Introduction: The Relationship Between Law and Bioethics

• Statutory Law
• Case Law

Ethical Issues

Statutory Laws Influencing Bioethics

Case Law Influencing Bioethics

Web Resources

Suggested Readings

Glossary of Legal Terms

Introduction

The Relationship Between Law and Bioethics

The Encyclopedia of Bioethics (Simon & Schuster Macmillan, 1995) defines bioethics as: "the broad terrain of the moral problems of life sciences, ordinarily taken to encompass medicine, biology, and some important aspects of the environmental, population, and social sciences." Laws often provide guidance to those confronted with bioethical problems because they establish restrictions and requirements for behavior, and may represent a general consensus of what is or is not ethical. For example, Title 21, a federal law, establishes when and under what conditions it is acceptable to conduct biomedical research on human subjects and is generally regarded as a set of rules arising out of ethical concerns and reflecting something of an ethical consensus. However, laws cannot always offer definitive answers. In some cases the law may even conflict with an individual's belief of what is ethical in a particular situation. Thus, laws affecting bioethical issues often create conflict and raise important questions.

How Laws Affect Bioethical Decisions

Most individuals will have to make a choice involving bioethics at some point in their lives. The study of bioethics is concerned with identifying all of the available options and considering the implications of each option.

In some cases, laws limit the available choices. For example, a Pennsylvania law requires minors to obtain parental consent in order to have an abortion. Thus, in Pennsylvania, a physician has limited legal options when confronted with a minor patient who requests an abortion but does not wish to inform her parents (discussed in Planned Parenthood v. Casey). The physician's choices are limited regardless of his or her beliefs regarding the validity of the patient's reasons for wishing to maintain her privacy. In this way, certain bioethical standards may be imposed on all members of society, based on legislative or judicial actions that may, or may not, represent societal consensus. Bioethicists often disagree about whether or not this is appropriate. At the same time, the creation and form of such laws may be
influenced by those working in the field of bioethics who actively engage in the legislative or judicial process.

Because laws can affect bioethics by limiting choices and bioethics can affect the creation of laws, the two fields are inseparable in many situations.

Laws can be created either through legislation which is called statutory law, or by opinions written by judges in court cases which is called case law. Below is an explanation of these two types of law. You can also access examples of statutory laws or case laws influencing bioethics further down on this page.

**Statutory law** is comprised of written laws enacted by either a state legislature or the Federal Congress. Statutory laws are either civil, including such things as licensing professions, building codes, and the establishment of holidays, or criminal. Civil laws represent the government's general power to influence or control activity, but do not involve criminal penalties. Violation of a criminal statutory law is considered a crime and may result in a fine and/or jail time.

Congress, the President, and various state officials often review reports or presentations by bioethicists while considering new legislation. (For an example of this, see the President's Council on Bioethics).

The legal options available to a person making a bioethical decision may be the same throughout the country, or may depend on the state in which that person is located.

The Constitution defines specific areas in which the federal government may make laws, preserving all other areas of law for the individual states. Once the federal government makes a law concerning a certain issue, that law is superior to any conflicting state law. Thus, if federal law addresses a specific issue, the legal options are the same in all states. If there is no federal law that applies, options are determined by state law and may differ among states.

In addition to specific laws, the federal government, and individual state governments, may also establish regulatory bodies with the power to regulate certain well-defined areas and practices. One example of a regulatory body affecting bioethics is the Office for Human Research Protections (OHRP), part of the U.S. Department of Health and Human Services (HHS). The OHRP regulates research involving human subjects.

[Click here](#) for a list of links to several federal and Minnesota state statutory laws.

**Case law**, often referred to as judge-made law, is comprised of decisions, in the form of written opinions, which determine the outcome of individual court cases by providing an interpretation of statutory laws, and often an interpretation of the U.S. Constitution. *Many of the legal rules affecting bioethics are the result of case law.*
Appellate courts may consider outside information in the form of amicus briefs, including those written by, or submitted on behalf of bioethicists, when ruling on cases and creating case law.

