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Coming into Being: Law, Ethics, and the Practice of Prenatal Genetic Screening

Michael J. Malinowski

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Coming into Being: Law, Ethics, and the Practice of Prenatal Genetic Screening

by

MICHAEL J. MALINOWSKI*

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I would also like to thank Patricia Kuszler, M.D., J.D., Philip Reilly, M.D., J.D., Eamonn Rogers, M.D., and Professor Mark Rothstein, Director of the Health Law and Policy Institute at the University of Houston, for providing insight and valuable research assistance; Dorothy Wertz, Ph.D., for catching a number of my errors; April Cook, a researcher working on the Human Genome Project, for taking the time to explain; Professor Jay Katz of Yale Law School, a true inspiration; Marc Rubinstein and the Editorial Staff at the Hastings Law Journal for their efforts in shepherding this piece into published form; and my students at the University of Houston during the spring of 1993 for all that they taught me. Finally, I would like to acknowledge Marianne Ryan, Gwen J. Samora, and Julie E. Sternberg for sharing their time, ideas, and patience, and W. Shaw McDermott for his helpful suggestions.

[1435]
Introduction

The perfect baby—a wide grin, ten fingers, ten toes, and the potential to become a doctor, Olympic athlete, or President of the United States. Prospective parents share this dream. The dream often becomes an expectation as prospective parents mentally attend their children's graduation ceremonies, weddings, and hundreds of similar events during the first and second trimesters of their existence. But, for many prospective parents, these hopes and expectations will not survive the birth of their children: genetic diseases and congenital malformations—and the physical and mental disabilities accompanying them—occur in approximately three- to five-percent of all live births.\(^1\) The increasing availability of prenatal genetic screening and advances in screening technology, coupled with the identification of more gene malfunctions responsible for diseases, now offer prospective parents the possibility of knowing that their children may suffer from serious physical and mental impairments at a time when abor-

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tion is still an option. Even when abortion is not an option because of legal or personal concerns, prenatal genetic screening offers an opportunity to prepare. In other words, although prenatal genetic screening may present an opportunity in the future to treat the unborn through genetic therapy, prenatal genetic screening is presently a tool for prospective parents, not their fetuses. The opportunity now associated with that technology is enhanced parental choice. The role of doctors and genetic counselors is to give prospective parents the information about their unborn they seek so that they can make an informed choice.

The objectives of this Article are to present an accurate portrayal of the practice of prenatal genetic screening; to analyze the opportunities it presents in the context of, and in contrast with, procreative liberty and abortion law; and to propose suggestions to ensure that the technology is welcomed, but with caution. Part I discusses how the international effort to map the human genome, the Human Genome Project, is making extensive prenatal genetic screening possible. It also discusses the practice of prenatal genetic counseling and how, perhaps as a result of the surge in technological capability arising from the Human Genome Project, the medical profession is offering genetic screening technology to prospective parents without first seriously questioning its social implications.

Part II approaches the practice of prenatal genetic screening from four different perspectives: a genetic counselor, a researcher working on the Human Genome Project, a woman who went through genetic counseling and terminated her pregnancy, and a family that includes a child with spina bifida. These perspectives are presented through a series of personal accounts, the purposes of which are to enable us to approach and analyze the practice of prenatal genetic counseling from the perspective of reality as well as from theory and to identify important issues that are presently being overlooked or ignored.

Part III analyzes the practice of prenatal genetic counseling in the context of abortion law and parental choice. Specifically, it addresses how the decision to terminate a pregnancy based upon the results of prenatal genetic screening is—because of the nature of the decision and its social implications—distinguishable from a basic exercise of procreative liberty.

2. See infra notes 95 (addressing the enhanced obligations to the fetus that may accompany gene therapy capabilities), 110 (addressing advances in gene therapy).
Part IV offers an assessment of the practice of prenatal genetic screening within the United States and identifies dependency on research laboratories for diagnostic purposes and a profound lack of scrutiny and conscious public policy decision making regarding this issue. It also discusses legislation proposed in France—expected to be enacted into law before the end of 1994—which will ensure that important public policy decision making surrounding prenatal genetic screening will be made by publicly accountable policy makers, rather than by France’s medical profession.

Part IV sets forth a proposal for applying regulations that presently exist in the United States to research-stage genetic testing and for erecting other regulations to establish boundaries around the practice of prenatal genetic screening in this country. The rationale undergirding this proposal is to ensure that the policy issues presented by prenatal genetic screening are addressed and subjected to public scrutiny. The proposal draws upon the legislation introduced in France; a report issued recently by the Committee on Assessing Genetic Risks, which operates within the Division of Health Sciences Policy of the Institute of Medicine; and the social implications of prenatal genetic screening identified throughout this Article.

I. The Technology to Know

Each of us has twenty-three pairs of chromosomes, which consist of strands of DNA (deoxyribonucleic acid). Our chromosomes contain 50,000 to 100,000 genes encoded in some three billion base pairs of DNA. Each of these genes is located along strands of DNA in an arrangement that resembles a ladder twisted into a spiral (a formation officially known as a “double helix”). Genes consist of a variable number of DNA base pairs known as nucleotides (the rungs on this ladder-like arrangement), and each gene provides the information to produce proteins responsible for the development of a single human trait—whether that trait be the color of our eyes, our tendency to be depressed or elated, our height, or our susceptibility to a specific disease. The human genome represents the complete pattern of human DNA, which means the entire nucleotide (base pair) composition.

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4. Sachs & Korf, supra note 1, at 458.
5. Allan Bruckheim, Genetic Engineering Helping to Resolve Inherited Diseases, Hous. Post, May 5, 1993; see generally R.C. Olby, Origins of Mendelism (1966) (trac-
A gene with an altered or deficient nucleotide composition will fail to produce the proteins needed for normal development of the trait it controls, thereby resulting in a genetic abnormality. Just as the development of specific traits may be traced to specific genes, the development of diseases with a genetic component—such as cystic fibrosis or Down’s Syndrome—may be traced to specific genetic abnormalities. The possibilities arising from the identification of the genetic abnormalities (aberrations in nucleotide composition) responsible for specific diseases are nothing less than miraculous. Consider, for example, that between three and four thousand medical disorders have been linked to altered genes, and that a single defect in a single gene is the cause of the most severe form of cystic fibrosis.

However, linking genetic abnormalities to specific diseases does not necessarily mean that a person with the specific genetic abnormality will suffer the physical and/or mental symptoms of the disease associated with that abnormality. The relationship between a person’s genotype (or the genetic makeup and the production of the proteins for which those genes are responsible) and a person’s phenotype (or observable physical and mental traits) is influenced by a number of factors. For example, many physical traits—some obvious, such as weight—are influenced by one or more environmental factors. More...
over, because our chromosomes are paired, we all carry two sets of genes. It is possible, therefore, for a person to have both a normally functioning gene and an abnormally functioning gene for a given trait. If the abnormal gene is recessive, the normal gene compensates for it so that the person's phenotype includes the normal trait that the gene controls. Such a person will be a carrier for the genetic abnormality but will not suffer its physical or mental symptoms. In addition, some diseases are “polygenic” or “multifactorial,” meaning that they are caused by some combination of genetic abnormalities. Finally, even if a dominant, abnormally functioning gene is conclusively identified and it is certain that the physical or mental symptoms of the disease linked to that genetic abnormality will be present, the symptoms may not always be severe. The severity of symptoms depends upon what protein the abnormally functioning gene is producing and the exact role of that protein.

An expanding body of knowledge about the normal gene content (or genome) of the forty-six human chromosomes is being obtained through the use of molecular techniques such as genomic mapping. This knowledge offers the possibility of identifying the specific genetic abnormalities responsible for countless medical disorders. Whenever such an identification is made, tests can be developed to determine

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11. However, when genetic abnormalities are dominant, they will affect the phenotype despite being paired with a normally functioning gene. Rosalind Skinner, Unifactorial Inheritance, in 1 Principles and Practice of Medical Genetics 53, 97 (Alan E.H. Emery & David L. Rimoin eds., 2d ed. 1990).

12. The sex distinction between males and females is attributable to an XX chromosome pairing in females as compared to an XY chromosome pairing in males. With sex-linked (monogenic) diseases, even though a male carries a recessive gene on his X chromosome, he has no complementing gene on his Y chromosome to offset it. In contrast, a female carrying the same gene on her respective X chromosome has another X chromosome, which may have a normally functioning gene to offset the abnormally functioning, recessive one.

13. See generally Friedrich Vogel, Mutation in Man, in 1 Principles and Practice, supra note 11, at 53; Suter, supra note 6, at 1857-58.

14. See Emery & Mueller, supra note 3, at 199. As explained by the Committee on Assessing Genetic Risks in its recent report,

Disorders resulting from changes in one gene alone are called monogenic (e.g., cystic fibrosis, sickle cell anemia, Duchenne muscular dystrophy). Disorders resulting from changes in several genes are called multifactorial. Multifactorial disorders (e.g., common types of coronary heart disease and most forms of diabetes) tend to affect far more individuals than do monogenic disorders. Assessing Genetic Risks, supra note 9, ch. 2, at 2.


whether fetuses carry the specific genetic abnormalities and the likelihood of their developing the associated medical disorder.

The following is a discussion of the efforts of the scientific community to map the human genome and how this technology presently is being made available to the public through the practice of prenatal genetic counseling.

A. The Human Genome Project

The Human Genome Project, an effort to map all forty-six chromosomes that was initiated by Congress in 1989, will receive an estimated two hundred million dollars in federal funds per year for the next ten to fifteen years—that is, unless the Project is completed sooner. The overall mapping initiative is being funded domestically by three major institutions: the National Institutes of Health (NIH), the Department of Energy (DOE), and the Howard Hughes Medical Institute. See generally Victor A. McKusick, The Human Genome Project: Plans, Status, and Applications in Biology and Medicine, in GENE MAPPING: USING LAW AND ETHICS AS GUIDES 18, 22-26 (George J. Annas & Sherman Elias eds., 1992); James D. Watson, The Human Genome Project: Past, Present, and Future, 248 SCIENCE 44 (1990). Federal funding of the project began in 1988:

In 1988, the first Congressional appropriation for this project amounted to $17.2 million. In fiscal year 1991, approximately $87 million was made available. It now is estimated that the project will require $200 million per year for the next 10-15 years. Similar research is being funded by other United States agencies, including the Department of Energy. Sachs & Korf, supra note 1, at 45 (footnotes omitted). A significant portion of this funding (four percent according to ASSESSING GENETIC RISKS, supra note 9, at 460) is being reserved for the Ethical, Legal, and Social Issues Joint Working Group (ELSI) to research the ethical implications of the resulting technology:

NIH’s National Center for Human Genome Research, for example, has pledged to spend as much as one to three percent of its research budget on the study of the “ethical, social and legal issues that may arise from the application of knowledge gained from the Human Genome Initiative.” The Center has also formed an “Ethics Committee” and hired a philosopher to help formulate and deal with ethical issues. Likewise, the international Human Genome Organization (HUGO), made up of forty-two scientists from around the world, has formed an ethics committee and “intends to provide a forum for the discussion of ethical, social, commercial, and legal considerations relating to the genome project.”

George J. Annas, Mapping the Human Genome and the Meaning of Monster Mythology, 39 EMORY L.J. 629, 650 (1990) (footnote omitted) [hereinafter Annas, Monster Mythology]. HUGO now has more than 42 members, and the organization may be contacted at: 7986 D. Old Georgetown Road, Bethesda, MD 20814; (301) 654-1477.

18. See generally U.S. Human Genome Project Updates Goals, HUMAN GENOME NEWS, Nov. 1993, at 1 (discussing how progress made over the last three years has put the overall project goals well within reach).

19. To take advantage of the opportunity presented by federal support and rapid advances in chromosome and DNA mapping techniques, the NIH established the National Center for Human Genome Research on October 1, 1989.
Work on deciphering the human genome also is being conducted by institutions in other countries. For example, European efforts are being coordinated by the Human Genome Organization (HUGO), a private organization.

In addition to identifying genes, the traits they control, and their locations on chromosomes, scientists are breaking genes down into their fundamental chemical components—the DNA base pairs that form them—in order to identify the composition of healthy genes and their abnormal counterparts responsible for specific diseases. Because identifying (or "sequencing") the DNA base pairs (nucleotides) responsible for health impairments is the key to genetic screening, \"[a]dvances in genetic research are occurring simultaneously with the development of new techniques for prenatal genetic testing . . . \" Since 1983, more than two thousand genes have been mapped to particular chromosomes. While this number is expected to soon rise sharply due to the recent completion of a map covering ninety percent of human DNA, present mapping capability is still not precise enough to pinpoint the location of all genes in DNA, and certainly not the DNA base pairs making up those genes.

At the present time, prenatal screening can be used to detect 600 of the 3,000 to 4,000 known genetic defects, and scientists have identified the genetic abnormalities responsible for 122 different genetic diseases. Advances in mapping technology are causing these numbers to grow exponentially. For example, \"[t]he gene for cystic fibrosis was mapped in about four years with a jumping technique, instead of the approximately eighteen years that 'walking' would have taken.\" The result is that mapping efforts are bringing about almost

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20. Annas, Monster Mythology, supra note 17, at 637.
21. Id. See also Sachs & Korf, supra note 1, at 458-59.
22. Sachs & Korf, supra note 1, at 458.
24. Scientists Draw Human DNA, BOSTON GLOBE, Dec. 16, 1993, at A17 (\"Researchers said the map will also help the Human Genome Project, an effort to reveal the sequence of DNA's 3 billion building blocks.\")
25. See supra note 7.
26. Thomas, supra note 23; see generally ASSESSING GENETIC RISKS, supra note 9.
27. Fletcher & Wertz, supra note 23, at 754. The common method for identifying DNA base pairs is called "shot gunning," and the present cost for identifying DNA base pairs is $1 to $1.50 per base pair. Earl Lane, Faster Deciphering of Genes Developed, Hous. CHRON., Dec. 13, 1992, at C13. That cost may be reduced to less than 50 cents within three years through a less repetitive and time consuming sequencing method known as "primer walking." Id.
daily discoveries of the genetic mutations responsible for common health impairments. Recent discoveries include the identification of a defective gene that may cause nearly one-third of all human brain tumors, a genetic abnormality responsible for breast cancer, a genetic abnormality responsible for brain tumors, a genetic abnormality responsible for breast cancer, and an estimated 1 in 25,000 people, the symptoms of which usually do not appear until people are in their 30s and 40s, and that results in death 10-15 years after onset), lung cancer (determining that the P53 gene is missing), bladder cancer (researchers have determined that a tumor-suppressor gene is missing), esophageal cancer (determining that the P53 gene is missing), and acute myelogenous leukemia (determining that a tumor-suppressor gene is missing). Leslie Loddeke, Geneticists on 'Threshold' of Discoveries, HOUS. POST, June 13, 1993, at A33, A34 [hereinafter Loddeke, Geneticists]; Leslie Loddeke, Baylor Researcher Discovers Disease-Causing Gene, HOUS. POST, July 1, 1993 [hereinafter Loddeke, Baylor] (reporting on July 1, 1993 findings appearing in NATURE GENETICS journal). The Baylor Human Genome Center, one of ten in the nation, is credited with making and/or substantially contributing to the following disease-gene discoveries: fragile X syndrome (mental retardation), myotonic dystrophy (a muscular disorder), Duchenne dystrophy (a muscular disorder), Charcot-Marie-Tooth syndrome (peripheral neuropathy), Lowe syndrome (a brain, eye, and kidney disorder), Kallman's syndrome (a sensory disorder), two immune-system disorders, and spinocerebellar ataxia type 1 (a neurological disease discussed above in more detail). Loddeke, Geneticists, supra, at A34; Loddeke, Baylor, supra.

29. See generally W.K. Cavenee, Accumulation of Genetic Defects During Astrocycoma Progression, 70(b) CANCER 1788-93 (1992) ("Scientists have tracked down a defective gene that may cause nearly a third of all human brain tumors, opening the way for new strategies to stop these cancers."); Scientists Find Gene that Causes Brain Tumors, HOUS. POST, Mar. 12, 1993, at A18. As for the significance of such a discovery, consider that about 15,600 Americans are diagnosed with brain tumors each year, and 11,500 die from them. Id.

30. Richard Saltus, Mutated Gene Tied to Early Breast Cancer Is Located, BOSTON GLOBE, Sept. 15, 1994, at 14, 30 (discussing the discovery of a mutated gene that puts some women at an enormously high risk of contracting breast and ovarian cancer, and recognizing that this discovery will make prenatal diagnosis an option for prospective parents); see S.R. Wolman, Genetic Markers as Prognostic Indicators in Breast Cancer, 70(b) CANCER 1765-76 (1992); see also Damaged Gene Linked to Cancers in Women, BOSTON GLOBE, Apr. 14, 1994 (addressing the identification of genetic links to inherited breast cancer, non-inherited breast and ovarian cancer, and cervical cancer). Women who inherit this gene have a 59 percent chance of developing breast cancer before they reach the age of 50, and an 80 percent chance of developing the disease by the age of 65. DNA Test Early Warning for Breast Cancer, HOUS. POST, Apr. 21, 1993, at A5 (discussing reports presented in the Journal of the American Medical Association). In comparison, women in general have only a 2 percent chance of developing breast cancer before the age of 50, and a 6 percent chance of becoming afflicted by the age of 65. Id. As a result of this discovery, genetic screening to detect the gene may make a life-and-death difference to the 600,000 women in the United States with inherited susceptibilities to breast cancer. Id.
nomic link to colon and rectal cancer, a genetic cause of hereditary melanoma, the genetic cause of Huntington's disease, and approximately ninety percent of the mutations responsible for cystic fibrosis. Within several years, prenatal tests may be widely available to identify predispositions for alcoholism, Alzheimer's disease, arthritis, various cancers, dementia, diabetes, dyslexia, glaucoma, heart disease, hypertension, manic depression, schizophrenia, and fundamental personality characteristics such as sexual orientation.


32. See Associated Press, *Gene May be Linked to Deadly Skin Cancer*, L.A. TIMES, Sept. 1, 1994, at A27 (stating that a mutated gene called p.16 is linked to inherited melanoma and may be involved in noninherited cases as well).

33. "After 10 backbreaking years in a research purgatory of false leads, failed experiments and long stretches of mordant despair, an international team of scientists says it has discovered the most coveted treasure in molecular biology, the gene behind Huntington's disease." *Huntington's Disease Gene Is Found at Last*, Hous. CHRON., Mar. 24, 1993, at A12. "Huntington's disease afflicts about 30,000 Americans, and as many as 150,000 are at risk of developing it." Id.


35. As a result of this discovery, "it is possible to identify approximately 80% of couples at risk of having an affected child and to offer prenatal diagnosis when both members of the couple are carriers." Sachs & Korf, supra note 1, at 459.

B. The Practice of Prenatal Genetic Counseling

Although its use has been widespread in the United States since the advent of amniocentesis in 1966,\(^3\) the practice of prenatal genetic screening is undergoing tremendous change as it assimilates the technology generated by the Human Genome Project.\(^3\) Thus, "[w]e stand at the brink of a virtual explosion of knowledge about human genetics that may change how we think about and what we do about disease."\(^3\) Specifically, with each success in identifying a genetic abnormality associated with the onset of a specific health impairment comes the potential to test fetuses for the presence of that genetic abnormality. The practice of prenatal genetic counseling involves making this technology available to prospective parents. It also involves using limited information—perhaps nothing more than a probability resulting from a research-stage test—under severe time constraints to help pro-

\(^37\). See infra note 48 (discussing amniocentesis and other prenatal diagnostic techniques).

\(^38\). See generally ASSESSING GENETIC RISKS, supra note 9, ch. 2, at 13-51; ch. 4, at 1-21; ANGELA RODDEY HOLDER, LEGAL ISSUES IN PEDIATRICS AND ADOLESCENT MEDICINE 25-46 (2d ed. 1985) (discussing amniocentesis, genetic counseling, and genetic screening).

\(^39\). Peter Conrad, Genetic Counseling as Work, HASTINGS CENTER REP., July/Aug. 1993, at 41 (reviewing CHARLES L. BOSK, ALL GOD's MISTAKES: GENETIC COUNSELING IN A PEDIATRIC HOSPITAL (1992) (based upon genetic counseling fieldwork conducted over a decade ago)).
spective parents make what might be the most traumatic decision of their lives.  

There are approximately 450 certified genetic counselors and 500 clinical geneticists in the United States today. Even if these numbers increase dramatically, there will be competition for limited access to counselors and geneticists as genetic tests are made more available and less expensive, and as more prospective parents are referred to and seek out the services of genetic counselors. For example, consider that, based upon the current number of counselors, just making cystic fibrosis counseling available to the entire population would occupy approximately seventeen weeks per counselor, per year.

The availability of genetic screening services in the United States fluctuates dramatically depending upon geographic location. The availability of basic testing and access to the full range of commercial and research-stage testing is maximized in cities such as Boston, Massachusetts and Houston, Texas, where there are internationally recognized medical facilities, research institutions participating in the Human Genome Project, and a highly educated population that expects and seeks out state-of-the-art medical treatment. Also, because medicine is a service profession, the availability of screening services is likely to be maximized in states that have recognized wrongful life and wrongful birth actions against doctors. In New York, for exam-

40. See Fletcher & Wertz, supra note 23, at 748 (“Medical geneticists are mediators between other fields in medicine with experience in dealing with ethical problems in human genetics.”). For a thorough discussion of the practice of genetic screening and the emotional impact of fetal abnormality on parents, see M. Neil Macintyre et al., The Impact of an Abnormal Fetus or Child on the Choice for Prenatal Diagnosis and Selective Abortion, in Abortion, Medicine, and the Law 524-44 (J. Douglas Butler & David F. Walbert eds., 1992); see also Thaddeus E. Kelly, Clinical Genetics and Genetic Counseling 365-93 (2d ed. 1986) (summarizing how clinical diagnoses are made based upon prenatal genetic testing). For discussion of how genetic screening can be utilized to confirm or replace clinical diagnosis for many genetic diseases, see C. Thomas Caskey, Genetic Predisposition and the Human Genome Project: Case Illustrations of Clinical Problems; Presymptomatic Genetic Diagnosis—A Worry for the United States, in Gene Mapping, supra note 17, at 178; Edward R.B. McCabe, Genetic Screening for the Next Decade: Application of Present and New Technologies, 64 Yale J. Biology & Med. 9, 9 (1991); McKusick, supra note 17, at 36-39.

41. Sachs & Korf, supra note 1, at 459; Peacock Presentation, infra note 79. There are 1,888 persons generally certified by the American Board of Medical Genetics and an additional 180 certified by the newly established American Board of Genetic Counseling (for master’s-level persons). The practice and profession of genetic counseling, including the certification and educational backgrounds of counselors, is described in detail infra Part II.A.

42. Sachs & Korf, supra note 1, at 459.

43. See Belinda L. Kimble, Wrongful Birth: A Practitioner's Guide to a New Arrival, 55 Ala. L. Rev. 84 (1994); see also Keel v. Banach, 624 So.2d 1022 (Ala. 1993) (recognizing a
people, the fear of liability has helped to inspire obstetricians to refer virtually all patients who are at any risk\textsuperscript{44} to genetic counselors. The result is that twenty-five-thousand women in the state of New York are screened for fetal genetic abnormalities each year.\textsuperscript{45}

As discussed above in Part I.A., as a consequence of the Human Genome Project, we will experience a period of tremendous expansion in genetic screening capability during the next several years.\textsuperscript{46} At the present time, although "[p]renatal diagnosis is now available for hundreds of conditions, ranging from profound mental retardation and early death . . . to disorders that affect daily living and shorten [one's] life span but do not cause serious mental incapacity[,] . . . and include[s] disorders that cause serious mental and physical deterioration but do not begin until middle age[,]"\textsuperscript{47} the prenatal diagnosis of

\begin{itemize}
  \item \textsuperscript{44} The list of factors indicating a risk for bearing a child with a genetic disorder includes:
    \begin{itemize}
      \item Advanced maternal age; previous offspring with a chromosomal aberration; chromosomal abnormality in either parent; family history of sex-linked condition; inborn errors or metabolism; neural tube defects; hemoglobinopathies; amniocentesis . . . . Inquiries should be made about the outcome of previous pregnancies, mental retardation, or other known or suspected inherited or metabolic disease.
    \end{itemize}
  \item George J. Annas & Sherman Elias, Legal and Ethical Implications of Fetal Diagnosis and Gene Therapy, 35 Am. J. Med. Genet. 215, 215-16 (1990). Moreover, because they share a greater percentage of genetic material, some ethnic groups are more prone to carry particular genetic abnormalities. See generally Kenneth L. Garver & Sandra G. Marchese, Genetic Counseling for Clinicians 60-68 (1986); Suter, supra note 6, n.47 (identifying a number of genetic diseases that have been identified as occurring at higher rates in particular ethnic groups); Reuters, Gene Tied to Blacks Health Risk, Boston Globe, Sept. 7, 1994, at 17. \textit{See also} Richard J. Herrnstein & Charles Murray, The Bell Curve: Intelligence and Class Structure in American Life 105 (1994) (concluding that 40 to 80 percent of one's intelligence is controlled by one's genes, and drawing a correlation between intelligence and race). But see E.D. Hirsch, Jr., Good Genes, Bad Schools, N.Y. Times, Oct. 29, 1994, at 19 (citing studies which refute the finding that race and intelligence are genetically linked).
  \item Kathleen Nolan, First Fruits: Genetic Screening, Hastings Center Rep., July/Aug. 1992, (Special Supplement), at S2.
  \item Assessing Genetic Risks, \textit{supra} note 9, ch. 2, at 13; \textit{see also} Thomas, \textit{supra} note 23.
\end{itemize}
fetuses is restricted by a number of technology limitations. These limitations include the analytical/diagnostic techniques available; the invasiveness of commonly used testing procedures, namely amniocentesis and chorionic villus sampling (CVS); and the risks that these testing procedures pose to fetuses. In the past, testing has

48. The “accepted” prenatal diagnostic technologies are: (1) amniocentesis; (2) CVS; (3) PUPS; and (4) ultrasound.

Amniocentesis: Amniocentesis, generally performed at 14 to 16 weeks gestation, involves entering the amniotic sac, removing some of the fluid that surrounds the fetus, and analyzing cells suspended in that fluid which have been shed by the fetus. ASSESSING GENETIC RISKS, supra note 9, ch. 2, at 15 (Box 2-2); Annas, Monster Mythology, supra note 17, at 641. Until 1986 this analysis consisted of little more than counting chromosomes—for example, to determine the sex of the child (“sexing”) so as to eliminate the possibility of sex-contingent diseases such as hemophilia, which occurs almost exclusively in boys. Since the advent of DNA-based diagnostics, the number of testings that can be done has increased immensely. However, given the limited applicability of these additional tests to a wide audience, determining number and structure of chromosomes and fetal sex is the extent of testing in most cases at the present time. See generally id. “The Council of Regional Networks for Genetic Services (CORN) has estimated, on a very limited sample of reporting centers, that over 1 million amniocenteses were performed in the United States in 1990[,]” which implies that twenty-five percent of all pregnancies in the United States undergo the procedure. ASSESSING GENETIC RISKS, supra note 9, ch. 2, at 15. “Limitations of amniocentesis are the relatively advanced gestational age at which it is performed and the waiting period associated with the culture of the amniotic cells before test results are available.” Id.

