

two

chapter two

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. BOTSFORD¹

LEARNING OBJECTIVES

The reader on completion of this chapter will be able to:

- Better understand the ethical concepts and how they can be applied in the resolution of health care ethical dilemmas.
- Have a better understanding of the following common ethical dilemmas:
 - Abortion
 - AIDS
 - Artificial insemination
 - Organ donations
 - Research, experimentation, and clinical trials
 - Sterilization
 - Wrongful birth, wrongful life, and wrongful conception
 - Surrogacy
 - Human genetics

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 life knowing that an unborn child will be born with severe disabilities, or should I choose abortion and thus prevent 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 over death, disregarding her wishes and right to self-determination? Should I encourage the abortion my pregnant daughter—the victim of a gang rape—wants, or should I choose life and “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 health care 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 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 health care ethics in general.

58,000 to 68,000 BC

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

1932–1972

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 (i.e., penicillin). They believed that they were receiving adequate care and unknowingly suffered unnecessarily. The Tuskegee syphilis study used disadvantaged, rural 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.

1932–1945

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.

1946

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.²

1949

The *International Code of Medical Ethics* was adopted 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.

1954

The *National Institutes of Health* published guidelines on human experimentation following the first kidney transplant³ 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 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 with no hope of recovery? Should those resources be better spent on preventative medicine that would improve the quality of life for all?

1964

The *World Medical Association*⁴ established guidelines for medical doctors conducting biomedical research involving human subjects. The *Declaration of Helsinki* is the basis for good clinical practices today.⁵

1968

The *Harvard Ad Hoc Committee on Brain Death* published criteria to determine 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.⁶

1970

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

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 unequalled 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, health care 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.⁷

1972

Informed consent in the *Canterbury v. Spence*⁸ 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.

1973

The *Roe v. Wade* 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

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.⁹

The commission was directed to consider the following:¹⁰

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

The Food and Drug Administration and the National Institutes of Health internal policy guidelines became federal regulation.

1975

The first successful cloning of frogs was achieved.

1976

The New Jersey Supreme Court *In the Matter of Karen Ann Quinlan*¹¹ rendered a unanimous decision providing for the appointment of Joseph Quinlan as personal guardian of his daughter Karen (*substituted judgment*). Mr. Quinlan was granted full power to make decisions regarding her treating physicians. After the concurrence of the guardian and family, if Karen's physicians concluded that there was no reasonable possibility of her emerging from her comatose condition to a cognitive, sapient state and that her life-support apparatus should be withdrawn, they were to consult with the ethics committee of the institution where Karen was then hospitalized. If that consultative body concurred in the prognosis, the life-support system could be withdrawn without any civil or criminal liability on the part of any participant, whether it be the guardian, physician, hospital, or others. In addressing itself to the question of possible homicide, the court concluded that there is a valid distinction between withdrawing life-support systems in cases such as Karen's and the infliction of deadly harm either on one's self or another. It saw a difference between Karen's situation and the unlawful killing that is condemned in statutory law. The court denied that the death following withdrawal of treatment would be homicidal. Rather, it would be the result of previously existing natural causes, not from the withdrawal of treatment, and, even if it were considered homicide, it could not be unlawful if done pursuant to the exercise of an explicitly recognized constitutional right.

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

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.¹²

1980

The *Hemlock Society* was formed to advocate for physician-assisted dying for the terminally ill, mentally competent patient.

1983

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.

1990

The *Patient Self-Determination Act of 1990*¹³ was enacted to ensure that patients are informed of their rights to execute advance directives and accept or refuse medical care.

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.¹⁴

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.

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.

Derek Humphry's popular text, *Final Exit: The Practicalities of Self-Deliverance and Assisted Suicide for the Dying*, was published.

1993

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.¹⁵

1994

Oregon's Death with Dignity Act, 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.

1996

The *Health Insurance Portability and Accountability Act* (Public Law 104-191) was enacted to protect the privacy, confidentiality, and security of patient information.

The Second and Ninth U.S. Circuit Courts of Appeals ruled that there is a constitutional right under the 14th Amendment for a terminally ill person to receive help from a physician when dying.

1997

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

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

The Supreme Court overturned both 1996 circuit decisions, ruling that it is up to the states to enact laws regarding medically assisted death.

Dolly the Sheep was successfully cloned.

1998

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

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

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

1999

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

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

2001

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.

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. In *State of Oregon v. Ashcroft*, CV01-1647 (D-Oregon), the judge allowed Oregon's law to remain in effect.

