hudson had been informed the infant was most likely unable to survive and should have his breathing tube removed pursuant to Chapter 166 of the Texas Health & Safety Code, the Advance Directives Act. Under this act, a doctor's recommendations to withdraw medical treatment can be followed, after they have been reviewed by the hospital's ethics committee and after 10 days' notice is given to the patient or guardian. Hudson was given 10 days from written notice to find a new facility to accommodate the infant, but was unable to do so.⁴⁵

Legal delays prevented the removal of the breathing tube, which would have occurred on November 28, 2004, but a judge ruled that the removal of the tube did not require Hudson's agreement. On March 15, 2005, Texas Children's Hospital personnel removed the breathing tube. Official reports state that he was sedated and asphyxiated in under a minute. Hudson disputed this and told reporters, who were not permitted entrance, 'I wanted y'all to see my son for yourself, so you could see he was actually moving around. He was conscious.'⁴⁶

2006***U.S. Supreme Court Upholds Death with Dignity Act***

On January 17, 2006, the U.S. Supreme Court voted six to three to uphold an Oregon physician-assisted suicide law in the case *Gonzales v. Oregon*,⁴⁷ ruling that former Attorney General John Ashcroft overstepped his authority in seeking to punish doctors who prescribed drugs to help terminally ill patients end their lives. In the decision, the Supreme Court said that the Oregon law supersedes federal authority to regulate physicians and that the Bush administration improperly attempted to use the Controlled Substances Act to prosecute Oregon physicians who assist in patient suicides.

Supreme Court Blocks Bush's Attempt to Punish Doctors

The Supreme Court blocked the Bush administration's attempt to punish doctors who help terminally ill patients die, protecting Oregon's one-of-a-kind assisted-suicide law.⁴⁸

Morning-after Pill

The Food and Drug Administration approved the morning-after pill to prevent contraception for use without a prescription. This decision added another dimension to the ongoing controversy between right-to-life and pro-choice advocates. Opponents claimed that it was just another way to end human life.

2009***Right to Know End-of-Life Options***

On January 1, the Terminal Patients' Right to Know End-of-Life Options Act, AB 2747, went into effect in California.

2010***California—Living Donor Registry***

Legislation was introduced in California that would make it the first state in the country to build a living donor registry. Under Senate Bill 1395, people could declare their wishes regarding organ donation by checking a box when obtaining or renewing their driver's license.

2013

Information and Referral Service for Kidney Donors

California launched a state-authorized information and referral service to inspire and inform people to be altruistic living kidney donors. Through its website, www.LivingDonationCalifornia.org, the free service provides information about living kidney donation and refers potentially eligible individuals for evaluation at a transplant center.⁴⁹

2017

UK Supreme Court Denies Right to Treatment

The parents of Charlie Gard, a 10-month-old British boy with mitochondrial DNA depletion disease, wanted to travel to the United States for an experimental therapy that may have provided some temporary benefit but likely would not have improved his neurological condition. Alternatively, they wanted the hospital to continue to provide advanced life support and palliative care for their son—respiration, nutrition, hydration—or to send him home on life support to eventually die. The hospital argued that removing life support was in the child's best interest. After a contentious court battle that generated international attention, the parents' requests were denied and the child's life support was turned off. He died in the hospital.⁵⁰

2018

Six States Have a Death with Dignity Act

Death with Dignity Acts have been passed into law in Washington, D.C. and six states: California, Colorado, Hawaii (in effect on January 1, 2019), Oregon, Vermont, and Washington.

States with Death with Dignity Legal by Court Decision

In Montana, legal physician-assisted suicide was established by a court decision in the 2009 case *Baxter v. Montana*, and efforts to pass laws forbidding it have failed in the legislature thus far.⁵¹

► ABORTION



We shall have to fight the politician, who remembers only that the unborn have no votes and that since posterity has done nothing for us we need do nothing for posterity.

—William Ralph Inge (1860–1954)

An *abortion* is the termination of pregnancy by removal or expulsion from the uterus of a fetus or embryo before it is viable. The question of viability has been strongly debated between advocates for the pro-life position (advocating that the fetus has a right to life) and the pro-choice position (advocating that the mother has the right to choose to terminate a pregnancy). An abortion can be spontaneous, often referred to as a miscarriage, or it can be an elective, meaning purposely induced; it is the latter that continues to be a hotly debated, controversial issue nationwide. The controversy in its simplest form involves the question of the rights of the fetus to be born versus the rights of the mother to make decisions regarding her body.

A consensus as to when human life begins has not been reached. There has been no final determination as to the proper interplay among a mother's liberty, the interests of an unborn child, and the state's interests in protecting human life. In abortion cases, the law presupposes a theory of ethics and morality, which in turn presupposes deeply personal ideas about being and existence. Answers to questions about when human life begins define ethical beliefs, and these ethical beliefs should determine how we govern ourselves. Abortion in this context is less a question about constitutional law and more about who we are as a people. This is a decision the Supreme Court cannot make. Taking these issues out of the public discourse threatens to foment hostility, stifle the search for answers, distance people from the Constitution, and undermine the credibility of that document.⁵²

With 44,498,750 reported abortions in the United States between 1970 and 2014,⁵³ it is certain that the conflict between pro-choice and pro-life advocates will continue to pervade America's landscape. The issues are numerous, and emotions run high. Common ethical dilemmas include:

- When does human life begin?
- Who decides?
- Who protects the unborn fetus?
- What are the rights of an unborn child when a woman has been raped?
- What are the rights of the spouse?
- What are the rights of the father of an unwed child or woman?
- What are the rights of society and the state to interfere with another's rights?
- Should the principles of autonomy and right to self-determination prevail?
- Should an abortion be considered murder?
- Can the use of contraception be considered a form of killing by preventing a birth that might have otherwise occurred?

- What are the religious implications for a woman who is Catholic, for example, who chooses to undergo an abortion?
- Is it morally acceptable to save the life of the mother by aborting the fetus?
- Is an abortion for mere convenience morally wrong?
- What role should education play in the woman's decision to undergo an abortion?
- What alternatives should the woman be educated about (e.g., the choice of adoption) before undergoing an abortion?
- At what age is a girl or woman sufficiently mature to make an informed decision about abortion?
- Should a woman considering abortion be offered counseling and cautions about the negative emotional consequences (e.g., guilt and regret) of her decision?
- Should rape victims receive counseling for emotional consequences (e.g., anger and resentment) of a decision to continue a rape-related pregnancy?
- When does control over one's body begin, and when does it end?

These are but a few of the many questions that need to be addressed in the pursuit of doing the right thing. As the following pages point out, for each new issue decided in the courts, new issues arise, all of which seem to involve both legal and moral questions as to what constitutes acceptable behavior. In addition to having substantial ethical, moral, and religious implications, abortion has proven to be a major political issue and will continue as such in the future. As the following court decisions illustrate, new laws will be enacted by the various states and challenged, often winding their way up to the Supreme Court for decision.

Right to Abortion

The *Roe v. Wade* 1973 landmark case gave strength to a woman's right to privacy in the context of matters relating to her own body, including how a pregnancy would end.⁵⁴ The U.S. Supreme Court has also recognized the interest of the states in protecting potential life and has attempted to spell out the extent to which the states may regulate and even prohibit abortions. The Supreme Court in this case found the Texas penal abortion law unconstitutional, stating, "State criminal abortion statutes . . . that except from criminality only a lifesaving procedure on behalf of the mother, without regard to the stage of her pregnancy and other interests involved, is violating the Due Process Clause of the Fourteenth Amendment."⁵⁵ The court then went on to delineate what regulatory measures a state lawfully may enact during the three stages of pregnancy.

First Trimester

During the first trimester of pregnancy, the decision to undergo an abortion procedure is between the woman and her physician. A state may require that abortions be performed by a licensed physician pursuant to law; however, a woman's right to an abortion is not unqualified because the decision to perform the procedure must be left to the medical judgment of her attending physician. "For the stage prior to approximately the end of the first trimester, the abortion decision and its effectuation must be left to the medical judgment of the pregnant woman's attending physician."⁵⁶

Second Trimester

In *Roe v. Wade*, the Supreme Court stated, "For the stage subsequent to approximately the end of the first trimester, the State, in promoting its interest in the health of the mother, may, if it chooses, regulate the abortion procedure in ways that are reasonably related to maternal health."⁵⁷ Thus, during approximately the fourth to sixth months of pregnancy, the state may regulate the medical conditions under which the procedure is performed. The constitutional test of any legislation concerning abortion during this period would be its relevance to the objective of protecting maternal health.

Third Trimester

The Supreme Court reasoned that by the time the final stage of pregnancy has been reached the state has acquired a compelling interest in the product of conception, which would override the woman's right to privacy and justify stringent regulation even to the extent of prohibiting abortions. In the *Roe v. Wade* case, the court formulated its ruling as to the last trimester in the following words: "For the stage subsequent to viability, the State in promoting its interest in the potentiality of human life, may, if it chooses, regulate, and even proscribe, abortion except where it is necessary, in appropriate medical judgment, for the preservation of the life or health of the mother."⁵⁸

Thus, during the final stage of pregnancy, a state may prohibit all abortions except those deemed necessary to protect maternal life or health. The state's legislative powers over the performance of abortions increase as the pregnancy progresses toward term.

Abortion Restrictions

The following cases illustrate a variety of abortion issues that the various states continue to address. The flow of cases both as they wind their way through both state and federal courts continue to arise with no end in sight.

Abortion Committee Review

In a 1973 companion decision, the U.S. Supreme Court ruled in *Doe v. Bolton*,⁵⁹ that Georgia's abortion statute requiring residency requirements for women seeking an abortion and calling for the procedure to be performed in a hospital accredited by the Joint Commission is constitutionally invalid. Further, the court found there was no constitutionally justifiable rationale for a statutory requirement necessitating advance approval by the abortion committee of the hospital's medical staff prior to abortion. The court ruled that "interposition of the hospital abortion committee is unduly restrictive of the patient's rights and needs that . . . have already been medically delineated and substantiated by her personal physician. To ask more serves neither the hospital nor the State."⁶⁰ Insofar as statutory consultation requirements are concerned, the court reasoned that the acquiescence of two co-practitioners has no rational connection with a patient's needs and, further, unduly infringes on the physician's right to practice.

Abortion Counseling

Abortion counseling continues to be an emotionally charged debate that involves a woman's right to choose and the right to life. The arguments are both compelling, and the division between opposing viewpoints appears to have no end. Case law continues to develop and expand as new legislation is enacted by the various states and federal courts issue new rulings.

The U.S. Supreme Court in 1983 in *City of Akron v. Akron Center for Reproductive Health*⁶¹ decided that the different states cannot (1) mandate what information physicians give abortion patients or (2) require that abortions for women more than 3 months pregnant be performed in a hospital. With respect to a requirement that the attending physician must inform the woman of specified information concerning her proposed abortion, it was found unreasonable for a state to insist that only a physician is competent to provide information and counseling relative to informed consent. A state may not adopt regulations to influence a woman's informed choice between abortion and childbirth.

With regard to a second-trimester hospital requirement, this could significantly limit a woman's ability to obtain an abortion. This is especially so in view of the evidence that a second-trimester abortion may cost more than twice as much in a hospital as in a clinic.

Undue Burden Rule

In *Planned Parenthood v. Casey*,⁶² the U.S. Supreme Court ruling, as enunciated in *Roe v. Wade*, reaffirmed:

- The constitutional right of women to have an abortion before viability of the fetus, as first enunciated in *Roe v. Wade*
- The state's power to restrict abortions after fetal viability, so long as the law contains exceptions for pregnancies that endanger a woman's life or health
- 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

The U.S. Supreme Court rejected the trimester approach in *Roe v. Wade*, which limited the regulations states could issue on abortion depending on the development stage of the fetus. In place of the trimester approach, the court will evaluate the permissibility of state abortion rules based on whether they unduly burden a woman's ability to obtain an abortion. A rule is an "undue burden" if its purpose or effect is to place a substantial obstacle in the path of a woman seeking an abortion before the fetus attains viability. The Supreme Court ruled that it is "not an undue burden" to require that a woman be informed of the nature of the abortion procedure and the risks involved, be offered information on the fetus and alternatives to abortion, and be given informed consent before the abortion procedure. In addition, it is not an undue burden to require parental consent for a minor seeking an abortion, providing for a judicial bypass option if a minor does not wish to or cannot obtain parental consent, and requiring a 24-hour waiting period before any abortion can be performed.

Funding

Some states have placed an indirect restriction on abortion through the elimination of funding. Under the Hyde Amendment, the U.S. Congress, through appropriations legislation, has limited the types of medically necessary abortions for which federal funds may be spent under the Medicaid program. Although the Hyde Amendment does not prohibit states from funding nontherapeutic abortions, this action by the federal government opened the door to state statutory provisions limiting the funding of abortions.

Denial of Financial Assistance for Elective Abortions

In *Beal v. Doe*⁶³ in 1977, the Pennsylvania Medicaid plan was challenged based on denial of financial assistance for nontherapeutic abortions. The U.S. Supreme Court held that Title XIX of the Social Security Act (the Medicaid program) does not require the funding of nontherapeutic abortions as a condition of state participation in the program. The state has a strong interest in encouraging normal childbirth, and nothing in

Title XIX suggests that it is unreasonable for the state to further that interest. The court ruled that it is not inconsistent with the Medicaid portion of the Social Security Act to refuse to fund unnecessary (although perhaps desirable) medical services.

Also in 1977, in *Maher v. Roe*,⁶⁴ the U.S. Supreme Court considered the Connecticut statute that denied Medicaid benefits for first-trimester abortions that were not medically necessary. The court rejected the argument that the state's subsidy of medical expenses incident to pregnancy and childbirth created an obligation on the part of the state to subsidize the expenses incident to nontherapeutic abortions. The Supreme Court voted six to three that states may refuse to spend public funds to provide nontherapeutic abortions for women.