Statutory law as amplified and interpreted by case law establishes principles and guidelines of behavior that must be followed at the risk of legal consequences in the form of civil lawsuits, enforcement actions by the government or its agencies, or criminal prosecution. An individual or agency that violates an established law may be susceptible to a lawsuit. As a result, a court may order the individual or agency to stop a particular activity and/or require them to pay monetary damages to the other party. If the actions of the individual or agency also violate a criminal law, the individual may be susceptible to criminal penalties, including jail time and/or fines. A government agency may also bring an action to suspend a license or stop an activity conducted in violation of the law.

If a person feels that her rights have been violated in some way, she can, in many cases, sue the individual or corporation responsible for that violation. In addition, an individual or entity can sue a state, a government agency, or even the federal government, if he or she believes that a particular law violates his or her rights.

Once a case is decided, the principle of stare decisis requires all lower courts to decide similar cases in the same way. The United States Supreme Court is the highest court. Decisions by the Supreme Court must be followed by all other courts, as well as the federal government and all state governments.

However, judicial decisions (case law), even by the Supreme Court, are interpretations of the statutory law, including the Constitution. State legislators and the Federal Congress may subsequently change laws or adopt new laws. The highest form of law is the U.S. Constitution, and courts must interpret laws consistent with the Constitution. The Constitution itself may be amended through the legislative process.
Ethical Issues

Defining the appropriate relationship between bioethics and laws presents some basic ethical questions, such as:

- Which bioethical choices, if any, should be limited by laws?
- Should laws make "immoral" activities illegal if there is no victim?
- How much weight should courts and legislators give to bioethical arguments when creating new laws?
- What is the proper balance between individual rights to treatment and the cost and efficacy of such treatment?

The following bioethical questions have been addressed in some way by laws:

- Should random drug testing of high school athletes be allowed?
- Should young children have the right to be informed of a genetic mutation that is sure to cause a
debilitating disease?

- Should a spouse or parent have the ability to choose to end life-prolonging treatment for a patient in a persistent vegetative state?
- Should a woman have the right to choose an abortion? Is there any point during a pregnancy when a woman should no longer have this right?
- Should a hospital perform life saving measures such as CPR even if the patient expresses a desire not to have such procedures performed?

Statutory Laws Influencing Bioethics

Although most laws affected by bioethics are created through case law, there are several statutory laws that also affect bioethical decisions. The following is a list of some of these laws, both at the federal and state level, as well as the government organizations responsible for overseeing such laws. If you are looking for statutory laws on a particular topic or a particular organization, you are likely to find it in the list below. If you are looking for case law, click here.

Code of Federal Regulations
United States Code
Federal Government Organizations
Minnesota Statutes
Minnesota State Organizations

Code of Federal Regulations (CFR)

The following are select federal rules and regulations with interest to the field of bioethics. The links refer to the National Archives and Records Administration website (July 2004 updates):

Title 21: Food and Drugs/Chapter 1: Food and Drug Administration, Department of Health and Human Services

Part 21: Protection of privacy
Part 50: Protection of human subjects
Part 56: Institutional Review Boards
Part 202: Prescription drug advertising
Part 1270: Human tissue intended for transplantation

Title 42: Public Health/Chapter 1: Public Health Service, Department of Health and Human Services

Part 2: Confidentiality of alcohol and drug abuse patient records
Part 2a: Protection of identity--research subjects
Part 121: Organ Procurement and Transplantation Network

Title 45: Public Welfare/Subtitle A: Department of Health and Human Services

Part 5b: Privacy Act regulations
Part 17: Release of adverse information to news media
Part 46: Protection of human subjects

United States Codes (laws passed by the U.S. Congress)

The following are select federal laws passed by the United States Congress that may have particular interest around bioethical topics and concepts. The links go to the United States House of Representatives at: uscode.house.gov.

Animal Welfare Act (7 USC Sec. 2131) - The Federal law concerning the welfare of animals in biomedical research (as well as other capacities).

Assisted Suicide Funding Restriction (42 USC Chapter 138) - This Federal law restricts government funding for specific acts that end life such as assisted suicide and/or euthanasia.

National Organ Transplant Act (42 USC Sec. 273) - The Federal law concerning organ procurement and allotment.