Chorionic villus sampling (CVS): CVS is now performed between nine and twelve weeks of gestation but may be performed as early as eight weeks, although not all conditions can be diagnosed with reliability at eight weeks. The procedure involves placing a fine plastic catheter or needle into the placenta and taking a small biopsy of placental tissue. ASSESSING GENETIC RISKS, supra note 9, ch. 2, at 15; Interview with Michael Mennuti, M.D., Chairman, Obstetrics & Gynecology, University of Pennsylvania, Good Morning America: CVS Prenatal Test (ABC television broadcast, Sept. 18, 1992). The amniotic cavity—the sac of fluid—is not entered. Id. “Rapid reporting of results in twenty-four hours is also an advantage compared to the ten to fourteen days required to grow cells from traditional second trimester amniocenteses.” ASSESSING GENETIC RISKS, supra note 9, at 15. However, CVS may carry an increased risk to the fetus. Specifically, “[w]hen the prenatal screening test commonly known as CVS [chorionic villus sampling,] was introduced in the mid-1980s, it was hailed as a major medical advance. . . . But now there’s fear that CVS may be causing birth defects in some babies.” Mennuti Interview, supra. According to Dr. Mennuti:

There have been a few children born after CVS who had defects of the hands and feet, missing fingers and toes, and several children who also had underdevelopment of the lower jaw and tongue. These are very rare defects, and so there was concern immediately that there might be a problem here . . . . Well, the theory is that these defects may occur because when the small pieces of placenta are removed, there may be bleeding or blood loss from the placenta, and that may cause decreased blood flow to the areas where we’re seeing the defects in the fetus. That decreased blood flow then may result in the defects.

Mennuti Interview, supra. See Sachs & Korf, supra note 1, at 460; Elsas, supra note 36, at 832 (“New techniques, such as transcervical and transabdominal chorionic villus biopsy (CVS), with unknown maternal or fetal risks, now enable diagnosis earlier in pregnancy. Is
been used generally only to detect the most common and devastating

the risk of having a chromosomally unbalanced liveborn greater than these procedural
risks of prenatal monitoring?" (footnote omitted)).

Percutaneous umbilical blood sampling (PUBS): Fetal blood is obtained at approximately
eighteen weeks gestation with a needle inserted—while being observed through ultra-
sound—into the umbilical cord. Assessing Genetic Risks, supra note 9, ch. 2, at 15. The
procedure is most often used to clarify ambiguous chromosomal analysis resulting from
amniocentesis or CVS, but because it has been associated with a five percent rate of fetal
loss, it is being reserved for situations in which rapid diagnosis is essential and in which
diagnostic information cannot be obtained by safer methods. Id.

Ultrasound: Ultrasound, a noninvasive procedure that involves viewing the fetus on a
monitor, can only be relied upon to detect observable, physical abnormalities. Although
ultrasound is becoming—or has become—a routine part of obstetrical practice in the
United States, standards for ultrasound equipment and training and certification of person-
nel have not been developed. Assessing Genetic Risks, supra note 9, ch. 2, at 16. The
importance of this is reflected by the observation that, although low sensitivity, specificity,
and predictive value of examinations make ultrasound a generally crude and unreliable
indicator of fetal abnormalities, "[w]hen ultrasound is performed by highly skilled opera-
tors, the sensitivity of this screening device in detecting congenital malformations can be as
high as 90 percent." Id.

"New" techniques in prenatal diagnosis include:

Early amniocentesis: Amniocentesis is now being used as early as week nine of gestation.
The safety and accuracy of this procedure has not been evaluated adequately. Assessing
Genetic Risks, supra note 9, ch. 2, at 19.

Fluorescence in situ hybridization (FISH): Originally, a DNA research tool that relies
upon DNA probes visualized by fluorescence methods, FISH is now being relied upon for
prenatal diagnosis. Id. "This technique has also been the source of recent controversy
about 'a rapid (but wrong) prenatal diagnosis' in which a prenatal diagnostic error resulted
from a test whose accuracy is said to exceed 99 percent." Id.

Diagnosis using fetal cells isolated from maternal blood: Fetal cells have been detected in
maternal blood as early as nine weeks of gestation, and first-trimester prenatal diagnosis of
Down's Syndrome as a result of this technique has been reported. Id. However, this tech-
nique is only at the research stage and it is highly subject to error because the slightest
contamination—for example, from a previous pregnancy—can result in both false-positive
and false-negative results. Id.

Preimplantation diagnosis and In-vitro fertilization (IVF): This technique involves remov-
ing ova (eggs) from a woman's ovaries, fertilizing them outside of the womb, removing
some cells when the eggs have divided, analyzing those cells, and then implanting the
healthy zygotes. See Andrea Bonnicksen, Genetic Diagnosis of Human Embryos, Has-
tings Center Rep., July/Aug. 1992, (Special Supplement), at S5; Barbara Katz Rothman,
Not all that Glitters Is Gold, Hastings Center Rep., July/Aug. 1992, (Special Supple-
ment), at S11-S15; see also Philip Elmer-Dewitt, Catching a Bad Gene in the Tiniest of
Embryos, Time, Oct. 5, 1992, at 81 (noting that days-old embryos are being tested for
genetic abnormalities outside the womb and discussing how this technique has been used
to detect several inherited ailments, including hemophilia, Duchenne muscular dystrophy,
and Tay-Sachs disease). Dr. Mark Hughes, Director of Baylor's Prenatal Genetics Center,
has developed a procedure for rapidly spotting the cystic fibrosis defect in a single strand of
DNA using a gene cloning technique called "polymerase chain reaction." Elmer-Dewitt,
Catching a Bad Gene, supra at 82. As stated by Dr. Hughes, "It's like finding one typo-
graphical error in a book 180 times the size of the Encyclopedia Britannica in about six
hours ...." Id; see also Good Morning America: Genetic Disease Test (ABC television
broadcast, Sept. 25, 1992). "The advantage of preimplantation testing is that it avoids the
disorders on women who are at an increased risk for having offspring with these disorders. But times are changing: As more of the genetic abnormalities responsible for health impairments are identified, tests to detect these abnormalities become available, testing techniques improve, and common knowledge about testing options expands, more prospective parents will be encouraged to undergo and seek out prenatal genetic screening. Perhaps within the not-too-distant future, rather than some prospective parents being asked whether they want prenatal genetic tests performed, all prospective parents will be asked which test or tests they want to be run. Moreover, as the gap between the deluge of laboratory information generated by the Human Genome Project and physicians and geneticists working with

need for screening and abortion after pregnancy has occurred. In addition, it opens the door eventually to gene therapy on the embryo . . . .” Robertson, supra note 36, at 706.

However, there are some major limitations to this kind of testing. First, the procedure subjects the pregnant woman to some risk. Second, because there is limited genetic material with which to work, only a limited number of tests can be run. Third, there is a limited time frame within which to work; all testing must be done within seventy-two hours. Moreover, IVF costs more than $15,000 per cycle and “only 14 percent of women deliver a live-born infant after one cycle of invitro fertilization, and the rate of live births is no better than 1 for every 10 embryos transferred at the centers with the best records.” Assessing Genetic Risks, supra note 9, ch. 2, at 20.

Embryoscopy: This technique, which involves penetrating the abdomen and outer layers of the amniotic sac with a scope smaller than a straw, is reported to carry the same level of danger as amniocentesis. See F. Albert Reece & Carol J. Homke, Embryoscopy, Fetal Therapy, and Ethical Implications, 57 Ala. L. Rev. 709 (1994) (discussing background information on embryoscopy, its applications, and ethical implications); Interview with Albert Reece, M.D., Chairman, Dep’t of Obstetrics, Temple University School of Medicine, Today Show (NBC television broadcast, July 11, 1993). Although highly experimental, embryoscopy may be used to diagnosis physical abnormalities in fetuses well within the first trimester of pregnancy and with certainty. See generally Reece & Homke, supra (addressing the potential applications of embryoscopy, including gene therapy); see also Gina Kolata, Miniature Scope Gives the Earliest Pictures of a Developing Embryo, N.Y. Times, July 6, 1993, at B6.

49. See Robertson, supra note 36, at 710. Specifically, [p]renatal diagnosis of fetuses can at present detect only a limited number of genetic disorders. Down’s syndrome, Tay-Sachs disease, spina bifida, sickle cell anemia, and cystic fibrosis are among the diseases that can be detected through prenatal screening of fetuses. Because the tests are invasive and pose some risk to the fetus, they are performed only on women who are at increased risk for having offspring with those disorders. Women over thirty-five, those with a prior handicapped birth, or those who are carriers of genetic disorders now choose these tests. If a maternal blood test became available, the demand for prenatal screening of fetuses would increase dramatically, even though it should not become a substitute for carrier screening.

Id.; see also Nobles, supra note 7, at 2087 (“Because of the inherent invasiveness and risk to the fetus of present screening techniques, prenatal screening is performed only on women with a genetic predisposition to conceive children with inherited diseases.”).
patients narrows, testing techniques will improve, thereby making it possible to do more extensive testing and to test more efficiently.\textsuperscript{50} Thus, an expansion of the practice of prenatal genetic screening is imminent.

C. Our Failure to Question

As discussed above, prenatal genetic screening involves the application of technology that, because of work on the Human Genome Project and related technological discoveries, is advancing exponentially. If one considers the research-stage tests available on a worldwide scale, even our present screening capability is nothing less than awesome. With such a surge in technology comes new ethical problems, problems for which established ethical principles may not be easily applied.\textsuperscript{51} Without public policy foresight and resulting regulation, there is some danger that society will not discover violations of its ethical principles until the technology and practices responsible for these violations have already been introduced and widely applied.\textsuperscript{52}

The confrontation over legalized abortion in the early 1970s divided our society and brought about a legal and ethical civil war that continues to rage.\textsuperscript{53} In contrast, we have warmly embraced the technological capability to test for genetic abnormalities, almost without

\textsuperscript{50} For example, consider that “[i]n a marriage of biology and electronics, members of the Genosensor Consortium are developing a microchip-driven DNA probe that holds the possibility of diagnosing diseases in a single second.” Thomas, supra note 23.

\textsuperscript{51} See Eric J. Cassell, \textit{The Sorcerer’s Broom: Medicine’s Rampant Technology}, HASTINGS CENTER REP., Nov./Dec. 1993, at 32 (“Like the broom in \textit{The Sorcerer’s Apprentice}, technologies come to have a life of their own, not only because of their own properties but also because of certain universal human traits.”); Jody W. Zylke, \textit{Examining Life’s (Genomic) Code Means Reexamining Society’s Long-Held Codes}, 267 JAMA 1715 (1992); see also \textit{Future Directions of Human Genome Project Considered}, HUMAN GENOME NEWS, July 1993, at 6 (“Participants [in a meeting held by the NIH National Center for Human Genome Research in April of 1993] observed that anticipating and addressing ethical, legal, and social implications (ELSI) of genome research will become more important as disease-gene mapping expands and improved sequencing technology makes available more-refined molecular diagnostics.”); \textit{Genetic Grammar}, HASTINGS CENTER REP., July/Aug. 1992, (Special Supplement), at S1. Cf. Albert R. Jonsen, \textit{The Birth of Bioethics}, HASTINGS CENTER REP., Nov./Dec. 1993, (Special Supplement), at S1. For a contrary opinion, see John Maddox, \textit{New Genetics Means No New Ethics}, 364 NATURE 97 (1993) (asserting that genome sequencing will not create novel problems, for the techniques are “hardly novel” and unlikely to be more troublesome than those involving the genetic manipulation of bacteria twenty years ago).

\textsuperscript{52} See generally HASTINGS CENTER REP., July/Aug. 1992, (Special Supplement) (addressing genetic screening capability and its implications).

\textsuperscript{53} For a general discussion of this conflict, the competing social values that continue to generate it, and an issue-by-issue discussion of the dozens of difficult questions it encompasses, see Laurence H. Tribe, \textit{Abortion: The Clash of Absolutes} (1990).
question.\textsuperscript{54} This is true despite the fact that late-term (for the purposes of this Article, generally meaning week twenty and thereafter)\textsuperscript{55} abortion is the only real option available, besides carrying and delivering the fetus, if a defect or disease is revealed by prenatal genetic screening.\textsuperscript{56} As recently recognized by the National Institutes of Health,


\textsuperscript{55} Genetic screening presently depends upon amniocentesis, which, because of the danger it can pose to the fetus, generally is not performed before the fourteenth week of pregnancy. \textit{See supra} note 47 and accompanying text; \textit{see also} Curt S. Rush, Note, \textit{Genetic Screening, Eugenic Abortion, and Roe v. Wade: How Viable is Roe's Viability Standard?}, 50 Brook L. REV. 113, 127 (1983). \textit{But see} Kolata, \textit{infra} note 118, at 1 (discussing how visible deformities may be detected as early as week six through embryoscopy).

\textsuperscript{56} Abby Lippman, \textit{Prenatal Genetic Testing and Screening: Constructing Needs and Reinforcing Inequities}, 17 AM. J.L. & MED. 15, 34 & n.90 (1991) (addressing fetal abnormality as one grounds for abortion). "Prenatal genetic diagnosis today only permits us to offer the patient termination of pregnancy. . . . Gene therapy, or gene supplementation, has not become a reality." Sachs & Korf, \textit{supra} note 1, at 460. In addition to technological limitations, gene therapy indisputably is treatment and, as such, it is subject to FDA approval.

The ultimate goals of Genome Project-related advances are the treatment, cure, and eventual prevention of genetic disorders, but effective interventions lag behind the ability to detect disease or increased susceptibility to disease. Thus, many genetic services today consist of diagnosis and counseling; effective treatment is rare. Nevertheless, as more genes are identified, there is growing pressure to broaden existing screening programs, and otherwise increase both the number of available genetic tests and the volume of genetic information they generate.57

One reason for our acceptance of extensive prenatal genetic screening is that it is being introduced to us through the health profession rather than through a social movement. Prenatal genetic screening is perceived, at least on the surface, as being about medical diagnosis rather than about rights—about the decision to abort a wanted child made by parents who will mourn the loss of its life. It is also a reflection of our increased acceptance of abortion when a fetus is physically or mentally impaired and, therefore, the premium we place on “normalcy.” Polls consistently show that seventy to eighty percent of people approve of abortion being legally available when the fetus has a serious abnormality, even if they may not be willing to have an abortion themselves under those circumstances.58

Nevertheless, however gentle its delivery, this new technology carries cutting ethical problems.59 Along with wonderful possibilities effects of medications. Id. Also, researchers have reported success with treating cystic fibrosis by introducing a corrective gene into the patient’s system through an inhaler. This effort is already considered a working-level project by the FDA. Id.


58. Robertson, supra note 36, at 713. Our society’s acceptance of abortion under these circumstances may even give rise to social pressure to abort:

Society does not truly accept children with disabilities or provide assistance for their nurturance. Thus, a woman may see no realistic alternative to diagnosing and aborting a fetus likely to be affected. . . . Regardless of the driving forces for dependency on this technology, the result is the construction of a particular “need”: the basic “need” to know the gestational age of the fetus; the additional “need” to demonstrate that the pregnancy is progressing “normally.” And the “needs” grow.

Lippman, supra note 56, at 32-33.

59. Some of these ethical problems are identified through the objections being raised to prenatal genetic screening:

Right-to-life groups oppose the practice as a search and destroy mission. Handicapped groups are afraid that it devalues the lives of existing handicapped persons. Others are concerned that these techniques are available only to the middle class and not to those without health insurance. Despite the freedom it offers, some feminists object to prenatal testing because it becomes implicitly obligatory—women are then expected to be tested and do not effectively have the right to say no. Still, prenatal diagnosis is now firmly established and is likely to expand as screening techniques move to earlier stages of pregnancy. For example,
such as the realization of a great expansion of parental choice, genetic screening gives rise to ethical problems at least as complex as the most difficult problems arising from the abortion issue. Moreover, especially in the absence of regulation through reliance on research laboratories rather than commercial testing and conscious choice at the public policy level, genetic screening soon will be the more common procedure. As discussed more fully in Parts II and III of this Article, genetic screening testing capability is expanding and that capability is being used for diagnostic purposes more readily than it is being questioned.

II. Law, Ethics, and Legal Storytelling

Law is a social instrument—something we share and, at least at a societal level, agree to. Individual laws are societal obligations we

tort law has recognized the obligation of physicians to offer prenatal testing to women in at-risk categories. Robertson, supra note 36, at 710 (footnotes omitted). Many of these issues are explored in Stuart Taylor, Jr., Blame-the-Moms-Defense, Am. Law., Mar. 1994, at 3, 27-29, a fictional account of a court case arising from a genetic therapy treatment to enhance intelligence.

For example, consider that the presence of a genetic abnormality does not necessarily mean that the disease it has been linked to will be present because “[m]any of these diseases probably result from the interaction of genes and the environment.” Sachs & Korf, supra note 1, at 459; see also supra Part I. Therefore, parents may be aborting wanted children based upon the presence of genetic abnormalities that will either never cause medical or physical impairments, or the emergence of which may be avoided through the manipulation of environmental factors. See Sachs & Korf, supra note 1, at 459. In sum, when the decision to abort a pregnancy arises from the result of genetic screening, there is often added conflict. The factors contributing to this conflict have been summarized as follows:

a) Beliefs about the higher moral status of the fetus at midtrimester when abortion decisions must be made following amniocentesis;
b) The wide spectrum of severity in some disorders (for example, sickle cell disease);
c) The treatability of some disorders (for example, phenylketonuria) which can now be diagnosed prenatally using DNA techniques;
d) The guilt that parents, who have a living child with a disorder, feel towards that child when considering abortion of a newly diagnosed fetus;
e) Concerns that the moral reasoning that justifies a practice of selective abortion may create a precedent for neglect of persons with genetic disorders who are born and survive (some critics compare the reasoning for abortion with arguments for active euthanasia in severely handicapped newborns);
f) Decisions about abortion in twin pregnancies where one twin is healthy and the other affected; and
g) The fact that a decision not to abort after a positive genetic finding can also be an ethical problem if the woman or couple involved are pressured to abort or threatened with loss of medical care.

Fletcher & Wertz, supra note 23, at 762-63.
codify and enforce. They are obligations we can fulfill, and can expect others to fulfill, on a daily basis. 61 In other words, they are expressions of "a basic minimum standard of human behavior considered acceptable in society." 62 Ethical principles, on the other hand, are the ideal. They are what we strive to be, but cannot realize necessarily on a daily basis and cannot expect others to realize. 63 "Ethics and law converge on morality, the practical guidance that communities of persons create and recreate to use in everyday life to resolve conflicts among desires, goods, principles, and rules." 64

Because laws codify what we can expect of ourselves and others, while ethics are aspirations of what we would like and would like others to be, it is natural and necessary that generally we maintain a gap between these two levels of behavior. To some extent, this gap is protected by the recognition of individual rights under the Constitution; 65 it is a recognition that ethical standards are not always shared

61. See generally Martin P. Golding, Philosophy of Law 52-53 (1975) ("This is the very basic issue of authority and freedom. What does a society have the right to demand of its members in the way of affirmative action or restraint? And what ought to be reserved to the individual as subject to his own choice and decision?"); Samuel Mermin, Law and the Legal System: An Introduction 5 (2d ed. 1982) (addressing the functions and limits of law). As stated by Mermin,

[the legal system constitutes a framework within which certain common expectations about the transactions, relationships, planned happenings, and accidents of daily life can be met (and this force for predictability and regularity can itself be viewed as a species of maintenance of order). We expect that our customary ways of behavior will be facilitated and not disrupted by law without strong reason; we expect that those who have suffered personal injuries—particularly those who were without fault—will be compensated for their injuries under the laws of tort; that those who have made promises will be held to their promises (or, if not, be required to make recompense) under the laws of contract; that those who own property can get the law to enforce their expectations that they have exclusive rights in it and are free to dispose of it as they wish.

Id. at 6 (emphasis in original) (footnote omitted).

62. Fletcher & Wertz, supra note 23, at 750.

63. Id. at 750 ("[E]thics aspires to an ideal of optimum behavior and conduct.").

64. Id. at 749; see also Alexander Morgan Capron, Why Law and the Life Sciences?, Hastings Center Rep., May/June 1994, at 42-43. The extent to which morality may be codified through laws has been phrased as the following question: "What are the spheres of morality that are in fact essential to society?" Golding, supra note 61, at 66 (addressing the concept of "public morality"). As explained by Professor Capron, "In a society in which ethical standards were clear, extensive, and strong, there would be no need for the law at all. Thus, might it be that we have turned to the law to tell people what they must do because ethics has failed to convince them of what they should do?" Capron, supra at 42; see also Joseph Campbell, The Power of Myth 3 (1988).

65. See Mermin, supra note 61, at 7 ("In the Constitution can be seen another vital function of our law: protection of the citizen against excessive or unfair government power. I refer mainly to the Bill of Rights—to such basic rights as freedom of speech, press, and religion, the right to privacy and against unreasonable searches and seizure, the privilege
and should not be imposed. A large part of legal training is learning to understand, and even to protect, this gap. Consider that many of us trained in law grow uncomfortable when this gap is narrowed—for example, when legal scholarship takes a highly deontological form, defining and approaching problems from the perspective of the individual, as is true with critical race theory and feminist theory. This discomfort arises from the understanding, whether conscious or subconscious, that law can no longer work as an enforceable standard if the behavior it prescribes engulfs morality and rises to the level of pure ethics.

The objective methods and tools of the law (formality in expression and interaction, the codification and enforcement of elaborate rules and procedures, reliance on precedent that has arisen out of fact patterns at least once removed from the case at issue) enable us to believe that law is neutral and fairly applied among us. Ethical standards, on the other hand, touch upon personal values and become subjective—a matter of one's own morality. Therefore, even though

66. Consider the experience of a first-year law school student being taught that "the law" is a set of constructs often at least once removed from what is "fair." Students are taught that rules are simply "the rules," and fairness is provided through notice that they exist and the understanding that all people are subjected to them equally and without exception. See generally Golding, supra note 61, at 118-25 (addressing "procedural justice" and "justice and equality," and noting that "[t]he prevailing tradition in philosophy relates the core sense of 'justice' to the idea of equality.").

67. See infra note 73 and accompanying text.

68. The distinction between law and ethics is reflected by the fact that, because they are the "highest truths," ethics remain steady while laws change: "Ethical principles and relationships, such as respect for persons and the physician-patient relationship, are fairly stable and uniform over time, even for centuries, and across cultures. Laws, on the other hand, may differ from state to state in this country. Laws change rapidly on specific issues." Fletcher & Wertz, supra note 23, at 750.
COMING INTO BEING

ethics may be respected and generally aspired to by all, their enforce-
ment is better left to the individual.69

Nevertheless, society is often confronted with problems that do
not lend themselves to solutions distanced from ethics.70 Abortion,
capital punishment, the right to refuse medical treatment71—these are
problems for which we, at least at the present time and on the national
level, do not have a shared understanding.72 We often approach such
issues from our personal ethical stances, and we question or cling to
the governing law, depending upon whether it supports or challenges
our own positions.