Funding Not Required for Therapeutic Abortions

In the 1980 *Harris v. McRae* decision,⁶⁵ the U.S. Supreme Court upheld the Hyde Amendment in a five-to-four vote, which restricts the use of federal funds for Medicaid abortions. Under this case, the different states are not compelled to fund Medicaid recipients' medically necessary abortions for which federal reimbursement is unavailable, but they may choose to do so.

Funding Bans Unconstitutional in California

The California Supreme Court in 1981 held that funding bans were unconstitutional; the court asked rhetorically:

If the state cannot directly prohibit a woman's right to obtain an abortion, may the state by discriminatory financing indirectly nullify that constitutional right? Can the state tell an indigent person that the state will provide him with welfare benefits only upon the condition that he join a designated political party or subscribe to a particular newspaper that is favored by the government? Can the state tell a poor woman that it will pay for her needed medical care but only if she gives up her constitutional right to choose whether or not to have a child?⁶⁶

Funding Discrimination Prohibited in Arizona

In 2002, the Arizona Supreme Court found in *Simat Corp. v. Arizona Health Care Cost Containment Sys.*⁶⁷ that the state's constitution does not permit the state and the Arizona Health Care Cost Containment

System (AHCCCS) to refuse to fund medically necessary abortion procedures for pregnant women suffering from serious illness while funding such procedures for victims of rape or incest or when the abortion was necessary to save the woman's life (A.R.S. § 35-196.02. AHCCCS). After the state has chosen to fund abortions for one group of indigent, pregnant women for whom abortions are medically necessary to save their lives, the state may not deny the same option to another group of women for whom the procedure is also medically necessary to save their health. An example is cancer, for which chemotherapy or radiation therapy ordinarily cannot be provided without harming the fetus, making an abortion necessary before proceeding with the recognized medical treatment. Other therapy regimens that must at times be suspended during pregnancy include those for heart disease, diabetes, kidney disease, liver disease, chronic renal failure, inflammatory bowel disease, and lupus. In many of the women suffering from these diseases, suspension of recognized therapy during pregnancy will have serious and permanent adverse effects on their health and lessen their life span. In such a situation, the state is not simply influencing a woman's choice but is actually conferring the privilege of treatment on one economic class and withholding it from another.

A woman's right to choose preservation and protection of her health, and therefore in many cases her life, is at least as compelling as the state's interest in promoting childbirth. The court's protection of the fetus and promotion of childbirth cannot be considered so compelling as to outweigh a woman's fundamental right to choose and the state's obligation to be evenhanded in the design and application of its healthcare policies. The majority of states that have examined similar Medicaid funding restrictions have determined that their state statutes or constitutions offer broader protection of individual rights than does the U.S. Constitution, and they have found that medically necessary abortions should be funded if the state also funds medically necessary expenses related to childbirth. The case was remanded to the trial court for further proceedings consistent with this opinion.

Refusal to Fund Abortion Counseling Not Unconstitutional

Federal regulations that prohibit abortion counseling and referral by family planning clinics that receive funds under Title X of the Public Health Service Act were found not to violate the constitutional rights of pregnant women or Title X grantees in a five-to-four decision by the Supreme Court in *Rust v. Sullivan*.⁶⁸

Proponents of abortion counseling argued that (1) the regulations impermissibly burden a woman's privacy right to abortion, and (2) by prohibiting the delivery of abortion information, even as to where such information could be obtained, the regulations deny a woman her constitutionally protected right to choose under the First Amendment. The question arises: How can a woman make an informed choice between two options when she cannot obtain information as to one of them? The plaintiff had argued that the government may not condition receipt of a benefit on the relinquishment of constitutional rights. In *Sullivan*, however, the Supreme Court found that there was no violation of a woman's or provider's First Amendment rights to freedom of speech. The court extended the doctrine that government need not subsidize the exercise of the fundamental rights to free speech.

Spousal Consent

The following cases describe a variety of issues where the husband's desires conflict with those of the spouse.

Husband's Interest Insufficient

Provisions of the Florida Therapeutic Abortion Act, which required a married woman to obtain the husband's consent before abortion, were found to be unconstitutional in *Poe v. Gerstein*.⁶⁹ The state's interest was found not to be sufficiently compelling to limit a woman's right to abortion. The husband's interest in the baby was held to be insufficient to force his wife to face the mental and physical risks of pregnancy and childbirth.

Husband's Required Consent Unconstitutional

In *Doe v. Zimmerman* (1975),⁷⁰ the court declared unconstitutional the provisions of the Pennsylvania Abortion Control Act, which required that the written consent of the husband of a married woman be secured before performing an abortion. The court found that these provisions impermissibly allowed the husband to withhold his consent either because of his interest in the potential life of the fetus or for capricious reasons. The natural father of an unborn fetus in *Doe v. Smith* (1988)⁷¹ was not entitled to an injunction to prevent the mother from obtaining an abortion. Although the father's interest in the fetus was legitimate, it did not outweigh the constitutionally protected right of the mother to an abortion, particularly in light of evidence that the mother and father had never married.

In the 1992 decision of *Planned Parenthood v. Casey*, the Supreme Court ruled that spousal consent would be an undue burden on the woman.

Parental Consent

A majority of states require parental consent for minors seeking an abortion. Notification of one parent is generally required 24 to 48 hours prior to the abortion. The following cases present a variety of cases demonstrating how the Supreme Court has ruled as the circumstances vary.

Competent Persons Under 18

The U.S. Supreme Court ruled in 1973 in *Danforth v. Planned Parenthood*⁷² that it is unconstitutional to require all women younger than the age of 18 years to obtain parental consent in writing prior to obtaining an abortion. The court, however, failed to provide any definitive guidelines as to when and how parental consent may be required if the minor is too immature to comprehend fully the nature of the procedure.

The U.S. Supreme Court in *Bellotti v. Baird*⁷³ ruled eight to one in 1979 that a Massachusetts statute requiring parental consent before an abortion for an unmarried woman younger than the age of 18 years was unconstitutional. Justice John P. Stevens, joined by Justices William J. Brennan, Jr., Thurgood Marshall, and Harry Blackmun, concluded that the Massachusetts statute was unconstitutional because under that statute, as written and construed by the Massachusetts Supreme Judicial Court, no minor, no matter how mature and capable of informed decision making, could receive an abortion without the consent of either both parents or a Superior Court judge, thus making the minor's abortion subject in every instance to an absolute third-party veto.

Incompetent Person

Abortion was found to be proper by a family court in *In re Doe* (1987)⁷⁴ for a woman who had become pregnant during her residence in a group home as a result of a sexual assault by an unknown person. The record had supported a finding that if the woman had been able to do so, she would have requested the abortion. The court properly chose welfare agencies and the woman's guardian *ad litem* (a guardian appointed to prosecute or defend a suit on behalf of a party incapacitated by infancy, mental incompetence, etc.) as the surrogate decision makers.

In selecting the surrogate decision maker, the trial justice was correct in determining that

the mother's contact with the child over the years of her placement with DCF was of such slight and sporadic quality as to disqualify her from making decisions on behalf of the child. The state agencies, as assisted by the guardian *ad litem*, acted in good faith and in the best interests of the incompetent person who had been placed in the custody of DCF and were properly considered by the court as the appropriate surrogates in attempting to exercise substituted judgment in respect to Jane Doe.⁷⁵

Parental Notification Permitted

The U.S. Supreme Court in 1981 in *H. L. v. Matheson*,⁷⁶ by a six-to-three vote, upheld a Utah statute that required a physician to "notify, if possible" the parents or guardian of a minor on whom an abortion is to be performed. In this case, the physician advised the patient that an abortion would be in her best medical interest but, because of the statute, refused to perform the abortion without notifying her parents. The Supreme Court ruled that although a state may not constitutionally legislate a blanket, unreviewable power of parents to veto their daughter's abortion, a statute setting out a mere requirement of parental notice when possible does not violate the constitutional rights of an immature, dependent minor.

Emancipated Minor

An Alabama trial court in the 1987 case *In re Anonymous*⁷⁷ was found to have abused its discretion when it refused a minor's request for waiver of parental consent to obtain an abortion. The record indicated that the minor lived alone, was within 1 month of her 18th birthday, lived by herself most of the time, and was employed full time.

Parental Notification Not Required

The issue in 2000 in *Planned Parenthood v. Owens*⁷⁸ was whether the Colorado Parental Notification Act,⁷⁹ which requires a physician to notify the parents of a minor prior to performing an abortion upon her, violates the minor's rights as protected by the U.S. Constitution. The act, a citizen-initiated measure, was approved at Colorado's general election. The act generally prohibited physicians from performing abortions on an unemancipated minor until at least 48 hours after written notice has been delivered to the minor's parent, guardian, or foster parent.

The U.S. District Court decided that the act violated the rights of minor women protected by the Fourteenth Amendment. The Supreme Court, for more than a quarter of a century, has required that any abortion regulation make an exception for an abortion that is medically necessary for the preservation of the mother's health. The Colorado act failed to provide such a health exception.

Informed Consent

The Fifth U.S. Circuit Court of Appeals determined that a Texas law requiring a pregnant mother to undergo an ultrasound prior to abortion is constitutional. Although a pregnant woman cannot be compelled to view the ultrasound image, the physician is required to describe what the image shows. The pregnant woman, however, has a concomitant right to refuse to listen to any detailed explanation. Chapter 171 of the Texas Health and Safety Code requires the following as prerequisites for a woman's informed and voluntary consent to an abortion:

- (1) the physician who is to perform the abortion, or a certified sonographer agent thereof, must perform a sonogram on the pregnant woman;
- (2) the physician must display the sonogram images "in a quality consistent with current medical practice" such that the pregnant woman may view them;
- (3) the physician must provide, "in a manner understandable to a layperson," a verbal explanation of the results of the sonogram images, including a variety of detailed descriptions of the fetus or embryo; and
- (4) the physician or certified sonographer agent must "make . . . audible the heart auscultation for the pregnant woman to hear, if present, in a quality consistent with current medical practice and provide . . . , in a manner understandable to a layperson, a simultaneous verbal explanation of the heart auscultation," . . .⁸⁰

States May Protect Fetus

The U.S. Supreme Court in 1979 in *Colautti v. Franklin*⁸¹ voted six to three that states can seek to protect a fetus that a physician has determined could survive outside the womb. Determination of whether a particular fetus is viable is, and must be, a matter for judgment of the responsible attending physician. State abortion regulations that impinge on this

determination, if they are to be constitutional, must allow the attending physician the room that he or she needs to make the best medical judgment.

Abortion Rights Narrowed

*Webster v. Reproductive Health Services*⁸² began the U.S. Supreme Court's narrowing of abortion rights by upholding a Missouri statute providing that no public facilities or employees should be used to perform abortions and physicians should conduct viability tests before performing abortions. The Court stated the statute did not prevent women from obtaining abortion services from private healthcare providers.

The Court also upheld Missouri Revised Statutes section 188.029 requiring physicians to conduct viability tests before performing abortions, when there was reason to believe the fetus had reached at least 20 weeks of gestational age.

Partial Birth Abortion

In 1998, the Supreme Court ruled on the case *Women's Medical Professional Corp. v. Voinovich*,⁸³ which involved an Ohio statute that banned the use of the intact dilation and extraction (D&X) procedure in the performance of any previability or postviability abortion. (The D&X procedure, also referred to colloquially as *partial birth abortion*, is a late-term abortion involving artificial ripening and dilation of the cervix prior to abortion of the fetus so that the aborted fetus may be delivered via the birth canal.) The Sixth Circuit Court of Appeals held that the statute banning any use of the D&X procedure was unconstitutionally vague. It is likely that a properly drafted statute will eventually be judged constitutionally sound.

Partial Birth Abortion Ban Struck Down

On June 28, 2002, the U.S. Supreme Court struck down a Nebraska ban on "partial-birth abortion," finding it an unconstitutional violation of *Roe v. Wade*.⁸⁴ The court found these types of bans to be extreme descriptive attempts to outlaw abortion—even early in pregnancy—that jeopardizes women's health.

Partial-Birth Abortion Ban Unconstitutional

The Partial-Birth Abortion Ban Act, 18 U.S.C. Section 1531, in *National Abortion Fed'n v. Gonzales*,⁸⁵ was found to be unconstitutional because it lacked any exception to preserve the health of the mother, where such exception was constitutionally required. Also, the act was unconstitutional because it imposed an

undue burden on a woman's right to choose previability abortion and was constitutionally vague.

Texas Restrictions on Women's Rights

The U.S. Supreme Court reviewed both the admitting privileges and Ambulatory Surgery Center requirements in Texas Health Bill House Bill 2.⁸⁶ The first provision of HB 2 required:

[a] physician performing or inducing an abortion . . . must, on the date the abortion is performed or induced, have active admitting privileges at a hospital that . . . is located not further than 30 miles from the location at which the abortion is performed or induced.

Previously, Texas law required abortion facilities to maintain a written protocol "for managing medical emergencies and the transfer of patients requiring further emergency care to a hospital."⁸⁷ The second provision of HB 2, referred to as the "surgical center requirement," required:

. . . the minimum standards for an abortion facility must be equivalent to the minimum standards adopted under [the Texas Health and Safety Code section] for ambulatory surgical centers.⁸⁸

Pre-existing Texas law already contained numerous detailed regulations covering abortion facilities, including a requirement that facilities be inspected at least annually. The record contained nothing to suggest that HB 2 would be more effective than pre-existing Texas law at deterring wrongdoers.

The United States Supreme Court struck down Texas's restrictions on a woman's right to choose to have an abortion on June 27, 2016. The Court determined that the two provisions of Texas's HB 2 violated the U.S. Constitution. The provisions of HB 2 did not offer medical benefits sufficient to justify the burdens placed upon women seeking a previability abortion.⁸⁹

State Abortion Statutes

The effect of the Supreme Court's 1973 decisions in *Roe v. Wade* and *Doe v. Smith* was to invalidate all or part of almost every state abortion statute then in force. The responses of state legislatures to these decisions were varied, but it is clear that many state laws had been enacted to restrict the performance of abortions as much as possible. Although *Planned Parenthood v. Casey* was expected to clear up some issues, it

is evident that the states have been given more power to regulate the performance of abortions.

