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ARTICLES

THREE LEGAL FRAMEWORKS FOR REGULATING GENETIC TECHNOLOGY

Wilson Huhn*

INTRODUCTION

Intellectual and technological revolutions of the past have fundamentally changed the way we live and vastly expanded the amount of knowledge we can master. The Renaissance, the Industrial Revolution and the Information Age each represent a “great leap forward” in human potential. The Genetic Age promises another exponential increase in human knowledge and potential.

With this new age there is also vast potential for harm. We must not forget Jesse Gelsinger, an eighteen-year-old who volunteered as a subject in a study at the University of Pennsylvania Institute for Gene Therapy (the Institute), which at that time was considered the leading program in the nation.1 The most common method for delivering DNA for gene therapy is by weakened adenoviruses.2 On September 13, 1999, researchers at the Institute inoculated Jesse with a massive dose of adenovirus.3 Jesse slipped into a coma and died four days later.4 Jesse’s mother said, “I have read that my son’s death has been called by one of

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2. “Success [of gene therapy], according to researchers, depends upon effective delivery of the new genetic material into the target cells of the patient using a vector, usually a disabled virus ....” Id. at 255. See also Gene Therapy Touted as Cancer Fighter, NEWSDAY, February 27, 2001, at A42.


4. See Cregan, supra note 1, at 267.
the leaders in this field as a pothole on the road to gene therapy. His death was no pothole. It was an avoidable tragedy from which I will never fully recover.\textsuperscript{5} Neither Jesse nor his family was told of the researchers' personal financial interest in the gene therapy trials.\textsuperscript{6} In addition, the resulting investigation revealed "serious deficiencies" in the way that the Institute monitored its study.\textsuperscript{7} The Food and Drug Administration (FDA) halted gene therapy trials at the University of Pennsylvania\textsuperscript{8} and a dozen other institutions.\textsuperscript{9} Congress is presently considering legislation that will provide additional protections for subjects of medical experimentation, as well as require the disclosure of any financial interest researchers have in the products they are testing.\textsuperscript{10}

There is, however, an even more serious impending risk. In 2001, Panos Zavos, a Ph.D. who runs a Kentucky fertility clinic that does not participate in voluntary programs that report success rates, and Severino Aninori, the Italian obstetrician who helped a sixty two year old woman become pregnant, announced plans to clone a human being, despite the fact that ninety-five to ninety-seven percent of cloned animals are deformed and often fail even to survive.\textsuperscript{11} Although Zavos and Aninori

\begin{footnotes}
\footnotetext[5]{Id. at 261.}
\footnotetext[6]{The lead researcher, Dr. James Wilson, failed to disclose that he owned thirty percent of Genovo, the company whose substance Wilson was testing. David Heath and Duff Wilson, \textit{System's Serious Flaws Have Led Many to Call for Regulatory Reform}, \textit{The Seattle Times}, March 15, 2001, at A11. Professor Baram characterizes researchers' failure to disclose their financial interest in the success of the trials as a "disturbing feature" of the violations at research institutions conducting human clinical trials. Baram, \textit{supra} note 1, at 256.}
\footnotetext[7]{Cregan, \textit{supra} note 1, at 267.}
\footnotetext[9]{Cregan, \textit{supra} note 1, at 267-68.}
\end{footnotes}
are unlikely to receive funding for this research, there is no federal law prohibiting these experiments.\textsuperscript{12}

Who will determine the future direction of genetic research? Who will channel and limit the permissible applications of genetic technology? Who will decide the scope and nature of societal regulation of this revolutionary science? Will it be individual citizens and their physicians? The biotechnology industry? Administrative agencies? Or judges and elected officials?

The path of human progress is being plotted by our exploration of the human genome, but it is vital that in the course of our discoveries we do not permit the exploitation of human beings. In her recent book Future Perfect, Lori Andrews offers three models of decisionmaking for the allocation of genetic services: the medical model, the public health model and the fundamental rights model.\textsuperscript{13} She concludes that the fundamental rights model will best protect the interests of individuals and society, both medically and in terms of human dignity.\textsuperscript{14}

This article describes three frameworks the law uses to regulate genetic technology: (1) Individual Rights and Duties; (2) Scientific Regulation by Administrative Agencies; and (3) Legislative Preemption. Each framework is invoked by a different decisionmaker and each imposes a different level of scrutiny over genetic technology.

Actions to enforce Individual Rights and Duties are initiated by individuals. This framework involves the lowest level of government oversight over genetic technology. The core of this approach is to establish legal rights for individual citizens under the traditional sources of law: the common law, specific remedial statutes and the Constitution. Under this framework people are free to act unless and until they harm others. The law makes no attempt to prevent harm other than to deter it by acknowledging the right of an affected person to sue for damages.

Scientific Regulation is conducted by administrative agencies and results in a higher level of scrutiny over genetic technology. This is

\textsuperscript{12} The Food and Drug Administration does have authority to regulate "drugs," "medical devices" and "biologic products," but its authority to regulate cloning has been questioned. See infra notes 34 and 132 and accompanying text. See generally Richard A. Merrill & Bryan J. Rose, FDA Regulation of Human Cloning: Usurpation or Statesmanship?, 15 HARV. J.L. & TECH. 85 (2001). Fashioning anti-cloning legislation is difficult in part because "the term 'cloning' covers a variety of research techniques, including several that have been used beneficially for many years," such as DNA testing or stem cell research. \textit{Id.} at 132.

\textsuperscript{13} LORI B. ANDREWS, FUTURE PERFECT 22-29 (2001).

\textsuperscript{14} \textit{Id.} at 170-173.
currently the most common form of regulating the biotechnology industry in the United States. Nevertheless, our national experience has not resulted in a very strict level of administrative oversight. Administrative regulations take years to develop because each agency bears the burden of justifying the regulations in court, and agency policy is subject to revision by each new presidential administration. Adding to the difficulty is the fact that administrative agencies in the United States have had to act under existing laws that have not been amended to deal with the novel challenges of genetic technology.

The highest level of oversight, Legislative Preemption, is essentially hostile to genetic technology and would severely restrict the application of this new science. The fundamental precept of this framework is “safety first” — the precautionary principle. Under this regulatory framework the government — usually the legislative branch — forbids or severely limits the development and application of new technology until it is proven safe. But because we do not yet know all of the consequences of genetic technology — since it cannot be proven safe in advance — this type of precautionary legislation operates as a virtual ban.

Each legal framework plays a critical role in regulating genetic technology. Individual rights must be protected, industries must be regulated and exploitative or dangerous practices banned. Furthermore, observers have identified a number of reforms that should be adopted within each framework. The law must enhance individual autonomy by more clearly recognizing rights to genetic privacy and nondiscrimination. Administrative agencies should adopt a more comprehensive regulatory framework, with stricter controls over the applications of genetic technology and stronger protections for human safety. Finally, the legislature should ban exploitative and dangerous experiments.

I. INDIVIDUAL RIGHTS AND DUTIES

There are three sources of individual rights and duties: the common law (that is, the decisions of the courts in fields such as torts, contracts, property and family law); specific statutes creating private causes of action; and state and federal constitutions. This article begins below with the common law.

A. Common Law Rights and Duties

The common law framework of individual rights and duties is historically the earliest legal framework, and it remains the dominant
mechanism in the United States for regulating the medical profession and health care institutions. The legal consequence of substandard medical performance is liability under the law of torts. This takes two principal forms: actions for medical malpractice and actions for defective products. To determine ownership of genetic products, courts use property, contract and family law.

15. State boards of health license health care providers and in egregious cases may suspend individuals or institutions that fall below state standards. However, nongovernmental professional accreditation associations and credentialing committees conduct most monitoring of health care providers. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) accredits approximately 5,400 hospitals. BARRY R. FURROW, THOMAS L. GREANEY, SANDRA H. JOHNSON, TIMOTHY STOLTZFUS JOST & ROBERT L. SCHWARTZ, HEALTH LAW 7 (1995). JCAHO is a private credentialing organization whose standards and findings are accepted by state and federal authorities.

Most states have incorporated JCAHO accreditation standards, some explicitly, into their hospital licensure standards. Some have accepted JCAHO accreditation in lieu of a state license. Under the Medicare statute, JCAHO-accredited hospitals are 'deemed' to have met requirements for Medicare certification. Although the Secretary retains a look-behind authority, JCAHO substitutes for the routine surveillance process.


Physicians' hospital privileges are granted and suspended by credentialing committees composed of the private physicians who comprise the medical staff. The medical staff traditionally has held substantial authority over the hospital's internal quality assurance system and its credentialing process, which is the process through which physicians receive and maintain privileges. Only the hospital's governing board has legal authority to grant, deny, limit or revoke privileges, but it is the hospital's medical staff that generally controls the credentialing process to that ultimate point. The medical staff structure has allowed substantial physician control over access to hospital privileges ....