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

2002

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

2003

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).¹⁶

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

2004

The 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 state and the federal governments.¹⁷

2006

The Supreme Court voted six to three to uphold the Oregon physician-assisted suicide law under the Death with Dignity Act.

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

2010

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.

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)¹⁸

An *abortion* is the termination of pregnancy by the removal or expulsion from the uterus of a fetus or embryo before it is viable. The question of viability has been strongly debated between pro-life (the right to life) and pro-choice (the right to choose) advocates. An abortion can be a *spontaneous abortion*, often referred to as a miscarriage, or it can be an *elective abortion*, meaning purposely induced, which 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 and the rights of the mother to make decisions regarding her body.

A consensus as to when 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 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 such questions as when 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.¹⁹

With more than 1 million abortions performed annually in the United States, 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 concerns include:

- When does life begin?
- Who decides?
- Who protects the unborn fetus?
- What are the rights of the child or woman who 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 of 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?
- Should a child or woman who has been raped have a right to abortion?
- 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 should the decision to abort be that of the mother?
- Should the feelings of guilt that may accompany an abortion and how those feelings may haunt the mother through the years be explained?
- Should the feelings that might occur after giving birth be explained to the victim of a rape (e.g., anger and resentment)?
- When does control over one's body begin, and when does it end?

These are but a few of the many questions yet to be fully resolved. As the following pages point out, for each new issue decided in the courts, numerous new issues arise, all of which seem to involve both legal and moral questions as to what is acceptable behavior in American society.

United States Supreme Court Decisions

Abortion is the premature termination of pregnancy. It can be classified as spontaneous or induced. It may occur as an incidental result of a medical procedure, or it may be an elective decision on the part of the patient. 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. More laws will be proposed, more laws will be passed, and more lawsuits will wind their way up to the Supreme Court.

Woman's Right to Privacy: Roe v. Wade (1973)

Roe v. Wade was a landmark case that 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;²⁰ however, the 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.

In *Roe v. Wade*, the United States Supreme Court held the Texas penal abortion law unconstitutional, stating this: "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.”²¹

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.”²²

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.”²³ 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.”²⁴

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.

Conditional Restrictions Unconstitutional: Doe v. Bolton (1973)

The Supreme Court then went on to delineate what regulatory measures a state lawfully may enact during the three stages of pregnancy. In the companion decision, *Doe v. Bolton*,²⁵ where the court considered a constitutional attack on the Georgia abortion statute, further restrictions were placed on state regulation of the procedure. The provisions of the Georgia statute

establishing residency requirements for women seeking abortions and requiring that the procedure be performed in a hospital accredited by the Joint Commission on Accreditation of Hospitals (JCAH) were declared constitutionally invalid. In considering legislative provisions establishing medical staff approval as a prerequisite to the abortion procedure, the court decided 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.”²⁶

The court was unable to find any constitutionally justifiable rationale for a statutory requirement of advance approval by the abortion committee of the hospital’s medical staff. 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.

Thus, by using a test related to patient needs, the court in *Doe v. Bolton* struck down four pre-abortion procedural requirements commonly imposed by state statutes: (1) residency, (2) performance of the abortion in a hospital accredited by the JCAH, (3) approval by an appropriate committee of the medical staff, and (4) consultations.

***Parental Consent Requirement Unconstitutional:
Danforth v. Planned Parenthood (1976)***

The Supreme Court ruled in *Danforth v. Planned Parenthood*²⁷ 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.

States May Deny Medicaid Benefits: Maher v. Roe (1977)

In *Maher v. Roe*,²⁸ the 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 the states may refuse to spend public funds to provide nontherapeutic abortions for women.

States May Protect Fetus: Colautti v. Franklin (1979)

The Supreme Court in *Colautti v. Franklin*²⁹ voted six to three that the states may 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.

Parental Consent Requirement Unconstitutional: Bellotti v. Baird (1979)

The Supreme Court in *Bellotti v. Baird*⁵⁰ ruled eight to one that a Massachusetts statute requiring parental consent before an abortion could be performed on 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.

States May Deny Medicaid Benefits: Harris v. McRae (1980)

In *Harris v. McRae*,⁵¹ the Supreme Court upheld in a five-to-four vote the Hyde Amendment, 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 may choose to do so.

H. L. v. Matheson (1981)

The Supreme Court in *H. L. v. Matheson*,⁵² 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 was 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.