24-Hour Waiting Period Not Burdensome

In 1992, the U.S. Supreme Court in *Planned Parenthood v. Casey*⁹⁰ determined that in asserting an interest in protecting fetal life, a state may place some restrictions on previability abortions, so long as those restrictions do not impose an “undue burden” on the woman’s right to an abortion. The court determined that the 24-hour waiting period, the informed consent requirement, and the medical emergency definitions did not unduly burden the right to an abortion and were therefore constitutional.

The 1993 Utah Abortion Act Revision, Senate Bill 60, provides for informed consent by requiring that certain information be given to the pregnant woman at least 24 hours before performing an abortion. The law allows for exceptions to this requirement in the event of a medical emergency. The Utah Women’s Clinic, in *Utah Women’s Clinic, Inc. v. Leavitt*,⁹¹ filed a 106-page complaint challenging the constitutionality of the new Utah law. It was determined that the 24-hour waiting period did not impose an undue burden on the right to an abortion. On appeal, a U.S. District Court held that the Utah abortion statute’s 24-hour waiting period and informed consent requirements do not render the statute unconstitutionally vague.

Abortions After 20 Weeks Prohibited

Governor Nikki Haley signed bill A183, R196, H3114 into law, prohibiting abortions 20 or more weeks post-fertilization, thus amending the code of laws of South Carolina by adding Article 5 to Chapter 41, Title 44, enacting the “South Carolina Pain-Capable Unborn Child Protection Act.” The South Carolina bill has no provisions for rape or incest. South Carolina is the 13th state to enforce such a ban, along with Alabama, Arkansas, Indiana, Kansas, Louisiana, Mississippi, Nebraska, North Dakota, Oklahoma, Texas, West Virginia, and Wisconsin. The act provides in part:

Section 44-41-440. Except in the case of a medical emergency or fetal anomaly, no abortion must be performed or induced or be attempted to be performed or induced unless the physician performing or inducing it has first made a determination of the probable post-fertilization age of the unborn

child or relied upon such a determination made by another physician. In making such a determination, the physician shall make such inquiries of the woman and perform or cause to be performed such medical examinations and tests as a reasonably prudent physician, knowledgeable about the case and the medical conditions involved, would consider necessary to perform in making an accurate diagnosis with respect to post-fertilization age.

Section 44-41-450. (A) No person shall perform or induce or attempt to perform or induce an abortion upon a woman when it has been determined, by the physician performing or inducing or attempting to perform or induce the abortion or by another physician upon whose determination that physician relies, that the probable post-fertilization age of the woman’s unborn child is twenty or more weeks, except in the case of fetal anomaly, or in reasonable medical judgment, she has a condition which so complicates her medical condition as to necessitate the abortion of her pregnancy to avert her death or to avert serious risk of substantial and irreversible physical impairment of a major bodily function, not including psychological or emotional conditions. No such greater risk must be considered to exist if it is based on a claim or diagnosis that the woman will engage in conduct which she intends to result in her death or in substantial and irreversible physical impairment of a major bodily function.⁹²

Abortions in South Carolina may be performed after 20 weeks only if the mother’s life is in jeopardy. However, there are no exceptions for rape or incest. Physicians who perform illegal abortions can face a \$10,000 fine and up to three years in prison.

Law and Morality of Abortion— Conflicting Beliefs

The abortion issue is obviously one that invokes strong feelings on both sides. Individuals are free to urge support for their cause through debate, advocacy, and participation in the political process. The subject also might be addressed in the courts so long as there are valid legal issues in dispute. Where, however, a case presents no legitimate legal arguments, the courthouse

is not the proper forum. Litigation, or the threat of litigation, should not be used as economic blackmail to strengthen one's hand in the political battle.⁹³

The morality of abortion involves philosophy, ethics, and theology. It is a subject wherein reasonable people adhere to vastly divergent convictions and principles. The obligation of society is to define the liberties of all and not to mandate one's own moral code.⁹⁴

Two or more ethical principles in conflict with one another are considered "ethical dilemmas," such as in the case of abortion. Further complication of ethical dilemmas occurs when laws and regulations affect the decision-making process and, further, when the courts enter the melting pot by interpreting laws and regulations while recognizing the rights of individuals as provided under the U.S. Constitution.

Pro-life advocates argue on constitutional, ethical, and religious grounds that the unborn child has a right to life, and that right must be protected. Pro-choice advocates argue that a woman has a right to choose preservation and protection of her health, and therefore, in many cases, her life is at least as compelling as the state's interest in promoting childbirth. These pose two viewpoints, as different as day and night, involving opposite opinions surrounded by highly charged emotional and religious beliefs as to what is right and what is wrong. Each side has drawn large numbers of supporters, but the law has continued to favor pro-choice.

Dr. Gosnell, a Philadelphia physician, was found guilty of murder in some instances by severing the spinal cord of a fetus during late-term abortions. As noted in part in the *Report of the Grand Jury*:

This case is about a doctor who killed babies and endangered women. What we mean is that he regularly and illegally delivered live, viable, babies in the third trimester of pregnancy—and then murdered these newborns by severing their spinal cords with scissors. The medical practice by which he carried out this business was a filthy fraud in which he overdosed his patients with dangerous drugs, spread venereal disease among them with infected instruments, perforated their wombs and bowels—and on, at least two occasions, caused their deaths. Over the years, many people came to know that something was going on here. But no one put a stop to it.⁹⁵

As noted in the Gosnell *Report of the Grand Jury*, opposing viewpoints stoke the flames of the ongoing abortion controversy in the news media.

NEWS **Philadelphia Abortion Doctor Guilty of Murder in Late-Term Procedures**

While abortion rights groups argued that Dr. Gosnell operated far outside the legalities and norms of women's health care, abortion opponents seized on the case to raise questions about the ethics of late-term abortions. Put simply, they asked why a procedure done to a living baby outside the womb is murder, but destroying a fetus of similar gestation before delivery can be legal.

—John Hurdle and Trip Gabriel,
The New York Times, May 13, 2013

NEWS **Pa. Abortion Provider Convicted of Murder**

... "Some abortionists may have cleaner sheets than Gosnell, and better sterilized equipment and better trained accomplices, but what they do—what Gosnell did—kill babies and hurt women is the same," Rep. Christopher H. Smith (R-NJ) said in a statement.

Meanwhile, abortion-rights groups insisted that Gosnell's crimes are an anomaly and that the abysmal conditions inside his clinic persisted only because numerous regulators ignored red flags for years.

—Brady Dennis, *The Washington Post*, May 14, 2013

To make the right choices in the resolution of ethical dilemmas, it is often necessary to value one ethical principle more than another. The difficulty in the abortion dilemma arises because beliefs, religion, culture, education, and life experiences can differ from person to person. Good people cannot be considered bad people merely because their beliefs differ from another's beliefs. Values differ, and, therefore, determining what is morally right or wrong can differ from person to person. It is certain that the controversies and ethical dilemmas surrounding abortion will continue for many years to come. Preferably common ground can be the beginning point for resolving this emotionally charged dilemma.

The landscape of political contention and differing religious beliefs and values of the human race will forever be a dark side in human history, making these natural phenomena of creation forever debated and written as a black mark in the annals of history. Rather in the

prevention of conception or the abortion of the fetus/unborn child depending on your beliefs will continue to be forever a contentious topic in the world order.

NEWS *Moral Persuasion on Abortion*

If you wish to persuade someone to adopt your viewpoint on any issue, it is usually counter-productive to begin by insulting that person. The reason is simple: Your target is likely to want to defend himself or herself from the insult, and consequently will not be in a position to hear your argument.

—Joseph B. Kadane, *Huffington Post*,
September 27, 2013⁹⁶

► STERILIZATION

Sterilization is the termination of the ability to produce offspring. Sterilization often is accomplished by either a *vasectomy* for men or a tubal ligation for women. A vasectomy is a surgical procedure in which the vas deferens is severed and tied to prevent the flow of the seminal fluid into the urinary canal. A *tubal ligation* is a surgical procedure in which the fallopian tubes are cut and tied, preventing passage of the ovum from the ovary to the uterus. Sterilizations are often pursued for such reasons as:

- Birth control
- Economic necessity
- Therapeutic necessity (e.g., prevent harm to a woman's health)
- Genetic concerns (e.g., prevent birth defects)

Elective Sterilization

Voluntary or *elective sterilizations* on competent individuals present few legal problems, so long as proper consent has been obtained from the patient and the procedure is performed properly. Civil liability for performing a sterilization of convenience may be imposed if the procedure is performed in a negligent manner. Like abortion, voluntary sterilization is the subject of a variety of debates concerning its moral and ethical propriety.

Therapeutic Sterilization

If the life or health of a woman may be jeopardized by pregnancy, the danger may be avoided by terminating: (1) her ability to conceive or (2) her husband's

ability to impregnate. Such an operation is a *therapeutic sterilization*—one performed to preserve life or health. The medical necessity for sterilization renders the procedure therapeutic. Sometimes a diseased reproductive organ has to be removed to preserve the life or health of the individual. The operation results in sterility, although this was not the primary reason for the procedure. Such an operation technically should not be classified as sterilization because it is incidental to the medical purpose.

Eugenic Sterilization

The term *eugenic sterilization* refers to the involuntary sterilization of certain categories of persons described in statutes, without the need for consent by, or on behalf of, those subject to the procedures. Persons classified as mentally deficient, “feebleminded,” and, in some instances, epileptic have been included within the scope of such statutes. Several states also have included certain sexual deviants and persons classified as habitual criminals. Such statutes ordinarily are designed to prevent the transmission of hereditary defects to succeeding generations, but several statutes also have recognized the purpose of preventing procreation by individuals who would not be able to care for their offspring.

Although there have been judicial decisions to the contrary, the United States Supreme Court in *Buck v. Bell*⁹⁷ specifically upheld the validity of such eugenic sterilization statutes, provided that certain procedural safeguards are observed. The U.S. Supreme Court determined:

It is better for all the world, if instead of waiting to execute degenerate offspring for crime, or to let them starve for their imbecility, society can prevent those who are manifestly unfit from continuing their kind. The principle that sustains compulsory vaccination is broad enough to cover cutting the Fallopian tubes. *Jacobson v. Massachusetts*, 197 U.S. 11. Three generations of imbeciles are enough.⁹⁸

Several states have laws authorizing eugenic sterilization. The decision in *Wade v. Bethesda Hospital*⁹⁹ strongly suggests that in the absence of statutory authority the state cannot order sterilization for eugenic purposes. Eugenic sterilization statutes provide the following: a grant of authority to public officials supervising state institutions for the mentally ill or prisons and to certain public health officials to conduct sterilizations; a requirement of personal notice to the person subject to sterilization and, if that person is unable to comprehend what is involved, notice to the person's

legal representative, guardian, or nearest relative; a hearing by the board designated in the particular statute to determine the propriety of the prospective sterilization; at the hearing, evidence that may be presented, and the patient, who must be present or represented by counsel or the nearest relative or guardian; and an opportunity to appeal the board's ruling to a court.

The procedural safeguards of notice, hearing, and the right to appeal must be present in sterilization statutes to fulfill the minimum constitutional requirements of due process. An Arkansas statute was found to be unconstitutional in that it did not provide for notice to the incompetent patient and opportunity to be heard or for the patient's entitlement to legal counsel.¹⁰⁰

Case Studies

Negligent Sterilization

Dr. Kenneth Chaffee performed a partial salpingectomy on Heather Seslar. The purpose of the procedure was to sterilize Seslar, who had already borne four children, so that she could not become pregnant again. After undergoing the surgery, however, Seslar conceived and delivered a healthy baby. Seslar sued Chaffee.

The Court of Appeals held in *Chaffee v. Seslar* that damages for the alleged negligent sterilization procedure could not include the costs of raising a normal healthy child. Although raising an unplanned child is costly, all human life is presumptively invaluable. A child, regardless of the circumstances of birth, does not constitute harm to the parents so as to permit recovery for the costs associated with raising and educating the child. As with a majority of jurisdictions, the court held that the value of a child's life to the parents outweighs the associated pecuniary burdens as a matter of law. Recoverable damages may include pregnancy and childbearing expenses but not the ordinary costs of raising and educating a normal, healthy child conceived after an allegedly negligent sterilization procedure.¹⁰¹

Ethical and Legal Issues

1. Do you agree with the court's decision?
2. Under what circumstances would you not agree with the court's decision?
3. Describe the ethical issues in this case.

► WRONGFUL BIRTH, LIFE, AND CONCEPTION

The improper performance of sterilization can result in lawsuits based on such theories as *wrongful birth*, *wrongful life*, and *wrongful conception*. Wrongful life suits are generally unsuccessful, primarily because of the court's unwillingness, for public policy reasons, to permit financial recovery for the "injury" of being born into the world.

Some success, however, has been achieved in litigation by the patient (and his or her spouse) who allegedly was sterilized and subsequently proved fertile. Damages have been awarded for the cost of the unsuccessful procedure; pain and suffering as a result of the pregnancy; the medical expense of the pregnancy; and the loss of comfort, companionship services, and consortium of the spouse. Again, as a matter of public policy, the courts have indicated that the joys and benefits of having the child outweigh the cost incurred in the rearing process.

There have been many cases in recent years involving actions for wrongful birth, wrongful life, and

wrongful conception. Litigation originated with the California case in which a court found that a genetic testing laboratory could be held liable for damages from incorrectly reporting genetic tests, leading to the birth of a child with defects.¹⁰² Injury caused by birth had not been previously actionable by law. The court of appeals held that medical laboratories engaged in genetic testing owe a duty to parents and their unborn child to use ordinary care in administering available tests for the purpose of providing information concerning potential genetic defects in the unborn. Damages in this case were awarded on the basis of the child's shortened life span.