1. Medical Malpractice

The principal control mechanism governing the quality of health care in the United States is the civil action for medical malpractice. Malpractice litigation is more common in the United States than in other nations.6 The American Medical Association (AMA) has proposed replacing the tort system with administrative determinations of medical liability and that medical errors could be reduced by strengthening the licensing and disciplinary powers of state medical boards.7 However, this proposal has not been adopted, and in the United States it is principally the fear of malpractice liability that drives health care providers to adopt the latest technology, as well as follow accepted clinical practice guidelines.8

Over the past twenty-five years the courts have introduced a number of significant reforms to the law of medical malpractice, including the discovery rule,9 national standards of care10 and enterprise liability.21 The

16. For example, the number of claims filed per physician is eight times higher in the United States than in Canada; ... Canadian physicians are sued for negligence about one-fifth as often as U.S. physicians .... [and] Canadian physicians also pay about one-ninth the amount paid by their U.S. counterparts for malpractice insurance.


18. The system is not without critics. [T]he tort-based medical liability system in the U.S. does a poor job of compensating injured parties, and its effectiveness at deterring negligent practice is questionable. Yet the costs of the system are substantial, both when measured in terms of direct premium costs and even more so when the costs of defensive medicine and of reduced access to care are considered.

Hottenroth, supra note 16, at 290.

19. In the past, the statute of limitations for medical malpractice typically commenced to run when the treatment was rendered. See, e.g., Shearin v. Lloyd, 98 S.E.2d 508 (N.C. 1957). This foreclosed many worthy claims. For example, in Goldsmith v. Howmedica, Inc, 491 N.E.2d 1097 (N.Y. 1986), the patient received a hip replacement in 1973, and the apparatus broke in 1981. The court held that the cause of action accrued in 1973 and that the claim was barred by the statute of
cumulative effect of these reforms has worked a sea change allowing patients unparalleled opportunities to redress medical harm.

Insurers and the health care industry have made determined efforts to limit injured patients' rights to recovery for medical malpractice as part of the "tort reform" movement. Tort reform proposals include caps on recovery for pain and suffering, medical screening panels, statutes of limitations. To correct this inequity the courts and legislatures adopted the "discovery rule," allowing the statute of limitations to commence running when the patient discovers the fact that medical malpractice occurred. Some courts have held that the statute of limitations does not begin to run until the plaintiff discovers "that the injury was caused by the wrongful conduct of another." Mastro v. Brodie, 682 P.2d 1162, 1168 (Colo. 1984).

20. Formerly, medical professionals were liable under "local" standards of care; how would the reasonable and prudent physician in that community have handled a case? Not only did this rule often lower the standard of care to which professionals were held, it limited the pool of possible experts who could testify for the plaintiff to physicians in the local community, which in many cases made it impossible for the plaintiff to prove that malpractice occurred. The courts now hold health care professionals and institutions to national standards of care, imposing liability if they do not stay abreast of technological and professional advancements. See, e.g., Bruni v. Tatsumi, 346 N.E.2d 673 (Ohio 1976); Hall v. Hilbun, 466 So. 2d 856 (Miss. 1985). Though Hall has been superceded by statute for other reasons, Mississippi still follows the national standard of care.

21. Historically hospitals enjoyed sovereign or charitable immunity from suit. See, e.g., McDonald v. Massachusetts General Hospital, 120 Mass. 432, 436 (1876). Today, however, charitable immunity has been abolished. Bing v. Thunig, 143 N.E.2d 3 (N.Y. 1957). Formerly, under the "independent contractor" doctrine hospitals were not liable for the medical malpractice of the physicians who rendered medical care at the hospital. Today, theories of liability such as apparent agency, agency by estoppel and the "essential function" test have made great inroads on the independent contractor doctrine. See Boyd v. Albert Einstein Medical Center, 547 A.2d 1229 (Pa 1988) (finding "a question of material fact as to whether the participating physicians were the ostensible agents of HMO."). In addition, liability is increasingly being imputed to hospitals and managed care organizations under theories of direct liability such as negligent credentialing and negligent utilization review. As one author states:

At least twenty-two states have adopted some form of the hospital corporate liability theory and provide some legal relief for the tort of negligent credentialing. With the advent of managed care and the emergence of new types of health care delivery systems, the theory of corporate liability has expanded to include these new health care delivery systems.

repose and stricter requirements for qualifying expert testimony.\textsuperscript{22} State courts have often declared these proposed laws unconstitutional under state constitutions for blocking patients' access to the courts.\textsuperscript{23} However, a federal statute, ERISA,\textsuperscript{24} has been held to preempt patients' claims against health insurers for denial of medical care.\textsuperscript{25}

Genetic-based medicine will be subject to civil liability for medical malpractice on the same basis as other forms of treatment. There will be actions for failure to diagnose genetic conditions, particularly birth defects.\textsuperscript{26} As in the case of Jesse Gelsinger, there will be actions

\begin{itemize}
\item \textsuperscript{22} See, e.g., Ohio Amended Sub. H.B. 350, discussed and declared unconstitutional in State ex rel. Ohio Academy of Trial Lawyers v. Sheward, 715 N.E.2d 1062, 1102 (Ohio 1999).
\item \textsuperscript{23} One author notes:
State supreme courts have invalidated damage caps on the following four grounds: (1) violation of the right to trial by jury enshrined in the state constitution, (2) violation of the equal protection guarantee of the state constitution, (3) violation of the due process clause of a state constitution, and (4) violation of the right-to-a-remedy (open courts) provision of a state constitution. David Fink, Best v. Taylor Machine Works, The Remittitur Doctrine, and the Implications for Tort Reform, 94 Nw. U. L. REV. 227, 266 (1999).
\item \textsuperscript{26} “Physicians have been successfully sued who failed to offer genetic testing to couples who gave birth to a child with a genetic disorder, who misinterpreted genetic test results, or who failed properly to inform couples about their risk of having a child with a genetic disorder.” Maxwell J. Mehlman, The Effect of Genomics on Health Services Management: Ethical and Legal Perspectives, 17 FRONTIERS HEALTH SERV. MGMT. 28, 42-43, 2001 WL 18452203 (citations
\end{itemize}
contending that the individual and institutional health care researchers did not conform to ethical or medical standards in conducting clinical trials.

Genetic science may cause a relatively rare type of lawsuit to become more common. Health care providers are typically not liable to non-patients. The rare exception has been the Tarasoff-type liability, named for a case where a psychotherapist failed to warn a person that his patient intended to kill her. Upon examining their patients, genetic health care providers will acquire immense knowledge not only about their patients, but also about their patients' relatives. This is knowledge that will often mean the difference between life and death. Will the providers of genetic services have a legal duty to warn these relatives of dangerous medical conditions? Will non-patients be permitted to sue for failure to warn? The trend of the case law is to allow suit by non-patients where physicians failed to warn their own patients of the risks to others.

omitted). For example, the Supreme Court of Ohio has held that when a child is conceived following a failed sterilization procedure, the parents may recover expenses incurred in connection with pregnancy and birth, but are not entitled to the costs of raising the child, “when the child’s birth defect was not reasonably foreseeable by the defendant who negligently performed the sterilization procedure.” Simmerer v. Dabbas, 733 N.E.2d 1169, 1174 (Ohio 2000). Cf. Smith v. Cote, 513 A.2d 341 (N.H. 1986) (allowing recovery). However, the great majority of courts have denied recovery in “wrongful life” actions brought by a child whose birth defects were not diagnosed. See Hester v. Dwivedi, 733 N.E.2d 1161 (Ohio 2000).

27. The Gelsingers' lawsuit was settled out of court. Huntly Collins, U Penn Scientists Discover Reason for Death of Gene-Therapy Teen, PITTSBURGH POST-GAZETTE, January 26, 2001, at B8. Their attorney, Alan Milstein, has subsequently brought suit against other medical research centers on behalf of patients harmed during clinical trials; in describing a suit against the Hutchinson Center Milstein stated, “The issue of whether or not the experiment here conformed with these worldwide ethical standards is a perfect issue for a class action.” Duff Wilson and David Heath, Class-Action Suit Filed Against 'The Hutch': Protocol 126 Broke Laws, Say Families of Cancer Patients, SEATTLE TIMES, March 27, 2001, at A1. For a thorough discussion of the practical and legal barriers to suing medical researchers, see James T. O'Reilly, Elders, Surgeons, Regulators, Jurors: Are Medical Experimentation's Mistakes Too Easily Buried?, 31 LOY. U. CHI. L.J. 317 (2000).


