APPENDIX A

THE UNITED STATES LEGAL SYSTEM

Laws adopted by federal and state legislatures, regulations promulgated by federal and state agencies, local ordinances, the decisions of federal and state courts, professional association guidelines, and international treaties all affect the development and use of genetic technologies. In order to understand the legal milieu in which these activities take place, it is helpful to explore the overall framework of the legal system in the United States.

The U.S. Constitution is the supreme law of the land; laws, regulations, ordinances, actions of governmental officials, and court decisions that contravene the Constitution will be overturned as unconstitutional. The federal Constitution protects certain individual rights (such as freedom of speech or the right to make certain procreative decisions) and guards the individual against unwarranted interference by the government and its officials. Moreover, the federal Constitution requires that federal or state statutes or regulations not be drafted too vaguely or too broadly. A criminal law must not be vague; it must provide people with clear guidance about which behaviors are appropriate and which are inappropriate. A law which potentially restricts fundamental individual rights (such as freedom of speech) can be struck down as unconstitutional if it is drafted so broadly that it potentially chills legitimate (not just illegitimate) activity.

In some instances, state constitutions go even further than the federal Constitution in protecting people's rights. For example, although the federal constitutional right to privacy has not been held to require the federal government to fund abortions,[1] some states have interpreted their own right to privacy provisions to require abortion funding for indigent women.[2]

In addition, the federal Constitution enumerates the powers of the federal government. It describes the power of Congress to make laws, the powers of the President and the executive branch to enforce the laws, and the powers of the judiciary to interpret the laws. One of the most important powers of the federal government is "to regulate commerce among the several states."[3] The types of laws passed by Congress based on this power are incredibly diverse. They include laws such as those within the Food and Drug Act to assure the safety and efficacy of medications, laws forbidding payment for organs, and laws prohibiting racial discrimination in certain settings. Congress also has the power to delegate to administrative agencies the authority to develop regulations. The Food and Drug Administration promulgates regulations for the manufacturing and marketing of drugs, for example. The Department of Health and Human Services has developed

---

1 *Maher v. Roe*, 432 U.S. 464 (1977); *Harris v. McRae*, 440 U.S. 297 (1980).

2 *Right to Choose v. Byrne*, 91 N.J. 287, 450 A.2d 925, 933 (N.J. 1982); *Committee to Defend Reproductive Rights v. Myers*, 29 Cal.3d 252, 172 Cal. Rptr. 866, 625 P.2d 778, 792, 796, 798 (Cal. 1981).

3 U.S. Const. art 1, § 8, cl. 3.

regulations for the protection of human subjects in federally-funded research. Statutes and regulations, however, must be consistent with the federal Constitution.

The state governments have jurisdiction over all issues not specifically provided by the federal Constitution to be within the federal government's power. Most issues with respect to medical practice, insurance, regulation of the professions, family relationships, and public health fall within the authority of the state. Even in areas where the federal government is given primary authority, state governments may act as well. For example, many states have their own laws governing the safety and efficacy of drugs. However, when there is a conflict between a federal law and a state law with respect to an issue in which the federal government has primary authority, the federal law governs.

Local governments also have their own power to make laws, known as ordinances, subject to similar constraints. A U.S. Supreme Court case analyzed a local ordinance regarding collection of blood from paid donors;[4] the regulation was more restrictive than the federal regulations on blood donation. The ordinance required blood donors to obtain an identification card, valid for six months, that allowed donation only at the one center specified on the card. They imposed more stringent testing requirements (requiring hepatitis testing, for example) and more stringent recordkeeping requirements. The Court upheld the ordinances against claims that the field had been pre-empted by the federal regulations, noting that "[t]he federal interest at stake here is to ensure minimum standards, not uniform standards." The Court stated that "[g]iven the presumption that state and local regulation related to matters of health and safety can normally coexist with federal regulations, we will seldom infer, solely from the comprehensiveness of federal regulations, an intent to pre-empt in its entirety a field related to health and safety."