Wrongful Birth

In a wrongful birth action, the plaintiffs claim that but for a breach of duty by the defendant(s) (e.g., improper sterilization), the child would not have been born. A wrongful birth claim can be brought by the parent(s) of a child born with genetic defects against a physician who or a laboratory that negligently fails to inform them, in a timely fashion, of an increased possibility that the mother will give birth to such a child, therefore precluding an informed decision as to whether to have the child.

In a New Jersey case, *Canesi ex rel. Canesi v. Wilson*,¹⁰³ the New Jersey Supreme Court reviewed the dismissal of an action for wrongful birth on the claim of the parents that had the mother been informed of the risk that a drug, Provera, which she had been taking before she learned that she was pregnant, might cause the fetus to be born with congenital anomalies such as limb reduction, she would have decided to abort the fetus. It was alleged that the physicians failed to disclose the risks associated with the drug. The physicians argued that the informed consent doctrine requires that the plaintiffs establish that the drug in fact caused the birth anomalies. The court rejected the argument and distinguished the wrongful birth action from one based on informed consent:

In sum, the informed consent and wrongful birth causes of action are similar in that both require the physician to disclose those medically accepted risks that a reasonably prudent patient in the plaintiff's position would deem material to her decision. What is or is not a medically acceptable risk is informed by what the physician knows or ought to know of the patient's history and condition. These causes of action, however, have important differences. They encompass different compensable harms and measures of damages. In both causes of action, the plaintiff must prove not only that a reasonably prudent patient in her position, if apprised of all material risks, would have elected a different course of treatment or care. In an informed consent case, the plaintiff must additionally meet a two-pronged test for proximate causation: She must prove that the undisclosed risk actually materialized and that it was medically caused by the treatment. In a wrongful birth case, on the other hand, a plaintiff need not prove that the doctor's negligence was the medical cause of her child's birth defect. Rather, the test of proximate causation is satisfied by showing that an undisclosed fetal risk was material to a woman in her position; the risk materialized was reasonably foreseeable and not remote in relation to the doctor's negligence; and had plaintiff known of that risk, she would have terminated her pregnancy. The emotional distress and economic loss resulting from this lost opportunity to decide for herself whether or not to terminate the pregnancy constitute plaintiff's damages.¹⁰⁴

With the increasing consolidation of hospital services and physician practices, a case could be made for

finding a hospital liable for the physician's failure to obtain informed consent where the hospital actually owns or controls the physician's practice or where both the hospital and the physician's practice are owned or controlled by another corporation that sets policy for both the hospital and the physician's practice.

Wrongful Life

Wrongful life claims are initiated by the parent(s) or child based on harm suffered as a result of being born. The plaintiffs generally contend that the physician or laboratory negligently failed to inform the child's parents of the risk of bearing a genetically defective infant and hence prevented the parents' right to choose to avoid the birth.¹⁰⁵ Because there is no recognized legal right not to be born, wrongful life cases are generally not successful.

[L]egal recognition that a disabled life is an injury would harm the interests of those most directly concerned, the handicapped. Disabled persons face obvious physical difficulties in conducting their lives. They also face subtle yet equally devastating handicaps in the attitudes and behavior of society, the law, and their own families and friends. Furthermore, society often views disabled persons as burdensome misfits. Recent legislation concerning employment, education, and building access reflects a slow change in these attitudes. This change evidences a growing public awareness that the handicapped can be valuable and productive members of society. To characterize the life of a disabled person as an injury would denigrate both this new awareness and the handicapped themselves.¹⁰⁶

A cause of action for wrongful life was not cognizable under Kansas law in *Bruggeman v. Schimke*.¹⁰⁷ Human life is valuable, precious, and worthy of protection. An evaluation that says it is more worthwhile to not be born rather than to be alive with deformities cannot be recognized. The Kansas Supreme Court held that there was no recognized cause for wrongful life.

In *Kassama v. Magat*,¹⁰⁸ Millicent Kassama alleged that Dr. Aaron Magat failed to advise her of the results of an alpha-fetoprotein blood test that indicated a heightened possibility that her child, Ibrion, might be afflicted with Down syndrome. Had she received that information, Kassama contends, she would have undergone amniocentesis, which would have confirmed that prospect. Kassama claims that if that had

occurred she would have chosen to terminate the pregnancy through an abortion.

The Supreme Court of Maryland decided that for purposes of tort law, an impaired life was not worse than nonlife, and, for that reason, life itself was not and could not be considered an injury. There was no evidence that Ibrion was not deeply loved and cared for by her parents, nor that she did not return that love. Studies have shown that people afflicted with Down syndrome can lead productive and meaningful lives. They can be educated and employed, form friendships, and get along in society. Allowing a recovery of extraordinary life expenses on some theory of fairness—that the physician or his or her insurance company should pay not because the physician was negligent causing the injury or impairment but because the child was born—ignores that fundamental issue.

Wrongful birth is based on the premise that being born and having to live with the affliction are disadvantages and thus cognizable injuries. The injury sued upon was the fact that Ibrion was born; she bears the disability and will bear the expenses only because, due to the alleged negligence of Magat, her mother was unable to terminate the pregnancy and avert her birth. The issue here is whether Maryland law is prepared to recognize that kind of injury—the injury of life itself.

The child has not suffered any damage cognizable at law by being brought into existence. One of the most deeply held beliefs of our society is that life, whether experienced with or without a major physical handicap, is more precious than nonlife. No one is perfect, and each person suffers from some ailments or defects (whether major or minor) that make impossible participation in all of the activities life has to offer. Our lives are not thereby rendered less precious than those of others whose defects are less pervasive or less severe. Despite their handicaps, Down syndrome children are able to love and be loved and to experience happiness and pleasure—emotions that are truly the essence of life and that are far more valuable than the suffering that may be endured.

The right to life and the principle that all are equal under the law are basic to our constitutional order. To presume to decide that a child's life is not worth living would be to forsake these ideals. To characterize the life of a disabled person as an injury would denigrate the handicapped themselves. Measuring the value of an impaired life as compared with nonexistence is a task that is beyond mortals.

Unless a judgment can be made on the basis of reason rather than the emotion of any given case, that nonlife is preferable to impaired life—that the child-plaintiff would, in fact, have been better off had he or she

never been born—there can be no injury, and if there can be no injury, whether damages can or cannot be calculated becomes irrelevant.

The crucial question, a value judgment about life itself, is too deeply immersed in each person's own individual philosophy or theology to be subject to a reasoned and consistent community response in the form of a jury verdict.

Wrongful Conception

Wrongful conception refers to a claim for damages sustained by the parents of an unexpected child based on an allegation that conception of the child resulted from negligent sterilization procedures or a defective contraceptive device.¹⁰⁹ Damages sought for a negligently performed sterilization might include:

- Pain and suffering associated with pregnancy and birth
- Expenses of delivery
- Lost wages
- Father's loss of consortium
- Damages for emotional or psychological pain
- Suffering resulting from the presence of an additional family member in the household
- The cost and pain and suffering of a subsequent sterilization
- Damages suffered by a child born with genetic defects

The most controversial item of damages claimed is that of raising a normal healthy child to adulthood. The mother in *Hartke v. McKelway*¹¹⁰ had undergone sterilization for therapeutic reasons to avoid endangering her health from pregnancy. The woman became pregnant as a result of a failed sterilization. She delivered a healthy child without injury to herself. It was determined that “the jury could not rationally have found that the birth of this child was an injury to this plaintiff. Awarding child-rearing expense would only give Hartke a windfall.”¹¹¹

The cost of raising a healthy newborn child to adulthood was recoverable by the parents of the child conceived as a result of an unsuccessful sterilization by a physician employee at Lovelace Medical Center. The physician in *Lovelace Medical Center v. Mendez*¹¹² found and ligated only one of the patient's two fallopian tubes and then failed to inform the patient of the unsuccessful operation. The court held that:

. . . the Mendezes' interest in the financial security of their family was a legally protected interest which was invaded by Lovelace's negligent failure properly to perform

Maria's sterilization operation (if proved at trial), and that this invasion was an injury entitling them to recover damages in the form of the reasonable expenses to raise Joseph to maturity.¹¹³

Some states bar damage claims for emotional distress and the costs associated with the raising of healthy children but will permit recovery for damages related to negligent sterilizations. In *Butler v. Rolling Hill Hospital*,¹¹⁴ the Pennsylvania Superior Court held that the patient stated a cause of action for the negligent performance of a laparoscopic tubal ligation. The patient was not, however, entitled to compensation for the costs of raising a normal, healthy child. "In light of this Commonwealth's public policy, which recognizes the paramount importance of the family to society, we conclude that the benefits of joy, companionship, and affection which a normal, healthy child can provide must be deemed as a matter of law to outweigh the costs of raising that child."¹¹⁵

As the Court of Common Pleas of Lycoming County, Pennsylvania, in *Shaheen v. Knight*, stated:

Many people would be willing to support this child were they given the right of custody and adoption, but according to plaintiff's statement, plaintiff does not want such. He wants to have the child and wants the doctor to support it. In our opinion, to allow such damages would be against public policy.¹¹⁶

► ARTIFICIAL INSEMINATION

Artificial insemination is the process by which sperm is placed into the reproductive tract of a female, for the purpose of impregnating the female by using means other than sexual intercourse. There are two sources of the sperm for impregnation of a female: homologous artificial insemination involves the use of the husband's semen to impregnate the female; and heterologous artificial insemination (HAI) involves the use of semen from a donor other than a woman's husband. The absence of answers to many questions concerning HAI may discourage couples from seeking to use the procedure and physicians from performing it. Some of the questions concern the procedure itself; others concern the status of the offspring, the effect of the procedure on the marital relationship, and the risk of multiple births that can be financially challenging.

Further worrying is the potential for legal actions for multiple births, which even led to the loss of a

physician's license to practice medicine when the Medical Board of California revoked Dr. Michael Kamrava's medical license after he transplanted multiple embryos, resulting in the birth of octuplets. The Medical Board determined that Dr. Kamrava had acted beyond the reasonable judgment of a physician by implanting a number of embryos that exceeded existing guidelines:

The Board subsequently found Kamrava guilty of gross negligence, repeated negligent acts, and inadequate medical records in the first case. In the additional two cases, Kamrava was found guilty of gross negligence and repeated negligent acts in one case and guilty of repeated negligent acts in the other case.¹¹⁷

Consent

The Oklahoma HAI statute specifies that husband and wife must consent to the procedure.¹¹⁸ It is clear that the wife's consent must be obtained; without it, the touching involved in the artificial insemination would constitute a battery. Besides the wife's consent, it is important to obtain the husband's consent to ensure against liability accruing if a court adopted the view that without the consent of the husband, HAI was a wrong to the husband's interest, for which he could sustain a suit for damages.

The Oklahoma statute also deals with establishing proof of consent. It requires the consent to be in writing, and it must be executed and acknowledged by the physician performing the procedure and by the local judge who has jurisdiction over the adoption of children, as well as by the husband and wife.

In states without specific statutory requirements, medical personnel should attempt to avoid such potential liability by establishing the practice of obtaining the written consent of the couple requesting the HAI procedure. The hospital's legal counsel should be consulted with in order to ensure that hospital policy is in compliance with statutory requirements.

Confidentiality

Another problem that directly concerns medical personnel involved in heterologous artificial insemination birth is preserving confidentiality. This problem is met in the Oklahoma HAI statute, which requires that the original copy of the consent be filed pursuant to the rules for filing adoption papers and is not to be made a matter of public record.¹¹⁹

► SURROGACY

Surrogacy is a method of reproduction whereby a woman agrees to give birth to a child she will not raise but hand over to a contracted party, who is often unable to conceive a natural child of her or his own. A surrogate “may be the child’s genetic mother (the more traditional form of surrogacy), or she may as a gestational carrier, carry the pregnancy to delivery after having been implanted with an embryo. In some cases, surrogacy is the only available option for parents who wish to have a child that is biologically related to them.”¹²⁰

Surrogacy raises a variety of ethical and legal issues that should be considered before searching for a surrogate mother. For example, is it ethical to enter a contract with a woman by offering her money in exchange for bearing a child and then transferring all parental rights and physical custody of the child to the “commissioning couple”? Although the long-term effects of surrogacy contracts are not known, the adverse psychological impact could be detrimental to the child who learns that he or she is the offspring of someone who gave birth only to obtain money. Would the child want to search for his or her gestational mother? Should records be kept, and should the child have access to the records? After the child is taken, the surrogate mother may be negatively affected as her feeling of isolation is felt along with the reality of the sale of her body.

Some believe that the surrogacy contract is based on principles that are contrary to the objectives of our laws. The surrogate contract is perceived to be illegal when a fee is involved because it is compared with baby selling, which is illegal in all states. Court decisions and legislation in the United States have historically been split on how they address surrogacy contracts. In the District of Columbia, as of April 7, 2017, surrogacy contracts are legal and enforceable. The law offered guidelines for parents and surrogates entering into surrogacy contracts and established how the intended parents should legally assert their parental rights.¹²¹

A BILL 21-16

ENGROSSED ORIGINAL

IN THE COUNCIL OF THE DISTRICT OF COLUMBIA

To amend Chapter 4 of Title 16 of the District of Columbia Official Code to permit collaborative reproduction and surrogacy agreements, establish requirements for surrogates, intended parents, and the contents of surrogacy agreements, establish parentage of a

child, provide for court orders of parentage, and establish the effect of a subsequent marriage or domestic partnership, dissolution of a marriage or domestic partnership, death of an intended parent, and withdrawal of consent.¹²²

Although there are arguments offered for and against surrogacy contracts, there are many parents who have experienced the joy of raising happy, psychologically well-balanced, and career-successful surrogate children. Those who have done their research and understand the issues live as happy together as those in any other family relationship.

► ORGAN DONATIONS

Becoming a Donor

Organ and tissue donation and transplantation provide a second chance at life for thousands of people each year. You have the opportunity to be one of the individuals who make these miracles happen.