Conditional Restrictions Unconstitutional: City of Akron v. Akron Center for Reproductive Health (1983)

The Supreme Court in *City of Akron v. Akron Center for Reproductive Health*⁵³ 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.

Abortion Tights Narrowed: Webster v. Reproductive Health Services (1989)

*Webster v. Reproductive Health Services*⁵⁴ began the 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 that physicians should conduct viability tests before performing abortions.

Refusal to Fund Abortion Counseling Not Unconstitutional: Rust v. Sullivan (1991)

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 decision by the Supreme Court in *Rust v. Sullivan*.⁵⁵ Proponents of abortion counseling argue that the regulations impermissibly burden a woman's privacy right to abortion. 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 1st Amendment. This question arises: How can a woman make an informed choice between two options when she cannot obtain information as to one of them? In *Sullivan*, however, the Supreme Court found that there was no violation of a woman's or provider's 1st Amendment rights to freedom of speech.

Abortions Restrictions—Undue Burden Rule:

Planned Parenthood v. Casey (1992)

In *Planned Parenthood v. Casey*,⁵⁶ the Supreme Court affirmed Pennsylvania law restricting a woman's right to abortion. The court was one vote shy of overturning *Roe v. Wade*. The 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 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 the minor does not wish to or cannot obtain parental consent, and requiring a 24-hour waiting period before any abortion can be performed.

Women's Medical Professional Corp. v. Voinovich (1998)

The Supreme Court in *Women's Medical Professional Corp. v. Voinovich*³⁷ denied certiorari for the first partial-birth case to reach the federal appellate courts. This case involved an Ohio statute that banned the use of the intact dilation and extraction (D&X) procedure in the performance of any pre-viability or post-viability abortion. 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: Stenberg v. Carhart (2000)

On June 28, 2002, the United States Supreme Court struck down a Nebraska ban on “partial-birth abortion,” finding it an unconstitutional violation of *Roe v. Wade*. The court found these types of bans to be extreme descriptive attempts to outlaw abortion—even early in pregnancy—that jeopardizes women's health [192 F.3d 1142 (8th Cir. 1999), 120 S. Ct. 2597 (2000)].

Partial Birth Abortion Ban Made Law (2003)

President Bush, on November 6, 2003, signed the first federal restrictions banning late-term partial-birth abortions. (The *partial-birth abortion*, also referred to as the D&X procedure, is a late-term abortion involving partial delivery of the baby before its being aborted.) Both houses of Congress passed the ban. The ban permits no exceptions when a woman's health is at risk or the fetus has life-threatening disabilities. A U.S. District Court in Nebraska issued a restraining order on the ban.

Hundreds of Thousands March to Support Abortion Rights (2004)

Hundreds of thousands of men and women from more than 60 countries marched in Washington, DC, on April 25, 2004, supporting women's

reproductive rights. The slogans at the rally included “Pro Choice—Pro Child,” “It’s Your Choice . . . Not Theirs,” “My Family My Choice,” “My Body My Choice,” “Justice for All,” “Who Decides?” and “Keep Abortion Legal.”

Informed Consent (2011)



NEWSPAPER CLIPPINGS: Judge Blocks Parts of Texas Abortion Law on Sonograms

A federal judge temporarily blocked key provisions of a Texas abortion law on Tuesday that would require women seeking the procedure to view a sonogram and listen to the heartbeat of their fetus. . . .

Sparks, an Austin-based federal judge for the Western District of Texas, also took a dim view of a provision that would force women pregnant from rape or incest to certify that in writing if they do not wish to hear a doctor’s explanation of the sonogram images. . . .

Supporters of the bill have said it was necessary to protect the rights of unborn children, while opponents said the measure was a basic intrusion into the privacy rights of women and doctors. . . .

“Every life lost to abortion is a tragedy and today’s ruling is a great disappointment to all Texans who stand in defense of life,” [Texas governor Rick] Perry said in a statement.

Jim Forsyth, Reuters, August 30, 2010⁵⁸



CASE: INFORMED CONSENT FOR ABORTIONS CHALLENGED

The plaintiffs in this case sought to represent the class of all Texas medical providers performing abortions and the patients of such providers, by challenging the constitutionality of Texas House Bill Number 15, an act “relating to informed consent to an abortion” H.B. 15, 82nd Leg., Reg. Sess. (Tex. 2011) (“H.B. 15”).

In part, the act amends Chapter 171 of the Texas Health and Safety Code to require 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,” H.B. 15, Sec. 2 (amending TEX. HEALTH & SAFETY CODE ANN. Ann. § 171.012).