Federal Government Entities and Regulating Agencies

Many entities and agencies within the federal government also have the power to set regulations that act much like statutory laws. Below is a list of some of these organizations with links to their websites:

- Center for Disease Control and Prevention: www.cdc.gov/other.htm
- Federal Judiciary: www.uscourts.gov
- Health Resources and Services Administration (HRSA): www.hrsa.gov
Case Law Influencing Bioethics

Many laws affecting bioethical decisions are a result of case law. Case law is constantly evolving as each new case adds to the interpretation of one or more statutory laws, usually for a very specific situation. Thus, there are a large number of cases. Below are descriptions of some of the key cases affecting the major topics in bioethics. If you are looking for cases on a particular topic, click the links below to go to
Case Law, Citations, and Opinions

What is a legal citation?
A legal citation is the identifying information that refers to a particular case. The citation will include:

Case Name, Volume Abbreviated Reporter Name Page # (Year)


What is a legal opinion?
At the conclusion of an appellate case, the judge (or judges) writes an opinion expressing his or her decision. An opinion generally contains the facts of the case, the judge's decision or ruling, and an explanation of the legal principles that lead to that decision.

How do you find out about a specific case and the opinion?
Opinions are published in regional reporters (books containing all law cases for that region) and are referred to by the case citation. This gives attorneys and courts a uniform way to cite and find previous cases establishing legal principles that may be used to decide the case at hand. All cases can now be found online through legal search engines, many of which require a paid subscription. Common cases can also be found for free on various websites, primarily those associated with law schools. Many of these cases and associated links are listed below. Using the legal citation is often the easiest way to search for a case. Finally, almost all law libraries carry hard copies of regional reporters that can easily be searched using this same citation.

Autonomy/Self Determination
Schloendorf v. Society of New York Hospital, 211 N.Y. 125, 105 N.E. 92 (1914).
Mary Schloendorf agreed only to an examination but while she was under anesthesia the doctor removed a tumor without her consent. The court found this to be a trespass, and thus established the importance of autonomy in medical procedures.

The case summary and full text of the opinion are both available on the University of Buffalo Center for Clinical Ethics website.


The patient in this case consented to a surgical procedure without being warned of the risk of paralysis associated with the procedure. The patient was paralyzed as a result of the procedure. The court found this to be a violation of informed consent, stating that "a physician violates his duty to his patient and subjects himself to liability if he withholds any facts which are necessary to form the basis of an intelligent consent by the patient to the proposed treatment."

A description of the case and its importance is available on the New Jersey Law Journal's website.


This case deals with the conflict between physician/patient confidentiality and the duty that a doctor may have to warn third parties of a risk that the patient poses. After telling a psychiatrist of his intentions, Prosenjit Poddar killed Tatiana Tarasoff. The Court found that Tatiana's parents could sue the psychiatrist for failing to warn them of Prosenjit's threats.

The opinion is available on Louisiana State University's website.


In this case, a hospital sought permission to perform a caesarean section on an unconscious pregnant woman. However, evidence was presented that the woman had expressed that she did not want the operation. The court refused to grant permission for the cesarean section and established that a pregnant woman's right to informed consent is superior to the goal of furthering the well being of an unborn fetus.


The Supreme Court found that drug testing of high school athletes is constitutional
because it reasonably serves the School District's important interest in detecting and preventing drug use among its students.

The opinion is available on the Cornell's Legal Information Institute website.

[Back to Case Law]

Medically Futile Treatment

**Matter of Baby K.** 609 So.2d 588 (Fla. 1992).

This case addresses the bioethical issue of medically futile treatment, declaring that the treatment of an anencephalic infant (an infant that is missing all or part of the brain and as a result will not survive) at parental request must be given by the hospital despite its futility.

[Back to Case Law]

Morals Legislation


Two men were arrested under a Texas statute that makes it a crime for two persons of the same sex to engage in certain intimate sexual conduct, after police found them engaged in such acts in the privacy of their home. The Supreme Court found this law to be unconstitutional under the Due Process Clause. In his dissent, Justice Scalia argues that this decision forbids all legislation for the purpose of protecting morals, giving new importance to the debate over the appropriateness of laws that are based only on morals and do not protect a victim.