29. Must physicians contact patients' relatives to warn them of a genetic danger, or is it sufficient to inform the patient of the risk to others? Compare Pate v. Threlkel, 661 So. 2d 278, 279 (Fla. 1995) (physician had duty to warn patient of risk to others), with Safer v. Pack, 677 A. 2d 1188 (N.J. 1996) (physician liable to child of patient if child can prove that the physician's failure to warn her of the risk of genetic disease violated the standard of care). See also Reisner v. Regents, 37
The threat of a lawsuit for medical malpractice is the principal method of regulating the quality of medical care and the law will have little difficulty adapting existing theories of liability for genetic-based medicine. In myriad cases the common law of medical malpractice has taken account of technological change. It is now commonplace for medical professionals and institutions to be subject to liability for failing to promptly adopt advances in technology or medical technique. However, a serious drawback to this method of regulating genetic technology is that it is completely reactive, not proactive. It does not prevent harm; it only deters it. No lawsuit can be brought until the damage has been done.

2. Products Liability

In addition to claims for medical malpractice, persons who are injured by genetic technology may seek redress under the law of products liability, which awards compensation for harm caused by defective products. Physicians and pharmaceutical companies may assert three principal defenses to products liability claims: a heightened standard that discourages recovery for design defects, federal preemption and the learned intermediary doctrine.

Under the law of products liability, it is particularly difficult to prove that a pharmaceutical product is defectively designed. In general, a product is defectively designed if the product is "not reasonably safe." In contrast, pharmaceutical products are considered to have a design defect only if the foreseeable risks of the drug were so great in relation to its therapeutic benefits that no reasonable physician would ever prescribe it "for any class of patients."

30. For example, in Washington v. Washington Hospital Center, 579 A.2d 177, 179 (D.C. 1990), the court affirmed a verdict finding the hospital liable for failure to provide its anesthesiologists with an end-tidal carbon dioxide monitor.

31. "One engaged in the business of selling or otherwise distributing products who sells or distributes a defective product is subject to liability for harm to persons or property caused by the defect." RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. §1 (1997).

32. See infra notes 31-38 and accompanying text.

33. RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 2(b) (1997).

34. A prescription drug or medical device is not reasonably safe due to defective design if the foreseeable risks of harm posed by the drug or medical device are sufficiently great in relation to its foreseeable therapeutic benefits that reasonable health-care providers, knowing of
Federal preemption may also prevent recovery by injured patients, as some courts have held that federal law preempts state law claims for products liability for defective "medical devices." However, federal law does not preempt claims for defective "drugs" or "biologic products." It may be difficult in some cases, particularly with combination products, to determine whether the product is a drug, a biologic, or a device.

Another barrier to recovery is the "learned intermediary doctrine," which is the principle that a manufacturer or distributor of prescription drugs need only provide warnings or instructions to the physician, not to the patient. This principle has come under attack as pharmaceutical companies have begun direct advertising to consumers.

such foreseeable risks and therapeutic benefits, would not prescribe the drug or medical device for any class of patients.


37. Id. at 20-21.

38. The Restatement of Torts describes the learned intermediary doctrine as follows:

A prescription drug or medical device is not reasonably safe due to inadequate instructions or warnings if reasonable instructions or warnings regarding foreseeable risks of harm are not provided to: (1) prescribing and other health-care providers who are in a position to reduce the risks of harm in accordance with the instructions or warnings; or (2) the patient when the manufacturer knows or has reason to know that health-care providers will not be in a position to reduce the risks of harm in accordance with the instructions or warnings.

**Restatement (Third) of Torts: Prod. Liab.** § 6(d).

3. Property, Contract, and Family Law

There are three types of human tissue that may be the subject of biotechnology: somatic tissue such as stem cells, individual human genes and early forms of human development including preembryos and embryos. Property, contract and family law determine ownership rights in these tissues.

The common law of property and contracts presently governs the ownership of human tissue, cell lines and genetic information. Medical researchers and biotech firms can gain ownership of human tissue by means of a contract, so long as there is adequate disclosure of both medical and financial implications to patients. When researchers removed a patient's spleen and took blood samples without informing the patient that they were developing a valuable cell line from his T-

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40. *See infra* notes 44-46 and accompanying text.


42. *See infra* notes 45, 47-48 and accompanying text.

43. *See infra* notes 44-48 and accompanying text.

44. The leading case governing ownership rights in human tissue is Moore v. Regents of the University of California, 793 P.2d 479 (Ca. 1990). In that case the court ruled that ownership of the patient's spleen was governed by the law of property, stating,

Since Moore clearly did not expect to retain possession of his cells following their removal, to sue for their conversion he must have retained an ownership interest in them. But there are several reasons to doubt that he did retain any such interest. First, no reported judicial decision supports Moore's claim, either directly or by close analogy. Second, California statutory law drastically limits any continuing interest of a patient in excised cells. Third, the subject matters of the Regent's patient—the patented cell line and the products derived from it—cannot be Moore's property.

*Id.* at 488-489 (footnote omitted).

45. *Id.* at 488-489. (holding that, "a physician who is seeking a patient's consent for a medical procedure must, in order to satisfy his fiduciary duty and to obtain the patient's informed consent, disclose personal interests unrelated to the patient's health, whether research or economic, that may affect his medical judgment." *See also* Joel N. Epross, *In Vitro Fertilization: Perspectives on Current Issues*, 32 JURIMETRICS 447, 459-461 (1992) (discussing the applicability of the law of property and contracts to human embryos).
lymphocytes, the Supreme Court of California ruled that the researchers were liable to the patient.46

New reproductive technology enables persons to create children with donated gametes and/or gestational surrogates. Efforts to plan technologically assisted procreation involve the law of contracts, which has threatened to supplant family law in determinations of parentage.47 The conflict between property, contract and family law has been the sharpest when divorcing couples have fought over ownership of "frozen embryos."48 These cases pale in comparison to battles between research institutions and biotech firms over the building blocks and initial forms of potential life.49

B. Specific Statutory Rights

The courts are not the only governmental body to recognize individual rights; they are also created by legislatures.50 As with common law rights and duties, legislatively created rights are designed to deter harmful

46. See Moore v. Regents, 793 P.2d at 480.

47. Three reported gestational surrogacy cases have addressed the question of the identity of the mother. Johnson v. Calvert, 851 P.2d 776 (Ca. 1993); Belsito v. Clark, 644 N.E.2d 760 (Ohio 1994); and Buzzanca v. Buzzanca, 72 Cal. Rptr. 2d 280 (1998). The California decisions gave primary effect to the intent of the parties in enforcing the surrogacy agreement. See Robert M. Kort, Johnson v. Calvert, California Supreme Court Enforces Surrogacy Contract, 26 ARIZ ST. L. J. 243 (1994). In contrast, the Ohio court emphasized the primacy of the genetic link in the absence of waiver or consent. See Ilana Hurwitz, Collaborative Reproduction: Finding the Child in the Maze of Legal Motherhood, 33 CONN. L. REV. 127, 137-38 (2000). Professor Malina Coleman has suggested that the law of contracts should not be applied rigidly to surrogacy agreements; instead, "there must be procedures in place which guarantee to the greatest extent possible that the decision to contribute one's reproductive function was freely made after careful deliberation on the part of all the individuals involved." Malina Coleman, Gestation, Intent, and the Seed: Defining Motherhood in the Era of Assisted Human Reproduction, 17 CARDOZO L. REV. 497, 529 (1996).


49. See Faith S. Fillman, Comment: Doctrine of Equivalents: Is Festo the Right Decision for the Biomedical Industry?, 33 St. Mary’s L.J. 493, 510-14 (2002) (detailing the critical importance of the “doctrine of equivalents” to protecting patents against competing companies in the field of biotechnology).

50. Statutes may either repeal or supplement the common law. Federal statutes may expressly or implicitly preempt conflicting provisions of state law.
In general, the government does not directly enforce these laws. Instead, the vast majority of legislatively created rights are enforced by individuals by means of civil lawsuits. It is as if the legislature makes every citizen a "private attorney general" empowered to enforce the law. In many cases, this is a more effective method of regulation than direct action by administrative agencies.

The preeminent statute creating rights in this field is the Americans With Disabilities Act (ADA). This law prohibits all discrimination in employment and in places of public accommodation against individuals who have an actual disability, or because the individual is regarded as having a disability. Proponents of the ADA assumed that it would protect employees from genetic discrimination.

Initially, there was reason for hope. In 1995, the Equal Employment Opportunity Commission (EEOC) issued official guidelines prohibiting genetic discrimination against employees and in 2000, President Clinton

51. For example, the Americans with Disability Act, 42 U.S.C. §§ 12101-12213 (2000), was intended to deter discrimination against persons on the basis of disability.

52. For example, the Supreme Court recently stated: "The object of civil RICO is thus not merely to compensate victims but to turn them into prosecutors, 'private attorneys general,' dedicated to eliminating racketeering activity." Rotella v. Wood, 528 U.S. 549, 557 (2000).