Another source of legal guidance is judge-made law. Each state has a court system with, generally, trial courts, appellate courts, and a state supreme court. There is also a system of federal courts with trial courts (known as district courts), appellate courts (known as circuit courts) and the U.S. Supreme Court. The federal courts may not hear cases based purely on state matters between parties from a single state. Federal court jurisdiction is limited to cases involving federal law or federal constitutional rights, cases in which the federal government or its officials are parties, certain types of cases in which the parties are citizens of different states, and limited other types of cases.

Some court cases deal with issues of public law (concerning the government or its relationship with individuals). These cases might involve the interpretation of laws, regulations, or ordinances. Other court cases involve issues of private law (concerning the relationship of individuals with each other). These cases might deal with contract issues, property issues, or tort issues.

Research in human gene therapy, to take one example, might give rise to numerous public law and private law cases. In the public law vein, a case might be brought against a state government challenging as unconstitutional a law banning

---

4 *Hillsborough County, Florida v. Automated Medical Laboratories, Inc.*, 471 U.S. 707 (1985).

gene therapy experimentation on embryos.[5] A case might be brought against a researcher for not complying with a local ordinance governing the conduct of research involving recombinant DNA.

In the private law vein, a contract case might be brought by a university against a professor who developed and patented a certain type of gene therapy; such a case might claim that the professor's employment contract gave the university the right to a certain percentage of the royalties. If the gene therapy was developed using a unique cell line from a particular patient, the patient might claim in a case that she had a property right in the tissue and was entitled to remuneration.[6] If the gene therapy was tested on a patient without the patient's knowledge or consent, she might bring a tort case claiming battery. If consent was obtained, but the therapy was performed negligently, she might bring a tort case charging malpractice.

To understand how court cases proceed, it is useful to explore a particular type of claim, a tort case, in slightly more depth. Tort cases deal with the duties and responsibilities of people to each other. Consider a situation in which a couple claim that they were given inadequate genetic counseling and, as a result, brought to term a fetus with a serious genetic disorder rather than undergoing an abortion. If the couple sues the genetic counselor, they are known as the plaintiffs and the counselor is known as the defendant. The first set of questions the court faces in such a case is common to all tort cases: whether the defendant had a duty to the plaintiffs, whether the defendant breached that duty, and whether the breach of duty led to the alleged harm (in this case, the birth of a child with a genetic disorder). In some instances, the trial court might say that the birth of a child with a genetic disorder under such circumstances is not a legally cognizable harm. In such a situation, the court decision will be that the couple failed to state a cause of action (i.e., that they did not assert a legally recognizable claim). A decision such as this which prevents the couple from pursuing their case can be appealed to a higher court, however. In some instances, the higher court might reverse the lower court and say that the couple did have a valid cause of action. When that happens, the couple can have their case heard at the trial court level.

Once it is recognized that the plaintiffs in a case are asserting a legally valid cause of action, the next inquiry is whether they brought the case within the appropriate time frame. Laws known as statutes of limitations set forth the time period within which a case may be brought. Within a particular state, the length of time in which a medical malpractice tort action may be brought may depend on whether the injured party is an adult or a child and whether the injury is immediately and reasonably obvious or latent. For example, in some states, a medical malpractice case involving an adult plaintiff must be filed within three years of the time when the alleged negligence occurs. If a surgeon accidentally amputates the wrong leg, for instance, the patient has three years to file a case. However, not all errors are so obvious. The effects of some forms of negligence are not felt until later

---

5 In Louisiana, a law banning fetal experimentation was struck down as unconstitutionally vague since it was unclear which activities would be considered experimentation. *Margaret S. v. Edwards*, 794 F.2d 994 (5th Cir. 1986). See also, *Lifchez v. Hartigan*, 735 F.Supp 1361 (N.D. Ill. 1990), aff'd without opinion, sub. nom., *Scholberg v. Lifchez*, 914 F.2d 260 (7th Cir. 1990), cert. denied, 498 U.S. 1069 (1991)).