The opinion and Justice Scalia's dissent are available on the Cornell Law website.

[Back to Case Law]

Parental Rights/Surrogacy


After contracting to be artificially inseminated in order to bear a child for a couple in return
for $10,000, the birth mother refused to turn over the child to the couple. In refusing to enforce the contract, the court limited the ability to contract for the rights to a child in a surrogacy situation. (The court did give the couple custody of the child, due to the best interests of the child, and not because of the contract.)

The full text for in the matter of Baby M is available on the Louisiana State University website.


After agreeing to give up all parental rights to the child, Anna Johnson entered into a contract to act as a gestational surrogate parent for the Calverts. Once the child was born, Johnson refused to surrender custody. In giving full custody to the Calverts the court declared that "when gametes of a husband and wife are implanted in the uterus of another woman (gestational, not genetic, surrogate), the natural parents of the child thus born are the husband and wife-the genetic parents."

A short summary is available on the surrogacy.com website.


A unique custody battle in which a divorced couple disagreed over the fate of seven frozen embryos. In resolving the dispute, the court created a system for determining the fate of pre-embryos where there is disagreement among genetic parents, establishing whose interests have priority in such disputes.

The opinion is available on Louisiana State University's law page.

[Back to Case Law]

Patent Law

Application of Bergy. 563 F.2d 1031 (C.C.P.A. 1977).

In this patent law case, the court found that microorganisms, although living, can be patented. Further developments in patent law decisions have caused this case to be dismissed by the Supreme Court as moot.

Chakrabarty filed for a patent on a human-made, genetically engineered bacterium capable of breaking down crude oil, which no naturally occurring bacteria can do. The Court found that genetically engineered bacteria are patentable microorganisms.

The opinion is available on FindLaw.

[Back to Case Law]

Physician Assisted Suicide


A Washington Law, RCW9A.36.06, made it a felony for a person to aid another in suicide. In determining that the law was unconstitutional, the Ninth Circuit Court of Appeals extended the right to refuse medical treatment even if resulting in death established in Cruzan, to include the right for competent terminally-ill adults to choose to hasten death by using drugs prescribed by a physician. The court here ruled that the Washington law was unconstitutional as it violated personal liberty by interfering with this right. Thus, the court precluded a state from bringing criminal charges against a doctor prescribing medication to a patient in order for that patient to end her life. It is important to note that this case was not heard by the Supreme Court, and the decisions is only binding in a few states. The ruling can still be reversed if a similar case involving this issue is heard by the Supreme Court.

The opinion is available from FindLaw Legal News.


The Oregon Death With Dignity Act (O.R.S. §127.805) makes it legal for a Physician, upon request by a competent terminally-ill adult, to prescribe medication for the purpose of ending the patient's life "in a humane and dignified manner." A district court granted a preliminary injunction against the Act's enforcement. The United States Court of Appeals for the Ninth Circuit removed the injunction, making it legal for a doctor to prescribe a lethal dose of medication under specified conditions in the state of Oregon. The Supreme Court refused to hear the case, leaving the issue up to the states.

An analysis of the law and court cases is available on compassionindying.org.

[Back to Case Law]
Property Rights Concerning One's Own Body


During the course of medical treatment, a doctor removed cells from Moore and used them for lucrative research purposes without Moore's consent. Moore then sued and the court found that although an individual does not have a property right to his cells, he can sue under informed consent laws if those cells are used in potentially profitable medical research without his permission.

The opinion is available on Louisiana State University's law page.

Reproductive Rights/Abortion


Although this case has since been overturned, it is historically important because the Supreme Court allowed sexual sterilization of a third generation mentally retarded woman by extending the public good theory previously used by courts to support mandatory vaccination laws.

The opinion is available from the Cuny Law School.


This is the case in which the Supreme Court established a woman's personal right to choose to have an abortion by extending a constitutional right to privacy in personal reproductive decisions.

A summary of the case as well as links to further resources can be found at www.oyez.com.


A disputed Pennsylvania law placed restrictions on the right of a woman to have an
abortion. In this case, the Supreme Court reaffirmed the right to abortion established in Roe v. Wade, but upheld the majority of a Pennsylvania law, allowing states to require a 24 hour waiting period before an abortion and mandatory parental consent for minors seeking abortions.