By deciding to be a donor, you give the gift of hope . . . hope for the thousands of individuals awaiting organ transplants and hope for the millions of individuals whose lives could be enhanced through tissue transplants. [organdonor.gov.]

—U.S. Department of Health and Human Services¹²³

There were approximately 114,895 people as of April 8, 2018, on the the Organ Procurement Transplant Network waiting for an organ transplant. Only 5,448 organ transplantations from 2,677 donors had been performed as of this same date.¹²⁴ To help resolve the shortage of donors, every eligible adult is encouraged to register in their state as a donor.¹²⁵

Federal regulations require that hospitals have and implement written protocols regarding their organ procurement responsibilities. The regulations impose specific notification duties, as well as other requirements concerning informing families of potential donors. It encourages discretion and sensitivity in dealing with the families and in educating hospital staff on a variety of issues involved with donation matters in order to facilitate timely donation and transplantation.

Organ transplantations are performed to treat patients with end-stage organ disease who face organ failure. Developments in medical science have enabled physicians to take tissue from persons immediately after death for use in replacing or rehabilitating diseased or damaged organs or other parts of living

persons. Interest in organ transplantation increased in 1954 when the Herrick twins became the first successful kidney transplant.¹²⁶ The success rates of organ transplants have improved because of advances in the patient selection process, improved clinical and operative management and skills, and immunosuppressant drugs that aid in decreasing the incidence of tissue rejection (e.g., cyclosporin A, which acts to suppress the production of antibodies that attack transplanted tissue); nevertheless, this progress has created the problem of obtaining a sufficient supply of replacement body parts. There is a corresponding cry for more organs as the success rate in organ transplantation increases. Because of the fear of people buying and selling organs, the National Organ Procurement Act was enacted in 1984, making it illegal to buy or sell organs. Throughout the country, there are tissue banks and other facilities that store and preserve organs and tissue that can be used for transplantation and other therapeutic services.

The ever-increasing success of organ transplants and the demand for organ tissue require the close scrutiny of each case, to make sure that established procedures have been followed in the care and disposal of all body parts. Section 1138, Title XI, of the Omnibus Budget Reconciliation Act of 1986 requires hospitals to establish organ procurement protocols or face a loss of Medicare and Medicaid funding. Physicians, nurses, and other paramedical personnel assigned this responsibility often are confronted with several legal issues. Liability can be limited by complying with applicable regulations. Organs and tissues to be stored and preserved for future use must be removed almost immediately after death; therefore, it is imperative that an agreement or arrangement for obtaining organs and tissue from a body be completed before death, or very soon after death, to enable physicians to remove and store the tissue promptly. Mark Zuckerberg, chairman and CEO of Facebook, launched an organ donation campaign in 2012 encouraging its users to help spread awareness of the need for organ donations.¹²⁷

Some people may wish to make arrangements for the use of their bodies after death for such purposes. A surviving spouse may, however, object to such disposition. In such cases, the interest of the surviving spouse or other family member could supersede that of the deceased.

Who Lives? Who Dies? Who Decides?

Who lives? Who dies? Who decides? These are but a few of the ethical questions that arise when deciding to whom an organ shall be given. The answers are not easy. The decision makers, even with guidelines to

follow, often become the judge and jury and often find that the answers to questions such as who lives and dies are not always easy decisions to make. If there were unlimited sources of organs, there would be no supply-and-demand issues. Because supply is limited, numerous ethical principles come into play. In the case of a 70-year-old patient with multiple life-threatening health problems, the patient may not be considered a suitable candidate for a transplant, whereas a 15-year-old patient with few health issues would be considered a more appropriate candidate.

Uniform Anatomical Gift Act

The American Bar Association endorsed a *Uniform Anatomical Gift Act* drafted by the Commission on Uniform State Laws. This statute has been enacted by all 50 states and has many detailed provisions that apply to the wide variety of issues raised in connection with the making, acceptance, and use of anatomical gifts. The act allows a person to make a decision to donate organs at the time of death and allows potential donors to carry an anatomical donor card. State statutes regarding donation usually permit the donor to execute the gift during his or her lifetime.

The right to privacy of the donor and his or her family must be respected. Information should not be publicized regarding transplant procedures as well as the names of the donor or donee without consent.

States have enacted legislation to facilitate donation of bodies and body parts for medical uses. Virtually all of the states have based their enactments on the Uniform Anatomical Gift Act, but it should be recognized that in some states there are deviations from this act or additional laws dealing with donation.

Individuals who are of sound mind and 18 years of age or older are permitted to dispose of their own bodies or body parts by will or other written instrument for medical or dental education, research, advancement of medical or dental science, therapy, or transplantation. Among those eligible to receive such donations are any licensed, accredited, or approved hospitals; accredited medical or dental schools; surgeons or physicians; tissue banks; or specified individuals who need the donation for therapy or transplantation. The statute provides that when only a part of the body is donated, custody of the remaining parts of the body shall be transferred to the next of kin promptly after removal of the donated part.

A donation by will becomes effective immediately on the death of the testator, without probate, and the gift is valid and effective to the extent that it has been acted on in good faith. This is true even if the will is not probated or is declared invalid for testimonial purposes.

Failure to Obtain Consent

Although failure to obtain consent for removal of body tissue can give rise to a lawsuit, not all such claims are successful. In *Nicoletta v. Rochester Eye & Human Parts Bank*,¹²⁸ emotional injuries resulted from the removal of the eyes of Nicoletta's son for donation after a fatal motorcycle accident. The hospital was immune from liability under the provisions of the Uniform Anatomical Gift Act because the hospital had neither actual nor constructive knowledge that the woman who had authorized the donation was not the decedent's wife. The hospital was entitled to the immunity afforded by the "good faith" provisions of Section 4306(3) of the act, under which its agents had made reasonable inquiry as to the status of the purported wife, who had resided with the decedent for 10 years and was the mother of their two children. The hospital had no reason to believe that any irregularity existed. The father, who was present at the time his son was brought to the emergency department, failed to object to any organ donation and failed to challenge the authority of the purported wife to sign the emergency department authorization.

There are several methods by which an organ or tissue donation authorization may be revoked. If the document has been delivered to a named receiving agency (such as a hospital or a surgeon expected to perform the extraction of donated tissues), it may be revoked by:

- A written revocation signed by the donor and delivered to the receiving agency
- An oral revocation witnessed by two persons and communicated to the receiving agency
- A statement to the attending physician during a terminal illness that has been communicated to the receiving agency
- A written statement that has been signed and is on the donor's person or in the donor's immediate effects

If the written instrument of donation has not been delivered to the receiving agency, the tissue donation may be revoked by destruction, cancellation, or mutilation of the instrument. If the donation is made by a will, it may be revoked in the manner provided for revocation or amendment of wills. Any person acting in good-faith reliance on the terms of an instrument of donation will not be subject to civil or criminal liability unless there is actual notice of the revocation of the donation.

Altruism vs. Sale of Organs

The shortage of organs has led to organs "being trafficked, sometimes with, and sometimes without, the consent of those to whom they belong. People have

been directly, or indirectly, being forced to sell their own organs for a low price, often to middlemen, who make thousands of Euros from poor vulnerable persons."¹²⁹

Iran addressed by legislation the shortage of organs in 1988 by allowing Iranians to sell a kidney with what has been described as a successful government decision.

In the 1980s, Iran had both a shortage of legally donated kidneys and subpar dialysis equipment to treat the growing segment of the population with end-stage renal disease (ESRD). It *did* have highly trained surgeons capable of performing organ transplants, though. So in 1988, the nation decided on a bold (and somewhat controversial) new strategy to eliminate the dangers that come with procuring or receiving an organ illegally: they made it legal for a living person to sell their kidney.

Nearly three decades later, Iran is one of the few nations without an organ shortage—every Iranian who needs a kidney can receive one. Should other nations follow suit?¹³⁰

The attempt to encourage people to voluntarily be placed on donor lists for organ transplantations has proven to be of limited success. The number of people waiting for an organ and waiting times indicate the need to provide other options such as the approach Iran, for example, has taken.

Because the organ shortage has become more severe worldwide, some from the transplant community believe that altruism alone is not enough to satisfy the needs of the thousands of patients who are on renal transplant waiting lists and that providing some financial incentives or social benefits is necessary to increase the number of deceased or living organ donations.

As mentioned, there is no role for a broker or an agency in this transplantation program. The association for patients with ESRD [end-stage renal disease] is a charitable organization and receives no incentives from donors or recipients. The government pays for all hospital expenses of renal transplantation. The medical and surgical fees for transplantation are greatly lower compared with the fees for similar services.

All transplant candidates who are poor receive renal transplantation. The elimination of renal transplant waiting lists means that

all patients with ESRD, either rich or poor, have equal access to renal transplant facilities; otherwise, many poor patients would remain on the renal transplant waiting list. The main reason for this equal access is the active role of charitable organizations that pay for many expenses of renal transplantation that the poor patients cannot afford.¹³¹

Altruism, which entails the unselfish regard or devotion for the welfare of others, has not generated sufficient public interest in helping others in the time of crisis. This may be due to the fear of being transported to an emergency department and being hastily declared not able to survive the injuries sustained, and therefore the organs are harvested for others on the donor list. Although there are safeguards to help prevent this from happening, there is always a risk, however remote, that the interest in declaring the patient unable to survive may have been for some cruel or selfish reason. Failure to obtain a sufficient number of organs may also be due to complacency and lack of knowledge. Whether by greed or financial crisis, donors who sell their organs are solving the problem in Iran. Therefore, it can be argued that more consideration should be given to enacting legislation allowing for each individual to pursue the option of selling his organ(s).

► RESEARCH, EXPERIMENTATION, AND CLINICAL TRIALS

Medical progress and improved patient care are dependent on advances in medicine made through research. Research studies are designed to answer specific questions, including a drug's or device's safety and effectiveness. Ethical considerations, to name but a few, that should be addressed when conducting research on human subjects include honesty, integrity, autonomy; self-determination; the Hippocratic maxim of do no harm; the application of justice; and how to fairly conduct blind trials. The basic principle of research is honesty, which must be ensured through institutional protocols. Honesty and integrity must govern all stages of research.

Federal regulations control federal grants that apply to experiments involving new drugs, new medical devices, or new medical procedures. Generally, a combination of federal and state guidelines and regulations ensures proper supervision and control over experimentation that involves human subjects. For example, federal regulations require hospital-based

researchers to obtain the approval of an *institutional review board*.

The science of medicine, which by its very nature studies the human body, is prevented from making progress through direct experimentation. A necessary part of research is to conduct laboratory tests on animals and observe their effects prior to testing them on humans. Advances in research occur by observation and study of how a normal, healthy body functions and when the body malfunctions, studying the cause of those changes that occur and finding a way to slow and possibly reverse the progression of a disease.

Right to Try Experimental Drugs

The U.S. Senate unanimously passed the “Right to Try Bill” in August 2017 that would allow terminally ill patients the right to access experimental treatments without oversight by the Food and Drug Administration. The House of Representatives, on March 21, 2018, passed a bill allowing patients the right to try experimental drugs prior to FDA approval.

NEWS *House Passes Bill That Would Give Patients Access to Experimental Drugs*

WASHINGTON—The House, spurred on by President Trump, passed a bill on Wednesday that would give patients with terminal illnesses a right to try unproven experimental treatments.

The measure, which was approved by a vote of 267 to 149, appears to have a good chance of becoming law. The Senate approved a similar proposal last year.

Supporters said the bill would give dying patients a chance to obtain potentially helpful prescription drugs without waiting for the completion of clinical trials or going through a process established by the Food and Drug Administration to allow the use of “investigational drugs” outside clinical trials.

—Robert Pear, *The New York Times*, March 21, 2018¹³²

The contents of that bill are provided in part here. This Act may be cited as the “Right to Try Act of 2017”.

SEC. 2. USE OF UNAPPROVED MEDICAL PRODUCTS BY PATIENTS DIAGNOSED WITH A TERMINAL ILLNESS.

(a) In General.—Notwithstanding the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301

et seq.), the Controlled Substances Act (21 U.S.C. 801 et seq.), and any other provision of Federal law, the Federal Government shall not take any action to prohibit or restrict—

- (1) the production, manufacture, distribution, prescribing, or dispensing of an experimental drug, biological product, or device that—
 - (A) is intended to treat a patient who has been diagnosed with a terminal illness; and
 - (B) is authorized by, and in accordance with, State law; and
 - (2) the possession or use of an experimental drug, biological product, or device—
 - (A) that is described in subparagraphs (A) and (B) of paragraph (1); and
 - (B) for which the patient has received a certification from a physician, who is in good standing with the physician's certifying organization or board, that the patient has exhausted, or otherwise does not meet qualifying criteria to receive, any other available treatment options.
- (b) No Liability or Use of Outcomes.—
- (1) No liability.—Notwithstanding any other provision of law, no liability shall lie against a producer, manufacturer, distributor, prescriber, dispenser, possessor, or user of an experimental drug, biological product, or device for the production, manufacture, distribution, prescribing, dispensing, possession, or use of an experimental drug, biological product, or device that is in compliance with subsection (a).
 - (2) No use of outcomes.—Notwithstanding any other provision of law, the outcome of any production, manufacture, distribution, prescribing, dispensing, possession, or use of an experimental drug, biological product, or device that was done in compliance with subsection (a) shall not be used by a Federal agency reviewing the experimental drug, biological product, or device to delay or otherwise adversely impact review or approval of such experimental drug, biological product, or device.¹³³

Approval by the Senate of this bill was pending at the time of this writing. At the state level, 38 states have passed similar laws.