53. For example, the "citizens' suit" provision of the Endangered Species Act has been utilized in dozens of cases to protect over 400 species of plants and animals. Douglas Jehl, Moratorium Asked on Suits That Seek to Protect Species, N.Y. TIMES, April 12, 2001, at A1. Representative George Miller of California compared the efficacy of citizen suits to agency action: "If you didn't have the citizens' suits, you'd basically have the power brokers determining if you were going to save the salmon or the spotted owl, and that just doesn't make sense." Id.


55. 42 U.S.C. § 12112(a) (2000). "The term 'disability' means, with respect to an individual - (A) a physical or mental impairment that substantially limits one or more of the major life activities of such individual; (B) a record of such an impairment; or (C) being regarded as having such an impairment." 42 U.S.C. § 12102(2) (2000).


57. 2 U.S. EEOC Compl. Man., Order 915.002, at 902-45 (1995). However, the Supreme Court has held that the EEOC does not have delegated authority to interpret the term "disability." Sutton v. United Air Lines, 527 U.S. 471, 479 (1999). In 2001 the EEOC forced the Burlington Northern Santa Fe Railroad to cease genetic testing of employees who had developed carpal tunnel syndrome.
issued an Executive Order forbidding the federal government from discriminating on the basis of genetic makeup. 58 Unfortunately, the United States Supreme Court, in a trio of decisions handed down in 1999, tore the heart out of the ADA. In Sutton v. United Air Lines 59 and its companion cases, 60 the Court held that employers could discriminate against people with imperfect vision or high blood pressure, even though these conditions were medically corrected. The court reasoned that this was not discrimination on the basis of disability because the employers did not regard the plaintiffs as completely disabled from working; the employers simply did not regard the plaintiffs as "ideally suited" for particular jobs, such as a global airline pilot. 61 The Court's crabbed interpretation of the ADA severely reduces the likelihood that the act will protect persons with asymptomatic genetic disabilities. 62

The lesson of Sutton is that federal laws protecting people from genetic discrimination will have to be very carefully drafted to prevent the courts from giving them a blinkered and narrow interpretation. Several competing genetic nondiscrimination bills have been introduced in Congress. 63 Even though thirty-five states outlaw genetic discrimination in

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61. The Court stated:
   [A]n employer is free to decide that physical characteristics or medical conditions that do not rise to the level of an impairment - such as one's height, build, or singing voice - are preferable to others, just as it is free to decide that some limiting, but not substantially limiting, impairments make individuals less than ideally suited for a job.
   527 U.S. at 490-91 (emphasis in original).
62. As one legal scholar noted: "Although none of these decisions concerned the issue of asymptomatic genetic disabilities, these cases restrict the definition of who is a qualified individual with a disability, and thus, they may ultimately have an impact on the issue.” Paul Steven Miller, Is There a Pink Slip in My Genes? Genetic Discrimination in the Workplace, 3 J. HEALTH CARE L. & POL'Y 225, 245 (2000). See also Brian M. Holt, Genetically Defective: The Judicial Interpretation of the Americans with Disabilities Act Fails to Protect Against Genetic Discrimination in the Workplace, 35 J. MARSHALL L. REV. 457 (2002).
health insurance coverage and twenty-three states ban the use of genetic information in employment, "under the current state and federal statutory schemes there are serious gaps in protection." Lori Andrews suggests that, to be effective, such laws should require a patient’s informed consent before testing, forbid classification of genetic disorders as "preexisting conditions" that may be used to deny insurance coverage and specifically prohibit employment discrimination based on genetic testing or family history.

C. Constitutional Rights and Duties

Federal constitutional rights will play a major role in shaping the law that will govern the use of genetic technology. The Constitution articulates our fundamental rights in broad terms. These provisions should be interpreted to guarantee the autonomy of parents and patients to make personal choices in reproduction and health; preserve the dignity of the human race by prohibiting ownership and exploitation of humans; protect health care providers and the biotechnology industry from undue restrictions on scientific inquiry and commercial speech; and defend the genetic autonomy of children.

on the basis of genetic information with respect to health insurance and employment).

64. See Bonnie Erbe, Genetic’s Gain is Privacy’s Loss, MILWAUKEE JOURNAL SENTINAL, February 14, 2001, at 13A.


67. Many of our fundamental rights are derived from broad language set forth in the First Amendment, ("Congress shall make no law . . . abridging the freedom of speech . . . .") U.S. CONST amend. I.) and the Fourteenth Amendment. ("No state shall . . . deprive any person of life, liberty, or property without due process of law; nor deny to any person within its jurisdiction the equal protection of the laws." U.S. CONST. Amend. XIV, § 1.).
1. Procreation

It is well established in the United States that people have procreative rights. *Skinner v. Oklahoma*, 66 *Griswold v. Connecticut* 69 and *Roe v. Wade* 70 stand for the proposition that people have the right to decide for themselves whether or not to have children. In order to regulate in this field, the government must have a "compelling governmental interest," 71 that is, a goal that outweighs and subordinates the interest of the individual in becoming or not becoming a parent. 72 Many legal scholars believe that this right to procreation extends to infertile couples the opportunity to take advantage of new reproductive techniques such as in vitro fertilization and gamete transfers. 73 But how far will this right extend? Will the right include cloning? 74

Furthermore, although health care itself has not been recognized as a fundamental right under the Constitution of the United States, 75 the courts

69. 381 U.S. 479 (1965) (invalidating a Connecticut law prohibiting any person from using a contraceptive drug or device).
70. 410 U.S. 113 (1973) (invalidating a Texas law that outlawed abortion at all stages of pregnancy).
71. For example, in *Roe*, the Court stated: "Where certain 'fundamental rights' are involved, the Court has held that regulation limiting these rights may be justified only by a 'compelling state interest' and that legislative enactments must be narrowly drawn to express only the legitimate state interests at stake ...." Id. at 155.
72. Concurring in *Griswold*, Justice Goldberg equated a "compelling" governmental interest with a "subordinating" one: "Surely the Government, absent a showing of a compelling subordinating state interest, could not decree that all husbands and wives must be sterilized after two children have been born to them." 381 U.S. at 496-97 (Goldberg, J., concurring).
75. "[T]he Constitution does not provide judicial remedies for every social and economic ill." Lindsey v. Normet, 405 U.S. 56, 74 (1972) (finding no constitutional right to housing), and Dandridge v. Williams, 397 U.S. 471, 485 (finding no constitutional right to welfare benefits). In DeShaney v. Winnebago County Department of Social Services, 489 U.S. 189 (1989), the Supreme Court gave clear expression to the "no affirmative duty doctrine," the principle that the purpose of the Constitution "was to protect the people from the State, not to ensure that the State protected them from each other." Id. at 196. However, President Franklin Roosevelt considered "adequate medical care" to be encompassed within the
have recognized that parents have the constitutional right to make decisions for their dependent children.\textsuperscript{76} This includes the right to make health care decisions for a child.\textsuperscript{77} This would certainly include the right to obtain somatic cell gene therapy for a child to combat disease.\textsuperscript{78} However, the parental right of control is not absolute.\textsuperscript{79} Will this right of parental control, coupled with their right of procreation, allow parents to arrange for the genetic engineering of gametes and embryos?\textsuperscript{80}


76. Parental rights were first recognized by the Supreme Court in Meyer v. Nebraska, 262 U.S. 390 (1923). In that case the Court held that parents had the right to have their children learn the German language, specifically stating that the word “liberty” in the Fourteenth Amendment encompassed “the right to bring up children.” Id. at 399.

77. See Burge v. City and County of San Francisco, 262 P.2d 6, 12 (Cal. 1953) (noting that medical decisionmaking for the child is within the realm of authority conferred upon a parent in the rearing of children).

78. However, ethicists have distinguished genetic \textit{treatment} from genetic \textit{enhancement}. “In the present state of knowledge any attempt by gene modification to change human traits not associated with disease would not be acceptable.” CLOTHIER COMMITTEE, REPORT OF THE COMMITTEE ON THE ETHICS OF GENE THERAPY 17 (1992).

79. For example, in Prince v. Massachusetts, 321 U.S. 158 (1944), the Supreme Court held that a parent did not have a constitutional right to allow a child to work in violation of child labor laws. “Parents may be free to become martyrs themselves. But it does not follow that they are free, in identical circumstances, to make martyrs of their children before they have reached the age of full and legal discretion when they can make that choice for themselves.” Id. at 170. See Adam Lamparello, Taking God Out of the Hospital: Requiring Parents to Seek Medical Care for Their Children Regardless of Their Religious Belief, 6 TEX. F. CIV. LIB. & CIV. RTS. 47, 48 (2001) (arguing that parents do not have the constitutional right to deny their children medical care for religious reasons).

Lawsuits presenting these claims may be brought by health care providers or even biotechnology companies. The plaintiffs in *Griswold v. Connecticut* were the Executive Director and Medical Director of Planned Parenthood in that state. The Supreme Court expressly held that they had standing to challenge the state statute that outlawed the use of birth control devices.