The technique of legal storytelling is a means to deal with the
interaction of law and ethics. A highly personal, human approach to
problems and a means to identify problems that have not been recog-
nized by society, "[t]he technique of legal storytelling is an effort to
communicate insight gained through personal experience to those
who have not shared in that experience."73 Through legal storytelling,

69. As explained by Fletcher and Wertz:
   Ethics inspires human potential and development to higher ideals of service,
   human betterment and fulfillment. . . . The authority to punish or to coerce gives
   law greater influence in society than morality, which has only the power of praise
   or blame. . . . Law maintains the stability of the social order, rather than making
   people into "better" human beings, although it may claim to accomplish this indi-
   rectly. . . . Law, despite its frequent association with the concept of justice, does
   not necessarily seek, nor achieve, justice; rather, law seeks to allocate power and
   claims to distribute the cost of risks and losses (compensation for injuries). Ethics
   on the other hand, is consciously concerned with seeking justice and bringing
   about social change to enhance the search for justice.
   Id. at 751.

70. As is discussed in more detail in Parts III and IV, many life-and-death decisions
   regarding medical treatment fall into this category. For example, decisions such as whether
   seriously impaired newborns should be treated are left to parents, doctors, and perhaps
   ethics committees. See Renée R. Anspach, Deciding Who Lives: Fatal Choices in
   the Intensive-Care Nursery (1993); David W. Meyers, The Human Body and the
   Law 83 (2d ed. 1990); see also Holder, supra note 38, at 82-122.

discussion of the doctrine of substituted judgment and the state's struggle to involve itself
in decisions embodying difficult ethical questions through that doctrine, see Louise Har-
mon, Falling Off the Vine: Legal Fictions and the Doctrine of Substituted Judgment, 100
Yale L.J. 1 (1990). For discussions of ethical and legal implications surrounding euthana-
sia, see Dying Well?: A Colloquy on Euthanasia & Assisted Suicide, Hastings Center

72. Nevertheless, Fletcher and Wertz have summarized six ethical principles com-
monly found in the literature of biomedical ethics: autonomy, nonmaleficence, benefi-
cence, justice, strict monetary utilitarianism, and non-moral reasons. Fletcher & Wertz, supra
note 23, at 775.

73. Michael J. Malinowski, "Hello, Dad. This is your daughter. Can I get an abor-
tion?": An Essay on the Minor's Right to Confidential Abortion, in Abortion, Medicine,
one is able to analyze the effects of law and the absence of law on an extremely practical and real level. Our own personal morality, which is shaped by our own perspectives and experiences, is tested and tempered by the experiences of others.

The following are such personal experiences: the insight of a genetic counselor, the perspective of a researcher working on the Human Genome Project, the experience of a woman who underwent genetic counseling and chose abortion, and the experience of a family that includes a child with spina bifida. These stories are offered as a way to understand the practice of genetic screening and its impact on families. They are also offered as a means to evaluate the need for enforcing existing legal restraints on, and erecting others around, the practice of prenatal genetic screening.

A. A Counselor's Story

The background needed to be a genetic counselor varies, depending on whether you want board certification. Most genetic counselors,
including myself, are master's level (meaning that we have a master's graduate degree in this field) and board-certified (meaning that we have a wide general knowledge of all aspects of genetics and genetic counseling). Master's level counselors have undergraduate degrees in the fields of science or psychology; our master's counselors are from genetic counseling programs. Numerous nurse-counselors and social workers do certain types of counseling. Non-master's level counselors used to be eligible for board certification, but in the mid-1980s, the qualification of graduation from a master's level training program in genetic counseling was added, limiting the ability of nurses and social workers to get board certification as general counselors.

Until this year, certification for master's level genetic counselors was done exclusively by the American Board of Medical Genetics, which also certifies M.D. and Ph.D. geneticists. Now it is done by the newly formed American Board of Genetic Counselors. This came about because medical genetics recently received formal recognition as a medical specialty by the American Board of Medical Specialties (ABMS). But, by ABMS guidelines, if the M.D. geneticists wish to maintain that recognition, their specialty board cannot also be certifying non-M.D./Ph.D.'s. So the counselors have formed a separate certification board. Several other divisions were also needed, which is sad because historically the M.D.'s, Ph.D.'s, and M.S.'s have all worked pretty closely with each other. But, to avoid losing cooperation, communicating boards have been set up.

Personally, I do primarily prenatal genetics. I see about 700 patients per year. According to the statistics of the National Society of Genetic Counselors (NSGC), the average counselor sees about 450.

These discussions took place during the spring of 1993. Much of the text was transcribed from audiotape, then edited by the author and transformed into the narrative presented. That tape, although confidential, is on file with the author.

The counselor responsible for most of the information presented asked me to note at the outset that terms such as "mother," "parent," and "couple" should be taken to mean the pregnant woman and her primary supporters, if she has any. The counselor also asked me to stipulate that this discussion is presented with the understanding that not all pregnant women are members of "couples," and that the father of a pregnancy should be as involved in prenatal counseling and decision making as possible.

76. See infra note 286 (discussing how who provides genetic counseling may have a tremendous impact on the counseling received by patients).

77. See Business Meeting Minutes, The American Society of Human Genetics (Nov. 12, 1992) (addressing the recognition of medical genetics as an official medical specialty, and stating that "to remain in compliance with the [American Board of Medical Specialties (ABMS)] requirements, the [American Board of Medical Genetics (ABMG)] must be restructured so that in the future masters level genetic counselors will be certified by a new Board, the American Board of Genetic Counseling (ABGC)").
patients per year, with the range being from 200 to one thousand. I see most patients only once, but I have seen some several times and had extensive telephone contact with others; it depends on what they need.

When I meet with a patient, I do a full pregnancy history: Have you been ill during the pregnancy so far? What’s your ethnic background? How much alcohol have you consumed? Is there any family history you are worried about? Sometimes patients have family history they are worried about, and we’ll talk about that. Sometimes it turns out that the mother is most worried about the fact that her sister’s child has cerebral palsy and the father is most worried about the fact that the mother hasn’t quit smoking. We’ll cover all those issues. We work through everything and pull it all together as best we can to find the most appropriate tests. We end up saying something like, “Based upon what you’ve told me, here is the testing we can offer. This one will tell you this, that one will tell you that. They cost ”X“ amount. It takes ”Y“ long to get the results. No test can guarantee a ‘perfect’ baby.”

We also discuss accuracy, ambiguity, potential risk of miscarriage, aftercare, and other things they have to know to make an informed decision, including anything else they want to talk about. I will ask them if they have thought about what they will do if the results indicate that there is a problem, and if they would like to hear more about particular disorders. A lot of people do not want to hear too many details; it’s too overwhelming. But there are things that need to be included to reach an informed decision.

After the decisions are made, I arrange for the procedures they have decided to undergo, make sure that whatever testing that is to be done is lined up, and then I follow through with the results. If everything is fine and the lab does not see any signs of an abnormality, great. I’ll call the parents and their OB (obstetrician) with the results, and they continue with their regular prenatal care. If an abnormality is detected, we will talk about it, and I work with them to help them make whatever decision is comfortable for them. If they decide to continue with the pregnancy, I let them know whether there are any pediatricians we recommend, the names of specialists they might need, parents groups, and things they will need to help get ready. For those who terminate, we make arrangement for this if their own OB isn’t comfortable doing so. We work with the parents so they’ll know what to expect during that procedure, and afterwards. I personally don’t do long-term extended grief and family counseling, but other
counselors have chosen to get additional training in those areas. Many centers coordinate support groups for those who have ended a pregnancy for genetic reasons, and a family therapist is often part of that team.

* * *

Biostatisticians figure that, on the forty-six chromosomes, there are between fifty and one hundred thousand different genes. We have identified about 4,000, but testing is only available for about 100. Not all testing is done at my center. We routinely send samples off to other facilities. Once you get past the basics, different labs have different areas of specialization and expertise. Research labs get very specialized and particular about what they will and will not take for analysis.78

People will come in and say, "Test for everything that you can." I'll explain that we can't do this. First, it's not feasible and second, the cost would be astronomical.79 Average amnio fees are currently about one thousand to twelve thousand dollars, including OB charges, sonogram, and basic lab fees. Of course, adding on extra testing increases that cost. Insurance coverage is a big factor for most people, given the cost. Most insurance companies will only pick up what's medically indicated.80 Medicaid isn't accepted by all laboratories, which is a reflection of the poor rate of payment. HMOs in particular get very touchy about adding anything on without proof of medical

78. See infra note 84 (addressing dependency on and the discretion of research laboratories).

79. According to one genetic testing facility, most testing beyond standard chromosome analysis will run approximately $250 for each test. It is important to note that the costs, availability, and utilization of tests may be greatly influenced by market forces: A test [for cystic fibrosis, carrier screening] is available for about $200 from several testing companies that have strong financial incentives to market their product aggressively. Many physicians are likely to offer the test to their patients—to meet patient demand, to minimize the risk of later malpractice claims, or to profit from providing an additional service. Robertson, supra note 36, at 699-700 (footnotes omitted).

There is talk in the scientific community about bringing down the cost of genetic screening through panel tests—one test that screens for several genetic abnormalities. For example, in the spring of 1993, Baylor's Institute for Molecular Genetics in Houston, Texas came out with a panel test that screens for cystic fibrosis, Tay Sachs, and Gaucher's. The panel is run on one blood sample for $150, and it carries a greater than 95 percent accuracy rate as to whether the subject carries any of the three diseases. See Sandra Grilliot Peacock, M.S., Baylor College of Medicine, Class Presentation, Abortion, Law, and Social Choice, University of Houston Law Center (Apr. 19, 1993).

80. See infra note 218 (addressing refusal of health maintenance organizations (HMOs) to provide care for children born with prenatally diagnosed ailments).
necessity. And then, if you want to do it at a lab outside of the HMO's network, you really better be able to back up your request.

Even though most insurance companies do not like to pay for the expensive treatment of an abnormality after birth, I tell patients up front not to expect insurance to cover termination. Some insurance companies will come through, though—especially on appeal. But you cannot count on that up front. Besides, termination clinics don't accept insurance, and terminations done in hospitals are more expensive.\footnote{In 1991, first-trimester terminations at a nonhospital-based clinic in the Houston area ranged from approximately $200 to $900. Second-trimester terminations ranged from $750 to $2,200 if done at a nonhospital-based clinic. Second-trimester, in-hospital terminations generally ranged from $1,200 to $5,000 depending on charges for use of hospital facilities and personnel, anesthesiology, medications, and doctor's fees. Post-termination options such as autopsy add more costs.}

We always try to get results back while termination is still a legal option.\footnote{Abortion is a legal option in Colorado, Florida, and Kansas well into the third trimester. See infra note 140.} Termination is legal until the twenty-fourth week of gestation in most states. Assuming it takes two to three weeks for results, twenty-one weeks is about the latest you want to send a sample to a lab for routine testing. If special testing is required and results are going to take longer, the testing obviously must be done sooner. Occasionally, a woman will request testing after the point of having termination as an option; she may have just raised the money for testing or just discovered a risk factor. Lots of people are surprised to learn that the law doesn't allow termination for fetal anomaly at all stages of pregnancy; others are surprised that termination is an option past the first trimester.

Many people would like the information from the testing as early as they can get it. That is why first-trimester testing like CVS was developed.\footnote{See supra note 48 (discussing CVS and other prenatal diagnostic techniques).} You can have it done between weeks ten and twelve of gestation and have the results back by week fifteen. Earlier options, earlier reassurance—these are the benefits, especially when compared with amnio, which is generally not done until week fifteen. Of course, with the recent controversy regarding allegations that CVS may cause limb defects, some patients are opting to wait for amnio. Amnio has been attempted earlier than week fifteen, but detailed studies on doing amnio at that stage have not been completed. There are techniques that can be done prior to conception for certain conditions, but they involve in-vitro fertilization (IVF) and they are primarily in the...
research stage. Another promising technique that is still in research is based on the premise that fetal cells will cross into maternal circulation. At some point during pregnancy, it should be feasible to draw blood from the mother, sort the fetal cells from the mother's cells, and analyze the fetal cells for genetic diseases without assuming any of the risks associated with amnio or CVS. Finally, it now may be possible to detect visible deformities in fetuses as early as week six.

We keep track of research advancements, but generally we only contact research labs directly if they are the best ones working on a disease for which a family needs testing. Research labs are definitely churning out testing advances faster than commercial labs can accept them. Certain research labs simply dominate the field with the quality of their work on specific diseases, and they will make their tests available for this reason. We'll occasionally find that the best place for a test to be run is in Canada, Europe, or Japan. We'll then coordinate with that researcher and take care of the test the same way we would if the test were done in the United States—except for we'll have to cope with international requirements for shipping medical specimens. If a researcher says that a test isn't ready for clinical application, we'll let the patient know that also. Sometimes patients will want to do testing even if the test is just in the beginning stages of research. They may feel that any information is better than none. Some tests will always stay "research" under current technology simply because the disease is so rare that no commercial lab is interested in doing the testing for it.

The labs with which I've worked have all been very much aware of the legal and medical liability of testing. If, for any reason, a lab is not satisfied with the quality of the sample or of the analysis, it will often recommend repeat testing. Most of the times repeat testing will show everything is fine, but I do know of families who opted not to do repeat testing and the baby was born with the suspected problem. It's

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84. According to several sources, facilities providing genetic screening and counseling services are more involved with research laboratories because they are pushing far ahead of the commercial laboratories. A related issue is whether research laboratories—which are often fully funded by grants and driven by different incentives than commercial laboratories—are even willing to run their tests on prenatal samples. For example, there are laboratories on the cutting edge of testing for certain diseases that discourage prenatal samples because the people running the laboratories do not believe in termination for the specific genetic diseases.

85. The direct contact between researchers and the public is discussed in more detail, infra Part II.B.
one of the reasons I raise the issues of accuracy and possible ambiguity during the initial session.\textsuperscript{86}

This is the one thing I’ll hear over and over again from patients who didn’t have full pre-procedural counseling—that they weren’t told of certain risks like ambiguity in the test results. Of course, you’ll also have patients who don’t recall being told about these issues even when you know that you covered them. There is also the chance that, because so much is raised during a session, the patient cannot remember clearly whether something was said or not. Some centers require that counseling be on a separate day from the procedure to give patients time to think fully about everything. It’s a good idea, but the reality is that many patients have difficulty getting off work, arranging day care, or just traveling to the center if it’s far away.

We strongly recommend that patients who have abnormal results indicating a fetus with a genetic condition return in person for further counseling. Again, logistics don’t always make this possible, but a good number do return—especially if the result is for a condition with which they may not be fully familiar, like a sex chromosome anomaly. We prefer to have both members of the couple come in, assuming the father is involved, and minors should come with a parent but, again, the world isn’t perfect and, logistically, this can’t always happen. For those who decide to continue pregnancies knowing that their baby has a genetic condition, we can put them in touch with support groups and specialists and give them ideas of how to work with their insurance companies—practical help in addition to trying to answer the questions of why did it happen and will it happen again.

If the patient decides to end her pregnancy, and her own OB has no recommendations to make, we put her in touch with a clinic or gynecologist who we feel is safe. We don’t generally get involved with ethics committees or such, as long as the pregnancy is under twenty-

\textsuperscript{86} See supra Part I.A. As for the general accuracy of tests, with some diseases, such as Down’s Syndrome, genetic testing can conclusively detect whether the disease is present. With other diseases that are caused by multiple mutations, geneticists are less specific because to give a 100 percent assurance that the disease is not present would require testing for the presence of all causative mutations. Consider that more than 230 mutations have been documented as causing cystic fibrosis, Assessing Genetic Risks, supra note 9, ch. 2, at 3, and no lab in the world is currently set up to test for all of them. According to a confidential source in the Houston area, at least with the most common commercial testing, market competition between Houston facilities has pushed genetic screening providers to the point of offering the highest degree of certainty at a fair price. For example, the reason that one Houston lab does a cystic fibrosis test for 24 mutations (the highest in the industry as of July 1993) is that other laboratories in Houston had already reached the point of testing for 12, then 14, and then 17.
four weeks and the hospital has no policies about doing so. Generally, termination is either by induction of labor or by dilation and evacuation of the uterus (D&E),\textsuperscript{87} depending on what the fetus's gestational age is, insurance coverage, whether an autopsy is needed, whether parents wish to view the baby, and other factors. If the parents do a labor induction, viewing the baby is encouraged because psychological literature shows that creating memories helps in resolving the grief by making the baby and diagnosis real. Basically, it says to the patient, "You really were pregnant; there really was a baby; there really was a disease; and here's physical proof."

We are more likely to involve hospital ethics committees if the couple is continuing a pregnancy but does not desire "heroic" care after delivery—for instance, if the baby is known to have a lethal condition like anencephaly (the baby will be born without a developed brain due to a failure of the neural tube—the precursor to the spinal cord and central nervous system—to close). It helps in these cases to make sure in advance that both the neonatologists and the mother (and father, if involved) are in agreement as to what constitutes "reasonable and humane care." I know of more than one woman who decided not to deliver at the tertiary care center because the neonatologists and she could not come to agreement on the care of the baby after delivery. In my view, the OB is the mother's doctor, not the baby's, so the OB cannot really influence these decisions.

Sometimes a hospital policy may be such that the baby doesn't have to be given to a neo's care immediately after delivery, but, still, calling the neo or the ethics team is hard to resist—especially if the baby's diagnosis is tentative. A variety of factors play in here: (1) an unprepared staff may not be aware that the specific diagnosis isn't needed if the possibilities are all fatal; (2) staff tend not to use cost as an immediate decision-making factor, even if they are aware of the potential financial burden since, in the United States, staff are trained to make full attempts at saving all lives regardless of costs; and (3) the potential legal liability of not calling in other specialists can be devastating if the patient were to sue later.

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A few couples have inquired about putting a baby with a genetic condition up for adoption. National organizations for conditions like Down's Syndrome and spina bifida state that they have lists of couples

\textsuperscript{87} The techniques used for performing a late-term abortion are summarized \textit{infra} note 117.
wanting to adopt children with these conditions. I haven’t worked with any couples who have pursued this option prenatally. Even those who have investigated it seriously have ended up not doing it. I get different answers as to why. Some say it would be completely against their morals to knowingly bring a child with a genetic disease into the world and then not be willing to care for the child. One girl said that she was going to adopt out the baby if it were healthy but not if it had a genetic disease. Her reason was that she would always wonder if her child was getting enough love and support, and to know that her child needed that much more love and support because of its condition would make her worry even more. The few parents I’ve met who have pursued the adoption option have done it when the baby was born with an unexpected genetic disease and, after trying to take care of the child within their own family, they found that they just couldn’t. The only family I’ve ever encountered personally who had adopted a child with a known genetic disease first got involved with children with genetic diseases through foster care and then moved to adoption.

A lot of the saddest cases seem to occur when the anomaly is not discovered until after twenty-four weeks and the patient is left with no legal option other than to deliver, or when the patient would like to terminate but doesn’t have the financial resources—for instance, if the mother is on Medicaid and state funds aren’t available for termination (federal funds can’t be used for this currently). Some of the diagnoses that are made late could have been made earlier if more aggressive care had been sought. But sometimes OB care isn’t started before twenty-four weeks, or sometimes the OB doesn’t scan for physical anomalies until after twenty-four weeks. The most frustrating cases are when an OB scans early, thinks he sees something, but then waits to see what happens rather than directly referring the patient for a full evaluation. For some really severe conditions, like anencephaly, the doctors can end the pregnancy at any point so long as they can provide proof of the diagnosis, but there is some controversy over the conditions that justify this and the proof needed. If there is any

88. See infra note 147 (addressing the availability of families willing to adopt children with health impairments).

89. Subsequent to the time the author transcribed this narrative, the Clinton Administration changed the policy regarding federal funding of abortions. Under the present policy, states must now pay for the abortions of poor women impregnated through rape and incest. See Medicaid Abortion Rule Seen as Peril, BOSTON GLOBE, Jan. 6, 1994.

90. According to one confidential source, another option for these patients is to refer them to states such as Kansas where one can legally terminate a pregnancy for genetic abnormalities up to 30 weeks. The cost just for the abortion procedure, based upon 1993
doubt about the diagnosis or the patient’s agreement with the decision to end the pregnancy, doctors tend not to offer this option.

Any couple who has a pregnancy with a genetic disease, whether they terminate or not, has to go through a mourning process. They mourn the loss of the normal child they hoped to have. No matter how glad they are that they terminated the pregnancy or how much they love the health-impaired child they decided to have, they still will be saddened for the loss of the child or the things their child cannot do. Both men and women grieve this loss, though they often do it differently. As part of the grief counseling, we try to make couples aware that they may grieve differently, but that they both will grieve.

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“What would you do in my situation?” People are always asking that of counselors. Although we are supposed to be nondirective, many people have no idea what to base their decision on. How directive is it to talk patients through the decision-making process? By “talking through” I mean discussing the things I would consider and I see others considering, such as: How stable is my marriage? Am I financially capable of raising this child? Is my job flexible enough to handle this? Should I stay at home instead? Will I psychologically and physically be able to handle the special needs of this child? What would it be like to raise this child? How would having the child affect my other children? What am I prepared to do and not do for the special needs, both physical and psychological, of this child?

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*91. The psychological impact of having a child with a health impairment is discussed infra note 144 and accompanying text.

92. Nondirective counseling has been defined as follows: “Nondirective” genetic counseling means that counselors refrain from giving moral advice, even if asked, out of respect for the moral autonomy of patients. Counselors encourage the patient or parental couple to make moral choices in light of [the patient's or parents'] own values. This stance is the prevailing ethical approach to genetic counseling in many nations. Fletcher & Wertz, supra note 23, at 765; see Annas & Elias, supra note 44, at 216-17 (quoting conclusions of the Judicial Council of the American Medical Association, and stressing that counselors should avoid the imposition of their personal moral values); see also infra note 286 (comparing natural science training to social science training in the context of counseling skills).
There has been a fair amount of controversy on non directiveness within the field. Some of the OBs and medical geneticists with whom I have worked with will get directive, especially if they feel the diagnosis is extremely severe or extremely mild. The concept of non directiveness gets undefined when you realize that it's considered "sad but okay" to terminate for sex chromosome anomalies that might have nothing to do with IQ or general functional physical health, but it's considered "bad and not okay" to terminate simply on the basis of the fetus's sex—no matter how poorly that child might be treated because of its sex. Telling someone that you consider his or her moral and ethical judgment to be okay for one situation but not for another is not non-directive. I think that it's about as directive as you can get to assert your opinion over theirs to the point that a person who honestly admits sex selection can't get the same kind of care at your center as someone who doesn't admit that sex selection is the intention. I'm part of the minority holding this opinion. I know that some centers have "solved" this problem by either referring such couples to a center known to permit sex selection (or prenatal paternity testing, or whatever the issue might be), or by doing the "okay" testing—say, for example, for a maternal age-related disease—but not releasing the sex or the paternity results until later in gestation.

It's generally accepted that termination is the primary option for most genetic diseases found prenatally. Fetal surgery and fetal therapy are coming along but are still far away from the point of general clinical applicability.93 Anytime you do surgery on the fetus, you are also doing surgery on the mother in order to access the fetus.94 The benefit of doing the surgery prenatally has to justify the risk to the mother, and often it can't.95 Currently, with very few exceptions, ben-

93. See supra note 56; infra note 110.
94. "We need to guard against imposing new technologies on patients, especially when the potential, and unproven, benefit for one (fetus or child) depends entirely on the acceptance of risk to another (pregnant woman or living related donor)." Marian G. Michaels et al., Ethical Considerations in Listing Fetuses as Candidates for Neonatal Heart Transplantation, 269 JAMA 401, 402 (1993). With this concern in mind, it has been proposed "that any attempts at therapeutic genetic intervention be carried out only a) when there is reasonable scientific evidence that it will cure or prevent a disabling disease, and b) with the informed, voluntary, competent, and understanding consent of the individuals involved." Annas & Elias, supra note 44, at 215.
95. An observation often overlooked is that advances in gene therapy may be accompanied by increased obligations to fetuses: "[T]he medical profession has begun to focus on therapeutic possibilities for fetal anomalies detected during the third trimester. As a consequence, the concept of the third-trimester fetus as a patient has emerged." Chervenak & McCullough, supra note 90, at 311 (footnote omitted). See also Reece & Homke, supra note 48, at Part VI (discussing how genetic therapy capability will enhance
efits to the fetus from prenatal surgery are the same as they would be if the surgery were done after delivery.

I think termination for fetal anomaly will always have to be an option. If you ban termination, what is society prepared to do to help these kids and their families—schooling, housing, therapies, medical expenses, and so on? Some of these kids are pretty severely affected. One of the benefits of prenatal diagnosis has been that people who wouldn’t have otherwise risked having another child with a genetic disease have been able to complete their families. Many parents say that they could handle a child with a genetic disease, but that they will not bring such a child into this world, a world that does not accept such children and their needs. The problem is that, if society is never asked to accept these children and what makes them different, it never will rise to that occasion.

B. A Researcher’s Story

I can only speak from a pure research perspective. The way the Human Genome Project is set up, most laboratories involved in basic research are working on a specific chromosome or chromosomal region. Many of these researchers are particularly interested in regions that contain genes for various human diseases. There is some overlap in this research. We have collaborators and competitors in Germany, Japan, and Russia; all of us are using different techniques to map and analyze the same chromosomal region. Personally, I am working on finding and characterizing the gene for a specific disease that maps to this region on the human chromosome—a disease that can be severe, but generally only causes mild deformities.