The U.S. District Court ordered, in part, that the defendants are enjoined from penalizing a physician, criminally or otherwise, under the act when multiple physicians perform an abortion, and any one of those physicians, or a combination of them, comply with the act’s requirements; defendants are enjoined from penalizing either physician, criminally or otherwise, under the act when one physician is scheduled to perform an abortion and complies with the requirements of the act, but a different physician actually performs the abortion because the original doctor is unexpectedly unavailable on the procedure date; defendants are enjoined from enforcing the penalty provisions of the act against either a physician or a pregnant woman if the physician does not place the sonogram images where the pregnant woman may view them, or does not make audible the heart auscultation, if the pregnant woman elects not to view the images or hear the heart auscultation; and defendants are enjoined from penalizing a physician, criminally or otherwise, for the physician’s failure to provide the materials required by section 171.0123 of the act, in cases where the physician does not know whether the woman has chosen to have an abortion.³⁹

Discussion

1. Do you agree with the court’s ruling? Discuss your answer.
2. Do you think a woman should have to look at the sonogram of a child she is about to abort? Discuss your answer.
3. What do you consider the pros and cons of this ruling?

State Abortion Statutes

The effect of the Supreme Court’s 1973 decisions in *Roe* and *Doe* 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

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*,⁴⁰ 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.

In 1992, the Supreme Court in *Planned Parenthood of Southeastern Pennsylvania v. Casey*⁴¹ determined that in asserting an interest in protecting fetal life, a state may place some restrictions on pre-viability 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 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."⁴²

Spousal Consent

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. 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.⁴³

In *Doe v. Zimmerman* (1975),⁴⁴ 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 permitted 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)⁴⁵ was not entitled to an injunction to prevent the mother from submitting to an abortion. Although the father's interest in the fetus was legitimate, it did not outweigh the mother's constitutionally protected right 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.

Incompetent Persons' Consent

Abortion was found to be proper by a family court in *In re Doe* (1987)⁴⁶ for a profoundly retarded woman. She had become pregnant during her residence in a group home as a result of a sexual attack 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.

Parental Consent

The trial court *In re Anonymous* (1987)⁴⁷ 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 held down a full-time job.

Parental Notification

The issue in *Planned Parenthood v. Owens*⁴⁸ is whether the Colorado Parental Notification Act,⁴⁹ which requires a physician to notify the parents of a minor prior to performing an abortion on her, violates the minor's rights protected by the United States Constitution. The act, a citizen-initiated measure, was approved at Colorado's general election. The act generally prohibits 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 United States District Court decided that the act violated the rights of minor women protected by the 14th Amendment. The Supreme Court, for more than a quarter of a century, has required that any abortion regulation except from its reach an abortion medically necessary for the preservation of the mother's health. The act fails to provide such a health exception.

Abortion and Conflicting Beliefs

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 Constitution.

To help us make 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, determinations of morality may differ.

It is certain that the controversies and ethical dilemmas surrounding abortion will continue for many years to come.



CASE: BANNING ABORTION

March 9, 2004: Governor Michael Rounds of South Dakota vetoed legislation that would have all but banned abortion in the state. The two houses of South Dakota's state legislature had voted overwhelmingly for the bill, which called for abortions to be banned in all cases except when a woman's life was in danger.

Ethical and Legal Issues

1. What are the ethical and legal issues in this case?
 2. Are limited state funds being spent wisely, considering the financial difficulties many states are already facing and the high cost of legal fees in pursuing such issues?
 3. Does the fact that this bill challenges the 1973 *Roe v. Wade* Supreme Court ruling influence your thinking?
-

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. The protection of a 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 health care policies.



CASE: UTAH WOMAN REFUSES C-SECTION

March 12, 2004: A 28-year-old Utah woman refused a C-section and was charged with criminal homicide after one of her twins died prior to delivery. The charge claimed that the mother showed a depraved indifference to human life by ignoring medical advice to deliver her twins by C-section. It is alleged that a nurse told police that the patient said she would rather lose one of the babies than be cut.

Ethical and Legal Issues

1. If convicted, what should happen to mothers who smoke, drink, or don't follow their physician's orders for diet and exercise? Explain your answer.
 2. Is it okay to charge this mother for murder because some do not like the choices she made? Discuss your answer.
-

There will most likely be a continuing stream of court decisions, as well as political and legislative battles, well into the 21st century. Given the emotional, religious, and ethical concerns, as well as those of women's rights groups, it is unlikely that this matter will be resolved anytime soon.