A summary and further resources are also available at oyez.com

*Stenberg v Carhart*

A Nebraska law made second trimester partial birth abortion, including the procedure of dilation and evacuation (D&E), illegal. The Supreme Court, relying on Roe v. Wade and Casey, found the law to be unconstitutional as it placed an undue burden on a woman choosing to obtain an abortion.

The opinion is available on the Cornell Law website.

[Back to Case Law]

**Right to Die**


After an auto accident, Karen Quinlan was found to be in a chronic persistent vegetative state, but not brain dead. Her father sought guardianship over her person with the intent to discontinue life support. After an in depth discussion of religious and privacy rights, and the right to die, the court determined that in order to protect a patient's right to die, the patient's family should be allowed to make decisions regarding care as they believe the patient would. The Court allowed Joseph Quinlan, Karen's father, to decide whether to discontinue life support.

The opinion is available on the University of Wisconsin website.


Elizabeth Bouvia, suffering from cerebral palsy, sought to have her own feeding tube removed, even though the removal would result in starvation. The court found that, constitutionally, a patient has the exclusive right to refuse any medical treatment or service, even lifesaving or life-prolonging. The court ordered doctors to remove the feeding tube.

The husband of a woman in a vegetative state sought authorization to remove a feeding tube from his wife. The court determined that the evidence presented was not sufficiently clear and convincing to determine the wishes of the patient, but that the right of a patient in an irreversibly vegetative state to determine whether to refuse life support should be exercised by the patient's family or close friends.


The parents of Nancy Cruzan, incompetent after an auto accident, sought a court order to terminate artificial nutrition and hydration. A state court refused and the Supreme Court ruled that in the absence of clear and convincing evidence of the patient's wishes, or evidence that the next of kin represent those wishes, a state is allowed but not required to substitute the judgment of the family.

The complete opinion for Cruzan v. Director, Missouri Department of Health is available on the Cornell University website.

Terri Schiavo - multiple court documents, ongoing

In this highly publicized right to die case, Terri's estranged husband wished to terminate nutrition and hydration, but her parents objected because they believed that this would be against Terri's wishes. Although a court allowed termination of nutrition and hydration, a new law was immediately passed allowing Governor Jeb Bush to issue an Executive Order to reinstate artificial nutrition and dehydration six days later. This case is still ongoing.

TerrisFight.org contains a great deal of up-to-date information including all relevant court documents.

Web Resources
Consortium on Law and Values in Health, Environment & the Life Sciences: The Consortium links sixteen Centers and Programs at the University of Minnesota to address the legal, ethical, and policy implication of the life sciences. Information is available online at: www.lifesci.consortium.umn.edu/.

American Society of Law, Medicine & Ethics (ASLME): This professional organization publishes The Journal and Law, Medicine, & Ethics, and The American Journal of Law and Medicine. Journal articles as well as information on ASLME conferences and publications are available online at: www.aslme.org.

Legal Information Institute (LII): An excellent resource with many cases, including text and analysis, from various federal courts and the United States Supreme Court, links to further resources, and an overview of health law. Located at the Cornell University Law School and on the internet at: www.law.cornell.edu

Supreme Court of the United States: This website provides a great deal of information about the Court itself as well as how to obtain oral argument transcripts, briefs, and written opinions. Available online at: www.supremecourtus.gov

Lexis-Nexis: This service provides full written opinions for any case (state or federal), including the text of state and federal laws and scholarly commentary on some laws and cases. There is a fee to use this site, so access is required. Most universities offer access to students. (Check your school library's list of internet resources.) Available online at: www.lexis-nexis.com.

Find Law: This service provides full written opinions on many major federal cases without requiring special access. Although cases are limited and may be harder to find, this is a good resource for those without academic institution privileges at sites like Lexis-Nexis. Available online at: www.findlaw.com

National Institutes of Health (NIH) Bioethics Resources on the Web: The NIH provides a long list of academic centers and education sites related to all areas of bioethics. Several links are specific to health law or to health law and bioethics. This is a great resource for a comprehensive search of law and bioethics issues. Available online at: www.nih.gov/sigs/bioethics/academic.html.