There is a patient and family whom we used in a genetic-linkage analysis before. The mother is pregnant now, and she has asked us to do an analysis on the fetal DNA to see if the child has inherited the disease. In this particular family, I can tell her if the child will have

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96. The following, transcribed from audiotape and edited by the author, is a narrative compiled from several sources and discussions that took place during the spring of 1993. The audiotape, although confidential, is on file with the author.

97. When questioned about direct contact between the public and researchers, a reliable source who wished to remain anonymous informed me that direct contact between researchers and the public is becoming more common—highly educated and motivated patients find the names of researchers through published papers and track them down. To avoid this, some institutions prevent their laboratory researchers from talking directly to patients and accepting samples that have not come through acceptable channels. Counsel-
the disease with a high degree of certainty. She already has one affected child, and she’ll abort this fetus if it has the disease. I am having some trouble with this because I do not think that it is that bad of a disease. I really don’t see why she would want to have an abortion. It is hard for me because I will actually perform the analysis on the DNA.

The lab is still trying to figure out if we can or should do it. This is the first time a patient has bypassed doctors and counselors and come straight to us. In fact, it would be the first time that we perform this analysis for this explicit purpose. Up to this point, we have used patient and family DNA provided by doctors or genetic counselors to do genetic linkage for research purposes only. Consequently, this analysis is “underdeveloped” in that it has not been rigorously tested for these purposes. The liability here is obvious. We have written to the legal advisor at our university to see what we can do. We are the only lab at this point that has the genetic markers needed to do the analysis, which leads to an obvious dilemma: if we turn down these people, it will make it harder to get more DNA samples from them for research. We collect DNA from these big families, from the grandparents down to the newborns. What are they getting out of providing samples if we don’t give something back? What motivation are they going to have to let us take blood to get DNA in the future? We have a federal grant and, to keep that grant, we have to continue to collect patients for research; we have to please people so that they keep giving us DNA to foster our research.

What we think is that, since what we are doing is research, we can write up a consent form that says this is research; so long as we tell them that the information is not completely reliable, we are safe from liability. There is no funding board I know of that has said, “Research labs, if you mess up a single research sample relied upon by someone in the public who is told it’s research, your funds are jeopardized.” There are human subject guidelines, and they are pretty good, but they do not expressly address this issue; we do not have guidelines about how to treat people.98 The grant funders want results, and too

ors, hospitals, physicians, and other genetics laboratories are all generally considered to be acceptable channels.

98. Despite the four percent of Human Genome financing devoted to the ethics of the project, ASSESSING GENETIC RISKS, supra note 9, at 460, one genetic counselor has estimated that it will be several years before the ethical, legal, and social issues subcommittee of HUGO releases consensus statements on clinical utilization, privacy, and insurance aspects of the project. The International Bioethics Committee (IBC) of the United Nations Educational, Scientific, and Cultural Organizational (UNESCO) is working toward an eth-
many regulations will slow down results. As soon as researchers reach a stage with sufficient results, there is pressure to get the test out into a commercial lab. You throw the test over as soon as you can because you do not want to take time out from research to run these tests. When to hand the test over is pretty much decided internally at this point. There are some regulations from the American College of Pathology (commonly referred to as “CAP regs”), but most decisions are the product of internal decision making and good faith.

Reputation is important. Some premature tests are being kicked out. It is worse with other countries; we are the powerhouse in science, so we do not need results to prove ourselves as much. At the last Human Genome conference in San Diego in '91, Dr. James Watson was critical of Japan. The Japanese walked out. He was saying, “You guys are saying you have stuff before you really have it.” Generally, though, scientists are pretty good. We have to be extremely ethical because it is so easy to cheat. We also have to be incredibly careful. The social norms are that, any mistake—you just have to publish one wrong thing—and you are out of the profession.

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I would like it if there were regulations to require counseling for the public. It would give us an out with the patients when they walk up to us and ask us to run a test. But patient demand can provide an

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99. For a discussion of these regulations, see infra Part IV.A.1 (discussing these regulations).

100. Watson, along with Frances Crick, identified the double helix structure of DNA and won the Nobel Prize for medicine in 1962 for this discovery.


102. Although there is a considerable degree of cooperation within the international scientific community, through its open support of the Human Genome Project, the United States has provoked what approaches constituting a cold war in genetic technology. The fact that the United States scientific community is internationally respected for the accuracy of its work raises an interesting question regarding the financing of the Human Genome Project:

[T]he Genome Initiative has already led to speculation about its role in international economic competition and to suggestions that the Japanese are not playing fair and should be cut out of any international information exchange on the genome. What role does, or should, international economic competition play in deciding how much federal funding should go to the Genome Initiative?" Annas, *Monster Mythology*, supra note 17, at 645 (footnote omitted).
incentive to move research along, both inside and outside of the lab. If you do not have a patient saying "Do the test, do the test," will you still have a force to push research to the commercial level? The portion of the Genome budget going to ethics concerns has not accomplished anything yet. I want them to make some rulings, to say you have to do this and that and that I have to tell patients "No." I want to be able to say, "I can't because the NIH says 'No.'"

C. A Parent's Story

At the beginning of my pregnancy, my obstetrician gave me a pamphlet that outlined some prenatal testing options. Everyone told me, "Oh, don't take those. You get a lot of false positives." But I decided to take an alpha-fetoprotein (AFP) test, which is just a simple blood test. It can determine the possibility of Downs, spina bifida, and other common diseases. I had miscarried during my first pregnancy, and I just felt the need to take it. I said, "There's not going to be anything wrong. I don't have a family history of any of these diseases. Let me just take it anyway."

103. This story is the result of an interview I conducted on July 19, 1993 in Houston, Texas. Although "Jennifer" is not this subject's real name, the experience and words are her own. My research method, the same method I used to gather the other stories presented in this Article, was to conduct an interview, transcribe that interview from audiotape, edit it into a coherent "story," and then give the subject at least one opportunity to review it for accuracy.

104. "Spina bifida," which is Latin for "spine that is split in two," arises during the fourth week after conception—a time when many women do not even know that they are pregnant, and the embryo is no larger than a grain of rice. In normal embryos, a flat strip of cells running down the center of the embryo folds in on itself and sinks into the center of the embryo. Beginning in the middle, the outer edges of this strip of cells meet, forming a tube. Ultimately, the upper end of this tube will become the brain and the lower end will become the spinal cord. Spina bifida arises when the cells fail to form a tube and sink into the embryo. The result is a jarring mass on the back and an open lesion. The higher the location of the lesion, the more severe the disease. Treatment for a child born with spina bifida involves (1) covering the lesion with a fold of skin to prevent infection, (2) placing a shunt (or tube) in the child's skull and down his or her neck to drain spinal fluid, which tends to build up in the brain, and (3) therapy and surgery to enhance functioning capability. The prognosis for severe forms of the disease generally includes no walking, no sitting without support, problems with respiration, neurological problems, lack of mental ability resulting from malformation of the base of the brain, no bladder function, no bowel function, and many surgeries.

The preceding discussion of spina bifida has been excerpted from Lisa Belkin, First, Do No Harm 212-16, 221-30, 251-52 (1993) (a reporter's account of the Hermann Hospital ethics committee). The reality of spina bifida is narrated through the story of Claire and Kenny Sparks and their first child, Landon, who was born with a severe case of spina bifida. It is also a story of how, because Claire and Kenny were unable to make a decision on their own, the ethics committee at Hermann Hospital in Houston, Texas was involved in their decision to save Landon's life.
So at my sixteenth week of pregnancy, I took the AFP. This was in the fall of 1990. The results took about two-and-one-half weeks and, during that time, I didn’t think much about it. When I went in for my regular check up, my OB came in and started measuring me. He was a male, and he started talking to his nurse, saying, “I think it’s just that her due date is off.” I had forgotten that I even took the AFP test and that there could be a problem, so I interrupted with, “Are you talking about me?” He sat down with me and told me that my AFP readings came out high. He said that a high reading could mean twins, a wrong due date, or spina bifida. When he strongly encouraged me to go through genetic counseling, I started panicking. To calm me down, he said, “Until you can get into UT [the University of Texas] which has the high-powered, level-three ultrasound, let’s just do an ultrasound here in my office with the equipment I have.” Throughout the ultrasound, he did not say a whole lot. Later on, I found out that he did see the problem in that he could tell there was only one fetus. The only remaining possibilities were a wrong due date, false reading, or spina bifida.

My OB referred me to UT on a Thursday, and I had an appointment for genetic counseling on the following Monday. At that time, my husband was concerned, but I think I was in total shock. It did not even phase me. I went into the first counseling session alone and with a very positive attitude. I kept telling myself that there was no family history, I was a healthy person, and I felt fine. The session lasted for about an hour, and during that time the counselors gave me statistics, carefully explained what spina bifida is and the range of severity, and told me what my chances were for having a baby with the disease. They also told me that, if genetic testing detected a problem, I would have a choice and that they would help me through that. At that point, I still was thinking, “I don’t fit into any of the high-risk groups, and I have taken good care of myself,” but I wasn’t quite as sure that there would not be a problem. The counselors definitely gave me a lot more to think about.

I was scheduled for an amnio on the following Wednesday. My husband and I went in for a second, short counseling session and then went in to get the amnio. They had told us that first they would take a glance with the ultrasound to see if they could spot something severe and then do the amnio. So we went in expecting to get an ultrasound, an amnio, and then wait about two weeks to get the result. I laid there

105. The amnio procedure is discussed supra note 48.
as they did the ultrasound, not thinking much of it. The doctors were taking a close look at everything, and they did not say much. It seemed like two hours—picture after picture, after picture, and doctors kept coming in and out (probably discussing what they saw behind closed doors). When they finished, they said, "Let's take a break." My reaction was, "What about the amnio?" but they told me that they wanted to talk first.

When my husband and I went into the counseling room and I saw my genetic counselor there, I knew something was wrong. I did not expect to know right away—to know right then. They basically confirmed that the baby had a severe case of spina bifida and, if the baby even lived to its due date, it would be born with severe nerve damage. That was when I fell apart. My husband and I had talked about it before, and we had decided that our decision would be based on the severity, on the child's potential quality of life, and on the fact that the world we live in is hard enough without going through life with a severe case of spina bifida. Neither my husband nor I could watch a child suffer through life, and we agreed 100 percent that we were going to terminate the pregnancy due to the circumstances.

The procedure was scheduled for the next day. I hadn't felt any movement throughout my pregnancy, but I felt a slight movement that day. That was very difficult. My family, genetic counselor, and the doctor who performed the procedure got me through it all. They were all great. The doctor (whom I became a regular patient of) tends to be conservative, and it is her practice to reevaluate the case before performing the procedure to make sure that the patient is well-informed and certain. She told us that there was no grey area in our case, and that put me at ease.

The actual procedure was horrible. I didn't think that it would be that painful and last so long. They used a saline solution and induced labor at about 11 o'clock that morning, and I did not start to get contractions until about 11 o'clock that night. They were mild at first, and I even sent my husband home to get a shower. By the time he got back, the pain was absolutely incredible, and he heard me screaming as he came down the hall. I have never experienced pain like that; it felt like the fetus was being pulled out of me. I just kept thinking, "I am going to get nothing out of this." In fact, I was worried that the baby would be born alive, but I was assured that it wouldn't happen.

When the baby was delivered, they encouraged me to see it and spend time with it to help me through the mourning process. It would be real small but fully formed, with the exception of the effects of the
spina bifida. But I just couldn’t do it. We did hold it, but it was wrapped. They told me that they would keep a picture on file for a year, in case we changed our minds. We never did.

I have had a healthy child since, a little girl. She’s wonderful. I got pregnant with her unexpectedly just four months after the termination. I read everything I could get my hands on that was about spina bifida, and I decided to have an amnio at twelve weeks. That was a tough decision. I kept thinking, “I lost one child, terminated my second pregnancy, and now I might endanger my chance of having a healthy child by running this test.” But I wanted to know and to avoid carrying another child late-term, only to then terminate the pregnancy because of another bad case of spina bifida.

* * *

After the termination was over, I told my counselor that, if she ever formed a support group, I wanted to be part of it. I thought that it would be great to help others going through the experience and feeling the loss. A support group has been formed since then, and I am a very active member. Even with having my daughter, I don’t think that you ever completely get over something like this, and it helps to talk.

If I could speak to the world, the one thing I would like to say is, “Unless you have stood in my shoes, you shouldn’t judge me. Everyone should have a right to choose.”

D. A Family’s Story

Bobby Lachapelle, usually called “little Bobby” because his dad and grandfather share the same name, is ten years old. He is smart, handsome, and likes attention—no, he demands it. Wheelchair or no wheelchair, he has a way of always being everywhere and making his sisters constantly call for their mother.

Bobby has spina bifida. In fact, he has meningomyelocele, the most severe form of the disease. His parents, Roni and Bob, own an

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106. See supra note 104 (discussing spina bifida in detail). Unlike Bobby, Landon Sparks has not done well. Although he was a bubbly child who loved to talk, listen to music, and play games, after nearly two years Landon developed bronchitis. As is common with spina bifida children, infection set in and Landon’s fever rose to 105 degrees during the course of one night. Claire and Kenny awoke at 3 a.m. to find Landon in the midst of a violent seizure, and he sustained severe brain damage. Landon was connected to life support and, this time, Claire and Kenny were able to make a decision without the ethics committee—they decided to turn Landon’s ventilator off. But when the machine was turned off, Landon continued to breathe. The end result is as follows:
oil business and service station in a small New England town of fourteen thousand. Many of their neighbors are also relatives and friends. Besides Bobby, Bob and Roni have three girls—Liz, who is twelve, eight-year-old Jessica, and six-year-old Alison. Bobby is not treated special; his parents expect just as much from him as they do from his sisters, and when he misbehaves, which is pretty often, he is scolded for it.

Because Roni already had Liz before she became pregnant with Bobby, she knew what to expect. And, when carrying Bobby, Roni experienced nothing unusual; it was a perfectly normal pregnancy. But the delivery did not go well—that was when the doctor knew something was wrong. After a struggle with forceps, Bobby was delivered. Almost immediately, Roni and Bob were told that their child needed to undergo a major operation.

There was never any question about closing the lesion on Bobby's back. The doctors basically told Roni and Bob that their baby was

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The Sparkses don't go out much. Money is tight—most of it goes to pay Landon's medical bills—and there are few baby-sitters who want to stay with an unresponsive four-year-old. Landon has developed bedsores on his back, which make it nearly impossible to put him in his car seat and take him out of the house. It has been a long time since Claire has gone any place other than the doctor, the children's school, her local church, or the Baytown[, Texas] mall.

Belkin, supra note 104, at 264.

107. If the lesion on the back of a child born with spina bifida is not closed through surgery soon after birth, infection will set in and the child will die. In many hospitals, at least when a child is born with a severe case of spina bifida and the child's parents are unable to reach a decision as to whether they would like to pursue treatment, an ethics committee may become involved in the decision. See generally Belkin, supra note 104. The same is true when a child is born with a mild or moderate case of the disease and his or her parents decide not to pursue treatment although, under these circumstances, the ethics committee may make the ultimate decision—possibly deciding to treat the child despite his or her parents' objections. Id.

Often, parents like Claire and Kenny Sparks simply cannot reach a timely decision—the kind of decision that must be made when facing the threat of infection:

Families already feel guilty in a situation like this. They're probably imagining everything they might have done to cause the situation in the first place. They'll only compound that guilt more by sitting and letting a baby die. They've come nine months through the waiting process, they've bonded to the baby even before it's born, and then suddenly there's a calamity. It's always met with guilt. They'll entertain the idea of withholding treatment, but in the last analysis almost all of them change their minds.

Id. at 238.

Claire and Kenny were brought in to meet with Hermann Hospital's ethics committee, and their experience offers insight as to the committee's decision-making process. The committee reached the following opinion:

What needs to be considered in this opinion is whether the benefits of surgical closure outweigh the burdens incurred by the procedure. The procedure is pallia-
going into surgery. Roni and Bob did not even know about Bobby's paralysis until after the lesion had been closed. It was then that they started to get the information and to understand—that is, to understand the costs, having to deal with insurance companies and schools, and developing long-term hopes. Their names were given to support groups, and they received telephone calls from others who had already gone through much of what they were being told was before them and their son. Eventually, Roni and Bob would be able to talk with these people, and it would help.

Beyond his spina bifida, Bobby is different. Along with the purity and honesty that you generally find in children, Bobby has the depth and awareness of his mortality that is acquired through survival. This quality is also readily apparent in his older sister Liz, and I expect that it is in his younger sisters as well.

Bobby and his family live with his spina bifida by accepting it and persevering the physical, financial, and emotional challenges it presents on a daily basis. One time, after helping Roni pack her kids into her station wagon, I asked her how she does it as we walked around to the driver's side and she got into the car. Bobby, out of his wheelchair and thrilled with his enhanced mobility in the back of the car (Bobby has incredible upper body strength) and the opportunity to tease his sisters, was already doing so. After looking in the rear view mirror and letting out a forceful "BOB," Roni looked up and, without the slightest hesitation, said, "You just do what you have to."

Id. at 246.

Nevertheless, although the ethics committee's opinion was delivered in a directive manner, because Landon's condition was so serious, the ultimate decision belonged to Claire and Kenny:

"You've already heard from three doctors that you can do one of two things," Dr. Oelberg said, ticking off the options from pinkie to thumb as he spoke. "These doctors aren't crazy, and they aren't incompetent. They're all very good doctors. They're disagreeing, and doctors will always disagree. So it's not that one is right and one is wrong. They're both right, depending upon what fits in with your family. There are plenty of babies who come through here with a meningomyelocele who can bring a lot of happiness to their parents. He's not going to play football. He may have problems at school from a cognitive point of view. But he may bring you just as much joy, if not more, than someone who starts out as a perfectly normal baby."

He paused, and then gave the persuasive push he had promised the Ethics Committee. "I would recommend that you repair it," he said. "If you feel otherwise, I'm willing to consider that, but I recommend you repair it. Otherwise I'm afraid you'll spend your life wishing that you had."

Id. at 46.
The preceding stories are linked by common themes. The practice of prenatal genetic screening is being largely left to the discretion of the medical profession and it is being performed for prospective parents, not for their fetuses. Prenatal genetic screening is about offering prospective parents difficult choices regarding the sacrifices they are willing to make to be parents, what mental and physical characteristics their children will have, and what kind of lives they want their children to have at a time when abortion is still an option. The assumption underlying voluntary genetic screening is that prospective parents will be given the information obtained and be allowed to act on that information. The choices created through prenatal genetic screening (whether to undergo genetic testing, which tests to run, the option to end a pregnancy based upon a broader spectrum of test results) will expand along with prenatal testing capability.

Although gene therapy will eventually create additional options, today, only two options are given to prospective parents who

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108. As explained by one observer, "[t]raditionally, the ethics of prenatal genetic counseling has required that prospective parents be given full information and then be allowed to choose which, if any, genetic diagnostic tests to pursue." Nolan, First Fruits, supra note 46, at 53-54.

109. Driven by a desire to know, many parents will undergo genetic screening even if their only option is to deliver their child:

In examining women at risk for having children with sickle cell disease, one investigator who interviewed thirty women found that the majority of them would want prenatal diagnosis even though only one quarter would abort an affected fetus. Another group of researchers who looked not at what women said but what they did found that of twenty-two pregnant women who were at risk for having a child with sickle cell anemia, fourteen had amniocentesis, and of the four fetuses found to be affected, three were aborted.

Clayton, supra note 74, at 116 (footnotes omitted).

110. See SoRelle, supra note 54 ("The March of Dimes believes gene therapy may soon become the most important and powerful weapon against birth defects and disease in human history."); Alexander Morgan Capron, Which Ills to Bear?: Reevaluating the "Threat" of Modern Genetics, 39 Emory L.J. 665, 674 (1990) ("In 1989, the HGTS [Human Gene Therapy Subcommittee] and the RAC [Recumbent DNA Advisory Committee] recommended, and the Director of NIH approved, the first officially sanctioned use of recombinant DNA technology in the treatment of human beings."); see also Richard Saltus, Doctors Try Gene Therapy on Clots, BOSTON GLOBE, Sept. 17, 1994, at 29, 32 (addressing a test for cardiovascular disease intended to provide new blood circulation in the legs of patients with artery blockages). The Clinton Administration's removal of restrictions upon research involving fetal tissue is likely to have a profound impact on the advancement of this technology. See Fletcher & Wertz, supra note 23, at 755-56 (discussing how the Bush Administration's policies regarding federal funding of research involving human embryos, the fetus, and fetal tissue restricted this research); see also Holder, supra note 38, at 50-81 (discussing fetal research and relevant regulations during the mid-1980s). Scientists may also develop the technological capability to identify and manipulate environmental factors...
receive genetic screening test results indicating a genetic abnormality: delivering children with a known health impairment or propensity for being unhealthy, and terminating the pregnancy. Despite our society's general discomfort with late-term abortions, several states permit abortion beyond the point of viability when a severe fetal abnormality is detected. Viability is generally considered to occur at the end of

that interact with genetic abnormalities and help to determine whether those abnormalities will cause health impairments or remain dormant. See Elsas, supra note 36, at 813.

Moreover, technological advances in testing may enable prospective parents to detect genetic abnormalities at a much earlier stage in pregnancy, thereby eliminating the demand for late-term abortion. For example, fetal blood aspiration from the umbilical cord has been the subject of research involving both diagnosis and therapy. See Sachs & Korf, supra note 1, at 460; Leon Jaroff, Brave New Babies, Time, May 31, 1993, at 56-57 (discussing three landmark experiments involving gene therapy to cure rare hereditary diseases through the use of stem cells collected from umbilical-cord blood). In the future, scientists may be able to isolate fetal cells from the maternal circulation and use them for diagnostic purposes, thereby facilitating prenatal testing for every patient. See Sachs & Korf, supra note 1, at 460. Similarly, in-vitro fertilization creates the possibility of identifying genetic abnormalities outside of the womb. See Elmer-Dewitt, Catching a Bad Gene, supra note 48. Moreover, visible deformities may be seen as early as six weeks through techniques such as embryooscopy. See supra note 49. Despite these possibilities, however, the present reality is that we will not be able to avoid late term abortion in the near future:

Although scientists have identified about 5,000 inherited diseases that could, in theory, be spotted in young embryos, including Huntington's disease and sickle-cell anemia, gene screening to catch these disorders is not likely to be widely available anytime soon—at least in the U.S. For one thing, it requires couples to go through in-vitro fertilization, a costly ($5,000 to $13,000) procedure with a success rate hovering around 10%. The gene-screening test adds an additional $2,000 for each in-vitro cycle, a bill the U.S. insurance industry has already indicated it has little interest in footing.

Elmer-Dewitt, Catching a Bad Gene, supra note 48.

111. See infra note 140 (citations to state statutes). Prior to Roe, many states adopted this exception through their implementation of the Model Penal Code, which provides that a mother may abort a severely defective fetus even in the third trimester regardless of whether the fetus is considered viable. See Rush, supra note 55, at 122 (1983). Ironically, Roe v. Wade, 410 U.S. 113 (1972), synonymous with the right of women to terminate their pregnancies, limited this exception to the point of viability (the end of the second trimester), for in Roe, the Court identified viability as the point in which preserving fetal life becomes compelling. See Rush, supra note 55, at 125. Adding to this irony, two widely reported episodes involving fetal abnormality that occurred in the decade preceding Roe are credited with turning public sentiment in favor of legalizing abortion, and thereby making Roe possible: (1) the story of Sherri Finkbine, a mother from Arizona who had taken thalidomide, a sedative prescribed to ease morning sickness, while in Europe; thalidomide was discovered to cause severe birth defects in approximately 8,000 babies in the 1950s and 1960s, and it was removed from the United States market in 1962, but was still available in other countries until later; and (2) an outbreak of rubella in 1962-65, which was also known to cause blindness, deafness, and severe mental retardation. See Tribe, supra note 53, at 37-38.

Many states have expressly codified prohibitions that forbid doctors from performing abortions on viable fetuses. See, e.g., Tex. Rev. Civ. Stat. Ann. art. 4495b, § 4.011 (West
the second trimester—that is, during the twenty-third or twenty-fourth week of pregnancy.\textsuperscript{112}

Therefore, the availability of prenatal genetic screening and the parental choices it creates are issues that weigh heavily upon procreative liberty\textsuperscript{113} and implicate abortion jurisprudence. The following is an analysis of prenatal genetic screening in the context of each of these more familiar and broader frameworks.

\textsuperscript{112} See Michael J. Flower, \textit{Coming Into Being: The Prenatal Development of Humans, in Abortion, Medicine, and the Law} 437-51 (J. Douglas Butler & David F. Walbert eds., 1992). Technology is unlikely to push the point of viability—the ability to live apart from one’s mother—much earlier than the twenty-third week of pregnancy due to the surge in fetal lung development which occurs at that time. \textit{See id; see also} Charles A. Gardner, \textit{Is an Embryo a Person?}, in \textit{Abortion, Medicine, and the Law}, supra, at 456; Claudia Wallis, \textit{Advancing Technology Further Complicates a National Dilemma}, \textit{Time}, July 6, 1987, at 82 (“Even at the most sophisticated hospitals, babies born before the 24th week of gestation or weighing less than 500 g (1.1 lb.) have virtually no chance of survival.”). Nevertheless, some doctors believe that technology will shift the point of viability well into the second trimester:

A handful of U.S. medical centers now use a constellation of devices that can assume some heart, lung, kidney and even digestive functions for full-term babies born with certain problems. Because the machines require the use of anticoagulants, they do not work for most preemies, who risk brain hemorrhages if given such drugs. But should technology leap this hurdle, it could reduce the viability standard to an absurdity.