Morality of Abortion

The morality of abortion is not a legal or constitutional issue; it is a matter of philosophy, ethics, and theology. It is a subject on which reasonable people can, and do, adhere to vastly divergent convictions and principles. Our obligation is to define the liberty of all, not to mandate our own moral code.⁵⁰

ACQUIRED IMMUNE DEFICIENCY SYNDROME

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 1981.⁵¹ It has been estimated that more than 21 million people have died of AIDS.⁵² 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 the HIV infection. HIV is a highly contagious blood-borne 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.



CASE: FALSE-POSITIVE TEST RESULTS

The patient-plaintiff had a blood specimen drawn and sent to a laboratory for testing for HIV. The laboratory informed the physician that his patient tested positive for HIV. The patient was informed that he had AIDS. Not believing that his symptoms mimicked those of an individual with AIDS, the patient was retested for HIV. On three separate occasions involving two separate laboratories, the patient tested negative for the virus. The patient-plaintiff filed a lawsuit against his physician and laboratory for the negligent interpretation and reporting of his blood samples as being HIV positive.

The West Virginia Supreme Court of Appeals ruled that the plaintiff had stated a claim for the negligent infliction of emotional distress. "Given the well-known fact that AIDS had replaced cancer as the most feared disease in America and, as defendant . . . candidly acknowledges, a diagnosis of AIDS is a death sentence, conventional wisdom mandates that fear of AIDS triggers genuine—not spurious—claims of emotional distress."⁵³

Ethical and Legal Issues

1. Do you agree with the court's finding? Explain your answer.
 2. If this same reasoning applied to hundreds of cases at one hospital laboratory, how would you determine awards? Consider what effect the awards granted might have on the hospital's financial viability, as well as the quality of services provided to the community. Discuss your answer.
 3. Review the news article at the end of this section on AIDS. Further discuss your thoughts as to right and wrong, and how the theories and principles of ethics might apply.
-

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.

Suits 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.

AIDS and Health Care Workers

Although transmission of HIV from an infected physician to his or her patient during invasive surgery is unlikely, it is a theoretical possibility and therefore foreseeable. Because of the potentially deadly consequence of such transmission, infected physicians should not engage in activity that creates a risk of transmission.

The ever-increasing likelihood that health care workers will come into contact with persons carrying the AIDS virus demands that health care 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),⁵⁴ 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 (i.e., a scalpel cut or needle stick), which may subject the patient to post-surgery HIV testing."⁵⁵

Confidentiality

Guidelines drafted by the Centers for Disease Control and Prevention call on health care 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 health care workers and patients claim that mandatory HIV testing violates their 4th 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 health care 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)⁵⁶ 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."⁵⁷

The hospital in *Tarrant County Hospital District v. Hughes* (1987)⁵⁸ 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),⁵⁹ 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.

Any new HIV-related regulations must continue to address the rights and responsibilities of both patients and health care workers. Although this will require a delicate balancing act, it must not be handled as a low-priority issue by legislators.



CASE: 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 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."⁶⁰

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.

AIDS: The Right to Treatment

More and more health care organizations are expressing 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 that "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.”⁶¹ Patients with HIV infection, therefore, should receive the same compassionate and competent care given to other patients.

News Media and Confidentiality

The Pennsylvania Superior Court in *Stenger v. Lehigh Valley Hospital Center*⁶² 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 1st 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: ADMINISTRATION OF THE WRONG BLOOD

The patient-plaintiff in *Bordelon v. St. Francis Cabrini Hospital* (1994)⁶⁵ 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 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.
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CASE: ERRORS POSSIBLE IN HIV TESTS

According to an article in the *Baltimore Sun* on March 11, 2004, approximately 640 patients at Maryland General Hospital may have received incorrect HIV and hepatitis test results. Some patients might have been told they were HIV-negative when in fact they were positive and vice versa, and the hospital failed to notify the patients of the problem. A former hospital employee had apparently filed a complaint. State health officials discovered in January that the hospital's laboratory personnel overrode controls in the testing equipment that showed the results might be in error and then mailed them to patients anyway.⁶⁴

Ethical and Legal Issues

1. What ethical theories and principles were violated in this case?
 2. What are the legal concerns for the hospital?
-



CASE: HIV AUTONOMY AND CONFIDENTIALITY

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 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 kids 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. What are the rights of the children?
 4. What are the rights of the parents?
 5. 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?
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NEWSPAPER CLIPPINGS: 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: 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 §§ 290-301 (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, i.e., 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.⁶⁵

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.