Suggestions for Further Reading
Books

*Assisted Conception: Research, Ethics, & Law*

*Encyclopedia of Bioethics*

*Law and Bioethics: An Introduction*

*Readings in Comparative Health Law and Bioethics*

*Ethics and Law in Biological Research*

Articles


Glossary of Legal Terms

**Amicus curiae brief:** A Latin term meaning "friend of the court" briefs. These briefs are filed with the court by someone who is not a party to the litigation, but who believes that the court's decision will be relevant to them.

**Appellate:** After a judge makes an initial ruling on a case, either party may have the right to appeal. An appeal must be based on a legal principal, such as incorrect application or interpretation of the law by the
A case that is appealed will then move to an appellate court for consideration. For more information, view the Court System Chart.

**Autonomy:** Respect for autonomy is one of the basic ethical principles of health care. The concept of autonomy respects and advocates for an individual to retain control, direct situations, and dictate circumstances.

**Clear and Convincing:** A relatively heavy burden of proof in which the judge or jury must be persuaded by the evidence that it is highly probable that the claim is true. Normally in a civil case (non-criminal), the burden of proof is a preponderance of the evidence, which means that the claim must be more likely to be true than not.

**Dilation and Evacuation:** The most common method for abortions in the second trimester, in which the physician dilates the cervix and removes the fetus, using some combination of suction and/or forceps (the practice varies slightly in this respect depending on the patient and the physician). Controversy exists as to whether or not this procedure should be grouped with partial-birth abortions in which the fetus is partially delivered outside of the mother's body before it is killed.

**Dissent:** Higher courts, like the Supreme Court, have several justices that rule on each case. When one justice does not agree with the opinion written by the majority, he or she may write a dissent. A dissent may offer a different analysis or view of the legal principles in the case, but does not create legal principles that must be followed in later cases.

**Due Process Clause:** The basis for many restrictions on both how laws are enforced and on the legal substance of laws. Due Process is the idea of ensuring fundamental fairness, justice, and liberty by limiting the kinds of control the majority can impose over minorities and individuals. Due Process is established by the 5th Amendment for the federal government and the 14th Amendment for state governments.

**Consent:** Voluntary approval or agreement as to some act or purpose. For example, one is asked to give consent for a police officer to search their home or person. For medical situations, see informed consent.

**Informed Consent:** Voluntary approval or agreement as to some act or purpose, as in consent, but also requiring that the person giving consent be informed of all of the relevant information, including risks and alternative treatment options, prior to giving that consent.

**Medically futile treatment:** Medical interventions that are unlikely to produce any significant benefits to the patient, either because the intervention is unlikely to produce any outcome or because the outcome produced is unlikely to benefit the patient. This term is often used to describe conditions in right to die cases.

**Moot:** A case that is moot no longer has any legal significance. This is often because later cases have developed contradictory or more specific versions of the same principle, causing the original case to lack
importance. The Supreme Court may also refuse to hear a case that is moot meaning that the resultant ruling would have no significance.

**Reaffirmed:** A ruling that the previous decision in a case was correct. When a case has been appealed, a higher court may send the case back to the original court with instructions to consider the case in light of certain facts or principles that the court points out. If the lower court considers these issues and still comes to the same conclusion, the court will reaffirm their previous decision.

**Stare decisis:** A Latin term meaning: "to stand by that which is decided." *Stare decisis* stands for the principle that previous decisions should be followed by the courts in future decisions. However, a court may overturn a previous decision and make a ruling contrary to it given sufficient reason and/or new developments in law and society.

**Surrogate parent:** A woman that becomes pregnant for the purpose of carrying a fetus to term for another woman, generally one that is unable to carry the fetus herself.

**Gestational surrogate:** The egg and sperm of the intended parents are joined, usually through in vitro fertilization, and then implanted into the surrogate who will carry the pregnancy to term.

**Genetic surrogate:** The surrogate's eggs are inseminated, usually artificially, with the intended father's sperm. Although the surrogate mother is also the genetic mother in this case, the baby is expected to be raised by the intended parents.