Wallis, supra, at 82.

113. The procreative liberty issues arising from genetic screening are discussed in Robertson, supra note 36, at 697:

Because the genetic knowledge at issue is relevant to individual or marital choices about reproduction, these issues may be usefully viewed through the lens of procreative liberty. Does a couple’s right to reproduce or avoid reproduction give them a right of access to this information? May decisions to conceive or continue a pregnancy be made on genetic grounds? Must couples learn their carrier status? Must they act on this information?

\textit{See also} John R. Harding, Jr., \textit{Note, Beyond Abortion: Human Genetics and the New Eugenics}, 18 \textit{Pepp. L. Rev.} 471, 504 (1991) (“Advocates of privacy rights in the use of genetic engineering argue that regulating positive genetic engineering may precipitate a collision between the constitutional values of procreative liberty as well as equal opportunity.”) (footnote omitted).
A. In the Context of Abortion

Abortion provides a means to avoid the violence inflicted upon unwanted children,\footnote{See generally Malinowski, supra note 73, at 209 n.101 (discussing foster care horror stories).} and it often follows the violence of nonconsensual intercourse. Nevertheless, witnessing a first-trimester abortion performed through a basic dilation and curettage\footnote{This procedure, the most commonly applied, is discussed infra note 117.} is enough to establish that abortion is a violent act.\footnote{Despite the fact that the majority of my students identified themselves as “pro-choice,” this was their general consensus after viewing The Silent Scream, a movie prepared by pro-life advocates that uses ultrasound technology to show the abortion of a fetus at 12 weeks. Class Session, Abortion, Medicine, and Social Choice, University of Houston Law Center (Mar. 8, 1993).} Even many of those who do not question the right of women to choose whether to carry fetuses to term are not comfortable with late-term abortion,\footnote{The techniques available for performing late-term abortions reflect the violence innate to this procedure: \textit{Dilation & Evacuation (“D&E”):} The cervix is dilated, and the physician then dismembers the fetus, crushes its skull, and vacuums it out. This is the most widely accepted and practiced procedure. Although the physician must be certain that the evacuation is complete, the procedure is relatively quick and inexpensive, and causes fewer side effects, less stress, and less discomfort for the patient. D&E also removes any possibility that the fetus will be born alive. \textit{Fetal Intracardiac Potassium Injection:} The fetus’s heart is injected with potassium, which causes cardiac arrest and eliminates the danger of delivering a viable fetus. This technique is used in conjunction with one of the other techniques. \textit{Hysterotomy:} The physician performs a mini-caesarean to remove the fetus from the uterus. This procedure involves the most invasive surgery, carries the highest risk of morbidity and mortality, and is the least practiced method. \textit{Prostaglandin:} The physician administers prostaglandin (a drug internationally recognized as an accompaniment to RU486) by direct injection into the uterus, intravenous infusion, or by vaginal suppositories. The prostaglandin induces contractions and other physiological activity associated with normal labor. Expulsion takes an average of 12 to 24 hours, and the patient usually requires hospitalization. The side effects include vomiting and diarrhea. The fetus is delivered whole, and there is a danger of it being delivered viable. \textit{Saline Method:} The physician injects hypertonic saline solution directly into the amniotic sac, the fetus is burned by the solution, labor is induced, and the physician then delivers the dead fetus. The entire procedure takes approximately 12 to 24 hours, and it usually requires hospitalization. The side effects include vomiting and diarrhea. The fetus is delivered whole, and there is a danger of it being delivered viable. See Jonathan B. Imber, Abortion and the Private Practice of Medicine 77 (1986); John Fletcher, Fetal Intracardiac Potassium Chloride Injection to Avoid the Hopeless Resuscitation of an Abnormal Fetus: Ethical Issues, 80 OB. & GYN. 310-13 (1986).} which is reflected by the fact that very few doctors are willing to perform this procedure voluntarily.\footnote{See Gina Kolata, In Late Abortions, Decisions are Painful and Options Few, N.Y. Times, Jan. 5, 1992, at 1 (“These abortions [for cases of fetal abnormality] are legal in about half the states, although most doctors simply refuse to do them.”); see also Judith} Although only 1.2 percent of all abortions are per-
formed between weeks twenty-one and thirty-six of gestation, the demand for late-term abortions will be affected by the increase in the technological capability to detect fetal abnormalities resulting from the Human Genome Project, greater accessibility to this technology through an increase in the availability of genetic counseling and testing services, and expansion of common knowledge about testing options. Consider that, although a fetus may not be able to live apart

Gaines & Richard Saltus, *Teenager Says Legal Abortion Denied*, *Boston Globe*, Jan. 16, 1994, at 29, 32 (teenager stating that she could not obtain a second-trimester abortion due to the unwillingness of hospital staff to participate in the procedure). Hospitals creating a demand for such services by performing genetic screening may stipulate that the doctors working with them and referring patients to them must perform late-term abortions if a genetic abnormality is detected in their patients. Peacock Presentation, supra note 79. Of course, not all doctors refuse to perform late-term abortions because of ethical concerns; many refuse to do so because of the increased risks (and liability) associated with this procedure. Dr. Howard Praver, Class Presentation, *Abortion, Law, and Social Choice*, University of Houston Law Center (Apr. 5, 1993) (a doctor with 25 years of experience performing abortions and the director of the first Planned Parenthood clinic opened in Texas after Roe, who will not perform abortions on fetuses older than 14 weeks).

To fully appreciate the dearth of doctors willing to perform late-term abortions, consider that doctors have been pressured away from the abortion procedure in general. See Tony Freemantle, *Slaying Sparks Fear as Abortion Issue Slips on Agenda*, *Hous. Chron.*, Mar. 14, 1993, at 4A (discussing the shooting of Dr. Gunn—"the first fatality in the 20-year-old war over a women's right to abortion"); Debbie Housel, *Doctors Ask Judge to Widen Protection from Protestors*, *Hous. Post*, June 23, 1993, at A1, A10 ("Claiming they are tired of having their kids told that ‘daddy kills babies,’ tired of being called murderers, of even being stalked, these doctors want a judge to give them the same protection from anti-abortion activists that they now have at their clinics."); 60 Minutes: *The Lambs of Christ* (CBS television broadcast, Aug. 23, 1992) (discussing how the harassment of doctors and their families—for example, reaching doctors by subjecting their children to harassment at school—is pressing them away from abortion). As a result, women are now taking the procedure into their own hands. See 20/20: *Abortion Among Friends* (ABC television broadcast, June 18, 1993) (discussing the procedure for at-home abortion, the fact that more than 2,000 women already have been trained to perform the procedure, and chronicling an actual at-home abortion); New Abortionist, *The West* (television broadcast Feb. 9, 1992) (women training other women to perform do-it-yourself abortions). In fact, during the week of June 13-20, 1993, Planned Parenthood of New York announced that it is training its own staff to perform abortions.

119. Lisa M. Koonin et al., *Abortion Surveillance, United States, 1988*, in *Abortion, Medicine, and the Law* tbl. 14, at 477 (J. Douglas Butler & David F. Walbert eds., 1992). 120. In short, as genetic testing grows more sophisticated, the number of detectable fetal conditions will become larger, thus increasing the number of circumstances that could lead to a decision to abort a pregnancy. The result may be that some couples will abort a pregnancy not only when an untreated disease is detected, but also when a merely undesired condition, such as the "wrong" gender or eye color, is detected. If aborting a fetus because it has Down's Syndrome is morally acceptable and aborting a fetus because of its gender is morally unacceptable, where is society to place conditions such as dwarfism, myopia, or susceptibility to heart disease?
from its mother until it reaches the point of viability, the fetus may cognitively experience pain as early as its twentieth week of development, for that is the point at which the rudimentary neocortex is in place.\textsuperscript{1} Moreover, there is genuine concern that our control over life at the genetic level will make life less special—that the miracle of life will become less of a miracle when we routinely manipulate it in such a fundamental way.\textsuperscript{12} In the context of prenatal genetic screening, this concern takes the form of a fear of eugenics: a fear that people will abuse technology to have nothing less than the "perfect" baby,\textsuperscript{123} and that there will be no acceptance of children like Bobby.\textsuperscript{124} In light

Robert Wachbroit, \textit{Making the Grade: Testing for Human Genetic Disorders}, 16 Hofstra L. Rev. 583, 596 (1988). However, as discussed supra note 110, technological advances—for example, the ability to remove fetal cells from maternal blood—may move our capability to perform genetic testing to earlier stages of pregnancy and to prevent genetic abnormalities from resulting in genetic diseases through gene therapy and the manipulation of environmental factors.

\textsuperscript{121} Flower, supra note 112, at 445-46.

\textsuperscript{122} See Harding, supra note 113, at 471.

\textsuperscript{123} "Abortion pits the rights of the mother against the rights of her child. Eugenic genetic engineering juxtaposes our ability to be potentially free from disease, perhaps even to reach the highest levels of human achievement, against the rights of all future generations to live their lives free from genetic control." Harding, supra note 113, at 510; Theodore Friedmann, \textit{Opinion: The Human Genome Project—Some Implications of Extensive "Reverse Genetic" Medicine}, 46 Am J. Hum. Genetics 407, 411 (1990).

\textsuperscript{124} Consider the words of Eileen Cronin-Noe, whose mother took thalidomide while pregnant, causing Eileen to be born without legs:

For my parents, who did not have this knowledge, abortion was not an option and would not have been even if they had been aware of my condition. My parents believe that it was God's decision, and they were content with that decision. For this same reason, they did not pursue any legal action. For them, a lawsuit never would have addressed the issue.

Their belief has led me to accept, even prefer, things for what they are. Many people may find this difficult to believe. They feel lucky that amniocentesis is available to screen out babies born with less severe deformities than mine.

This thought frightens me, because I know that amniocentesis can't tell any parents what kind of child they will have. It can only tell what disability might exist in that child.

Amniocentesis could never have told my mother that I would have artistic talent, a high intellectual capacity, a sharp wit and an outgoing personality. The last thing amniocentesis would tell her is that I could be physically attractive.

My point is that we demean the value of an individual's worth by adhering to a medical label such as "disabled." What is worse, most medical professionals aren't even aware of the attitude they may convey to prospective parents—that a disabled life is not worth living.

Eileen Cronin-Noe, \textit{"Thalidomide Baby" Grows Up}, Wash. Post, reprinted in House Chron., July 26, 1987, § 7, at 5. Also consider the physical impairments of Stephen Hawking who, although so physically impaired that he has confined to a wheelchair and cannot speak, has made a significant contribution to quantum physics. See Stephen W. Hawking, A Brief History of Time (1988).
of the option to terminate pregnancy based upon gene malfunctions associated with health impairments, advances in the technology to di-
agnose serious health impairments prenatally may retard the advance-
ment of technology to treat those impairments and diminish tolerance for biological variation. Ultimately, society may even develop a gen-
eral tolerance for “characteristic shopping” on the part of prospective parents.

Nevertheless, and especially in light of the present state of genetic screening, valid arguments can be made to remove the viability cut-off for legal abortions when severe fetal abnormalities are detected.\textsuperscript{125} There are, for example,

clear examples of cases in which it is ethically justified to recom-
mend alternatives to aggressive management, even when one re-
gards the third-trimester fetus as a patient. Anencephaly and triplody are anomalies that can be detected with certainty. These anomalies involve either immediate lethality or, in the rare cases of short-term survival, the absence of cognitive developmental capac-
ity. . . . Recommending nonaggressive management as an option is jus-
tified because it does not increase the already unavoidable risk of death . . . \textsuperscript{126}

It has even been suggested that, because the justification for prohibit-
ing abortion at the point of viability is the state’s interest in preserving the potential life of the fetus,\textsuperscript{127} the state’s interest is lessened—and the viability cut-off for abortion should be removed—when the fetus is not healthy.\textsuperscript{128} More palatable is the argument that, since the par-
ents of a severely impaired newborn generally are given the option of withholding aggressive health treatment (for example the parents of a child born with severe spina bifida may be given the option of not closing the child’s lesion),\textsuperscript{129} the prospective parents of a fetus carry-

\textsuperscript{125} See Rush, supra note 55, at 130 (“A more fundamental question, however, is whether, in the case of a mother seeking to abort a severely defective fetus, there should be any viability criterion at all.”).

\textsuperscript{126} Chervenak & McCullough, supra note 90, at 313 (footnotes omitted).


\textsuperscript{128} See Rush, supra note 55, at 119-20 (suggesting that, not only is the mother’s right to choose an abortion stronger in the case of a severely defective fetus, but also that the state’s interest in restricting such abortions is significantly weaker, so that at no point during the term of the mother’s pregnancy does the state’s interest become compelling enough to allow it to prohibit such abortions.).

\textsuperscript{129} See ANSPACH, supra note 70; HOLDER, supra note 38, at 82-117; MEYERS, supra note 70, at 105 (“Traditionally, in the United States, as in the United Kingdom, parents and physicians have made decisions to allow seriously handicapped newborn infants to die by not providing life-sustaining medical care. This practice has been judicially recognized.”). As explained by Meyers, courts consider a number of factors before compelling medical treatment over the objection of parents:
ing a genetic abnormality should not be forced to carry their fetus to
term before being able to make that choice. After all, such a child
has no chance of survival without the dedicated support, love, and
care of parents such as Roni and Bob Lachapelle. Such a relationship
cannot be imposed through laws; properly caring for a seriously im-
paired child requires the kind of dedication and unconditional love
that can only come voluntarily. The problem with this argument is
that our society has not acknowledged the fact that the choice not to
treat is already being made; these choices have been left to families
and the medical profession through widely shared but unwritten
norms. As is discussed below, the potential for abuse of prenatal
genetic technology is simply too great for our society to avoid public
policy discussion of the issue.

B. Beyond a Basic Exercise of Procreative Liberty

It is easy to overlook the fact that prenatal genetic screening (or
the opportunity to abort a late-term fetus based upon the presence of
a genetic abnormality) involves more than the basic exercise of pro-

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Several relevant factors must be taken into consideration before a state insists
upon medical treatment rejected by the parents. The state should examine the
seriousness of the harm the child is suffering or the substantial likelihood that he
will suffer serious harm; the evaluation for the treatment by the medical profes-
sion; the risks involved in medically treating the child; and the expressed prefer-
ences of the child. Of course, the underlying consideration is the child’s welfare
and whether his best interests will be served by the medical treatment.

*Id.* at 104-05 (footnotes omitted).

130. The rationale undergirding this practice is that
[the law should not require more than reasonable conduct, for fear of discourag-
ing compliance with unattainable or unfair standards of conduct. No one is better
situated than parents and physicians to act in the best interests of the infant. . . .
Fortunately, the law requires neither perfection or cure from parents or physician.
It does require that they act as reasonable persons would, in the circumstances, act.

*Id.* at 109-10.

131. See *Anspach*, *supra* note 70; *Belkin*, *supra* note 104 (an “insider’s” perspective
on Hermann Hospital’s ethics committee); *Jay Katz, M.D., The Silent World of Dr.
AND PATIENT* (1984); *Meyers, supra* note 70, at 105-08. The Reagan Administration’s
“John Doe” policy is discussed in *Anspach, supra* note 70, at 170-73. This policy arose
after President Reagan was made aware of a case in which treatment was withheld from a
child with Down’s Syndrome (“John Doe”). The Administration responded by introducing
federal regulations demanding treatment for all babies born with “a chance of survival.”
These regulations were backed up with a threat that federal funding would be withheld
from facilities violating them, and toll-free numbers were set up to report violations. No
doctor or facility ever was found guilty of violating the regulations. The fact is that
whether a baby has a chance for survival is generally a judgment call that physicians are
able to make without being questioned so long as they use prudence and involve ethics
committees, review boards, and other physicians when necessary. *Id.*
creative liberty. Prenatal genetic screening is not about the right to choose whether or not to have a child, nor is it necessarily about the option of choosing whether to have an unhealthy child. Rather, in most instances, the capability to detect the presence of genetic abnormalities is well ahead of the capability to predict the actual health of a child born with those genetic abnormalities. Because genetic abnormalities may take many forms (or no form at all absent an environmental component), the present state of technology is not precise.

132. The fundamental distinction is between the right to rear a family and the desire/right to control the genetic makeup of the members of that family. See Bonnie Steinbeck, Reproductive Rights and Responsibilities, HASTINGS CENTER REP., May/June 1994, at 15-16. This distinction will have to be addressed as genetic screening capability is enhanced and perfected.

133. See generally supra Part I.A. For example, consider that, although genetic testing can predict whether or not a child will have Down's Syndrome, it cannot predict the severity of the disease. See ABC News Special: The Perfect Baby (ABC television broadcast, 1990). The best that genetic screening can do at the present time is to inform prospective parents about possibilities and give them a choice to abort. See supra note 110 and accompanying text.

134. See generally supra Part I.A. Many diseases only arise when a genetic abnormality is combined with an environmental component:

Although all of us carry five to seven lethal recessive genes as well as a still undetermined number of genes that make us susceptible to developing diseases based on interaction with the environment (through work, diet, etc.), persons who carry those particular genes for which screening first becomes available are in greater danger of suffering discrimination because of their apparent singularity.

Capron, supra note 110, at 690. To better identify environmental components, more states must establish reliable registries to track newborn and fetal abnormalities. The Texas Legislature, inspired by the high rate of anencephaly in southern Texas (primarily in the Rio Grande Valley around the Brownsville area), has allocated $750,000 to establish such a registry. See Bonnie Gangelhoff, Tragedy Spurs Mother to Back Birth Registry, Hous. Post, July 11, 1993, at A1, A20. The United States had a similar experience with testing newborns for sickle cell disease:

Widespread screening of children and adults for sickle cell disease was implemented publicly [during the 1970's] before public or private understanding was clear on the objectives or on the use of screening results. One out of every twenty of those screened was found to be a heterozygous carrier of the sickle gene. Many of these asymptomatic adults were stigmatized by life insurance companies with higher premiums and excluded from certain jobs or educational opportunities. Although these screening laws of the 1970s were aimed at providing the at-risk Black population with reproductive information, they were implemented before the public was fully informed, and they did not provide for genetic counseling. There were no methods available for prenatal diagnosis of an affected fetus. Thus, the only potential benefits of these early screening laws was to deter heterozygotes from having children, an outcome that produced individual and societal misunderstandings.

Elsas, supra note 35, at 827-28 (footnotes omitted); see infra note 219 (addressing the insurance implications of this mistake); see also Assessing Genetic Risks, supra note 9, ch. 2, at 8 (table listing newborn genetic screening in 1990 conducted in 53 states, commonwealths, and territories of the United States). In the context of prenatal genetic screening,
and because research-stage testing is being made accessible for diagnostic purposes, genetic screening is, to a large extent, nothing more than an ability to make statistical predictions.\(^\text{135}\) When there is a strong possibility that a fetus will be born with ailments so severe that his or her parents will be given an opportunity to refuse treatment once he or she is born, the viability cut-off for abortion (a cut-off that such mislabeling will result in the late-term abortion of wanted pregnancies for health conditions that would not have arisen.

Moreover, genetic screening—whether it be on newborns or fetuses—is subject to error. See infra notes 268-281 and accompanying text (quoting the findings of the Committee on Assessing Genetic Risks). Error may arise both from testing limitations and from human mistake:

Another set of problems arises because newborn screening, like any medical test, is not completely accurate. Even under the most ideal testing conditions, some children who actually have disease will be missed, and some healthy children will inappropriately be labelled as “ill.” From one perspective, “false negative” tests that fail to detect affected children should not seem particularly troubling. After all, the argument goes, the disease surely would have gone undetected had there been no program at all, so children are not harmed when the program fails to work.

Things, however, are not that simple. To begin with, the existence of newborn screening programs can create a false sense of reassurance in physicians, possibly causing them to fail to make a diagnosis as quickly as they would have were there no screening in place once symptoms begin to appear.

The most common reason that affected children are missed, however, is not because of the inherent inaccuracy of testing but because the tests were not properly administered, if at all.

Clayton, supra note 74, at 103 (footnotes omitted).

135. See supra Part I (explaining that the presence of a genetic abnormality does not necessarily mean that the mental and/or physical symptoms will be present, or that, if present, they will be severe); supra note 60 (explaining that genetic testing generally cannot determine the severity of a disease and that it involves identifying the presence of abnormalities linked to diseases—not necessarily the presence of diseases). Genetic screening technology has been described as follows:

Today, in fact, the multiplicity of genetic variation relegates most prediction at a molecular level to indirect linkage analysis, where the observed variation in nucleotide sequences by itself has no effect on the human’s physiology. Thus in most situations, the geneticist makes statistical predictions rather than exact diagnoses and has no “cure” for the diagnosis in a traditional sense.

Elsas, supra note 36, at 826. In the past, when doctors have relied upon screening technology prematurely for newborn genetic screening, the result has been mislabelling:

Inadequate medical knowledge also causes mislabelling. For example, when screening for PKU began, it was not known that some children with high levels of phenylalanine did not in fact have PKU, but rather had hyperphenylalaninemia, which does not cause significant mental retardation. Until this fact was understood, children with this later, benign condition were inappropriately thought to be ill and subjected to the restrictions and expense of treatment. Ironically, the treatment actually harmed some of these children, causing the very mental retardation that screening was supposed to avoid.

Clayton, supra note 74, at 106 (footnotes omitted).
will force parents to make rash decisions, perhaps based upon inadequate test results or no test results) seems destructive. However, when the "abnormality" is mild and/or questionable (not associated with mental and physical health impairments) and discovered on the cusp of viability, perhaps as the result of a research-stage test, there is justification for questioning the parental choice created through the technology of genetic screening. The medical profession generally has dealt with such decision making by establishing guidelines to decide both the severest and the mildest cases. For the most difficult cases, those falling in the center of these two extremes, the medical profession is involving ethics committees in the decision-making process.

As the counselor's story and the researcher's story reveal, the utilization of genetic counseling services is essentially a matter of discretion on the part of hospitals, physicians, and researchers. Generally, ethics committees are not involved in the decision to abort prior to the twenty-second week of pregnancy, and counseling may not even take place. The understanding is that, so long as the patient is informed about the research-nature of a test, the unreliability of a given test sample, the fact that the genetic abnormality may not result in a genetic disease without environmental factors, and the uncertainty regarding the severity of the impairments associated with the diseases at

136. Consider that we have already identified genetic abnormalities responsible for predispositions for developing cancer and heart disease—conditions that are often treatable and arise later in life. See Sachs & Korf, supra note 1, at 461.

137. See generally Belkin, supra note 104 (an account of Hermann Hospital's ethics committee); Anspach, supra note 70; Victor R. Fuchs, Who Shall Live? (1983). Although ethics committees generally work with parents, ethics committees are able to override the decisions of parents to withhold treatment when dealing with live births:

The American courts, as we have seen, have been more willing to impose treatment over the wishes of the mother. This has resulted not in small part from a strong preference for the physicians involved in many such cases to impose treatment, the traditional deference paid to medical views by the courts, and the fact most such cases arise in a highly charged environment calling for immediate action where the views of the mother may often be unrepresented. Faced with saving the life of an apparently salvageable fetus, the pressures on the judges involved to order treatment are great, particularly, where medical evidence suggests no material harm to the mother.


138. See supra Parts II.A. & II.B.

139. But see Elsas, supra note 36, at 816 ("It should be recognized that the practice of medical genetics is a clinical subspecialty which is already guided and constrained by prece-dents of professional ethics and medical laws.").
issue, liability is eliminated. Moreover, under many states' laws, a positive test result—no matter how unreliable—and the assurance of a physician that a genetic abnormality is present constitute adequate grounds to terminate a pregnancy up until the point of viability. In some states, the right to abort lasts even longer.

In sum, prenatal genetic screening has the potential to offer prospective parents an opportunity to know much about who their child will be well before it is born. Whether the right to terminate pregnancies based upon that knowledge will accompany the expanding availability of prenatal genetic testing adds a new dimension of controversy to the abortion debate.

IV. An Assessment and Proposal

Roni Lachapelle loves her son as much as any mother can love her child. Nevertheless, when I asked for her opinion of the current practice of making even research-stage testing available, she immediately responded with, “Parents should know about everything.” This is also the conclusion reached by Sandra Peacock, who has worked with hundreds of patients such as Roni Lachapelle; her position is that parents should know and understand—that genetic counseling should

140. COLO. REV. STAT. § 18-6-101 (1994); FLA. STAT. ch. 390.001 (1994); KAN. STAT. ANN. § 65-6703 (1994). States are being encouraged by the medical profession to pass statutes respecting parental choice in the context of prenatal genetic screening. For example, the American Society of Human Genetics (ASHG) has endorsed a proposal for abortion bills to protect options of women at risk for bearing children with “serious” genetic or congenital disorders. The ASHG's model statutory language provides:

Regardless of any other provision of this statute or other laws of this jurisdiction, any pregnant female whose pregnancy has not reached the point of viability and who has been informed by a licensed or certified health care professional that her fetus (or fetuses) is likely to have a serious genetic or congenital disorder shall have the right, among other options, to choose to terminate her pregnancy. This right shall extend to situations where the female is at significantly increased risk for bearing a child with a serious disorder for which precise prenatal diagnosis is not available.