ARTIFICIAL INSEMINATION



NEWSPAPER CLIPPINGS: Octuplets' Mom: Can She Afford to Raise 14 Kids?

University of Pennsylvania bioethicist Arthur Caplan said there are serious ethical concerns surrounding the decision to move forward with multiple-fetus pregnancies—particularly if the babies were conceived through in-vitro fertilization, which Suleman has indicated was the case with her daughter.

"Anyone who transfers eight embryos should be arrested for malpractice," Caplan said.

Maria Yamaguchi, Associated Press, February 5, 2009

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: (1) *Homologous artificial insemination* involves the use of the husband's semen to impregnate the female; and *Heterologous artificial insemination* involves the use of semen from a donor

other than a woman's husband. The absence of answers to many questions concerning *heterologous artificial insemination* 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 and the effect of the procedure on the marital relationship.

Consent

The Oklahoma heterologous artificial insemination statute specifies that husband and wife must consent to the procedure.⁶⁶ It is obvious 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, heterologous artificial insemination 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 heterologous artificial insemination procedure.

Confidentiality

Another problem that directly concerns medical personnel involved in heterologous artificial insemination birth is preserving confidentiality. This problem is met in the Oklahoma heterologous artificial insemination 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.⁶⁷

ORGAN DONATIONS

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 transplantation is done 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 and use it to

replace or rehabilitate diseased or damaged organs or other parts of living persons. Interest in organ transplantation began about 25 years ago when attempts were made to transplant kidneys between twins.⁶⁸ Success rates have improved because of better patient selection, 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.

There is a shortage of cadavers needed for medical education and transplantation. 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 who lives and dies are not always easy to determine. If there were unlimited sources of organs, there would be no supply-and-demand issues. Because there is not an unlimited supply, 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 has 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 disseminated regarding transplant procedures that publishes the names of the donor or donee without adequate 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*,⁶⁹ 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 a donation may be revoked. If the document has been delivered to a named donee, it may be revoked by:

- A written revocation signed by the donor and delivered to the donee
- An oral revocation witnessed by two persons and communicated to the donee
- A statement to the attending physician during a terminal illness that has been communicated to the donee
- 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 donee, it 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.

RESEARCH, EXPERIMENTATION, AND CLINICAL TRIALS



NEWSPAPER CLIPPINGS: **Coddling Human Guinea Pigs**

Endless red tape and paternalism toward study volunteers is having a stifling effect on clinical research.

Let's agree that people who are altruistic enough to volunteer for experiments should know what they're in for if the study is testing a drug that has harmed lab animals, for instance, or if it involved a psychological manipulation that might have emotional scars. That's why all federal funded research on people must be vetted by panels charged with protecting "human subjects."

Doing studies on people "is so full of red tape that even experienced researchers are increasingly reluctant to tackle it," a scientist from the University of California, San Diego, told me. "It is so much simpler to deal with a mouse." But haven't we cured enough of them?

Sharon Begley, Newsweek, August 25, 2008

A research study is designed to answer specific questions, sometimes about a drug or device's safety and its effectiveness. Being in a research study is

different from being a patient. For patients, one's personal physician has a great deal of freedom in making health care decisions. For research subjects, the protocol director and the research staff follow the rules of the research study (protocol) as closely as possible, without compromising the patient's health.⁷⁰

Ethical principles 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.

Ethical considerations that must be addressed when conducting research on human subjects include: personal autonomy, self-determination, the ethical considerations involved in using persons as subjects of research, the Hippocratic maxim of "do no harm" and the Hippocratic oath's requirement that physicians benefit their patients "according to their best judgment," research involving subjects, and various meanings of the term "justice," such as whether burdens are to be distributed to each person equally, to each according to his needs, to each according to his societal contribution, or to each according to merit.

The science of medicine, by the very nature of that which it studies, the human body, is often prevented from making progress through direct experimentation. It must resort to necessary tests in laboratories and on animals, whose reactions are similar to humans, but most of all, it advances by observing how the body functions in health and in disease. It is natural that much of this laboratory experimentation and clinical observation should be done in the hospital. To increase the possibility of advancement by observation, clinical records must be accurate and complete in every case, no matter how trivial, and they should be preserved in such a manner as to be available for the study of similar cases. New remedies of all kinds should be tried out under conditions that favor accurate observation. Laboratories should be available under the direction of scientific physicians, and results of examinations should be carefully compiled and studied. Systematized research is possible only when directed by a physician with a scientific specialty, and it is rare not to find one such individual working in every hospital.