### 2. Slavery

So far, this article has considered and explored the constitutional limitations on government regulation of genetic technology. However, does the Constitution prevent individuals or private corporations from engaging in certain types of genetic experimentation? Generally, the Constitution does not govern the actions of individuals. However, there is one provision of the United States Constitution that limits the kinds of relationships that persons may establish with each other. Section one of the Thirteenth Amendment abolishes slavery. Under that clause, no person in the United States may own or enslave another. Furthermore, under Section Two of the Thirteenth Amendment, the Supreme Court has ruled that Congress has the power to abolish the "badges" and incidents of slavery.

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81. 381 U.S. at 480.
82. Id. at 481.
83. "Neither slavery nor involuntary servitude, except as a punishment for crime whereof the party shall have been duly convicted, shall exist within the United States, or any place subject to their jurisdiction." U.S. CONST. amend. XIII, § 1.
84. *See Civil Rights Cases*, 109 U.S. 3, 20 (1883). The Supreme Court held that "The [13th] [A]mendment is not a mere prohibition of State laws establishing or upholding slavery, but an absolute declaration that slavery or involuntary servitude shall not exist in any part of the United States." *Id.*
85. "Congress shall have power to enforce this article by appropriate legislation." U.S. CONST. amend. XIII, § 2.
86. *Civil Rights Cases*, 109 U.S at 21 (1883) (holding that Congress not only has the power to prohibit slavery, but also, "Congress has a right to enact all necessary and proper laws for the obliteration and prevention of slavery, with all its badges and incidents ...".). Accordingly, Congress is authorized to enact laws restricting slavery itself, but also any activity that constitutes a "badge" or "incident" of slavery.
In 1987, the United States Patent Office issued a policy statement stating that the Constitution outlawed patents on humans. In an attempt to test this ruling, the Foundation on Economic Trends applied for a patent on a half-human, half-animal chimera. The Patent Office denied this application on the ground that the creation of half-human chimeras was contrary to public policy and morality and therefore not "useful" within the meaning of the Patent Act.

It is clear that any attempt to create human beings like the Epsilons of Aldous Huxley's *Brave New World* who were genetically engineered to perform menial tasks would violate the Thirteenth Amendment. It is equally apparent that it would violate the fundamental rule of morality, Emmanuel Kant's categorical imperative, that no person may be treated solely as a means to other people's ends.

90. "We decant our babies as socialized human beings, as Alphas or Epsilons, as future sewer workers or future [world controllers]." ALDOUS HUXLEY, *BRAVE NEW WORLD* 13 (1998). One could argue that the Alphas were just as enslaved, just as deprived of individuality, as the Epsilons.
91. This is the "Formula of the End Itself" version of the categorical imperative: "Act in such a way that you always treat humanity, whether in your own person or in the person of any other, never simply as a means, but always at the same time as an end." THE INTERNET ENCYCLOPEDIA OF PHILOSOPHY, Categorical Imperative, at http://www.utm.edu/research/iep/c/catimper (last visited Oct. 14, 2002).
3. The Right to Scientific Inquiry

There is little doubt that there exists a constitutional right to engage in scientific inquiry. In *Epperson v. Arkansas*,92 the Supreme Court struck down an Arkansas law that prohibited the teaching of evolution in the public schools, acknowledging "the fundamental values of freedom of speech and inquiry and of belief."93 The Court has noted that human progress depends upon freedom of inquiry: "Teachers and students must always remain free to inquire, to study and to evaluate, to gain new maturity and understanding; otherwise our civilization will stagnate and die."94

The more difficult question is: may the government limit scientists' ability to conduct experiments on living matter?95 It was settled in *Roe v. Wade* that an embryo, even a third-trimester fetus, has no constitutional rights because the fetus is not a person within the meaning of the Fourteenth Amendment.96 Accordingly, the only rights that a fetus or embryo possesses are those conferred upon it by state or federal statutes.97 In *Roe*, the Supreme Court held that a woman may abort a fetus prior to viability.98 However, in that case the court was balancing the state's interest in protecting fetal life against a woman's procreative rights and her right to bodily integrity, and the Court found that prior to viability the

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92. 393 U.S. 97 (1968).
93. *Id.* at 104.
94. Sweezy v. New Hampshire, 354 U.S. 234, 250 (1954). In an obscenity case, the Court observed: "The protection given speech and press was fashioned to assure unfettered interchange of ideas for the bringing about of political and social changes desired by the people." Roth v. United States, 354 U.S. 476, 484 (1957).
96. "*[T]he word 'person', as used in the Fourteenth Amendment, does not include the unborn.*" *Roe*, 410 U.S. at 158.
97. For example, the current Presidential administration has chosen to issue regulations that recognize fetuses as children under federal law. See Vicki Kemper, *White House Issues Regulation That Defines Fetuses as Children*, L.A. TIMES, September 28, 2002, page A23 ("The Bush administration . . . issued a final regulation defining human fetuses and embryos as children, saying it would allow states to offer prenatal health care to greater numbers of poor women.").
98. "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 ...." *Roe*, 410 U.S. at 164-65.
state's interest in protecting fetal life was not compelling enough to outweigh the woman's fundamental rights.99

What if there were no procreative rights or rights to bodily integrity to weigh in the balance? What if the only right interposed against the state’s interest in protecting embryonic or fetal life was the First Amendment right to scientific inquiry? The courts might well uphold a governmental ban on fetal or embryonic experimentation.100

4. Commercial Speech

To what extent is the biotechnology industry free to advertise advances in genetics and offer these services to the public? Commercial speech enjoys protection under the First Amendment.101 The Supreme Court has held that entities engaging in constitutionally protected activity must be allowed to advertise.102 Furthermore, all entities engaged in lawful activities must be allowed to engage in truthful, non-misleading advertising unless the government can demonstrate that a ban or limit on advertising directly serves a substantial governmental interest.103 To the extent that the uses of genetic technology are lawful, speech advertising these services will be protected.104

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99. The Court stated: “With respect to the state’s important and legitimate interest in potential life, the ‘compelling’ point is at viability.” Id. at 163.


101. The first Supreme Court decision holding that the First Amendment applies to commercial speech was Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, 425 U.S. 748, 770 (1976).


104. The biotechnology industry has already invoked this principle. In International Dairy Foods v. Amestoy, 92 F.3d 67, 74 (2nd Cir. 1996), the United States Court of Appeals for the Second Circuit struck down a Vermont labeling law that required retailers to provide notification to consumers if milk they sold had been derived from cows treated with recombinant bovine somatotropin (rBST). The Court held that Vermont's interest was not substantial enough to justify the law: “[C]onsumer curiosity alone is not a strong enough state interest to sustain the compulsion of even an accurate, factual statement.” Id. at 74.
5. The Rights of Children

The "undiscovered country" in the field of Constitutional Law is the articulation of the fundamental rights of children. The history of our Constitution is a story of expanding human rights, and a growing understanding and appreciation of human potential. Basic human rights have been extended to African-Americans\textsuperscript{105} and other minority groups.\textsuperscript{106} In addition, women have earned equal rights under the Constitution.\textsuperscript{107} Gays and lesbians are in the process of winning equal recognition as well.\textsuperscript{108}

As yet, however, the rights of children are still circumscribed by the same "paternalism" that once characterized the treatment of slaves and married women. The notion of children as independent legal entities is as foreign to us as racial and gender equality was to our ancestors who drafted the Constitution. But the organic growth of our Constitution, along with the progress of our nation in the recognition of human rights, will one day accord substantial protection to children.

This has special importance in the field of genetics. May we screen embryos for implantation for the purpose of creating a tissue match?\textsuperscript{109}

\begin{itemize}
\item \textsuperscript{105} The Constitutional struggle for racial equality has raged for generations, beginning with the Civil War Amendments, and marked by the eventual abolition of official segregation in Brown v. Board of Education, 347 U.S. 483, 489 (1954).
\item \textsuperscript{107} The seminal gender discrimination case was decided a mere thirty years ago. Reed v. Reed, 404 U.S. 71 (1971).
\item \textsuperscript{109} As of 1994, over forty children had been conceived for the specific purpose of donating bone marrow to a sibling. Vicki G. Norton, Unnatural Selection: Nontherapeutic Preimplantation Genetic Screening and Proposed Regulation, 41 U.C.L.A. L. REV. 1581, 1598 (1994).
\end{itemize}
May we create a child who has no legal parents? May a child's genetic makeup be altered prior to birth, obviously without its consent?

The responsibility for regulating genetic technology by developing the common law, applying statutes creating individual rights and interpreting the Constitution will belong to the courts. However, the enforcement of these rights lies wholly in the hands of individuals. This model of regulation reflects the nineteenth century ideal of the state as a neutral arbiter; a government that merely adjudicates disputes between competing social interests. This was the model of "classical legal thought" that dominated American law in the 19th and early 20th Centuries.