American Society for Human Genetics Statement on Clinical Genetics and Freedom of Choice, 48 AM. J. HUM. GENET. 1011 (1991). The ASHG also issued a suggested general statement to accompany the model language, which provides:

In some states laws and regulations have been proposed which would, if enacted, prohibit women from having the choice of terminating a pregnancy in which the fetus is diagnosed with or is at significant risk of having a serious genetic or congenital disorder. The model statutory language approved by the ASHG is its effort to help elected and appointed officials to protect this option. It will be provided by the ASHG to those jurisdictions considering legislation or regulations which would eliminate this option.

Id.

141. See, e.g., KAN. STAT. ANN. § 65-6703.
be performed by those trained in the social sciences so that they can help patients understand the limitations of the information being given to them, as well as the reality of raising a child with a serious mental and/or physical impairment. Moreover, there is something telling about the fact that “[g]eneticists in all nations consider it essential to protect rights of parental choice.”

The technological capability to identify genetic abnormalities associated with health impairments prenatally and to determine the genetic basis for generally shared physical and mental characteristics will continue to expand, and policy makers simply cannot ignore this capability. Restricting the practice of prenatal genetic screening means restricting what prospective parents will be able to learn about the health of their fetuses while there is still time to terminate their pregnancies. At the very least, it will restrict prospective parents’ opportunities to prepare for a genetic abnormality before being confronted with the impairment after delivery—a time when parents are often too emotionally charged and physically drained to understand, despite the fact that the difficult decisions about aggressive treatment may need to be made at that time. And, beyond the procreative

142. See Peacock Presentation, supra note 79 (supporting the assertion that genetic counseling must be performed by those trained in the social sciences).
143. Fletcher & Wertz, supra note 23, at 787.
144. Roni described the frustration of knowing something was wrong but being too tired to understand—the frustration of knowing decisions were being made regarding her child, and not being able to participate. See also supra note 104 (the story of Claire, Kenny, and Landon Sparks). For a full discussion of the emotional effects of the birth of a health-impaired child on that child's family, see Macintyre et al., in ABORTION, MEDICINE, AND THE LAW, supra note 40, at 535-44. For a thorough discussion of how prenatal genetic screening may prove beneficial even when prospective parents do not consider abortion to be an option, see Steven L. Clark & Gregory R. DeVore, Clinical Commentary: Prenatal Diagnosis For Couples Who Would Not Consider Abortion, 73 OB. & GYN. 1035, 1036 (1989) (“In all our dealings with such couples who knew in advance about their child's handicap, we have yet to encounter one who was not grateful for the advance knowledge.”). The reasons identified by Clark and DeVore are as follows:
1. The prospective parents may change their minds.
2. The odds favor a normal child, and, in most cases, the overall impact of prenatal genetic screening will simply be to alleviate parental worrying and help family relationships.
3. The testing may alert clinicians to an increased risk of pregnancy complications.
4. The testing may allow specialized perinatal intervention which would benefit the fetus. For example, a cesarean delivery may benefit fetuses with certain anomalies.
5. Prospective parents are given an opportunity to make decisions regarding medical treatment for their newborns.
6. Parents are given an opportunity to prepare emotionally, physically, and financially.
liberty interests of parents, society simply cannot demand more than it is willing to give. Although the limitations are somewhat self-imposed and the product of choice, it is a reality that our society has limited health care dollars. As reflected in the inadequate financial assistance given to children, such as Bobby, and their parents, those born with serious impairments are often beyond the scope of the available resources. In the absence of adequate financial assistance (one might add acceptance and compassion), it would be nothing less than hypocritical to restrict the late-term abortion option of prospective parents, when genetic testing reveals that their fetuses carry genetic abnormalities that will result in serious impairments. In short, genetic screening accompanied by the option to abort may allow some children to avoid suffering and some parents to avoid the guilt and pain of not being able to meet their child's needs. It may also enable society to

Clark & DeVore, supra at 1035-36.

145. For a discussion of the economics of health care and the reality of rationing, see generally Henry J. Aaron & William B. Schwartz, The Painful Prescription: Rationing Hospital Care (1984) (Brookings studies in social economics); Fuchs, supra note 137; Paul Starr, The Social Transformation of American Medicine (1982) (a full discussion of the history behind and business of our system of medicine). See also G. Calabresi, Tragic Choices (1978) (a law-and-economics analysis of this issue). The higher level of rationing associated with national health care will, of course, require a complete change in the socialization of our medical community—a profession historically trained to preserve life without the constraints of cost—and a public that has come to believe that it is entitled to coverage and every opportunity to live. See The Place of Ethics in Health Care Reform, Hastings Center Rep., May/June 1994, at 7-12.

146. The financial strain of trying to give a child with Bobby's needs an opportunity to develop confidence—for example, trying to keep a growing child in an easily maneuverable (and aesthetic) wheelchair so that he or she can keep up with his or her peers—is virtually insurmountable for most families. This strain is heightened by the fact that, in our society of "latch-key" children, children such as Bobby need a parent to be available at all times, especially while they are young and undergoing surgeries.

147. It also follows that healthy, viable fetuses have more of an existence independent from that of their parents, because society—through adoption, for example—is able and willing to care for them without placing any demands on their parents. However, according to Dr. Winstrom, infra note 157, there are families waiting to adopt children with serious health impairments. See Tara Bradley-Steck, In the Migliaccio Family, 25 is Not Enough, Hous. Post, Oct. 20, 1985, at G13 (couple that adopts youngsters "that no one else wants"); Leslie Sowers, Adoptive Mother-Daughter Bond Thrives Despite Severe Handicap, Hous. Chron., Sept. 23, 1985, at 1 (discussing the adoption of a child without a cerebral cortex by a mother with cerebral palsy; acknowledging that Spaulding for Children, a United Fund agency, specializes in such adoptions); Martha Swift, Abortion Unrelated to Placement of Children, Hous. Chron., May 14, 1992 ("[P]arents are also available to adopt children with Down's syndrome, spina bifida, AIDS and various other disabilities."); Geoffrey Tomb, Supermom: Florida Woman Adopts 17 Disabled Babies, Hous. Chron., May 30, 1991, at D4. But see Jennifer Dixon, Thousands of Infants Left in Hospitals in '91, Boston Globe, Nov. 9, 1993 (discussing how thousands of unhealthy babies are left in hospitals by their parents).
make a substantive difference in the lives of the fewer children born with serious health impairments.148

Nevertheless, the practice of prenatal genetic screening is becoming a standard component of prenatal care and, as such, it needs to be questioned, debated, and subjected to some level of scrutiny in both the medical profession and society at large. Although the recent surge of successes in identifying genetic abnormalities linked to health impairments and in developing tests to detect those abnormalities have been impressive, the presently available genetic screening technology represents merely the beginning of an era of testing capability almost incomprehensible just a few years ago. As recently recognized by the Institute of Medicine,

The national investment in the Human Genome Projects will greatly increase the capacity to detect genes leading to disease susceptibility and the availability of genetic testing over the next 5 to 10 years, identifying the genetic basis for diseases—even some newly discovered to be genetic—and increasing the number of tests for detecting them. The emergence of the biotechnology industry increases the likelihood that these findings will be rapidly translated into widely available test kits and diagnostic products.149

Many of these tests will be for predispositions rather than for actual mental and physical impairments, for “the development of genetic tests for diseases that manifest in middle and late life is just beginning to be explored.”150 Moreover, “[m]any disease genes can be detected in individuals before symptoms occur, but for many common diseases with some genetic basis, such as heart disease and cancer, the detection of genetic alterations might only indicate

148. See supra note 56. However, it is perhaps more likely that the inadequate financial assistance given to such children and their families will continue because the expansion of the practice of prenatal genetic screening is not likely to cure society of its lack of acceptance and compassion for such children:

Expanding prenatal diagnostic services may circumvent but will not solve the “problem” of birth defects; they focus on disability, not on society's discriminatory practices. . . . Women's desire for children without disability warrants complete public and private support. The question is how to provide this support in a way that does no harm. . . . Though it is more than twenty years since the first fetal diagnosis of Down's syndrome by amniocentesis, we do not yet know the full impact of prenatal testing and screening on women's total health, power and social standing.

Lippman, supra note 56, at 45-46 (footnotes omitted); see also Harding, supra note 113, at 499 (“There is also a fear that society's search for genetic perfection will serve to ostracize other less fortunate members of society such as the mentally retarded, the infirm, the disabled, or the elderly.”).

149. ASSESSING GENETIC RISKS, supra note 9, exec. summ. at 1.

150. Id. preface at 2.
susceptibility, not the certainty of disease.” The National Institutes of Health has acknowledged that,

[while interpretation of tests for single gene disorders of late onset, including familial cancer, is not easy, the complexities of testing and interpretations for the gene constellations that predispose to many common diseases such as coronary heart disease, diabetes mellitus, hypertension and others raise new problems. These dilemmas will become particularly thorny if testing for the yet undiscovered genes predisposing to common psychiatric diseases such as schizophrenia and manic depressive disorders becomes a reality.]

Prospective parents are vulnerable, and many, when made aware of genetic screening’s possibilities, will seek a conclusive determination as to whether they are going to have a healthy baby. They will find themselves pursuing an answer that current technology cannot provide or relying upon research-stage tests that may be grossly inconclusive. Moreover in the absence of regulation, “[m]any genetic tests will be ordered and interpreted by primary care health practitioners, and not by geneticists or genetic counselors.” Similarly, “[o]bstetricians, squeezed by legal constraints not to ‘miss’ a defective fetus, will generally provide their patients with prenatal diagnosis on demand.” Accordingly, prospective parents may even be pushed to undergo prenatal genetic testing by care-givers driven to limit their own liability in a doctor-hostile legal system and then find themselves confronting choices that they never wanted and are unprepared to make. For example, such parents may be forced to decide whether to abort their wanted pregnancy when a research-stage test indicates that there is a forty-percent possibility the child would carry a genetic abnormality responsible for a severe health impairment.

151. Id. exec. summ. at 1.
152. Id. preface at 2.
153. Id. “[G]enetic testing is no longer just for specialists. Increasingly, primary care providers will be called upon to administer tests, counsel patients, and protect their privacy.” Id. exec. summ. at 2.
154. Elsas, supra note 35, at 832; see also Robertson, supra note 36, at 703; “[O]bstetricians and primary care providers need assurance that they will not be sued for failing to offer the test to persons with a negative family history for CF. Absent this assurance, their desire to minimize malpractice exposure may lead them to offer (in effect, order) the test on a routine basis, thus bringing about the very situation that the experts now claim is undesirable.
155. All prospective parents who undergo prenatal genetic screening face the possibility of being presented with one of the tough cases—for example, the possibility of parenting a child who is likely to live a short but fairly “normal” life. Consider the story of Kim Lynch whose daughter, Catherine, has cystic fibrosis. The Perfect Child, supra note 133. Kim again became pregnant with the knowledge that there was a strong possibility that her second child would have cystic fibrosis and, should it be determined through genetic testing that her child would suffer from the disease, she and her husband would face an all-or-
more, although undergoing genetic counseling may release obstetricians from liability, it may also subject prospective parents to a loss of privacy and choice. For example, under the present insurance scheme, there is a possibility that genetic screening test results nothing decision. The Lynches never had to make that decision, for the tests indicated that the genetic abnormalities responsible for the disease were not present.

Also consider the story of a young man with cystic fibrosis who is in his twenties. See id. He stated that, even if there is a 50% probability that he will have a child with cystic fibrosis, he will still have the child. In his words, “I have never met a person with cystic fibrosis who regretted being born.” But also consider the pain of losing a child one has gotten to know and love. Cf. CHARLES STROUSE, FLOWERS FOR ALGERNON (1980); George Miller, Lorenzo’s Oil (unpublished manuscript).

156. Clayton, supra note 74, at 108 (“Even when a condition requires no intervention, mere entry of the diagnosis into medical records makes it available to a wide array of people and institutions.”). See also SoRelle, supra note 54 (“Of those surveyed, 98 percent said one has the right to know if his or her spouse carries a genetic defect. Surprisingly, 58 percent said the person’s insurer should know and 33 percent said an employer has the right to know.”). The issue of disclosure of genetic information among family members is discussed in Suter, supra note 6. For a broader discussion of privacy issues arising from the practice of prenatal genetic screening, see Fletcher & Wertz, supra note 23, at 753 (“Laws against genetic discrimination are clearly necessary.”); id. at 763-64 (listing disclosure dilemmas). Some of these issues are (1) whether there should be full disclosure of laboratory results that are conflicting, ambiguous, or simply subject to controversial interpretations, id. at 768; (2) whether the paternity of the child should be released, id. at 769; (3) whether there is a duty to disclose psychologically sensitive information that might harm the patient, id. at 770-71; and (4) whether there is a duty to warn relatives about the possibility that they are carriers of genetic abnormalities, id. at 770. As for this last issue, it has been proposed that

it would be ethically acceptable to breach confidentiality and disclosure to relatives if three conditions are met: 1) there is a high probability of harm, 2) harm to identifiable individuals is serious, and 3) precautions are taken to limit disclosure to appropriate genetic information . . . . This essentially restates the “Tarasoff rule” in the genetic counseling case, providing an exception to a general rule of confidentiality where serious harm could accrue to an identifiable individual that could be prevented by a disclosure.

Annas & Elias, supra note 44, at 216-17 (quoting conclusions of the Judicial Council of the American Medical Association). But see infra note 203 (stating that the therapeutic privilege does not pertain to genetic counseling).

157. According to pro-life feminist theorists, abortion removes the choices of women by making sex available to men on demand. Dr. Margit Winstrom, Class Presentation, Abortion, Law, and Social Choice, University of Houston Law Center (Apr. 5, 1993); see Catharine A. MacKinnon, Reflections on Sex Equality Under Law, 100 YALE L.J. 1281, 1300 n.93 (1991) (“Juli Loesch, a self-styled ‘pro-life feminist’ associated with Operation Rescue, says, ‘the idea [of abortion] is that a man can use a woman, vacuum her out, and she’s ready to be used again . . . .’” (citation omitted)); cf. Catharine A. MacKinnon, Toward a Feminist Theory of the State 190 (1989) (“The availability of abortion removes the one real consequence men could not easily ignore, the one remaining legitimized reason that women have had for refusing sex besides the headache.”). Dr. Winstrom considers the fetus to be a “second patient,” and although she does not dispute abortion when the fetus is severely deformed, her philosophy is that the opportunity to abort fetuses for all genetic abnormalities is accompanied by societal pressure to do so.
will be treated as if the fetus has already received a diagnosis of a preexisting condition. This possibility creates a strong disincentive to undergo prenatal genetic screening and testing to determine whether one carries a genetic abnormality unless one is willing to abstain from having children or undergo an abortion if the abnormality is detected in the fetus. Before any tests are run, prospective parents should be made aware of all of these dangers. They must also be made aware of the importance of environmental factors in affecting the onset and severity of many diseases linked to genetic abnormalities and the overall limitations of testing capability.

Finally, we must give consideration to the fact that fetuses aborted as a result of genetic screening are often older than twenty weeks and babies delivered as early as twenty-three weeks are being kept alive, albeit often with severe health impairments. Because our society is less intolerant of late-term abortion when a fetal abnormality is detected, the pre-viability, late-term abortion of a fetus based upon the result of genetic screening will not receive the same scrutiny as the decision to refuse treatment to a seriously-impaired newborn. This is true even though a newborn’s impairments are

158. See Zylke supra note 51, at 1715; Vicki Quade, Protecting the Essence of Being, BARRISTER, Summer 1993, at 9. Consider that all humans carry from four to ten genetic defects. Id.

159. Clayton, supra note 74, at 113-14 ("Even if parents want to provide economic security for their child, receiving this sort of information may actually limit rather than expand parents' options. Many health insurance policies do not cover preexisting conditions.") (footnotes omitted).

160. See supra note 60 (addressing the importance of environmental components). The relationship between a person's genetic makeup and production of proteins (genotype) and a person's observable traits (phenotype) is fully discussed in Suter, supra note 6, at 1856-59.

161. Although many state's abortion laws still reflect the trimester framework erected in Roe v. Wade, 410 U.S. 113 (1973), according to the Supreme Court's recent decision in Planned Parenthood v. Casey, 112 S. Ct. 2791 (1992), women have a right to choose abortion up to the point of viability. See supra note 127. According to a recent study reported in the New England Journal of Medicine, doctors “should aggressively try to save premature babies born at 25 weeks gestation but not those born before 22 weeks.” Study Details Critical Time for Preemies, WORCESTER TELEGRAM & GAZETTE, Nov. 25, 1993, at A31. According to this study, “[o]nly 2 percent of those born at 23 weeks escaped severe abnormalities, compared with 21 percent born at 24 weeks and 69 percent at 25 weeks.” Id.

162. See supra notes 129-130 and accompanying text.

163. Even the scrutiny given to decisions to withhold treatment from seriously impaired newborns may be nonexistent. See ANSPACH, supra note 70; see also Martha A. Field, Killing “The Handicapped”—Before and After Birth, 16 HARV. WOMEN'S L.J. 79, 79 (1993) (a constitutional law treatment of the issue that discusses, among other things, how “support of a ‘right to life’ for newborns with handicaps is consistent with belief in a broad right to choose abortion”).
certain and defined, while the genetic screening test results that create an opportunity to abort a pregnancy late-term may be far from conclusive and may detect nothing more than the propensity for developing a treatable condition. What is most disturbing is the fact that, because the technology underlying prenatal genetic screening is in its infancy and a great deal of genetic screening is being conducted by research laboratories that are not being properly regulated (or relevant regulations are not being enforced), it is subject to a level of error not acceptable for diagnostic purposes. As acknowledged by the Committee on Assessing Genetic Risks, errors in genetic testing performance are likely to continue for the following reasons:

- Many clinical laboratories are unfamiliar with the recombinant DNA techniques used in most new genetic tests;
- The use of very small samples with PCR increases the chance of contamination with foreign DNA;
- The large volume of tests increases the chance of unintentional switching of samples;
- The vast majority of results will be in the normal range, a tendency that reduces the vigilance of those performing the test;
- The nature of genetic disorders increases the chance of errors in interpretation;
- Tests at the DNA level may not detect all disease-causing or susceptibility-conferring mutations, resulting in false negative results; and
- A positive test result cannot always predict disease severity and, in some instances, may falsely predict the future occurrence of disease particularly in tests for predispositions to multifactorial disorders and disorders of variable expressivity.

We must confront the fact that such errors often will result in the late-term abortion of wanted pregnancies. Accordingly, rather than accepting the reliance upon unspoken norms associated with the decision making surrounding seriously impaired newborns, we should "codify the substance of widely shared but unwritten moral agreements found in the practice of medical genetics." At the very least,

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164. This is discussed infra Part V.C.
165. ASSESSING GENETIC RISKS, supra note 9, ch. 3, at 1.
166. See supra note 129.
167. Fletcher & Wertz, supra note 23, at 760; id. at 785 ("[T]his study supports the claims made above for this Article's fourth premise that strong agreements are present world-wide on some crucial approaches to several of the major ethical problems in the old and new genetics."). However, survey studies, such as the study completed by Fletcher and Wertz, have been criticized on the grounds that

[Such questionnaires, in which physicians are asked to comment on hypothetical dilemmas, evoke responses that are suggestive, but not indicative, of decisions in actual practice. Case records, the second source of data, are retrospective accounts of decisions, often written with an eye to the hospital administration and
in light of its social implications, we should erect some legal restrictions around the practice of prenatal genetic screening (or at least apply the existing restrictions imposed on commercial laboratories, as discussed in Part IV.C. of this Article) to ensure that our society's level of reliance upon the underlying technology to terminate pregnancies is the product of debate and conscious choice, and subject to at least a minimum level of public scrutiny.

The following is an assessment of the present status of regulation of the practice of prenatal genetic screening in the United States. As is set forth below, in the absence of efforts to control it and through the unlimited access to nascent technology made possible by research laboratories, the practice of prenatal genetic screening is currently being expanded by: the influence of legal liability; the insurance industry's drive to minimize risk; market pressures on laboratories and hospitals; and the emergence of a powerful biotechnology industry.

A. The Absence of Minimum Bioethical Standards

The definitive evaluation of the state of prenatal genetic screening in the United States at the present time is a report recently issued by the Committee on Assessing Genetic Risks, Division of Health Sciences Policy, of the Institute of Medicine.168 The Committee concluded that,

[w]hile existing standards may have been adequate for the past, new standards must be developed in response to rapid developments in genetic testing methods that are now experimental. In particular, additional standards are needed for prenatal diagnosis, predispositional testing, and multiplex testing. Research and policy analysis is needed in prenatal genetic diagnosis to address problems such as: the complexities of fetal identification of cells in maternal blood, maternal serum alpha-fetoprotein screening, notions of "perfectibility," use of prenatal diagnosis and selective abortion to choose the sex of the fetus, the special impact of prenatal diagnosis on women, and carrier detection in pregnancy rather than prior to conception .... Standards are also needed for genetic testing for predisposition to late-onset disorders. There is an important "window of opportunity" for considering these issues now, before predispositional genetic testing becomes widespread.169

The Committee also acknowledged that,
In its efforts to complete a comprehensive overview of issues in genetic testing and screening, the Committee identified significant gaps in data, research, and policy analysis that impede informed policy making for the future. Surprisingly few data exist on the extent of genetic testing and screening today, for example, and no system is in place to gather data or to assess practices in relation to the committee's principles and recommendations for the future.¹⁷⁰

The George Washington University's recent announcement that its researchers successfully cloned human embryos drew international attention to the fact that there are no national bioethical restraints on the human genome-related research of private institutions in this country—the most powerful, advanced, and capable collection of such institutions in the world. Specifically, "the only checks on such research are a patchwork of guidelines, state laws, advisory committees and recommendations by professional associations."¹⁷² In fact, although the fetal cloning experiment did immediately generate the circulation of a report from the Congressional Office of Technology Assessment critical of Congress's silence regarding biomedical advances,¹⁷³ currently there is not even so much as a movement to enact a federal privacy law related to genetic screening.¹⁷⁴ This regulatory vacuum reflects the fact that "the U.S. government has no official body to make policy on dilemmas raised by biomedical advances."¹⁷⁵ Over the past few decades, commissions have been formed to address specific biomedical issues—one such commission, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (National Commission), is responsible for the ban

¹⁷⁰ Id. exec. summ. at 20 (emphasis added).
¹⁷¹ This research was done by a team headed by Dr. Jerry Hall.
¹⁷³ See OFFICE OF TECHNOLOGY ASSESSMENT, BIOMEDICAL ETHICS IN U.S PUBLIC POLICY—BACKGROUND PAPER, OTA - BP-BBS-1-5 (U.S. Gov't Prtg. Office 1993). In this report, the Office of Technology Assessment (OTA) stated that it is ill-equipped to address many of the quandaries arising from advances in biology and medicine, and it urged Congress to take an active role in deciding public policy related to bioethics. Id. See also George J. Annas, Will the Real Bioethics Commission Please Stand Up?, HASTINGS CENTER REP., Jan./Feb. 1994, at 19 [hereinafter Annas, Real Bioethics Commission]; Richard Saltus, France Weighs Restrictive Biomedical Science Law, BOSTON GLOBE, Oct. 23, 1993, at A6 [hereinafter Saltus, France]. The OTA also stated in its report that, at present, the federal government analyzes implications of novel research on an ad hoc basis and added that this is "the least desirable mechanism to address bioethical dilemmas." OFFICE OF TECHNOLOGY ASSESSMENT, supra.
¹⁷⁵ Saltus, Embryo Duplication, supra note 172, at A1.
on human experimentation without the subject's consent. These commissions generally have been quickly disbanded, the last such effort being the Biomedical Ethics Advisory Committee that was allowed to expire four years ago before it reached any conclusions about biomedical research. In contrast, at least twenty-seven other countries have set up national commissions to debate issues such as genetic privacy and reproductive technology.

The public's reaction to the George Washington University's fetal cloning experiment as reported by the media has been much of speculation about the social implications arising from the everyday application of such technology. As has been emphasized throughout this Article, the United States has not had the same level of head-on confrontation with prenatal genetic screening. It is ironic that, while the nation speculates about the social implications of human cloning, the practical significance of which is perhaps a decade once removed, hundreds of women are undergoing prenatal genetic screening on a daily basis.

176. See also Annas, Real Bioethics Commission, supra note 173, at 19-21. The four predominant efforts concentrated on in the OTA report are: the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (in existence 1974-1987); the Presidential Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research (in existence 1979-1983); the Biomedical Ethics Advisory Committee (in existence 1988-1989); and the Ethics Advisory Board (in existence 1977-1980).

177. The Biomedical Ethics Advisory Committee was "a victim of the abortion controversy . . . ." Editorial, An Embryonic Debate, BOSTON GLOBE, Oct. 31, 1993, at 86.

178. Id. at A1; see generally, OFFICE OF TECHNOLOGY ASSESSMENT, supra note 173, at 43-68. For example, in 1990 the United Kingdom enacted such legislation as a result of work done from 1982 through 1984 by the Warnock Commission. Id. at p. 51-52. "[C]areful study and debate [generated by the Commission] produced a national consensus." Id.