Office of Research Integrity

The Office of Research Integrity (ORI) oversees and directs Public Health Service (PHS) research integrity activities on behalf of the Secretary of Health and Human Services with the exception of the research integrity activities of the Food and Drug Administration. The ORI carries out its responsibility by developing policies, procedures, and regulations related to the detection, investigation, and prevention of research misconduct and the responsible conduct of research. The ORI is responsible for implementing activities and programs to teach the responsible conduct of research, promote research integrity, prevent research misconduct, and improve the handling of allegations of research misconduct. The ORI administers programs for: maintaining institutional assurances, responding to allegations of retaliation against whistleblowers, approving intramural and extramural policies and procedures, and responding to Freedom of Information Act and Privacy Act requests.

Food and Drug Administration

The Food and Drug Administration (FDA) regulates the conduct of clinical trials. A variety of regulations that describe good clinical practices for studies with both human and nonhuman animal subjects are listed next. More detail on these and other research-related regulations can be found at the FDA website:¹³⁴

- Electronic records
- Protection of human subjects
- Informed consent elements
- Financial disclosure by investigators
- Institutional review boards
- Investigational drug new application
- Investigational device exemptions
- Good laboratory practice for nonclinical laboratory studies
- Expanded access to investigational drugs for treatment

The FDA—after much criticism over the years because of the red tape involved in the approval of new drugs—issued new rules to speed up the approval process. The rules permit the use of experimental drugs outside a controlled clinical trial if the drugs are used to treat a life-threatening condition. In *Abigail Alliance for Better Access to Developmental Drugs v. Eschenbach*, the U.S. Court of Appeals for the District of Columbia ruled that terminally ill patients have a “fundamental right” protected by the U.S. Constitution to access experimental drugs that have not yet been fully approved by the FDA. The appeals court ruled that

once the FDA has determined, after Phase I trials, that a potentially lifesaving new drug is sufficiently safe for expanded human trials, terminally ill patients have a constitutional right to seek treatment with the drug if no other FDA-approved drugs are available. The court said that if the FDA wishes to prevent such patients from gaining access to investigational drugs that have completed Phase I trials, it bears the burden of demonstrating that its restrictions are “narrowly tailored” to serve a compelling governmental interest.

Patients participating in research studies should fully understand the implications of their participation. Healthcare organizations involved in research studies should have appropriate protocols in place that protect the rights of patients. Consent forms should describe both the risks and benefits involved in the research activity.

Institutional Review Board

Healthcare organizations conducting medical research must have a mechanism in place for approving and overseeing the use of investigational protocols. This is accomplished through the establishment of an institutional review board (IRB). An IRB is a committee designated by organizations (e.g., hospitals) conducting clinical trials to provide initial approval and periodic monitoring of biomedical research studies. The primary responsibilities of an IRB include:

- Protecting the rights and welfare of human subjects
- Ensuring protocols are presented by the sponsor(s)
- Ensuring sponsor(s) of a protocol discloses
 - Areas of concern that might give the impression of a conflict of interest in the outcome of the clinical research
 - Financial interests that might occur should the clinical trials prove to be successful or give the impression of success, including stock options and cash payouts
 - Reviewing, monitoring, and approving clinical protocols for investigations of drugs and medical devices involving human subjects
 - Ensuring that the rights, including the privacy and confidentiality, of each individual are protected
 - Ensuring that all research is conducted within appropriate state and federal guidelines (e.g., FDA guidelines)

Under FDA regulations, an IRB is an appropriately constituted group that has been formally designated to review and monitor biomedical research involving human subjects. In accordance with FDA regulations, an

IRB has the authority to approve, require modifications in (to secure approval), or disapprove research. This group review serves an important role in the protection of the rights and welfare of human research subjects.

The purpose of IRB review is to assure, both in advance and by periodic review, that appropriate steps are taken to protect the rights and welfare of humans participating as subjects in the research. To accomplish this purpose, IRBs use a group process to review research protocols and related materials (e.g., informed consent documents and investigator brochures) to ensure protection of the rights and welfare of human subjects of research.¹³⁵

Informed Consent

NEWS Patients Involved in Clinical Trial Understand Risks

My husband . . . participated in a clinical trial involving both an autologous (self) and allogeneic (donor) transplant for a hopeful cure of the disease. We both understood the risks involved and the no-promise guarantee, as such is the nature of a clinical trial. The ultimate responsibility for whatever the outcome rested with us, as we were the ones who voluntarily entered into the program. Three years later, we have just learned of the disease's progression, but we continue to look forward, remain optimistic, and support those who dedicate their lives for the betterment of those afflicted with these cursed cancers.

The reality is that someday, probably sooner than later, my husband will lose the battle with this tenacious enemy, but we are still thankful for the compassionate and learned members of the Fred Hutchinson Cancer Research Center who helped and are still helping us to navigate a most challenging road.¹³⁶

—Mary Ellen Stokes and Bill Stokes, “Relentless Assault on a Research Hospital,” *Wall Street Journal*, March 15, 2004

Healthcare organizations involved in research studies should have appropriate protocols in place that protect the rights of patients. Patients participating in research studies should fully understand the implications of their participation. Physicians have a clear duty to warn patients as to the risks, benefits, and alternatives of an experimental procedure. Written consent should be obtained from each patient who participates in a clinical trial. The consent form must not contain any coercive or exculpatory language through which the patient is forced to waive his or her legal rights,

including the release of the investigator, sponsor, or organization from liability for negligent conduct.

Organizations conducting clinical trials on human subjects, at the very least, must:

- Fully disclose to the patient the inherent risks, benefits, and treatment alternatives to the proposed research protocol(s)
- Determine the competency of the patient to consent
- Obtain written consent from the patient
- Educate the staff as to the potential side effects, implementation of, and ongoing monitoring of protocols
- Require financial disclosure issues associated with the protocols
 - Promote awareness of ethical issues
 - Promote education in regard to ethical decision making
 - Increase nurse participation in ethical decision making
 - Have ongoing monitoring of approved protocols

The Centers for Medicare and Medicaid Services (CMS) accreditation survey process for nursing facilities includes a review of the rights of nursing facility residents participating in experimental research. Surveyors will review the records of residents identified as participating in a clinical research study. They will determine whether informed consent forms have been executed properly. The form will be reviewed to determine whether all known risks have been identified. Appropriate questions may be directed to both the staff and residents or the residents' guardians.

Possible questions to ask staff include:¹³⁷

- Is the facility participating in any experimental research?
- If yes, what residents are involved? (Interview a sample of these residents.)¹³⁸
- Residents or guardians may be asked questions, such as:

- Are you participating in the study?
- Was this explained to you well enough so that you understand what the study is about and any risks that might be involved?

Experimental Subject's Bill of Rights

The following is a bill of rights developed by the Veterans Administration system for patients involved in research studies. Human subjects have the following rights. These rights include, but are not limited to, the subject's right to:¹³⁹

- Be informed of the nature and purpose of the experiment
- Be given an explanation of the procedures to be followed in the medical experiment and any drug or device to be used
- Be given a description of any attendant discomforts and risks reasonably to be expected
- Be given an explanation of any benefits to the subject reasonably to be expected, if applicable
- Be given a disclosure of any appropriate alternatives, drugs, or devices that might be advantageous to the subject, their relative risks, and benefits
- Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise
- Be given an opportunity to ask questions concerning the experiment or the procedures involved
- Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation without prejudice
- Be given a copy of the signed and dated consent form
- Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision

Case Studies

Medical Research and Duty to Warn

About 5,000 patients at Michael Reese Hospital and Medical Center, located in Chicago, Illinois, were treated with X-ray therapy for some benign conditions of the head and neck from 1930 to 1960. Among them was Joel Blaz, now a resident of Florida, who received this treatment for infected tonsils and adenoids while a child in Illinois from 1947 through 1948. He has suffered various tumors, which he now attributes to this treatment. Blaz was diagnosed with a neural tumor in 1987.

In 1974, Michael Reese set up the Thyroid Follow-Up Project to gather data and conduct research among the people who had been subjected to the X-ray therapy. In 1975, the program notified Blaz by mail that he was at increased risk of developing thyroid tumors because of the treatment. In 1976, someone associated with the program

(continues)

Case Studies

(continued)

gave him similar information by phone and invited him to return to Michael Reese for evaluation and treatment at his own expense, which he declined to do.

Dr. Arthur Schneider was placed in charge of the program in 1977. In 1979, Schneider and Michael Reese submitted a research proposal to the National Institutes of Health stating that a study based on the program showed “strong evidence” of a connection between X-ray treatments of the sort administered to Blaz and various sorts of tumors: thyroid, neural, and others. In 1981, Blaz received but did not complete or return a questionnaire attached to a letter from Schneider in connection with the program. The letter stated that the purpose of the questionnaire was to “investigate the long-term health implications” of childhood radiation treatments and to “determine the possible associated risks.” It did not say anything about “strong evidence” of a connection between the treatments and any tumors.

In 1996, after developing neural tumors, Blaz sued Michael Reese’s successor, Galen Hospital in Illinois, and Dr. Schneider, alleging, among other things, that they failed to notify and warn him of their findings that he might be at greater risk of neural tumors in a way that might have permitted their earlier detection and removal or other treatment. There is a clear duty to warn the subject of previously administered radiation treatments when there is a strong connection between those treatments and certain kinds of tumors. The harm alleged, neural and other tumors would here be reasonably foreseeable as a likely consequence of a failure to warn and was in fact foreseen by Schneider. A reasonable physician, indeed any reasonable person, could foresee that if someone were warned of “strong evidence” of a connection between treatments to which he had been subjected and tumors, he would probably seek diagnosis or treatment and perhaps avoid these tumors, and if he were not warned he probably would not seek diagnosis or treatment, increasing the likelihood that he would suffer from such tumors. Other things being equal, therefore, a reasonable physician would warn the subject of the treatments.¹⁴⁰

Ethical and Legal Issues

1. Discuss the ethical and legal principles violated in this case.
2. What preventative measures should be taken to prevent recurrence of cases such as this?

Patient Responsibilities

Patients in National Institutes of Health (NIH) clinical trials have responsibilities, as well as rights. The following extract from the NIH Clinical Center Patient Handbook describes the responsibilities of NIH patients.

In the spirit of working together toward a common goal, our patients (and their parents, guardians, and surrogates) have responsibilities as partners in medical research and as patients at the Clinical Center.

You have the responsibility:

1. To provide, to the best of your knowledge, complete information about your current medical condition and past medical history, including current illness, prior hospitalizations, current medications, allergies, and all other health-related matters;
2. To discuss your protocol (study or treatment plan) with the research staff before indicating agreement to take part in it by signing a consent;
3. To inform the medical staff about your wishes regarding treatment plans. You may provide for a duly authorized family member or spokesperson to make medical decisions on your behalf in the event that you become unable to communicate;
4. To comply with your protocol, to cooperate with hospital staff, to ask questions if directions or procedures are not clear, and to participate in your health care decisions. You may withdraw from the study for any reason, but it is desirable to discuss your concerns with the attending physician before taking that action. Parents of pediatric patients have the responsibility to indicate if and how they want to be involved in their child’s plan of care;
5. To refrain from taking any medications, drugs, or alcoholic beverages while participating in the protocol, except those approved by an NIH physician;
6. To adhere to the no-smoking policy of the NIH;
7. To report on time for scheduled procedures and to keep all clinic appointments. If unable to do so, you have the

- responsibility of notifying the protocol physician and canceling and rescheduling the appointment;
8. To report promptly to the medical or nursing staff any unexpected problems or changes in your medical condition;
 9. To inform the appropriate staff or the patient representative of any concerns or problems with the care and treatment that you feel are not being adequately addressed;
 10. To respect the property of the U.S. government, fellow patients, and others; to follow NIH rules and regulations affecting patient care and treatment; to respect the rights of other patients and hospital staff. This includes the responsibility of respecting the privacy of other patients and treating information concerning them as confidential;
 11. To pay all medical or laboratory expenses incurred outside the Clinical Center, except when you have received written authorization on the appropriate NIH form to have such expenses billed to the NIH;
 12. To obtain medical care and medications from your own health care provider for all conditions unrelated to the protocol in which you are participating, except while being treated as an inpatient at the Clinical Center;
 13. To provide your own transportation to and from the Clinical Center and to pay living expenses except when all or part of these expenses are covered by the protocol or authorized by the responsible NIH physician; to advise accompanying escorts or others who travel to and remain in the Bethesda area that they must pay for their travel and living expenses except when designated by NIH as a guardian for you when your expenses are covered;
 14. To provide complete information, so that contacts and communications to schedule visits and monitor health status can be maintained. This information should include (1) your current address and phone number; (2) the names, addresses, and phone numbers of next of kin or persons to be notified in the event of an emergency; and (3) the names, addresses, and phone numbers of physicians responsible for your ongoing care, including your family physician and the physician(s) who referred you to the NIH;

15. To return to the care of your own health-care provider when participation in the protocol is completed or stopped and your medical condition permits.¹⁴¹

If you have questions about your rights, you may contact the Clinical Center Patient Representative.¹⁴²

NEWS *Where Are the Cures? How Patent Gridlock Is Blocking the Development of Lifesaving Drugs*

A curious thing happened on the way to the biotech revolution. While investment in biotech research and development has increased over the last three decades, new drugs that improve human health have not been forthcoming at the same rate.

What explains this drug discovery gap? Patent gridlock plays a large role. Since a 1980 Supreme Court decision allowing patents on living organisms, 40,000 DNA-related patents have been granted. Now picture a drug developer walking into an auditorium filled with dozens of owners of the biotech patents needed to create a potential lifesaving cure. Unless the drug maker can strike a deal with every person in the room, the new drug won't be developed.

Peter Ringrose, former chief science officer at Bristol-Myers Squibb, told the *New York Times* that the company would not investigate some 50 proteins that could be cancer-causing, because patent holders would either decline to cooperate or demand big royalties.

—Michael Heller, *Forbes*, August 11, 2008

Discussion

1. Discuss the ethical principles (e.g., beneficence [doing good] and nonmaleficence [avoiding causing harm]) and issues of morality of a legal system that delays research because of the legal rights of patent holders.
2. Discuss what steps could be taken to right the wrongs of patents that delay and often discourage research.