Medical progress and improved patient care are dependent on advances in medicine made through research. The basic principle of research is honesty, which must be ensured through institutional protocols. Fraud in research is not uncommon, and it must be condemned and punished. Honesty and integrity must govern all stages of research.

The Nuremberg Code and the Declaration of Helsinki is an international code of ethics that governs human research and experimentation. It was set in place after the discovery of Nazi medical atrocities of World War II. The code requires that human subjects be fully informed as to the nature and societal benefits of the research being undertaken. The code provides guidelines

for the development of federal regulations for medical research and the protection of human subjects. 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*. This board functions to review proposed research studies and conduct follow-up reviews on a regular basis.

Informed Consent

Physicians have a clear duty to inform patients about the risks and benefits of an experimental procedure, as well as about the alternatives to a proposed experimental procedure.

Written consent should be obtained from each patient who participates in a clinical trial. Consent should include the risks, benefits, and alternatives to the proposed treatment protocol. 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

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:⁷¹

- 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: 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 citizen 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 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 put 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 other. 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.⁷²

Ethical and Legal Issues

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

Patient Responsibilities

Patients in NIH clinical trials have responsibilities, as well as rights. The following 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.⁷⁵

Food and Drug Administration

The Food and Drug Administration (FDA) regulates clinical trials for investigational drugs. The FDA—after much criticism over the years because of the red tape involved in the approval of new drugs—issued 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; however, clinical trials of new drugs and medical devices have been referred to as endangered because manufacturers have been taking their devices overseas for faster approvals.

Patients participating in research studies should fully understand the implications of their participation. Health care 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

Each organization 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 an institution to provide initial approval and periodic monitoring for biomedical research studies. The IRB should include community representation. The IRB's primary responsibilities 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)

Nursing Facilities

The Centers for Medicare and Medicaid Services survey process includes a review of the rights of any 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:⁷⁴

- Is the facility participating in any experimental research?
- If yes, what residents are involved? (Interview a sample of these residents)⁷⁵
- 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?

Patients participating in research studies should fully understand the implications of their participation. Health care 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.

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.⁷⁶

Patents Delay Research

The legal system—caught up in the rights of patent holders—has resulted in delayed cures. What happens to the rights of those who would have benefited from the cures? The rights of the few, those who could be viewed as seeing money as the ultimate good, hold the rights of the many hostage. That is, until they need the cure. Ethical concerns seem to be ignored by the courts. The legal system is so ruled by rules that it cannot get out of its own harmful way.



NEWSPAPER CLIPPINGS: 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 non-maleficence [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.

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 sought because of:

- Economic necessity, to avoid the additional expense of raising a child
- Therapeutic purposes, to prevent harm to a woman's health (e.g., to remove a diseased reproductive organ)
- Genetic reasons, to prevent the birth of a defective child

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.

Regulation of Sterilization

Like abortion, voluntary sterilization is the subject of many debates concerning its moral and ethical propriety. Some health care institutions have adopted policies restricting the performance of such operations at their facilities.

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 a 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, feeble-minded, and, in some instances, epileptic are included within the scope of the statutes. Several states also have included certain sexual deviants and persons classified as habitual criminals. Such statutes ordinarily are said to be 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 many judicial decisions to the contrary, the United States Supreme Court in *Buck v. Bell*⁷⁷ specifically upheld the validity

of such eugenic sterilization statutes, provided that certain procedural safeguards are observed. Several states have laws authorizing eugenic sterilization. The decision in *Wade v. Bethesda Hospital*⁷⁸ strongly suggests that in the absence of statutory authority the state cannot order sterilization for eugenic purposes. At the minimum, 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.⁷⁹



CASE: NEGLIGENT STERILIZATION

Chaffee performed a partial salpingectomy on 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 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.⁸⁰

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

There is substantial legal debate regarding the impact of an improperly performed sterilization. Suits have been brought 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. Such litigation originated with the California case in which a court found that a genetic testing laboratory can be held liable for damages from incorrectly reporting genetic tests, leading to the birth of a child with defects.⁸¹ 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. v. Wilson*,⁸² 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:⁸³

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.