179. See, e.g., An Embryonic Debate, BOSTON GLOBE, supra note 177, at 87 ("Guidance by the federal government is needed now if cloning is to be brought under the control of the broader society."); Ellen Goodman, The Embryo Imbroglio, BOSTON GLOBE, Oct. 31, 1993 ("But you don't have to believe in Frankenstein to worry about the effect of having a clone of your own in the freezer."); 3 of 4 Polls Say Cloning is Wrong, BOSTON GLOBE, Oct. 31, 1993 (a poll, based upon a survey of 500 people, revealed that 58% of those questioned believe it is morally wrong to clone a human being); see also Reader Feedback: Should Legal Limits be Set on Scientists' Genetic Tinkering with Humans?, BOSTON GLOBE, Oct. 28, 1993, at 52 (stating that, of 306 callers who responded, 222 said that "there should be legal limits on the genetic manipulation of humans")

180. If there are approximately 500 genetic counselors and each sees approximately five hundred patients per year, about 250,000 women are undergoing prenatal genetic counseling on an annual basis. See supra Part II.A. (estimating that, in the summer of 1993, there were approximately 450 genetic counselors, each seeing between 200 and 1,000 patients annually).
The legal forces in this country do, in fact, directly influence the practice of prenatal genetic screening. However, their effect is not to ensure any level of public debate, conscious policy making by those accountable to the public, or a minimum level of accountability on the part of the institutions and individuals making this technology available to the public. Thus, while there are law-based regulatory forces influencing the practice of prenatal genetic screening, their ability to impose control is trailing far behind the reality of the technology. In fact, the practice of prenatal genetic screening has not been directly addressed by our public policy makers and, as is explained below, the overall influence of the existing regulatory forces is to expand the practice of prenatal genetic screening at the expense of caution.

(1) Self-Regulation by the Medical & Genetic Professions

"[T]he United States is the only developed country in the world without a social insurance or statutory system to cover basic expenses arising out of its application:

Since there have been large-scale genetic screening and counseling programs for such diseases as Tay-Sachs, sickle cell disease, PKU, and neural tube defects, it might be supposed that the major social policy issues raised by such screening have been solved. This supposition would be incorrect. This in part results from the fact that each genetic disease has unique characteristics and thus poses unique issues. For example, some diseases occur most frequently in specific racial or ethnic groups, raising potential issues of discrimination and stigmatization. Other screening tests, such as those for neural tube defects, can be done only on pregnant women, and abortion is the only "treatment." Still others can be performed only on newborns, and screening for conditions such as PKU that require immediate treatment to prevent harm has been made mandatory by almost all states. Annas, Monster Mythology, supra note 17, at 641 (footnotes omitted). The technology is advancing, and perhaps the most that can be done is to put more effort into addressing the ethical problems it is creating:

There are some who argue that without first addressing the ethical challenges that would result from advances in genetic research, it is inappropriate to perform the research. Some criticisms directed at the Human Genome Project are appropriate, but whether we like it or not, the project has begun and is being carried out in many parts of the world.

Sachs & Korf, supra note 1, at 460. The groups of societal issues arising from the Genome Project have been identified as follows:

In the Human Genome Initiative there are three major societal issues: population-based genetic screening, resource allocation and commercialization, and eugenics. More specifically, the questions raised by the project are to what uses its fruits should be put to screen groups of people, such as applicants for the military, government workers, immigrants, etc.; what priority should the genome project have for federal funding and what role should patenting laws play; and finally, should we attempt to use the new genetics to improve our citizens, either by trying to eliminate specific genetic diseases or by enhancing desirable traits.

Annas, Monster Mythology, supra note 17, at 639 (footnote omitted).
for medical services for most of its population," and the medical profession within the United States enjoys an incredible amount of autonomy. On the other hand, peer pressure within the medical profession is a powerful regulatory force, and it works on the local, regional, national, and international levels—often simultaneously. At the present time, there are no less than "eleven active gene therapy protocols worldwide; nine more have been approved and many more are in various stages of organization." Moreover, various organizations within the medical community are publishing statements on issues relating to prenatal genetic screening. The American Society of Human Genetics (ASHG) has issued some guidelines in recent years and because the ASHG is democratic in nature, these guidelines are likely to be taken seriously. Unfortunately, many of the medical profession’s ethical norms have not been formally recognized and codified into regulations. And, finally, some genetic testing quality assurance is being provided by the Council of Regional Net-

182. *Assessing Genetic Risks*, supra note 9, exec. summ. at 17.

183. Fletcher & Wertz, supra note 23, at 753 (“Because the genome mapping project is international in scope, ethical issues in human genetics must be addressed by national and international societies of geneticists and colleagues in allied fields.”); id. at 744 (presenting a list of the 10 major ethical issues identified through an international study performed on medical geneticists).

184. Sachs & Korf, supra note 1, at 460. See also supra note 98 (addressing IBC/UNESCO efforts to establish an international agreement); *Assessing Genetic Risks*, supra note 9.

185. See National Society of Genetic Counselors (NSGC), Statement of Guiding Principles on Confidentiality of Test Results (1991); American Society of Human Genetics Statement on Clinical Genetics and Freedom of Choice, 48 AM. J. HUM. GENET. 1011 (1991); Kenneth J. Ryan, Transactions of the Tenth Annual Meeting of the American Gynecological and Obstetrical Society, 166 AM. J. OB. GYN. 1029 (1992); see also Richard Saltus, Scientist Opposes Potential 'Gay Gene' Abortions, BOSTON GLOBE, Feb. 22, 1994. In its recent report, the Committee on Assessing Genetic Risks acknowledged that although the American Society of Human Genetics, National Society of Genetic Counselors, American Academy of Pediatrics, American College of Obstetricians and Gynecologists, and other professional organizations have developed policy statements on key policy issues in genetic testing, genetic testing has moved beyond the domain of genetics specialists alone.

186. See ASHGA Ad Hoc Committee on Identification by DNA Analysis, Principles on the Protection of DNA Data and DNA Data Banking (1990); see also supra note 140 (proposed language issued in 1990).

187. See generally *Assessing Genetic Risks*, supra note 9. Two scholars have conducted an international survey to compile geneticists’ reactions to difficult genetic screening case scenarios. See Fletcher & Wertz, supra note 23. The result of their effort is the discovery of consensus and shared ethical norms, but that “geneticists persist with an oral tradition in ethics to the detriment of their specialty.” *Id.* at 760; see also supra note 9 (identifying a weakness in this study).
works of Genetic Services (CORN), the College of American Pathologists (CAP), and the Centers for Disease Control (CDC), all of which have helped to develop specific genetic tests or tests for specific disorders.\textsuperscript{188}

(2) Federal Regulation

Perhaps the greatest social danger arising out of the Human Genome Project comes from a lack of regulation enforcement regarding researchers who may not be conscious of the social impact of their work.\textsuperscript{189} Although it would be natural for the Food and Drug Administration (FDA) to regulate researchers running genetic tests and developing test kits, relevant regulations have not been implemented and regulations carefully and directly tailored to prenatal genetic screening have not been drafted.\textsuperscript{190} The Committee on Assessing Genetic Risks of the Institute of Medicine found that, "although adequate legislative authority exists to oversee the quality of genetic testing, this authority is not in fact being implemented for genetic testing."\textsuperscript{191} The Committee also acknowledged that

\begin{quote}
the emergence of the biotechnology industry increases the likelihood that [genetic screening] findings will be rapidly translated into widely available test kits and diagnostic products. Entrepreneurial pressure may also lead to the development of commercial and academic ‘genetic testing services’ that would not be regulated under current FDA procedures.\textsuperscript{192}
\end{quote}

Another source of federal regulation over prenatal genetic screening is the NIH, which has had a profound influence over researchers through regulations accompanying NIH grants,\textsuperscript{193} including, for example, guidelines for research involving recombinant DNA mol-

\begin{footnotes}
\item[\textsuperscript{188}] Assessing Genetic Risks, supra note 9, ch. 3, at 5.
\item[\textsuperscript{189}] See id.
\item[\textsuperscript{190}] See infra Part IV.C. (addressing existing regulations that could be implemented to enforce caution).
\item[\textsuperscript{191}] Id. at 9.
\item[\textsuperscript{192}] Id. exec. summ. at 1.
\item[\textsuperscript{193}] National Institutes of Health Workshop Statement: Reproductive Genetic Testing: Impact on Women, 51 Am. J. Hum. Genet. 1161 (1992). The NIH has acknowledged that, although reproductive genetic testing, counseling, and other services have the potential to (1) increase the knowledge of pregnancy outcomes; (2) provide reassurance during pregnancy; (3) allow women the opportunity to choose whether to continue their pregnancies; and (4) facilitate prenatal or early infant therapy, they also carry the potential to (1) increase anxiety and place excessive responsibility, blame, and guilt on women for the health of their newborns and general pregnancy outcomes; (2) interfere with mother-infant bonding; and (3) disrupt relationships between a woman, her family members, and her community. Id. at 1161. The NIH has also recognized that "[t]he value that women and their families place on these services depends heavily on a mixture of psychological and ethno-
\end{footnotes}
ecules. The NIH has also formed subcommittees to address specific issues. One such committee is the Human Gene Therapy Subcommittee (HGTS), a committee created to provide the NIH with an additional, specialized review of all research in which recombinant DNA would be used to insert a "foreign" gene into a human being. Moreover, "[r]ecognizing the enormity of the ethical and social questions presented by the genetic research, the NIH and the Department of Energy have established [ELSI]."\textsuperscript{194}

Finally, it is worth acknowledging that, in the event that the executive branch of our government is returned to an anti-choice administration, it is likely that prenatal genetic screening—as its presence becomes more widely recognized—will be affected by abortion re-

\begin{itemize}
  \item \textit{1. Services should not be used to pursue "eugenic" goals}. \textit{Id.} at 1161 ("The ideals of self-determination in family matters and respect for individual differences ... are jeopardized whenever the primary goal of these services becomes the prevention of the birth of individuals with a disorder or a disability.").
  \item \textit{2. The primary goal should be to enhance personal reproductive decisions}. \textit{Id.} at 1162.
  \item \textit{3. The services should be value sensitive}: Training of professionals who will provide these services should include special emphasis on influences of psychological, sociodemographic, religious and moral values, and ethno-cultural diversity in women's needs and interests regarding reproductive genetic testing services. The true impact that the providers' gender, race, ethnicity, class, and educational discipline have on how services are provided must be evaluated. \textit{Id.} at 1162.
  \item \textit{4. The standards of care for reproductive genetic services should emphasize genetic information, education, and counseling rather than testing procedures alone.}
  \item \textit{5. Social, legal, and economic constraints on reproductive genetic services should be removed.}
  \item \textit{6. It must be recognized that genetic screening services may further stigmatize individuals affected by a particular disorder or disability}. \textit{Id.} at 1162-63 ("Individuals with disabilities, who have a variety of information, experiences, and views to share, must be involved in the development and implementation of further research to be carried out in this area."). \textit{See also} Capron, \textit{supra} note 110, at 670; Elsas, \textit{supra} note 36, at 830-31 (footnotes omitted):
\end{itemize}

Any proposed investigation which involves recombinant DNA and applies for National Institute of Health (NIH) funds is reviewed by the NIH Recombinant DNA Advisory Committee (RAC) and its working group on Human Gene Therapy. At the local level, recombinant DNA research is reviewed by institutional biosafety committees. Similarly, the Food and Drug Administration (FDA) or the Department of Human and Health Services (HHS) will review all gene therapy projects and require prior approval by local institutional review boards. Now, layers of review, advice and regulation of non-therapeutic genetic research activity in humans are generally applied to proposals for federally funded research. \textsuperscript{194} Sachs & Korf, \textit{supra} note 1, at 460.
lated restrictions, such as the Reagan-Bush era restrictions on fetal tissue research. So long as abortion is the only feasible option other than giving birth to a child with a genetic abnormality, a reinstatement of conservative abortion policy—or expansion of the Hyde Amendment—could limit the availability of prenatal genetic services at institutions receiving federal funds.

(3) Legal Liability

Legal liability is presently the most profound force working to transform advanced prenatal genetic screening technology into a standard component of prenatal care. The medical profession has recognized the liability (actual and potential) arising from the practice of prenatal genetic screening. For example, this liability was the inspiration for the American College of Obstetricians and Gynecologists' first professional liability alert, which was issued in 1985.

The increasing liability imposed on obstetricians is arising out of the judiciary's greater recognition of wrongful birth and wrongful life actions and state legislatures' passage of statutes authorizing such actions. Both causes of action stem from the right of patients to make choices. In the context of prenatal genetic screening, the issue is the right of parents to choose what is best for themselves and for their

195. Fletcher & Wertz, supra note 23, at 755-56 (footnote omitted); see Paul Recer, U.S. Funds Fetal Tissue Research, BOSTON GLOBE, Jan. 5, 1994, at 3 (with the caption “Action is first since ban lifted”). However, conservative politics in the United States aside, it is important to recognize that reservations regarding fetal tissue research also have been shared by many throughout the world. See Elsas, supra note 36, at 836 (“In fact, the moral objectives of preserving human dignity, combined with the variety of conflicting definitions of when life begins, have forced a moratorium on fetal research throughout the world. This moratorium is currently under reconsideration.”).

196. See B.J. George, Jr., State Legislatures Versus the Supreme Court: Abortion Legislation into the 1990s, in ABORTION, MEDICINE, AND THE LAW 67-69 (J. Douglas Butler & David F. Walbert eds., 1992). The Hyde Amendment banned the use of federal Medicaid funding for nontherapeutic abortions or therapeutic abortions other than for certain restricted reasons. Id.

197. Annas & Elias, supra note 44, at 215 (“Physicians now face numerous ethical dilemmas with uncertainty and confusion while practicing in a climate in which malpractice suits threaten even the most competent and conscientious practitioner.”).

198. See Aubrey Milunsky, Screening for Birth Defects: A Professional Liability Alert, LAW, MED. & HEALTH CARE, Sept. 1985, at 142 (“An obstetrician who elects not to screen all patients in routine pregnancy or who fails to offer and discuss this screening test invites a malpractice action should a patient deliver a child with a neural tube defect or Down's Syndrome.”). It should be noted that the testing which generated this warning was directed at a noninvasive blood draw rather than at invasive blood draw associated with amnio and CVS that is necessary for much of the genetic testing that is the subject of the article. See supra note 48.
Wrongful birth actions are premised upon the right of parents to choose to terminate a pregnancy due to a genetic abnormality; wrongful life actions are premised upon the right of children not to have been born. In states recognizing such actions, parents are likely to be told increasingly about even the most remote possibility of a genetic abnormality as prenatal genetic counseling bridges the gap between medicine and counseling, for there is no therapeutic privilege—the privilege to withhold information for the benefit of patients—in counseling. Although only three states have fully
recognized causes of action for wrongful life at the present time and some states have expressly rejected such causes of action,204 most states fall somewhere in between.

Moreover, obstetricians are finding themselves subjected to general malpractice liability for: failing to suggest genetic counseling when there is even the slightest indication that it might prove helpful;205 failing to fully inform prospective parents about the tests that are available; failing to explain the risks of testing;206 failing to choose responsible laboratories to run tests; and failing to monitor the quality of test samples.207 Liability may even arise from informing or failing

Normally, a physician may assert a therapeutic privilege and not fully inform the patient of all the material facts if in the physician's judgment the information would do the patient more harm than good. However, for several reasons, the therapeutic privilege is not applicable when the issue is the disclosure of test results from genetic counseling.

Carolyn Lee Brown, Note, Genetic Malpractice: Avoiding Liability, 54 U. Cin. L. Rev. 857, 874-75 (1986) (citation omitted). The reasons why the therapeutic privilege does not apply to the practice of prenatal genetic screening have been summarized as follows: (1) the concept of informed consent mandates disclosure; (2) genetic screening generally does not mandate immediate decision making—"immediate" meaning that a decision must be made within 24 hours; (3) recognition of procreative liberty and the privacy of family life; and (4) the fact that the basic purpose of undergoing genetic counseling is to obtain the very information that the therapeutic privilege would withhold. Id. But see supra note 157.

204. The states barring such actions generally do so out of the belief that they encourage abortion and result in non-appreciation for fetal life. See Dawe, supra note 202, at 474 n.6. This same fear has resulted in states such as Louisiana, Missouri, Minnesota, and Illinois passing laws prohibiting the discarding of embryos. See Robertson, supra note 36, at 707 (citation omitted). In addition, Pennsylvania has expressly banned wrongful birth and wrongful life actions. ACTIONS FOR WRONGFUL BIRTH & WRONGFUL LIFE, PA. CONS. STAT. ANN. § 8305 (1994)

205. The Council on Scientific Affairs, a division of the American Medical Association, has summarized the indications for genetic counseling as follows: "birth defects in one or more family members, behavioral problems or mental retardation in a child previously born, advanced age of the mother, certain ethnic backgrounds, drug use by parent, exposure to mutagens by parent, three or more spontaneous abortions, or infertility." Brown, supra note 203, at 865.

206. Id. at 870 ("Regardless of which standard is adopted, the physician has a duty to inform the patient of the risks involved in amniocentesis so that the patient can decide intelligently whether or not to undergo the procedure."); see Kimble, supra note 43; see also Keel v. Banach, 624 So. 2d 1022 (Ala. 1993).

207. See Brown, supra note 202, at 870. In sum,

[g]enetic counseling actually consists of three stages: the patient-counselee must directly approach or be referred to the genetic counselor; the genetic counselor must obtain all necessary information to allow for a proper diagnosis; and, ultimately, the genetic counselor must communicate his diagnosis to the patient-counselee. At each step, the potential for genetic malpractice exists.

Id. at 859.
to inform other family members when a mutant gene is discovered. Moreover, this liability has been enhanced by the recognition of prenatal genetic counseling as a medical subspecialty, and it will expand as additional prenatal genetic screening tests are made available.

In sum, obstetricians are facing a growing legal duty to refer patients to genetic counselors, and they are beginning to make referrals to counselors when there is even the slightest indication that counseling might prove helpful for "[t]he legal guidelines for doctors in the field of genetic counseling are few and unclear." Moreover, it is expected that, in the near future, "[m]any genetic tests will be ordered and interpreted by primary care health practitioners, [rather than] only by geneticists or genetic counselors."

(4) State Laws

Although "[a]t present, only 10 states have some form of specific requirements for the licensing of clinical laboratories providing genetic tests," state law directly affects prenatal genetic screening through abortion statutes. As discussed above, many states have codified exceptions to restrictions on late-term abortion when fetal abnormalities are present. The applicability of these exceptions to genetic testing results is currently a matter of discretion on the part of the medical community. As state legislatures become aware of the reli-

208. Id. at 878 ("The best answer is for the physician to have the counselee sign an advance statement allowing the physician to disclose necessary information to necessary relatives.").

209. As discussed in Brown:

It is the generally accepted rule that a physician who holds himself out as a specialist is held to a higher standard of knowledge and skill than a general practitioner. Therefore, an obstetrician usually will be held to a higher standard than a general practitioner and a genetic counselor will be held to a higher standard than an obstetrician.

Brown, supra note 202; see also supra note 77 and accompanying text (discussing recognition of genetic counseling as a medical subspecialty).

210. Id. at 863.

211. Id. at 858. Wrongful birth suits are discussed in Annas & Elias, supra note 44, at 216:

The choice for these children is never to be born healthy, but only to be born with a handicap (such as Down’s syndrome or Tay Sachs disease) or never to be born at all. We think that future courts are likely to limit such actions to serious handicaps, those in which fetuses, if they could speak to us (which, of course, they can do only through their parents), would agree with an ‘objective societal consensus’ that their own best interests would be served if they were aborted. Put another way, they would be better off, from their own perspective, if they never existed.

See also Kimble, supra note 43.

212. Assessing Genetic Risks, supra note 9, preface at 2.

213. Id. ch. 3, at 2.
ance on genetic testing for determining the presence of fetal abnormalities and the limitations of the underlying technology, it is likely that at least some state legislatures will impose restrictions—for example, requiring that genetic testing meet the international research “true-positive” standard of reliability before being relied upon as an indicator of fetal abnormality. Specifically, state legislatures may require that the genetic testing being relied upon (a) indicate that an identified abnormality is present, (b) be specific for the given disease, and (c) be capable of detecting the abnormality in ninety to 100 percent of population samples. To enforce such standards, especially in states such as Louisiana and Pennsylvania that heavily regulate and restrict abortion within their borders, state legislatures may also require post-mortem genetic analysis on the fetuses aborted (which would raise the costs of these abortions) and require health professionals to report their prenatal genetic screening related activities.

(5) Insurance Law

The role of the insurance industry in the practice of prenatal genetic screening is yet to be defined, and its potential role raises a number of difficult issues. Among these are the possibility of mandatory testing, the confidentiality of testing results, coverage issues regarding the costs of testing, coverage issues regarding the cost of care when parents choose not to abort despite prenatally diagnosed conditions, the insurance impact of being identified as a carrier...

215. See Suter, supra note 6, at 1887-1905.
217. See Sachs & Korf, supra note 1, at 831 (“Most insurance companies now consider prenatal diagnosis to be a generally acceptable practice and will pay for these medical services.”).
218. I spoke with several members of the Houston-area medical community regarding insurance coverage for genetic screening, and they independently identified several common stories and issues, some of which I have been able to confirm through research. For example, a genetic counselor and insurance administrator both mentioned an instance in San Francisco where a fetus was diagnosed prenatally as having cystic fibrosis, its parents refused to terminate, and their HMO refused to cover the child's health costs on the ground that the cystic fibrosis was a preexisting condition. According to both accounts and the discussion of the case in the media, enough controversy was raised to make the health maintenance organization (HMO) agree to provide coverage for the child. See Beth Healy, Genetic Testing Has Attention of Insurers, Boston Bus. J., Oct. 11, 1994, at 4; see also Zylke, supra note 51, at 1715 (addressing this case). Another common concern is that
rier of a genetic abnormality, the availability of testing services, and the potential impact of a movement toward a nationalized health care system on the decision to undergo genetic screening and abort pregnancies when the genetic abnormalities responsible for serious impairments are detected. Although the Clinton Administration’s proposed health care reform package may address some of the difficult insurance industry issues regarding prenatal genetic screening, currently these issues either are not being addressed or are being addressed at the state level. Assuming that the Clinton Administration is successful in at least initiating some reforms in the direction of a nationalized health care system, one difficult issue likely to be addressed, given the expense of assisting a seriously impaired child, is coverage will be denied to prospective parents who undergo testing which determines that the prospective parents are carriers for genetic abnormalities, even though carrier status does not create any risk to their own health nor does it necessarily mean that the trait they carry will arise in their offspring. Cf. Quade, supra note 158, at 9 (profile of a lawyer who was deprived of insurance coverage at the age of 28 because her father was incorrectly diagnosed with Huntington’s disease).

219. For example, testing programs for sickle cell anemia in the 1970s were carried out with a misunderstanding about the difference between carriers of the disease and those who actually had the disease. As a result, many carriers suffered from insurance and employment discrimination as well as unfounded fear about their own health. See Leslie Roberts, One Worked: The Other Didn’t, 247 SCIENCE 18 (1990). Carriers of genetic abnormalities linked to cystic fibrosis may now be subjected to these same problems. See Benjamin S. Wilfond & Norman Fost, The Cystic Fibrosis Gene: Medical and Social Implications for Heterozygote Detection, 263 JAMA 2777, 2778 (1990).

220. “Women who receive prenatal diagnosis are disproportionately white, well-educated, and financially secure” and “unequal access or no access to services is the most widespread ethical problem in human genetics.” Fletcher & Wertz, supra note 23, at 756, 761-62 (proposing that genetic services be included in the “floor of services” made available through a nationalized health care system); see also Harding, supra note 113, at 487 (“Women in higher economic strata, for example, have greater access to amniocentesis.”); U.S. DEP’T OF HEALTH AND HUMAN SERVS., HEALTH, UNITED STATES 1989, at 31 (1990) (“An estimated 24% of all new mothers annually receive no prenatal care in the first trimester of pregnancy.”).

221. See ASSESSING GENETIC RISKS, supra note 9, exec. summ. at 17; ch. 7, at 1-10; see also Case Study, HASTINGS CENTER REP., July/Aug. 1992, (Special Supplement), at S18-S20 (with commentaries by Paul Billings, Mark A. Rothstein, and Abby Lippman).

222. Consider California’s effort to provide regulation in this area:

A provision [of the California State Civil Rights Act] (which will remain in effect until January 1, 2000) prohibits health insurers from either not enrolling or overcharging individuals carrying disease genes. Similarly, firms that write life and disability insurance cannot refuse an application for insurance based on a person’s genetic characteristics. . . . Although a gene may indicate that an individual is at risk, the person may not develop the disease if the condition results from an interaction between the environment and the gene. . . . It is hoped that the Ethical, Legal, and Social Issues Joint Working Group will recommend model laws that can be enacted by states to prevent insurance discrimination.