The Cures Act

The *Cures Act*, formally known as H.R. 34 or the 21st Century Cures Act, passed in the U.S. House of Representatives and Senate in the 114th Congress and was signed into law by President Barack Obama on December 13, 2016. It included important changes affecting the Food and Drug Administration and the

National Institutes of Health.¹⁴³ The Cures Act established and appropriated funds “(1) for biomedical research, including high-risk, high-reward research and research conducted by early stage investigators; (2) to develop and implement a strategic plan for biomedical research; and (3) to carry out specified provisions of this Act.”¹⁴⁴

► HUMAN GENETICS

The most promising frontier of the future of medical practice is in the area of human genetics, which describes the study of inheritance as it occurs in human beings. It includes such areas as stem cell research, clinical genetics (e.g., genetic disease markers), and molecular genetics. Inevitably there will be ethical issues that will become manifest in these new areas. We have already had a preview of this in the controversy regarding the use of fetal stem cells versus adult stem cells for research and therapy.

The ethics of modern science is a challenging and evolving area, but it is nothing new. In ancient China, for instance, physician Sun Simiao (AD 580–682) had a difficult medical ethical dilemma. In his book *Qianjinfang (Prescriptions Worth a Thousand Pieces of Gold)*, he is credited with formulating the first ethical basis for the practice of medicine in China. The ethical conundrum he faced was the clash between Confucian and Buddhist ethics. The relatively new religion of Buddhism had taboos against using any animal-derived product for the treatment of disease, as this violated the principle of respect for all life. The more ancient Confucian idea of compassion and kindness could be interpreted to overrule this, however. Sun Simiao dealt with this conflict by prohibiting a “standard physician” from using any medication derived from an animal source. He then included many prescriptions in his book that did have animal-sourced remedies. In other words, he seems to have artfully navigated an ethical gray zone between the two philosophies but with a less than clear distinction between right and wrong. Now in modern times we are still faced with continuing and evolving issues of ethics in the practice of medicine.¹⁴⁵

Genetic Markers

Genetic markers are genes or DNA sequences with a known location on a chromosome that can be used to identify specific cells and diseases, as well as individuals and species. They are often used to study the relationship between an inherited disease and its genetic cause in order to determine an individual’s predisposition/proclivity to a specific disease. Genetic markers show

observable information in DNA sequence variation, which may arise as a result of mutation of a specific gene. There are companies that will evaluate a person’s DNA for these markers and provide a person with a report of his or her potential health risks. Health insurers, life insurers, employers, and others could potentially use this information to determine one’s insurance premiums and even one’s job future and so forth. There is going to be ethical issues that will arise. For instance, suppose a woman has a family history of breast cancer and has a genetic marker for it, but she is young (e.g., 30 years old) and free of any evidence of cancer. If a physician recommends prophylactic mastectomy or if the patient wants a prophylactic mastectomy, should this be covered by insurance? Should this same logic be extended to other body organs?

Genetic Information Nondiscrimination Act of 2008 (HR493)

On May 21, 2008, President George W. Bush signed into law the Genetic Information Nondiscrimination Act (GINA), which resulted largely from the efforts of Senator Ted Kennedy. The law prohibits discrimination on the basis of genetic information with respect to the availability of health insurance and employment. The GINA prohibits group health plans and insurers from denying coverage to a healthy individual or charging that person higher premiums based solely on a genetic predisposition to developing a specific disease (e.g., cancer or heart disease) at some future time. The GINA also prohibits employers from using an individual’s genetic information when making hiring, firing, job placement, or promotion decisions.

The relatively recent mapping of the human genome and the likelihood of increasing clinical application of advances in genetic disease markers make this an issue of potential increasing importance in the practice of medicine. Most states also have legislation that addresses this issue. Unfortunately, there remains, no federal legislation that protects the individual from discrimination in the availability of life insurance, disability insurance coverage, or long-term care insurance. Because of this loophole, patients and their doctors need to consider the potential downside of ordering prognostic genetic tests.¹⁴⁶

Stem Cell Research

Stem cell research involves the use of embryonic stem cells to create organs and various body tissues. It continues to be a highly controversial issue generally involving religious beliefs and fears as to how far scientists might go in their attempt to create, for example,

another human being. Researchers must be free to unlock the secrets that stem cells hold and learn from them with the hope to develop effective therapies.

Some opponents of stem cell research argue that this practice is a slippery slope to reproductive cloning and fundamentally devalues the worth of a human being. Contrarily, some medical researchers in the field argue that it is necessary to pursue embryonic stem cell research because the resultant technologies could have significant medical potential and that excess embryos created for in vitro fertilization could be donated with consent and used for the research. This, in turn, conflicts with opponents in the pro-life movement, who advocate for the protection of human embryos. The ensuing debate has prompted authorities around the world to seek regulatory frameworks and highlighted the fact that embryonic stem cell research represents a social and ethical challenge that includes concern for the natural order of the ecosystem and, ultimately, the survival of the human race.

Acquired Immune Deficiency Syndrome

NEWS WHO Issues New HIV Recommendations Calling for Earlier Treatment

GENEVA—New HIV treatment guidelines by WHO recommend offering antiretroviral therapy (ART) earlier. Recent evidence indicates that earlier ART will help people with HIV to live longer, healthier lives, and substantially reduce the risk of transmitting HIV to others. The move could avert an additional 3 million deaths and prevent 3.5 million more new HIV infections between now and 2025.

—World Health Organization, *News Release*, June 30, 2013

The epidemic of *acquired immune deficiency syndrome (AIDS)* is considered to be the deadliest epidemic in human history. The first case appeared in the literature in 1981.¹⁴⁷ It has been estimated that more than 35 million people have died of AIDS.

Global situation and trends: Since the beginning of the epidemic, almost 70 million people have been infected with the HIV virus and about 35 million people have died of AIDS. Globally, 34.0 million (31.4–35.9 million) people were living with HIV at the end of 2011. An estimated 0.8% of adults

aged 15–49 years worldwide are living with HIV, although the burden of the epidemic continues to vary considerably between countries and regions. Sub-Saharan Africa remains most severely affected, with nearly 1 in every 20 adults (4.9%) living with HIV and accounting for 69% of the people living with HIV worldwide.¹⁴⁸

AIDS, generally, is accepted as a syndrome—a collection of specific, life-threatening, opportunistic infections and manifestations that are the result of an underlying immune deficiency. AIDS is caused by the human immunodeficiency virus (HIV) and is the most severe form of HIV, a highly contagious bloodborne virus. It is a fatal disease that destroys the body's capacity to ward off bacteria and viruses that ordinarily would be fought off by a properly functioning immune system. Although there is no effective long-term treatment of the disease, indications are that proper management of the disease can improve the quality of life and delay progression of the disease. Internationally, AIDS is posing serious social, ethical, economic, and health problems.

Spread of AIDS

AIDS is spread by direct contact with infected blood or body fluids, such as vaginal secretions, semen, and breast milk. Currently, there is no evidence that the virus can be transmitted through food, water, or casual body contact. HIV does not survive well outside the body. Although there is currently no cure for AIDS, early diagnosis and treatment with new medications can help HIV-infected persons remain healthy for longer periods. High-risk groups include those who have had unprotected sexual encounters, intravenous drug users, and those who require transfusions of blood and blood products, such as hemophiliacs.

Blood Transfusions

The administration of blood is considered to be a medical procedure. It results from the exercise of professional medical judgment that is composed of two parts: (1) diagnosis, deciding the need for blood, and (2) therapy, the actual administration of blood.

Lawsuits often arise as a result of a person with AIDS claiming that he or she contracted the disease as a result of a transfusion of contaminated blood or blood products. In blood transfusion cases, the standards most commonly identified as having been violated concern blood testing and donor screening. An injured party generally must prove that a standard of

care existed, that the defendant's conduct fell below the standard, and that this conduct was the proximate cause of the plaintiff's injury.

The most common occurrences that lead to lawsuits in the administration of blood involve:

- Transfusion of mismatched blood
- Improper screening and transfusion of contaminated blood
- Unnecessary administration of blood

- Improper handling procedures (e.g., inadequate refrigeration and storage procedures)

The risk of HIV infection and AIDS through a blood transfusion has been reduced significantly through health history screening and blood donations testing. Since May 1985, all blood donated in the United States has been tested for HIV antibodies. Blood units that do test positive for HIV are removed from the blood transfusion pool.

Case Studies

Administration of the Wrong Blood

The patient-plaintiff in *Bordelon v. St. Francis Cabrini Hospital* (1994)¹⁴⁹ was admitted to the hospital to undergo a hysterectomy. Before surgery, she provided the hospital with her own blood in case it was needed during surgery. During surgery, the patient did indeed need blood, but was administered donor blood other than her own. The patient filed a lawsuit claiming that the hospital's failure to provide her with her own blood resulted in her suffering mental distress.

The court of appeals held that the plaintiff stated a valid cause of action for mental distress. It is well established in law that a claim for negligent infliction of emotional distress unaccompanied by physical injury is a viable claim of action. It is indisputable that HIV can be transmitted through blood transfusions even when the standard procedure for screening for the virus is in place. The plaintiff's fear was easily associated with receiving someone else's blood and therefore a conceivable consequence of the defendant's negligent act. The hospital had a "duty" to administer the plaintiff's own blood. The hospital breached that duty by administering the wrong blood.

Ethical and Legal Issues

1. Do you agree with the court's decision? Explain your answer.
2. In cases such as this, do you believe that financial awards are effective in preventing future incidents? Explain your answer.

Healthcare Workers

HIV Test Urged for 7,000 Oklahoma Dental Patients

Health officials are urging 7,000 patients of an Oklahoma dentist to be tested for potential exposure to HIV, hepatitis B and hepatitis C.

...
Harrington, an oral surgeon who has been licensed since the 1970s, surrendered his credentials March 20 and discontinued his practice after investigators discovered alleged health and safety violations. Authorities say he is cooperating.

—Katharine Lackey and Michael Winter, *USA Today*,
March 28, 2013¹⁵⁰

Although transmission of HIV from an infected dentist, physician, or other caregiver to his or her patient during invasive procedures is not a common occurrence, there is a foreseeable risk. Because of the

potentially deadly consequence of such transmission, physicians should not engage in any activity that creates a risk of transmission.

The ever-increasing likelihood that healthcare workers will come into contact with persons carrying the AIDS virus demands that healthcare workers comply with approved safety procedures. This is especially important for those who come into contact with blood and body fluids of HIV-infected persons.

An AIDS-infected surgeon in New Jersey was unable to recover on a discrimination claim when the hospital restricted his surgical privileges. In *Estate of Behringer v. Medical Center at Princeton* (1991),¹⁵¹ the New Jersey Superior Court held that the hospital acted properly in initially suspending a surgeon's surgical privileges, thereafter imposing a requirement of informed consent and ultimately barring the surgeon from performing surgery. The court held that in the context of informed consent, the risk of a surgical accident involving an AIDS-positive surgeon and implications thereof would be a legitimate concern to a surgical patient that would warrant disclosure of the risk. "The 'risk of harm' to the patient includes not

only the actual transmission of HIV from the surgeon to patient but the risk of a surgical accident (e.g., a scalpel cut or needle stick), which may subject the patient to post-surgery HIV testing.”¹⁵²

Confidentiality

Guidelines drafted by the Centers for Disease Control and Prevention call on healthcare workers who perform “exposure-prone” procedures to undergo tests voluntarily to determine whether they are infected. The guidelines also recommend that patients be informed. Both healthcare workers and patients claim that mandatory HIV testing violates their Fourth Amendment right to privacy. The dilemma is how to balance these rights against the rights of the public in general to be protected from a deadly disease.

State laws have been developed that protect the confidentiality of HIV-related information. Some states have developed informational brochures and consent, release, and partner notification forms. The unauthorized disclosure of confidential HIV-related information can subject an individual to civil and/or criminal penalties. Information regarding a patient’s diagnosis as being HIV positive must be kept confidential and should be shared with other healthcare professionals only on a need-to-know basis. Each person has a right to privacy as to his or her personal affairs. The plaintiff surgeon in *Estate of Behringer v. Medical Center at Princeton* (1991)¹⁵³ was entitled to recover damages from the hospital and its laboratory director for the unauthorized disclosure of his condition during his stay at the hospital. The hospital and the director had breached their duty to maintain confidentiality of the surgeon’s medical records by allowing placement of the patient’s test results in his medical chart without limiting access to the chart, which they knew was available to the entire hospital community. “The medical center breached its duty of confidentiality to the plaintiff, as a patient, when it failed to take reasonable precautions regarding the plaintiff’s

medical records to prevent the patient’s AIDS diagnosis from becoming a matter of public knowledge.”¹⁵⁴

The hospital in *Tarrant County Hospital District v. Hughes* (1987)¹⁵⁵ was found to have properly disclosed the names and addresses of blood donors in a wrongful-death action alleging that a patient contracted AIDS from a blood transfusion administered in the hospital. The physician–patient privilege expressed in the Texas rules of evidence did not apply to preclude such disclosure because the record did not reflect that any such relationship had been established. The disclosure was not an impermissible violation of the donors’ right of privacy. The societal interest in maintaining an effective blood donor program did not override the plaintiff’s right to receive such information. The order prohibited disclosure of the donors’ names to third parties.

In *Doe v. University of Cincinnati* (1988),¹⁵⁶ a patient who was infected with HIV-contaminated blood during surgery brought an action against a hospital and a blood bank. The trial court granted the patient’s request to discover the identity of the blood donor, and the defendants appealed. The court of appeals held that the potential injury to a donor in revealing his identity outweighed the plaintiff’s modest interest in learning of the donor’s identity. A blood donor has a constitutional right to privacy not to be identified as a donor of blood that contains HIV. At the time of the plaintiff’s blood transfusion in July 1984, no test had been developed to determine the existence of AIDS antibodies. By May 27, 1986, all donors donating blood through the defendant blood bank were tested for the presence of HIV antibodies. Patients who had received blood from donors who tested positive were to be notified through their physicians. In this case, the plaintiff’s family was notified because of the plaintiff’s age and other disability.