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.⁸⁴ 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.⁸⁵

A cause of action for wrongful life was not cognizable under Kansas law in *Bruggeman v. Schimke*.⁸⁶ Human life is valuable, precious, and worthy of protection. Not to 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*,⁸⁷ Kassama alleged that Dr. 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 or 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 caused 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.⁸⁸ 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*⁸⁹ 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.”⁹⁰

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*⁹¹ 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:⁹²

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.

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 Hills Hospital*,⁹³ 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."⁹⁴

As the Court of Common Pleas of Lycoming County, Pennsylvania, in *Shaheen v. Knight*, stated:⁹⁵

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.

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."⁹⁶

Surrogacy raises many ethical and legal issues to consider before searching for a surrogate mother. For example, is it right to enter a contract with

a woman, taking advantage of her circumstances 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 those? After the child is taken, the surrogate mother may be negatively impacted as her feeling of isolation is felt along with the reality of the sale of her body. One might ask this: How does this differ from those circumstances in which a donor would legally (which is not the case at present) be allowed to sell an organ strictly for financial purposes, thus allowing a donee to live as a result of the purchase?

Finally, 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 are split on the issue of whether or not to prohibit surrogacy contracts.

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 (580–682 AD) 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 less than a 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.⁹⁷

Genetic Markers

The use of *genetic markers*, like any new scientific discovery, can lead to good and bad, which in turn can raise a wide range of ethical issues and debates. A genetic marker is a gene or DNA sequence that has a known location on a chromosome and can be associated with a particular gene or trait. Genetic markers can identify certain diseases that can be detected in the blood and used to determine whether an individual is at risk for developing a disease.

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 are 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 mastectomies or if the patient wants prophylactic mastectomies, should this be covered by insurance?

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 of the states also have legislation that addresses this issue. Unfortunately, there remains, however, 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.⁹⁸

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. After all, a sheep named Dolly was cloned and born in 1996, and who knows what goes on behind the doors of research, which are closed to the outside world.

Some opponents of the 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.⁹⁹

The controversy continues, as stem cell research is ongoing in laboratories around the world. Some of this research is most likely of serious concern to the natural order of the ecosystem and, ultimately, the survival of the human race.

CHAPTER REVIEW

1. An ethical dilemma arises 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 above).
3. *Abortion* is the premature termination of a pregnancy, either spontaneous or induced.
4. 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.
5. *Partial birth abortion* is a late-term abortion that involves partial delivery of the baby prior to its being aborted.
6. *Acquired immune deficiency syndrome* is a fatal disease that destroys the body's ability to fight bacteria and viruses.
7. *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.

8. Organ Donations: Federal regulations require that hospitals have and implement written protocols regarding the organization's organ procurement responsibilities.
9. Organ transplantation is the result of the need for treating patients with end-stage organ disease and who face organ failure.
10. Research, Experimentation, and Clinical Trials.
11. The 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. 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.
12. 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.
13. *Sterilization* is defined as the termination of the ability to produce offspring.
14. As long as proper consent is obtained and the procedure is performed properly, *elective sterilizations* present few legal problems. A *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.
15. *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.
16. 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.
17. Human genetics describes the study of inheritance as it occurs in human beings.
18. The Genetic Information Nondiscrimination Act (GINA) prohibits discrimination on the basis of genetic information with respect to the availability of health insurance and employment.
19. Stem cell research is being conducted to create tissues and organs that can be matched to patients for transplant.
20. Genetic markers are genes or DNA sequences that have a known location on chromosomes and can be associated with particular genes or traits.

TEST YOUR UNDERSTANDING**Terminology**

artificial insemination

abortion

AIDS

elective sterilization

ethical dilemma

eugenic sterilization

genetic marker

institutional review board

partial birth abortion

Roe v. Wade

stem cell research

sterilization

surrogacy

therapeutic sterilization

Uniform Anatomical Gift Act

wrongful birth

wrongful life

wrongful conception

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 AIDS, and how is it spread?
9. 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.
10. What is artificial insemination? What questions should be asked when considering artificial insemination?
11. Discuss the importance of organ donations.
12. Describe the ethical considerations that should be addressed before conducting research on human subjects.

REVIEW QUESTIONS (continued)

13. Why is it important that written consent be obtained from each patient who participates in a clinical trial?
14. What is sterilization, as discussed in this chapter? Do you agree that eugenic sterilization should be allowed? Explain your answer.
15. Describe the distinctions among wrongful birth, wrongful life, and wrongful conception. Discuss the moral dilemmas of these concepts.
16. Describe the controversy over surrogacy.
17. Discuss why there is controversy over genetic markers and stem cell research.

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