6 *Moore v. Regents of the University of California*, 793 P.2d 479 (Cal. 1990).

in time. If a sponge is left in the patient's body, the ill effects of its presence may not take hold until much later. For such a circumstance, some state laws provide that the time period in the statute of limitations does not start until after the negligence has been discovered. This is known as the discovery rule. If a state has a three-year statute of limitations and a discovery rule and a negligent surgery occurred in 2002, but the injury was not discovered until 2004, the patient would have until 2007 (three years after discovery) to bring his or her claim. As a further wrinkle on the statue of limitations issue, some states have yet another law to set an outside time limit within which a medical malpractice suit by adult plaintiffs must be brought. Let's say a state had a three-year statute of limitations, a discovery rule and a ten-year absolute limit from the time the negligence occurred. If the negligence occurred in 2002, but was not discovered until 2011, the patient would not have three years from the date of discovery to bring a case. He or she would have only one year (until 2012, which is ten years after the negligence occurred). If the negligence was not discovered by the patient until 2013, the patient would not be able to sue at all since more than ten years would have elapsed since the occurrence of the negligence.

State laws used to provide that when the person injured by medical negligence was a child, the statute of limitations would not begin to run until after the child reached majority. If the age of majority was 18, and the statute of limitations was three years, the child would have until age 21 to bring a medical malpractice suit, even if the negligence had occurred when he or she was an infant. Although some states still have a long time period covering medical malpractice involving children, other states have shortened it somewhat. In California, for example, when the minor injured is under age six, the action must be brought within three years of the wrongful act or before his or her eighth birthday, whichever is longer.[7]

At trial, the plaintiff has the burden of proof to establish that the defendant actually breached a duty and that the breach led to harm. In most medical malpractice cases, the plaintiff must use medical experts to establish what the duty is of a particular health care practitioner in a particular situation by describing what is common practice among such practitioners in such situations. For example, the plaintiff might call upon genetic counseling experts to establish that it is standard medical practice to offer amniocentesis to women over age 35. Once the plaintiff establishes the duty, he or she will use other witnesses to demonstrate that in fact this particular defendant did not meet that duty and that the result of the breach was the birth of a child with a serious genetic disorder.

Once a decision has been rendered in a case, there is a certain time period during which the plaintiff or defendant can appeal to the next higher level of court. (After a decision is rendered at that level, there is yet another time period in which an appeal to a third level is possible.) Because each state has its own court system, states may develop different approaches to a legal problem. For example, the courts

---

7 Cal. Civ. Proc. Code § 340.5.

in some states recognize a cause of action for wrongful life,[8] while the courts in other states do not.[9]

A court decision serves as precedent for future decisions by the particular court or lower courts under it with respect to future cases with similar facts. The holdings of the U.S. Supreme Court on issues of federal constitutional law are binding on all state and federal courts.

The law is constantly developing, much as medical science is. When courts perceive a harm that should be remedied, they have a certain limited power to innovate – for instance, by recognizing a new cause of action. Courts in some states have extended the law by recognizing a cause of action for wrongful birth, for example.

Legislatures have even more leeway for shaping the law. John Flood points out that the regulation of wages and hours, of insurance, and of building safety "all first appeared as statutory innovation."[10]

"Much of law is uncertain," writes George Seidel III. "Rules of law often fail to guarantee particular results in individual controversies. Lawyers are many times unable to predict with authority the outcome of current conflict . . . . But in a sense uncertainty about the law is a virtue and the law's greatest strength. Its opposite, legal rigidity, produces decay by inhibiting initiative with respect to economic growth and the development of social institutions."[11]

---

8 See, e.g., *Turpin v. Sortini*, 31 Cal. App. 3d 220, 182 Cal. Rptr. 337, 643 P.2d 954 (1982); and *Pocanik v. Cillo*, 97 N.J. 339, 478 A.2d 755 (1984).

9 See, e.g., *Beardsley v. Wierdsma*, 650 P.2d 288 (Wyo. 1982); and *Azzolino v. Dingfelder*, 315 N.C. 103, 337 S.E.2d 528 (1985), cert denied, 107 S. Ct. 131 (1986).

10 J. Flood, The Legal Profession in the United States 3d 6 (1985).

11 Seidel, "Introduction to Law and the Legal System," 1, 3-4 in A. Southwick, The Law of Hospital and Healthcare Administration (1978).