Just as economic depression and world war called forth a new, more active conception of the state, the challenges of genetic technology will necessitate greater government oversight. In the following section, this article will describe scientific regulation by administrative agencies.

II. SCIENTIFIC REGULATION

Administrative agencies are creatures of statute. They are not established by the Constitution, nor can they call themselves into existence by the Constitution. They are creatures of statute. They are not established by the Constitution, nor can they call themselves into existence by the Constitution.

110. A California trial court concluded that a child created with donated gametes and gestated by a surrogate "had no legal parents." Buzzanca, 72 Cal. Rptr. 2d at 282. The Court of Appeals reversed, finding that the "intended parents" were the lawful parents. Id.

111. "Arguments against such research cite the fact that genetic experiments inevitably involve human embryos and, thus, are performed without the consent of the experimental subject." John R. Harding, Beyond Abortion: Human Genetics and the New Eugenics, 18 PEP. L. REV. 471, 486-87 (1991).


113. Id. at 20, 33. "From the beginning of the twentieth century, Classical Legal Thought found itself confronted by an increasingly powerful critique of its basic premises. In one legal field after another, Progressive thinkers challenged both the political and moral assumptions of the old order and the structures of legal doctrine and legal reasoning that were designed to represent those assumptions as neutral, natural, and necessary." Id. at 169.

114. See generally id. at 213-246 (Chapter 8, Legal Realism, The Administrative State, and the Rule of Law), and 247-72 (Chapter 9, Post War Legal Thought).

115. The Founders did, however, anticipate the creation of administrative agencies. The Constitution provides that the President "may require the Opinion, in writing, of the principal Officer in each of the executive Departments, upon any Subject relating to the Duties of their respective Offices," U.S. Const. art. II, § 2, cl. 1, and that "Congress may by Law vest the Appointment of such inferior
creation. The statutes that create and empower administrative agencies – statutes called "enabling acts" – are fundamentally different from statutes that create individual rights and duties. Aggrieved citizens enforce statutes that grant individual rights. In contrast, the agencies themselves enforce the statutes that create them. Statutes granting individual rights are interpreted in the first instance by the courts. Those statutes that create and empower administrative agencies are primarily interpreted by the agencies themselves. To be effective, statutes protecting individual rights must be clear and unambiguous, while enabling acts should use the broadest possible language in granting rulemaking authority to administrative agencies.

Officers, as they think proper, in the President alone, in the Courts of Law, or in the Heads of Departments." U.S. CONST. art. II, § 2, cl. 2.

116. "[U]nder our constitutional system, agencies are creatures of the legislature. They do not spring up on their own, and they cannot be created by courts. Agencies function only insofar as a legislature has given them the authority to function." WILLIAM F. FOX, JR., UNDERSTANDING ADMINISTRATIVE LAW 4 (3d ed. 1997).

117. See, e.g., the Federal Violence Against Women Act (VAWA), which provided in relevant part:

A person (including a person who acts under color of any statute, ordinance, regulation, custom, or usage of any State) who commits a crime of violence motivated by gender and thus deprives another of the right declared in subsection (b) of this section shall be liable to the party injured, in an action for the recovery of compensatory and punitive damages, injunctive and declaratory relief, and such other relief as a court may deem appropriate.


This provision of the VAWA was declared unconstitutional in United States v. Morrison, 120 U.S. 598 (2000), on the ground that Congress lacked power under the commerce clause of Article I and the enforcement clause of the Fourteenth Amendment to enact the statute.

118. See FOX, supra note 116, at 145-46 (noting that in the context of agency rulemaking, "the Supreme Court has admonished federal courts to defer to an agency's technical judgments.").

119. In the United States, this principle of judicial interpretation of the law may be traced to the seminal case of Marbury v. Madison, 5 U.S. 137 (1803), where the Court stated: "It is emphatically the province and duty of the judicial department to say what the law is." Id. at 177.

120. See infra notes 134-36 and accompanying text (describing the broad discretion agencies may exercise in interpreting enabling acts under the Chevron doctrine).

121. For example, if the language of the ADA had specifically provided that the term "disability" includes corrected disabilities, the claimants in Sutton would have
Administrative agencies are collectively a fourth branch of government. Each agency is designed to carry out a specific function, such as to protect the environment, fund the arts or oversee the military. Each of the traditional three branches of government has some power to oversee this fourth branch. The President appoints agency heads with the consent of the Senate. He may remove the heads of executive branch agencies at will, and the heads of the independent agencies for cause. Congress establishes an agency by enacting the enabling act, which defines the agency's mission and the scope of its powers. Congress also allocates the funds for agencies and exercises other oversight functions. The courts review the actions of administrative agencies to ensure that their decisions are consistent with their enabling acts, the Administrative Procedure Act and the Constitution.

Since the 1930s the United States has relied upon administrative agencies to regulate American industry, but the administrative model prevailed; in the alternative, if the Supreme Court had deferred to the EEOC's interpretation of the ADA providing that disabilities included corrected disabilities, the claimants would have prevailed. See Rebecca Hanner White, Deference and Disability Discrimination, 99 Mich. L. Rev. 532, 559-562 (2000). However, the Supreme Court declined to decide whether the EEOC's interpretation of the ADA was entitled to deference: “Although the parties dispute the persuasive force of these interpretive guidelines, we have no need in this case to decide what deference is due.” Sutton, 527 U.S. at 480. As one author noted: “The EEOC's lack of authority to promulgate substantive regulations under Title VII, the statute with which the agency has been most closely identified, has fostered a perception that the EEOC is a weak agency.” White, supra at 549.

See Fox, supra note 116, at 21 (summarizing the ways in which the three branches of the federal government exercise control over federal administrative agencies).

“[The President] shall ... nominate, and by and with the Advice and Consent of the Senate, shall appoint ... all other Officers of the United States ....” U.S. CONST. art. II, § 2, cl. 2.


“This principle – that the legislature creates agencies and sets limits on their authority – should be regarded as cardinal rule number one of administrative law.” Fox, supra note 116, at 5.

See Fox, supra note 116, at 39-41 (“Congress polices day-to-day agency action through what is known as the oversight process....There are many other examples of congressional controls. The power to set an agency's budget may be as important as all the other controls combined.”).

followed in the United States has several inherent biases against regulation. First and foremost, agencies have the burden of establishing grounds for regulation. The agency must support any proposed ruling for regulation with evidence in the record, it must explain its proposal in detail and it must allow for comments by interested parties. Substantive rules take years to adopt and they may also face years of court battles. Above all, the agency must demonstrate that its decisions are grounded in science. If an agency cannot demonstrate an adequate scientific basis for a decision, the courts will strike it down.

Furthermore, the decisions of federal agencies, though they carry the force of law, are always subject to being overturned when a new

129. The APA provides: "Except as otherwise provided by statute, the proponent of a rule or order has the burden of proof." 5 U.S.C. § 556(d) (2000). For example, in the Benzene case, Justice Stevens, writing for the plurality, stated: "As we read the statute, the burden was on the Agency to show, on the basis of substantial evidence, that it is at least more likely than not that long-term exposure to 10 ppm of benzene presents a significant risk of material health impairment." AFL-CIO v. American Petroleum Institute, 448 U.S. 607, 653 (1980).

130. The APA reads: "After notice required by this section, the agency shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for oral presentation. After consideration of the relevant matter presented, the agency shall incorporate in the rules adopted a concise general statement of their basis and purpose." 5 U.S.C. § 553(c) (2000). This rule making procedure has been criticized as overly cumbersome: "Our system of legality and administrative law requires building a huge 'record' that will withstand judicial review as a precondition to government regulation." E. Donald Elliott, Environmental Markets and Beyond: Three Modest Proposals for the Future of Environment Law, 29 CAP. U.L. REV. 245, 253 (2001).

131. The exhausting battle over automobile airbags is instructive. "The mandatory passive restraint controversy began with the passage of the Safety Act and has since raged for over thirty years, outlasting seven presidents, eight heads of the Department of Transportation, and more than eight Directors of the NHTSA." John F. McCauley, Cipollone & Myrick: Deflating the Airbag Preemption Defense, 30 IND. L. REV. 827, 832 (1997).

132. For example, the Clean Air Act requires that air quality criteria "shall accurately reflect the latest scientific knowledge," 42 U.S.C. § 7408(a)(1)(C)(2) (2000), and the Occupational Safety and Health Act requires the Secretary of Labor to take into consideration "the latest available scientific data in the field." 29 U.S.C. § 655(b)(5) (2000).