HIV-related regulations must continue to address the rights and responsibilities of both patients and healthcare workers. Although this will always be a delicate balancing act, it must be handled with privacy, safety, and compassion in mind.

Case Studies

Disclosure of Physician’s HIV Status

The physician, Doe, was a resident in obstetrics and gynecology at a medical center. In 1991, he cut his hand with a scalpel while he was assisting another physician. Because of the uncertainty that blood had been transferred from Doe’s hand wound to the patient through an open surgical incision, he agreed to have a blood test for HIV. His blood tested positive for HIV, and he withdrew himself from participation in further surgical procedures. The medical center and Harrisburg Hospital, where Doe also participated in surgery, identified those patients who could be at risk. The medical center identified 279 patients, and Harrisburg identified 168 patients, who fell into this category. Because hospital records did not identify those surgeries in which physicians may have accidentally cut themselves, the hospitals filed

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Case Studies

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petitions in the Court of Common Pleas, alleging that there was, under the Confidentiality of HIV-Related Information Act [35 P.S. § 7608(a)(2)], a “compelling need” to disclose information regarding Doe’s condition to those patients who conceivably could have been exposed to HIV. Doe argued that there was no compelling need to disclose the information and that he was entitled to confidentiality under the act.

The Pennsylvania Supreme Court held that a compelling need existed for at least a partial disclosure of the physician’s HIV status.

The medical experts who testified agreed that there was some risk of exposure and that some form of notice should be given to the patients at risk. Even the expert witness presented by Doe agreed that there was at least some conceivable risk of exposure and that giving a very limited form of notice would not be unreasonable. Failure to notify the patients at risk could result in the spread of the disease to other noninfected individuals through sexual contact and through exposure to other body fluids. Doe’s name was not revealed to the patients, only the fact that a resident physician who had participated in their care had tested HIV positive. “No principle is more deeply embedded in the law than that expressed in the maxim *Salus populi suprema lex . . .* (The welfare of the people is the supreme law), and a more compelling and consistent application of that principle than the one presented would be quite difficult to conceive.”¹⁵⁷

Ethical and Legal Issues

1. Do you agree that there was a need for a partial disclosure of the physician’s HIV status?
2. If “the welfare of the people is the supreme law,” did the court fall short of its responsibility by not allowing disclosure of the physician’s name? Discuss your answer.

News Media and Confidentiality

The Pennsylvania Superior Court in *Stenger v. Lehigh Valley Hospital Center*¹⁵⁸ upheld the Court of Common Pleas’ order denying the petition of The Morning Call, Inc., which challenged a court order closing judicial proceedings to the press and public in a civil action against a hospital and physicians. A patient and her family had all contracted AIDS after the patient received a blood transfusion. The access of the media to pretrial discovery proceedings in a civil

action is subject to reasonable control by the court in which the action is pending. The protective order limiting public access to pretrial discovery material did not violate the newspaper’s First Amendment rights. The discovery documents were not judicial records to which the newspaper had a common-law right of access. Good cause existed for nondisclosure of information about the intimate personal details of the plaintiffs’ lives, disclosure of which would cause undue humiliation.

Case Studies

HIV Autonomy and Confidentiality

Mr. Jones, a divorcee with two children, was sentenced to 10 years in prison for repeated robberies of three banks. He was in prison for 8 years. His wife, Nora, disappeared shortly after he was sentenced. Five of his close inmate friends at Sing Prison had tested positive for the HIV virus and had since passed away. Prison officials wanted to test Mr. Jones for the HIV virus. He objected and sought legal counsel. Local school officials were informed of the deaths of Mr. Jones’s friends and his refusal to be tested for the HIV virus. Strangely, the community at large became aware of Jones’s situation and the fact that his children were attending school with their children. The parents insisted that the Jones children be removed from school or else they would remove their children from class. Meanwhile, Nora showed up at a local Navy recruiting station posing as a single woman with no children. She admitted to being bisexual several years earlier but claimed that she was now straight. The Navy learned of this situation and required her to undergo HIV testing. She objected and sought legal counsel.

Ethical and Legal Issues

1. What are Mr. Jones’s rights?
2. What are the rights of other prisoners?
3. Is there a legitimate need for a physician to disclose otherwise confidential testing data to the spouse and other intimate sexual partners of an HIV-infected patient?

The Right to Treatment

A variety of healthcare organizations have included in their ethics statements that HIV-infected patients have a right not to be discriminated against in the provision of treatment. The Ethics Committee of the American Academy of Dermatology, for example, states “it is

unethical for a physician to discriminate against a class or category of patients and to refuse the management of a patient because of medical risk, real or imagined.”¹⁵⁹ Patients with HIV infection, therefore, should receive the same compassionate and competent care provided to other patients.

Basketball Camp’s Exclusion of HIV-Positive Boy Ruled Discrimination

An HIV-positive 10-year-old boy was discriminated against when he was denied admission to a New York basketball camp, a federal judge has ruled. Judge Donald C. Pogue granted a motion for declaratory relief, finding the camp had violated the Americans with Disabilities Act. “The court agrees that defendants were obligated to protect other campers from a very serious, life-threatening viral infection,” Pogue said. “But this obligation does not excuse defendants’ actions when based on unsubstantiated fears.”

—Mark Hamblet, *New York Law Journal*,
January 22, 2010

Case Studies

Discrimination in the Community

The plaintiff Adam Doe claimed that the defendants, Deer Mountain Day Camp, Inc. (DMDC) and Deer Mountain Basketball Academy (DMBA), discriminated against him by denying him admission to a basketball camp on the basis of his disability, an HIV infection, in violation of the Americans with Disabilities Act (ADA), 42 U.S.C. §§ 12101–213 (2000) (ADA) and the New York State Human Rights Law (NYHRL), N.Y. Exec. Law §§ 290301 (2004) (NYHRL).

Adam had contracted HIV at birth due to a perinatal infection. He took antiretroviral medications to treat his condition, and his syndrome has been undetectable for years. On the advice of Dr. Neu, Adam’s HIV specialist, Adam and his mother had kept and continued to keep Adam’s HIV seropositivity confidential. Adam liked to play basketball, and in 2004, his HIV clinic recommended that he attend a basketball camp.

Mrs. Doe had been notified that the camp was unable to make reasonable accommodations for Adam and, as a consequence, they could not allow him to attend DMBA. According to Mrs. Doe, she was told that Adam could potentially transmit HIV through blood in his urine or in his stool. Mrs. Doe denied that Adam had problems with bloody stool or urine. Mrs. Doe, however, was told that DMBA could not accept Adam. She later received a refund of Adam’s admission fees.

The plaintiff brings this action for violations of Title III of the ADA and the NYHRL, arguing that the defendants unlawfully discriminated against him on the basis of his disability, e.g., his HIV-seropositivity, by excluding him from participation in the basketball camp. To redress his injuries, including emotional and psychological harm, Adam requested declaratory, compensatory, and injunctive relief, as well as attorney’s fees and costs.

Both parties made motions for summary judgment. The defendants failed to present any evidence of the objective reasonableness of their determination that the plaintiff’s condition posed a threat to other campers.

In their cross motions for summary judgment, the parties placed before the court the issues of whether HIV-seropositivity qualifies as a “disability” and whether defendants’ denial of admission constitutes discrimination “on the basis of” that disability. The plaintiff’s motion argued that the defendants conclusively qualify as “public accommodations,” thus prohibiting them from engaging in such discrimination.

The United States District Court, S.D. of New York, granted the plaintiff’s motion for Summary Judgment of ADA and NYHRL declaratory relief, as to DMDC’s discrimination “on the basis of” Adam’s disability, and denied the defendants’ motion for summary judgment in its entirety.¹⁶⁰

Ethical and Legal Issues

1. Since Adam’s HIV syndrome has been undetectable for years, discuss why you agree or disagree with the basketball camp’s decision to revoke Adam’s registration.
2. Do you agree with the court’s ruling? Discuss your answer.

AIDS Education

The ever-increasing likelihood that healthcare workers will come into contact with persons carrying HIV demands continuing development of and compliance with approved safety procedures. This is especially important for those who come into contact with blood and body fluids of HIV-infected persons. The Centers for Disease Control and Prevention (CDC) expanded its infection control guidelines and has urged hospitals to adopt universal precautions to protect their workers from exposure to patients' blood and other body fluids. Hospitals are following universal precautions in the handling of body fluids, which is the accepted standard for employee protection.

A wide variety of AIDS-related educational materials is available on the market. One of the most important sources of AIDS information is the CDC. The process of staff education in preparing to care for patients with AIDS is extremely important and must include a training program on prevention and transmission in the work setting. Educational requirements specified by the Occupational Safety and Health Administration (OSHA) for healthcare employees include epidemiology, modes of transmission, preventive practices, and universal precautions. See the following websites for some helpful information: www.aids.gov and <http://www.caps.ucsf.edu/>.

▶ CHAPTER REVIEW

1. Ethical dilemmas arise whenever a choice has to be made in which something good has to be given up or something bad has to be suffered no matter what is chosen.
2. Noteworthy historical events (see text at the beginning of the chapter).
3. *Abortion* is the premature termination of a pregnancy, either spontaneous or induced.
 - The morality of abortion is not a legal or constitutional issue; it is a matter of philosophy, ethics, and theology. It is a subject where reasonable people can and do adhere to vastly divergent convictions and principles.
 - *Partial birth abortion* is a late-term abortion that involves partial delivery of the baby prior to its being aborted.
4. *Sterilization* is defined as the termination of the ability to produce offspring.
 - *Therapeutic sterilization* is performed to preserve life or health.
 - *Eugenic sterilization* refers to the involuntary sterilization of certain categories of persons described in statutes, without the need for consent by, or on behalf of, those subject to the procedures.
 - *Wrongful birth* actions claim that, but for breach of duty by the defendant, a child would not have been born.
 - *Wrongful life* suits—those in which a parent or child claims to have suffered harm as a result of being born—are generally unsuccessful.
 - *Wrongful conception/pregnancy* actions claim that damages were sustained by the parents of an unexpected child based on the allegation that the child's conception was the result of negligent sterilization procedures or a defective contraceptive device.
5. *Artificial insemination* most often takes the form of the injection of seminal fluid into a woman to induce pregnancy.
 - *Homologous artificial insemination* is when the husband's semen is used in the procedure.
 - *Heterologous artificial insemination* is when the semen is from a donor other than the husband.
6. Surrogacy refers to a method of reproduction whereby a woman agrees to become pregnant for the purpose of gestating and giving birth to a child she will not raise but hand over to a contracted party.
7. Organ donations: Federal regulations require that hospitals have and implement written protocols regarding the organization's organ procurement responsibilities.
 - Organ transplantation is the result of the need for treating patients with end-stage organ disease facing organ failure.
 - Uniform Anatomical Gift Act has many provisions that apply to the wide variety of issues raised in connection with the making, acceptance, and use of anatomical gifts.
 - Act allows a person to make a decision to donate organs at the time of death.
 - Allows potential donors to carry an anatomical donor card.
8. Research, experimentation, and clinical trials.
 - Ethical principles that are relevant to the ethics of research involving human subjects include respect for person, beneficence, and justice.
 - These principles cannot always be applied to resolve ethical problems beyond dispute.

- The objective in applying ethical principles is to provide an analytical framework that will guide the resolution of ethical problems arising from research involving human subjects.
9. Human genetics describes the study of inheritance as it occurs in human beings.
 - The Genetic Information Nondiscrimination Act (GINA) prohibits discrimination on the basis of genetic information with respect to the availability of health insurance and employment.
 10. Stem cell research is being conducted to create tissues and organs that can be matched to patients for transplant.
 - Genetic markers are genes or DNA sequences that have a known location on chromosomes and can be associated with particular genes or traits.
 11. *Acquired immune deficiency syndrome* (AIDS) is a fatal disease that destroys the body's ability to fight bacteria and viruses.
 - Concerns involve the spread of AIDS, issues of confidentiality, discrimination, and AIDS education.

► TEST YOUR UNDERSTANDING

Terminology

abortion
 AIDS
 artificial insemination
 elective sterilization
 ethical dilemma
 eugenic sterilization
 genetic marker
 institutional review board
 partial birth abortion
 paternalism
 reasonable man standard
Roe v. Wade
 stem cell research
 sterilization
 surrogacy
 therapeutic sterilization
 undue burden
 Uniform Anatomical Gift Act
 wrongful birth
 wrongful conception
 wrongful life

► REVIEW QUESTIONS

1. Discuss under what circumstances ethical dilemmas arise.
2. Discuss the controversy over the Supreme Court decision in *Roe v. Wade*.
3. What ethical principles surround the abortion issue? Discuss these principles.
4. Do you agree that individual states should be able to impose reasonable restrictions or waiting periods on women seeking abortions? Who should determine what is reasonable?
5. Should a married woman be allowed to abort without her husband's consent?
6. Discuss the arguments for and against partial birth abortions.
7. Why is the medical issue of abortion an example of legislating morality?
8. What is artificial insemination? What questions should be asked when considering artificial insemination?
9. Discuss the importance of organ donations.
10. Describe the ethical considerations that should be addressed before conducting research on human subjects.
11. Why is it important that written consent be obtained from each patient who participates in a clinical trial?
12. What is sterilization, as discussed in this chapter? Do you agree that eugenic sterilization should be allowed? Explain your answer.
13. Describe the distinctions among wrongful birth, wrongful life, and wrongful conception.
14. Discuss the moral dilemmas of these concepts.
15. Describe the controversy over surrogacy.
16. Discuss why there is controversy over genetic markers and stem cell research.
17. What is AIDS, and how is it spread?
18. Discuss the controversy that can occur when considering a patient's right to know whether a caregiver has AIDS and the caregiver's right to privacy and confidentiality.

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