133. For an article arguing that courts should exercise tighter control over agencies' use of science, see D. Hiep Truong, Daubert and Judicial Review: How Does an Administrative Agency Distinguish Valid Science from Junk Science?, 33 AKRON L. REV. 365 (2000).
Presidential Administration assumes office. Enabling acts are terribly broad, generally empowering agencies to regulate in the name of the "public interest"134 or to "to protect the public health."135 Under the Chevron doctrine, agencies have discretion when interpreting their own enabling acts.136 Agency heads accomplish this by issuing regulations that have the force of law.137 The President has the power to remove the heads of executive branch agencies at will, and a new President invariably does so. As a result, new administrations frequently interpret the law in a manner that is diametrically opposed to the interpretations given by the former administration. For example, administrative agencies under the Clinton administration took steps to reduce carbon dioxide emissions into the atmosphere and the level of arsenic in the water, to fund international agencies that offer abortion counseling and to institute ergonomic regulations in the workplace, but upon taking office the Bush administration immediately reversed course on these and a number of other positions.138

Thus, substantive administrative law may be considered primarily a matter of decree by the executive branch. These decrees are always subject to being reversed when the Presidency changes hands. All in all, the scientific administrative model has a number of weaknesses that allow

134. For example, the Supreme Court upheld the delegation of power in the Communications Act of 1934 that authorized the FCC to regulate broadcast licensing in the "public interest." National Broadcasting Company v. United States, 319 U.S. 190, 225-27 (1943).

135. The Supreme Court recently upheld the key provision of the Clean Air Act that confers power upon the EPA to set ambient air quality standards that "are requisite to protect the public health." Whitman v. American Trucking Ass'n, 531 U.S. 457 (2001) (upholding 42 U.S.C. § 7409(b)(1) (2000)).

136. In Chevron the Supreme Court established the rule that agencies have presumptive authority to interpret their enabling acts, stating: "[I]f the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute." Chevron v. Natural Resources Defense Council, Inc., 467 U.S. 837, 843 (1984).

137. See Peter L. Strauss, The Place of Agencies in Government: Separation of Powers and the Fourth Branch, 84 COLUM. L. REV. 572, 665-66 (1984) (noting that even President Reagan's Executive Order 12,291 requiring OMB supervision of impact-analysis process "recognizes (as it must) that the authority to issue the rules subject to the impact analysis process remained in the agency head, subject to whatever political discipline the President might bring to bear.") (footnotes omitted).

138. See Larry Eichel, It Makes a Difference: Close Elections Have Real Consequences, MILWAUKEE J. SENTINEL, April 1, 2001, at 02J.
American industry to escape effective regulation. Agencies are slow to act, and even when they do, their decisions may be reversed by the courts or by a succeeding Presidential administration.

During the Reagan administration, the executive branch made three fateful decisions that weakened administrative regulation of genetic technology. First, the administration decided not to consolidate regulation of the biotechnology industry in a single agency, but to allocate oversight responsibilities among existing agencies under the umbrella of a "Coordinated Framework." Despite its name, the regulatory framework has often lacked coordination. Second, the administration decided not to seek specific statutory authority to regulate the novel aspects of biotechnology, but decided instead to attempt regulation under existing statutes. This has forced agencies to be creative in their interpretation of the law in order to exercise jurisdiction over genetic engineering. As noted above, the Patent Office stated that a half-human creation would not be a "useful" invention under the Patent Act. In another example of creative statutory interpretation, the Environmental Protection Agency (EPA) has considered genes that are inserted into plants to confer resistance to insects or viruses to be "pesticides" or "pesticide chemicals" under the Insecticide, Fungicide, and Rodenticide Act, and the Food, Drug, and Cosmetic Act (FDCA). Third, at least in regard to agricultural uses of genetic technology, the government decided not to treat the process of genetic engineering in agriculture as inherently dangerous, but that only the products of genetic engineering would be


140. Referring to the FDA and NIH oversight of human gene therapy, one commentator notes: "There is significant overlap in the regulatory duties of both agencies, resulting in a confusing duplication of reporting requirements for researchers." Cregan, supra note 1, at 263.

141. "Upon examination of the existing laws available for the regulation of products developed by traditional genetic manipulation techniques, the working group concluded that, for the most part, these laws as currently implemented would address regulatory needs adequately." Coordinated Framework, supra note 139, at 23,303.

142. See Commissioner of Patents and Trademarks, supra note 87 and accompanying text.


tested for safety.\textsuperscript{146} Thus, the government regards a genetically engineered tomato as still a tomato.\textsuperscript{147}

Under this lax administrative regime, the agricultural biotech industry has flourished, largely without public knowledge or debate. Twenty-four percent of the corn grown in the United States last year was genetically engineered, along with sixty-three percent of the soybeans and sixty-four percent of the cotton.\textsuperscript{148} The vast majority of consumers are unaware that over sixty percent of the processed food that is consumed contains genetically engineered products.\textsuperscript{149}

At present, the FDA and National Institutes of Health (NIH) administer regulatory control of genetic technology as applied to human beings, but the jurisdiction of these agencies is limited. The NIH guidelines are binding only upon recipients of federal funds, but have no legal effect on other individuals or institutions.\textsuperscript{150} The FDCA gives the FDA authority to "protect the public health by ensuring that human and veterinary drugs are safe and effective,"\textsuperscript{151} and the FDA has defined gene

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146. "The application of traditional genetic modification techniques is relied upon broadly for enhanced characteristics of food (e.g., hybrid corn, selective breeding), manufactured food (e.g., bread, cheese, yogurt), waste disposal (e.g., bacterial sewage treatment), medicine (e.g., vaccines, hormones), pesticides (e.g., \textit{Bacillus thuringiensis}) and other uses. Federal agencies implement an array of laws which seek to ensure the safety of these products." \textit{Coordinated Framework, supra} note 139, at 23, 302.

147. "FDA believes that the new techniques [of genetic engineering] are extensions at the molecular level of traditional methods and will be used to achieve the same goals as pursued with traditional plant breeding. The agency is not aware of any information showing that foods derived by these new methods differ from other foods in any meaningful or uniform way, or that, as a class, foods developed by the new techniques present any different or greater safety concern than foods developed by traditional plant breeding." Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22984, 22991 (May 29, 1992).

148. \textit{See Philip Brasher, Farmers to Plant More Biotech Soybeans, THE DES MOINES REGISTER, March 31, 2001,}\textit{at} 6D.

149. The Grocery Manufacturers of America estimate that sixty to seventy percent of processed food contains genetically modified corn or soy. Philip Brasher, \textit{Most Consumers Unaware of Biotech Foods, COLUMBIAN, Mar. 27, 2001,}\textit{at} E1.

150. "The RAC [of NIH] has only ever had authority over federally-funded projects and institutions." Rainsbury, \textit{supra} note 3, at 597.

therapy as a "biologic product"\textsuperscript{152} and cloning as a "biologic product" or a "drug"\textsuperscript{153} within the meaning of the FDCA. However, before the agency can regulate genetic engineering, it must be found that Congress intended to include genetic engineering within the meaning of the FDCA. In a recent decision that, by analogy, might threaten administrative control of genetic engineering, the Supreme Court held that the FDA had no authority to regulate nicotine in cigarettes even though nicotine is without question a powerfully addictive drug, because the Court found that Congress did not intend to give that power to the FDA.\textsuperscript{154}

Many scholars were initially skeptical of the federal government's "coordinated framework" for regulating biotechnology.\textsuperscript{155} Today, attorney Joseph Rainsbury characterizes federal oversight of human gene therapy trials as "a regulatory success story,"\textsuperscript{156} in that NIH review of gene therapy protocols has been "measured, informed, and, most importantly,

\begin{quote}
152. "Nucleic acids or viruses used for human gene therapy will be subject to the same requirements as other biological drugs." 51 Fed. Reg. 23,309 (June 26, 1986). As one commentator has noted, "Human gene therapy products defy easy classification under the existing regulatory schemata of drugs, devices, or biologics." Rainsbury, \textit{supra} note 3, at 589.

153. The FDA asserts that it has authority to regulate human cloning under the Health Service Act and the Food, Drug, and Cosmetic Act. It asserts that human cloning may be considered either a "biologic product" or a "drug," and that therefore scientists must request permission from the FDA before undertaking cloning research. However, some lawmakers have expressed concern that the courts would not recognize the FDA's authority to regulate cloning. Anthony Shadid, \textit{Debate Flares Over Cloning of Humans – Complex Questions Arise on Regulation Amid Announcements of Planned Efforts}, \textit{The Boston Globe}, April 4, 2001, at D4. \textit{See also} Baram, \textit{supra} note 1, at 259.

154. FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 126 (2000). The Court stated:

In this case, we believe that Congress has clearly precluded the FDA from asserting jurisdiction to regulate tobacco products. Such authority is inconsistent with the intent that Congress has expressed in the FDCA's overall regulatory scheme and in the tobacco-specific legislation that it has enacted subsequent to the FDCA. In light of this clear intent, the FDA's assertion of jurisdiction is impermissible.

155. John B. Attanasio, Review Essay, \textit{The Genetic Revolution: What Lawyers Don't Know}, 63 N.Y.U. L. REV. 662, 715-16 (1988). A typical criticism was that "an essential component of any oversight scheme must be greater centralization. The sheer mass of evolving genetic enterprise suggests that the government concentrate its efforts in a single agency. The gaps and incoherence of the current ad hoc endeavors render them inadequate to address the problems at hand." \textit{Id.}

156. Rainsbury, \textit{supra} note 3, at 600.
He notes, however, that as private corporations replace universities as centers of research, the open and public nature of NIH review will give way to FDA procedures that protect the confidentiality of proprietary information. In addition, as the focus of genetic research turns from somatic cell therapy to more controversial procedures such as human cloning, embryo research or germ line therapy, regulatory agencies will have a more difficult time achieving a consensus on approving research protocols.

Attorney Judith Cregan has recorded a number of “serious problems” with FDA and NIH regulation of human gene therapy, including “concerns about patient safety, confidentiality of patient information, agency effectiveness, a lack of clear, adequate oversight for the industry, and a need for protection of proprietary information.” She proposes five specific changes that would centralize and improve the regulatory framework for human gene therapy. She suggests that Congress should:

1. establish a standing subcommittee to monitor gene therapy;
2. place the RAC under the direct control of the Secretary of Health and Human Services, and make its directives binding on both the NIH and the FDA;
3. increase the budget of the FDA to improve oversight of gene therapy trials;
4. appoint independent advocates for the subjects of gene therapy trials; and
5. prohibit strict products liability for design defects in human gene therapy products. An alternative possibility is to turn to a scheme of legislative preemption, as set forth in the following section.

### III. LEGISLATIVE PREEMPTION

Many other nations of the world are suspicious of genetic technology and have expressed this hostility by enacting a host of laws that would

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157. *Id.*
158. See *id.* at 599-600.
159. See *id.* at 600.
161. *Id.* at 278.
162. The RAC is the Recombinant DNA Advisory Committee of NIH. This body “approves novel protocols and monitors the protocols and adverse reactions for researchers using NIH grant money.” *Id.* at 263.
163. See *id.* at 284-87. Professor Baram also suggests a number of reforms that the FDA and the NIH should implement in their oversight of human clinical trials of gene therapy. See generally Baram, *supra* note 1.
limit or ban its use.\textsuperscript{164} Because genetic engineering of plants and animals has proceeded much further than human genetic engineering – a number of genetically engineered crops have already come to market, while no human gene therapy treatments have been approved – it is appropriate to consider, by analogy, legislative reaction to these agricultural products.

For example, France, Luxemburg and Austria have banned the cultivation of genetically engineered corn.\textsuperscript{165} Furthermore, in a decision that is potentially devastating to American agriculture, the European Parliament, in Regulation 98-1139, requires all products containing genetically engineered ingredients to carry a label stating that the product is “genetically modified.”\textsuperscript{166} The practical effect of this labeling requirement would be to drive imported American food from the market.\textsuperscript{167}

Professor Marsha Echols, who has written about the effects of cultural values on the regulation of genetic engineering, notes, “the U.S. regulatory approach permits a great deal of industry self-regulation, while Europeans usually adopt a more detailed regulatory scheme.”\textsuperscript{168} In general, Europe embraces the precautionary principle,\textsuperscript{169} that is, the idea that new products

\begin{itemize}
\item \textsuperscript{164} See generally Enrique Freire de Oliveire Souza, \textit{Genetically Modified Plants: A Need for International Regulations}, 6 ANN. SURV. INT’L & COMP. LAW 129 (2000).
\item \textsuperscript{165} Id.
\item \textsuperscript{166} See id. at note 51; Matthew Franken, \textit{Fear of Frankenfoods: A Better Labeling Standard for Genetically Modified Foods}, 1 MINN. INTELL. PROP. REV. 153, 168 (2000).
\item \textsuperscript{167} Id. at 173.
\item \textsuperscript{168} \textit{Quoted in Souza, supra} note 164, at 143.
\item \textsuperscript{169} “Underlying the swelling support for the ‘precautionary principle’ in Europe is a protest against the high information costs imbedded in the culture of regulation by the legalistic bureaucracy in the United States.” Elliott, supra note 130, at 253.
\end{itemize}
or processes should not be adopted until proven to be safe.\textsuperscript{170} The drawback to the precautionary principle, of course, is that the safety of genetic engineering cannot be determined in advance. Most other nations, however, agree with the European approach.\textsuperscript{171} One hundred thirty-eight nations (not including the United States) have negotiated an International Biosafety Protocol that would govern the export, use and sale of transgenic products.\textsuperscript{172} This protocol would allow nations to exclude a product and subject it to testing until a determination can be made as to its risks.\textsuperscript{173} The protocol also includes notice and labeling requirements.\textsuperscript{174}

In contrast, the American position is consistent with the scientific model of regulation that dominates in the United States. The United States Secretary of the Department of Agriculture responded to the European actions by noting that the United States "base[s] decisions on rigorous analysis and sound scientific principles."\textsuperscript{175} The United States trade representatives and the biotech industry assert that since there is no proven scientific basis for believing that genetically modified foods are harmful, that any ban is unscientific and amounts to trade protectionism.\textsuperscript{176} As a result, the United States has called for trade negotiations to ensure that "biotechnology and genetically engineered food products are not discriminated against."\textsuperscript{177}

There is precedent supporting the American position. In 1997, the World Trade Organization held that the European ban on importation of beef from cows treated with synthetic growth hormones was not based on "scientific evidence, risk assessment, or relevant international standards,"

\textsuperscript{170} One formulation of the precautionary principle is the Wingspread Consensus Statement, drafted by environmental activists, which states that "[w]hen an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically." Jonathan H. Adler, More Sorry Than Safe: Assessing the Precautionary Principle and the Proposed International Biosafety Protocol, 35 Tex. Int'l L.J. 173, 194 (2000).

\textsuperscript{171} "The precautionary principle has become a staple of international environmental law." \textit{Id.}


\textsuperscript{173} See \textit{id.} at 811.

\textsuperscript{174} See \textit{id.} at 812-14.

\textsuperscript{175} Souza, \textit{supra} note 164, at 142.

\textsuperscript{176} See Saigo, \textit{supra} note 172, at 811.

and the European Union was ordered to pay over $100 million to the United States.\footnote{178}

What does the analogy to agricultural regulation tell us about regulating research into the human genome? At least this – the United States, an individualistic society with a capitalistic economy, is likely to continue to approach these issues from a rights or a scientific regulation perspective, while more communitarian societies that have a stronger commitment to traditional values will opt for a stricter regulatory regime or for legislative preemption. National preferences for different models of regulation will hamper the development of a rational and comprehensive scheme of international regulation of biotechnology.\footnote{179}

The United States Congress is presently considering whether to categorically prohibit human cloning.\footnote{180} Almost all researchers and scholars agree that because of the high failure rate it is premature to attempt to clone human beings and that irresponsible experimentation should be halted. However, there are some responsible scholars who have suggested that human cloning may ultimately be beneficial in certain limited kinds of situations,\footnote{181} for example, for procreative purposes to allow an infertile couple to have a child who is genetically solely related to one of them\footnote{182} or for therapeutic purposes to create cells, tissue and organs for transplantation.\footnote{183}

Should the United States enact a ban on the cloning of human beings? In a larger sense, when is legislative preemption justified? Deontological ethics requires society to ban experiments and practices that exploit human beings, while teleological ethics requires society to ban

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178. See Souza, supra note 164, at 170-71.

179. To solve this problem, Professor Sean Murphy recommends the creation of an "epistic community" from many nations to develop "convergent policies and expectations" for the international regulation of biotechnology. Sean D. Murphy, Biotechnology and International Law, 42 HARV. INT'L L.J. 47, 139 (2001)


183. See Shadid, supra note 153.
experiments and practices where the risks of research are disproportionately great in relation to the expected benefits.

CONCLUSION

Each of the three legal frameworks discussed in this article performs a valuable function and each should play a role in the regulation of genetic technology. The common law must continue to hold the medical community to high levels of professional competence and protect patients and research subjects under the principle of informed consent. Additional antidiscrimination and genetic privacy laws must be adopted because the Americans With Disabilities Act is not sufficiently specific to protect individuals from genetic discrimination in employment or insurance. The courts should acknowledge the constitutional rights of patients, parents, subjects and researchers to be free of laws that infringe upon personal choices, practices that constitute slavery and regulations that infringe upon the right to inquire. The "Coordinated Framework" of administrative regulation in the United States has failed to create a thorough, consistent and rational scheme of regulation. It is time for Congress to adopt enabling legislation that expressly establishes administrative jurisdiction over the biotech industry, centralizes administrative authority and targets the specific concerns created by genetic technology. Administrative agencies must be given more comprehensive power to oversee genetic engineering and must institute stricter protections for human safety. Finally, society should legislatively forbid genetic experiments or practices that exploit people or that create an unacceptable risk of harm to research subjects.