Sachs & Korf, supra note 1, at 460-61.
the accessibility of prenatal genetic screening and late-term abortion services in the event that genetic abnormalities are detected.223

(6) Intellectual Property Law

Patent protection offers the ability to protect investment and discovery in the area of prenatal genetic screening.224 In fact, “private parties have quietly been obtaining patents on bits and pieces of the human genome from the Patent and Trademark Office (PTO).”225 Moreover, trade secret battles already are being waged over such information.226

It is generally recognized that to put this new technology—genetic screening and splicing techniques, for example—to practical use, either private business must be allowed to “own” and profit from it as

223. See Fletcher & Wertz, supra note 23, at 756. Despite procreative liberty concerns and the cost of caring for seriously impaired children, it is unlikely that testing under such a system would be made completely accessible. For example, “[i]t has been estimated that if a national screening program were introduced, it would cost $2.2 million for each case of cystic fibrosis avoided.” Sachs & Korf, supra note 1, at 459. See Medicaid Abortion Rule Seen as Peril, BOSTON GLOBE, Jan. 6, 1994 (discussing new federal rule requiring states to pay for abortions for poor women who are impregnated through rape and incest). Should the Clinton Administration succeed in introducing a national health care system, “[m]uch can be learned in the United States about the role of genetic services in the total health care systems of other nations, which is now well-described in eighteen other nations.” Fletcher & Wertz, supra note 23, at 758.

224. Applying patent law to this technology involves a new application of the products of nature doctrine recognized in patent law. See Rebecca S. Eisenberg, Patenting the Human Genome, 39 EMORY L.J. 721,723 (1990). “[T]he cases suggest that the patentability of such inventions turns on whether the claimed invention is a new product or process resulting from human intervention and, if so, whether the intervention is obvious in light of the prior art, including previously available natural products.” Id. at 725. Applying established patent law principles to human DNA sequences,

[olne could argue that a newly cloned human gene that previously existed within the chromosomes of human cells is analogous to a newly isolated or purified chemical that previously existed in impure form. . . . Moreover, a cloned gene provides a means of producing its corresponding protein in larger quantities and in a more pure form than may be obtained conveniently from human cells. The cloned gene thus has distinct advantages over the gene as it exists naturally in the chromosomes of human cells, just as purified vitamin B12 has distinct advantages over impure vitamin B12 as it exists in cow liver.

Id. at 729. However, because the DNA sequences themselves are not original, the best that patent law may be able to do is protect the only known means of detecting a particular sequence. Id. at 734. “[A]s a practical matter a patent on the only known means of making an unpatented product may be effective only for as long as it takes someone to develop another means of making the same thing, which may be far less time than the duration of the patent term.” Id. at 736.

225. Id. at 721 & n.4 (listing patent citations).

226. See Victoria Slind-Fiol, Biotech Firms in Fight Over House Patent, BUSINESS WATCH, Mar. 25, 1994, § B.
an investment, or the federal government must directly underwrite investment cost, as is being done through the Human Genome Project. Given these options, it is important to recognize that, although the federal government is investing some $200 million per year in the Human Genome Project, this amount is trivial in comparison to private investment in biotechnology research and development, which, for example, is estimated to have reached $1.5 to $2 billion in 1987. The potential regulatory force of patent law includes its ability to encourage putting the research accomplishments resulting from the Human Genome Project to practical use. However, before introducing patent law into the scientific community for genetic screening...

227. See Eisenberg, supra note 224, at 721.
228. Id. at 737-38 (footnote omitted). The following are American companies and organizations working to turn Human Genome Project-related knowledge into marketable drugs and therapies:

<table>
<thead>
<tr>
<th>Company</th>
<th>Location</th>
</tr>
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<tbody>
<tr>
<td>Darwin Molecular Technologies</td>
<td>Seattle, WA</td>
</tr>
<tr>
<td>Genome Systems Inc.</td>
<td>St. Louis, MO</td>
</tr>
<tr>
<td>Genomyx</td>
<td>San Francisco, CA</td>
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<tr>
<td>Genzyme</td>
<td>Cambridge, MA</td>
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<tr>
<td>Human Genome Sciences</td>
<td>Rockville, MD</td>
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<tr>
<td>Incyte Pharmaceuticals</td>
<td>Palo Alto, CA</td>
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<tr>
<td>Institute for Genomic Research</td>
<td>Rockville, MD</td>
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<tr>
<td>Mercator Genetics</td>
<td>Menlo Park, CA</td>
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<tr>
<td>Millennium Pharmaceuticals</td>
<td>Cambridge, MA</td>
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<tr>
<td>Myriad Genetics</td>
<td>Salt Lake City, UT</td>
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<tr>
<td>Nanotronics</td>
<td>San Diego, CA</td>
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<tr>
<td>SEQ Limited</td>
<td>Princeton, NJ</td>
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<tr>
<td>Sequana Therapeutics</td>
<td>La Jolla, CA</td>
</tr>
</tbody>
</table>

Lawrence M. Fisher, Profits and Ethics Clash in Research on Genetic Coding, N.Y. TIMES, Jan. 30, 1994, at 1, 18. All but three of these companies were founded in the last two years. Id. at 18. See also Richard Saltus, Latecomer Boston Labs Eyeing Gene Therapy, BOSTON GLOBE, Feb. 22 1993, at C1, C4 (listing companies); Ronald Rosenberg, Biotech Thrives on Hot Idea, BOSTON GLOBE, Apr. 10, 1994, at A77, A80 (discussing the efforts of Millenium Pharmaceuticals and the gene testing industry).

229. "[E]ven if public funding were sufficient to generate the sequence information itself, the lack of intellectual property rights in DNA sequences might undermine incentives for the private sector to support subsequent research to put this information to practical use. Since 1980, federal law has promoted private exploitation of patent rights in inventions emanating from federally-sponsored research as a means of promoting the development of these inventions." Eisenberg, supra note 224, at 744. However, Senator Hatfield has introduced a bill, entitled the “Life Patent Moratorium Act,” which would result in patents on DNA sequences being withheld for two years while Congress addresses ethical implications. The research and development community has responded to this bill by arguing that the resulting lack of patent protection will remove incentives for genetic research.
purposes, the overall impact of patent law on the dissemination of information must be evaluated.\textsuperscript{230} This process is currently under way.\textsuperscript{231}

(7) Summation

In the absence of enforceable regulations establishing minimum standards for genetic screening and ensuring that the technology is applied with caution, the practice of prenatal genetic screening is currently being expanded by the effects of legal liability, the insurance industry's drive to minimize risk, national and international market pressures on laboratories and hospitals providing research and genetic screening services, and the emergence of a powerful commercial biotechnology industry. Prenatal genetic screening technology is being applied, for the most part, by the medical profession in conjunction with research laboratories and essentially without reservation—that is, without public scrutiny and legal restraint. In fact, it is now used as a means to avoid legal liability. This is occurring even though research-stage genetic screening technology, which is nascent technology coming into being, is increasingly being relied upon as the basis for making choices to terminate wanted pregnancies. As recognized by the Committee on Assessing Genetic Risks, "the misinterpretation of test results is more likely in genetic tests than in many other areas of clinical

\textsuperscript{230} "Although both the patent law and the scientific community reward priority of invention and thus place a premium on prompt disclosure of new discoveries, patent applicants are likely to publish their discoveries later than scientists who are indifferent to intellectual property rights." \textit{Id.} at 741. In other words, a scientist is likely to publish her findings as soon as they are reliable so as to claim her victory, while an inventor seeking patent protection may delay disclosure to protect her investment. Introducing patent protection into the scientific community may skew the scientific community's norms, for "[p]atent protection may also impede scientific progress even after disclosure occurs if it gives patent holders the power to stop others from using their discoveries in subsequent research." \textit{Id.} at 742 (footnote omitted).

The difficulty of estimating the potential impact of patent protection on genetic testing technology is somewhat enhanced by the fact that our patent system may soon change. A bill was introduced in Congress in 1993 to change the United States' patent system from awarding patents to the "first to invent" to awarding them to the "first to file." \textit{See} Thomas Smith, \textit{Debate Heats Up Over First-to-file Patent System}, \textit{NAT. L.J.}, Aug. 8, 1994, at C7, C10. The quid pro quo for obtaining a patent is disclosing how an invention works, and the "first to file" theorists argue that this change in the patent system will result in earlier disclosure of inventions, thereby fostering increased communication of scientific advances. This proposed "first to file" system would bring the United States in line with most other countries. \textit{See id.}

testing, and misinterpretation may have more serious consequences particularly in fetal diagnosis." These consequences and the potential implications for individuals and society—such as a loss of privacy and even less tolerance for children who deviate from perfection—are as unnoticed as the diagnostic applications of research-stage genetic testing technology that are presently being conducted and relied upon by prospective parents.

B. A Legislative Paradigm: The Efforts of France to Identify and Codify its Minimum Societal Standards

In contrast with our country's failure to directly address the implications of prenatal genetic screening at a national, public policy level, France is in the process of enacting sweeping legislation that will confront prenatal genetic screening and other biomedical advances. The articulated purpose of this legislation is to ensure that public policy decisions resulting from the rapid advances of biomedical science and the emergence of a powerful biotechnology industry are made by France's chosen public policy makers—and thereby subject to public scrutiny—rather than by its individual doctors on a case-by-case basis.

Specifically, three proposed statutes have been drafted by France's Constitutional Counsel (the equivalent of our Supreme Court) and approved by the French National Assembly. This pro-


233. See supra Part V.A. (quoting findings of the Committee on Assessing Genetic Risks that existing standards are outdated and adequate data regarding prenatal genetic screening is nonexistent); see also infra note 286.

234. See Richard Saltus, *Law on the Biomedical Frontier*, *Boston Globe*, Oct. 22, 1993, at 18; Saltus, *France, supra* note 173. France's proposed legislation was discussed at a symposium conducted on October 22-23, 1993 in Boston, Massachusetts. The symposium, which was organized by Suffolk University Law School and the University of Massachusetts Medical Center, addressed the legal, ethical, and public policy ramifications of biomedical advances. See id. Justice Noelle Lenoir of France's Constitutional Council, a coauthor of the proposed legislation, spoke at this symposium. (Justice Lenoir is also president of a UNESCO advisory committee on bioethics, discussed supra note 98, and a member of an advisory committee on Ethics of Biotechnology to the European Economic Community). Justice Lenoir stated that the legislation is necessary because discoveries regarding the human genetic makeup are outpacing existing laws and regulations. She also stressed that the proposed legislation embodies an important principle innate to French culture—a belief that "it is not the mission of medicine to solve social problems." Saltus, *France, supra*, at A6 (quoting Justice Lenoir).

235. *See Draft Law Adopted by the National Assembly on the Human Body, No. 66, 1st Reg. Sess. (1992-93); Bill Adopted by the National Assembly, No. 67, 1st Reg. Sess. (1992-93) ("regarding the donation and utilization of parts and products of the human body, to medically assisted procreation, and to prenatal diagnostics, as well as to
posed legislation has received an abundance of public support, and it is expected to be approved, in some version, by France’s Senate. The purpose of the proposed legislation is set out in Title One of bill number sixty-six, which provides that: “The primacy of the person is the foundation of society. The law ensures that this principle is reconciled with the legitimate requirements for the progress of scientific knowledge and for safeguarding the public health. It guarantees respect for every human being as soon as life begins.” \(^\text{236}\) Bill number sixty-six also provides that the proposed legislation: (1) “guarantees the dignity of the human body”; (2) “ensures the inviolability and inalienability of the human body”; and (3) “protects the integrity of the human species.” \(^\text{237}\) Moreover, it states that:

- “Only therapeutic necessity or the law may authorize interference with the integrity of the human body.” \(^\text{238}\)
- “The intervention may not have as its effect to interfere with the health of others or with that of future generations.” \(^\text{239}\)
- “No one may interfere with the integrity of the human species.” \(^\text{240}\)
- “Any eugenic practice tending toward the selection of the genes, the sex or the physical or racial traits of human beings is prohibited.” \(^\text{241}\)
- “No change may be made in the genome or in the human cells of a person for the purpose of altering his/her offspring.” \(^\text{242}\)
- “The organs, tissues, cells, genomes and products of the human body as such cannot be the object of a patent.” \(^\text{243}\)
- “[T]he study of the traits of a person by genetic examination may be undertaken only for medical or scientific research purposes, and in the cases provided for by law.” \(^\text{244}\)

To accomplish these broad public policy objectives, the proposed legislation calls for the creation of a National Consultative Commission on Ethics for Life Sciences and Medicine. This Commission will render advice and publish recommendations regarding ethical problems raised by research and practice in the fields of biology,

\(^{236}\) No. 66, supra note 235, art. 1A.
\(^{237}\) Id. art. 2.
\(^{238}\) Id. art. 19.
\(^{239}\) Id.
\(^{240}\) Id. art. 20.
\(^{241}\) Id.
\(^{242}\) Id.
\(^{243}\) Id. art. 21.
\(^{244}\) Id. ch. III, art. 25.
COMING INTO BEING

medicine, and health. Although the Consultative Commission may exercise jurisdiction over any question relevant to its competence and publish recommendations, it is also intended to be the recipient of matters referred to it by the President of the National Assembly, the President of the Senate, the Prime Minister, any institution of higher education, and any public institution or recognized foundation of public utility, the principal activity of which is technological research and development. One of the Commission's primary missions is to keep the public informed about biomedical research and advances.

The proposed legislation also provides for the creation of a National Commission of Medicine and Biology of Reproduction and Prenatal Diagnostics, which will be composed of "practitioners designated by proposals of their representative organizations; personalities selected by reason of their competence in the fields of procreation, prenatal diagnostics, genetic counseling and the right of filiation; and representatives of the involved governmental agencies as well as a representative of family associations." This National Commission will be "in charge of giving an opinion on the requests for authorization to exercise medically assisted procreation activities and prenatal diagnostics as well as approval requests from multidisciplinary centers of prenatal diagnostics." It will also be responsible for conducting follow-up procedures and evaluating the operations of these facilities.

Along with genetic privacy, in-vitro fertilization, and other issues related to biomedical science, the proposed legislation regulates "medically assisted procreation," which it defines as "medical and biological techniques permitting procreation beyond natural processes." The legislation also identifies the purpose of medically assisted procreation as being "to alleviate an infertility of a pathological character that has been medically determined or to prevent the transmission of a particularly serious and incurable disease to the child."

The proposed legislation permits medically assisted procreation procedures only when "performed under the responsibility of a practitioner specifically approved for such purpose in each establishment or
laboratory authorized to practice them.”252 All establishments and laboratories authorized to practice prenatal diagnostics “must present to the minister in charge of health, an annual report of activities.”253

The legislation also directly addresses prenatal diagnostics (prenatal genetic screening and therapy), the purpose of which is a “diagnostic or therapeutic intervention on the embryo or the fetus.”254 Specifically, the bill provides that:

• The goal of prenatal diagnostics “can only be to anticipate or to treat an ailment of a particular gravity in the interest of the child to be born”;255

• “Genetic counseling as well as analyses of molecular and chromosomal genetics in view of establishing a prenatal diagnostic can be practiced only in health establishments and in medical biology analysis laboratories [expressly] authorized [to do so].”;256

• “When any prenatal diagnostic leads to envision a voluntary interruption of pregnancy for a therapeutic motive, it must be confirmed by two authorized physicians, one of which must exercise his activity in a multidisciplinary prenatal diagnostics center.”;257 and

• “Registers shall be established and kept by the multidisciplinary prenatal diagnostics centers, and shall indicate the causes of the therapeutic pregnancy interruption and shall permit verifying the authenticity of the anomaly detected by the prenatal diagnostic.”258

To ensure compliance, the proposed legislation also includes penal and administrative sanctions. For example, one provision provides that “[a]ny violation noted in the establishment or the laboratory and hence of the legislative and regulatory requirements applicable to medically assisted procreation or to prenatal diagnostics leads to the temporary or definitive revocation of the authorizations [to provide medically assisted procreation activities].”259 Another provides,

[the persons found guilty of one of the offenses provided in the present chapter are also liable to a complementary penalty of prohibition, for a duration of not more than ten years, to practice the professional or social activity in the exercise of which or at the occasion of which the infraction was committed.260

In sum, the legislation proposed in France demonstrates an effort to address the public policy concerns of prenatal genetic screening at a

254. Id. art. 10 (bis) (to be codified at VI Pub. H. Code, tit. II (bis), art. 673-6).
255. Id. (emphasis added).
256. Id.
257. Id.
258. Id.
societal level before the impending capability of prenatal genetic screening is fully realized and before the existing capability is introduced to the public. Serving as a point of comparison, it also highlights the obvious failure of the United States to address the issue.

C. A Proposal for Regulation Within the United States

It would be naive to suggest that the United States simply follow the precedent for genetic technology regulation set by European nations because of both the differences in our health care system, which reflects a high level of deference and autonomy to the medical profession, and our chronic struggle with the issue of abortion—an issue over which the populous of France and England reached societal resolutions long ago. Nevertheless, due to our culture, the United States may be even more in need of such legislation. The availability of prenatal genetic screening technology is likely to reinforce insecurities arising from our survival-of-the-fittest norms, and those same norms may compel prospective parents to act on their insecurity.


262. These same norms are epitomized in the premium we place upon “Jeffersonian pluralism,” and they result in our relatively fractious society that resists national regulation and compromise. See generally ARTHUR M. SCHLESINGER, JR., THE DISUNITING OF AMERICA (1992); see also Annas, The Real Bioethics Commission, supra note 173, at 20-21 (“Because of how America is constituted and because of our Constitution, no government commission can define ‘American Bioethics,’”). As explained above, especially where issues are innately personal, subjective, and ethics-oriented, our pluralistic nature makes it relatively difficult for us to find shared norms to codify. See generally supra Part II (addressing the relationship between law, ethics, and shared norms).

263. Our reaction to health impairments is, at least to some extent, cultural: For example, the fact that doctors perform amniocentesis most frequently in this country to afford women an opportunity to abort fetuses that have Down’s syndrome, a condition leading to mental retardation among other things, demonstrates that many upper-class whites view the birth of such a child as a result that they should avoid. Other cultures may view the burden of retardation as less onerous. One recent study cited the statement of a Haitian man in New York who said that there was no reason to diagnose Down’s Syndrome prenatally. . . . Indeed, there is no word for Down’s syndrome in the Haitian language even though the incidence of this syndrome around the world varies only with the age at which women have children. This investigator also noted that people in other cultures view conditions leading to physical defects as more handicapping than mental retardation.

Clayton, supra note 74, at 115 n.130.
Although the medical profession should be involved in all genetic screening regulatory efforts, we need to enact legislation around the practice of prenatal genetic screening to control the breadth of its application and make it the subject of public scrutiny.\textsuperscript{264} This could be accomplished by directly addressing the practice of prenatal genetic screening through existing regulatory bodies and coordinating these efforts through a national, nonpartisan, multidisciplinary commission similar to the commissions that will be created in France under that country's proposed legislation.\textsuperscript{265} The primary missions of this commission should be to (1) keep the public informed as to biomedical research efforts and advances, thereby generating national and state-level debate on important issues related to prenatal genetic screening and (2) make published recommendations (regarding everything from counseling guidelines and informed consent requirements to insurance regulations and patent law) to the medical profession, state legislatures, the FDA, PTO, other administrative agencies, and Congress.

\textsuperscript{264} The federal government's potential regulatory role regarding prenatal genetic screening has been addressed by others, and one scholar has summarized it as follows:

The government's regulatory role is to protect consumers of genetic information by assuring that genetic information is accurately provided by competent professionals. It achieves that goal by licensure and certification, or by after-the-fact accountability for deviations from appropriate standards of care.

A second governmental role would be to provide access to genetic services to those who lack the resources or knowledge to obtain them on their own.

As genetic knowledge increases, however, proposals to mandate certain kinds of reproductive behavior to prevent genetically handicapped offspring will undoubtedly arise. Some persons will clamor loudly that individuals have a moral obligation to learn their carrier status and to avoid reproduction when there is a high risk that their offspring will have serious genetic disease.

Debate on these issues will be improved if two key distinctions that often are missed in discussions of reproductive responsibility are made. The first distinction is in the locus of harm from the alleged irresponsible reproductive behavior. Is the alleged harm visited upon the offspring or on others? This distinction is important, because negligently or even intentionally bringing a genetically handicapped child into the world cannot really be considered a wrong to offspring. The "responsible" reproductive behavior urged as the preferable alternative would have prevented birth altogether, hardly a gain for the offspring being protected.

Robertson, supra note 36, at 715-17 (footnote omitted). Some localities, dissatisfied with federal regulations, have generated their own. Perhaps the most noted example of this is Cambridge, Massachusetts—the home of Harvard University and the Massachusetts Institute of Technology. See Annas, Monster Mythology, supra note 17, at 653. As early as 1976, Cambridge developed regulations calling for laboratory inspections by a publicly-appointed committee. \textit{Id.}

\textsuperscript{265} See Nolan, First Fruits, supra note 46, at S4 (suggesting that a pragmatic solution to difficult genetic screening ethics issues might be found through decision making by interdisciplinary organizations and citing the American Academy of Pediatrics "Red Book Committee" as an example).
There is precedent within the United States for the creation of such a commission, a committee that blends the concerns of scientists, government officials, and ethicists, to deal with difficult legal-ethical-medical issues, both at the national and local level.\textsuperscript{266} An example of the latter are the hundreds, if not thousands, of ethics committees that have been formed at hospitals across the United States over the past decade to resolve difficult ethical questions regarding whether aggressive treatment is appropriate—questions usually generated by the capability to sustain life created through advanced medical technology.\textsuperscript{267} These committees are essentially "reasonable person" constructs, which is reflected by the fact that they are being formed both to resolve difficult ethical questions and to avoid legal liability for withholding treatment.

An example of such a committee at the national level is the Committee on Assessing Genetic Risks created by the Institute of Medicine, the multidisciplinary committee that recently issued the report on genetic screening (the definitive statement on the practice of prenatal genetic screening within the United States at the present time) which has been cited throughout this Article. Among the conclusions reached and suggestions made by this multidisciplinary committee are the following:

• "Informed consent should be an essential element of all screening. These principles and procedures described above should apply to genetic testing regardless of the setting . . . ."\textsuperscript{268}

• "Anyone considering prenatal diagnosis must be fully informed about the risks and benefits of both the testing procedure and the possible outcomes, as well as alternative options that might be available[.]."\textsuperscript{269} "[O]btaining informed consent should be the method of ensuring that genetic testing is voluntary."\textsuperscript{270}

• "Genetic professionals and all others offering or referring for genetic testing should be trained in the ethical, legal, and social issues surrounding genetic diagnosis, testing, and screening[.]."\textsuperscript{271} Anyone who is offering (or referring for) genetic testing must provide (or

\textsuperscript{266} As evidenced by the media, there is at least some popular support for the creation of such a committee. See Editorial, \textit{An Embryonic Debate, supra} note 177, at 86 ("The problems and opportunities of genetic research could best be put in an American context by a committee that blends the concerns of scientists, government officials, ethicists and religious leaders.").

\textsuperscript{267} \textit{See} \textit{BELKIIN, supra} note 104, at 246.

\textsuperscript{268} \textit{ASSESSING GENETIC RISKS, supra} note 9, exec. summ. at 3.

\textsuperscript{269} \textit{Id.} exec. summ. at 6.

\textsuperscript{270} \textit{Id.} exec. summ. at 18.

\textsuperscript{271} \textit{Id.} exec. summ. at 16.
refer for) appropriate genetic counseling and education prior to testing."\textsuperscript{272}

- "Standards of care for prenatal screening and diagnosis should also include education and counseling before and after the test, either directly or by referral, and ongoing counseling should also be available following termination of pregnancies."\textsuperscript{273}

- "Prenatal diagnosis should only be offered for the diagnosis of genetic disorders and birth defects . . . . Reproductive genetic services should not be used to pursue eugenic goals, but should be aimed at increasing individual control over reproductive options[;]"\textsuperscript{274} "[t]he goal of reducing the incidence of genetic conditions is not acceptable, since this aim is explicitly eugenic . . . ."\textsuperscript{275}

- "Population screening for late-onset diseases should only be considered for treatable or preventable conditions of relatively high frequency and only after appropriate, reliable, sensitive, and specific tests become available . . . ."\textsuperscript{276}

- "The safety and effectiveness of genetic tests should be established before they are used routinely and, even when that comes to pass, great care should be taken in performing the tests and interpreting the results . . . . [T]he committee believes the nature of genetic tests and their interpretation and the magnitude of the personal and clinical decisions which may be made based on those results—including the abortion of affected fetuses—warrant a standard with close to "zero-error" chance of error for such tests."\textsuperscript{277}

- "Legislation should be adopted to prevent medical risks, including genetic risks, from being taken into account in decisions on whether to issue or how to price health care insurance[;]"\textsuperscript{278} "[t]he committee recommends that insurance reform preclude the use of genetic information in establishing eligibility for health insurance[;]"\textsuperscript{279} and "[i]n order to develop appropriate financing for genetic testing and counseling services, private and public health plans, and geneticists and consumers should work together to develop guidelines for the reimbursement of genetic services."\textsuperscript{280}

- "For effective overall and continuing policy oversight, the majority of the committee recommends the creation of a broadly representative National Advisory Committee and Working Group on Genetic Testing to oversee professional practices and determine when new genetic tests are ready for wide-scale use in medical practice."\textsuperscript{281}

Whether or not such a national commission is created, legal boundaries must be erected around the practice of prenatal genetic
screening. Steps have to be taken to prevent the practice of prenatal genetic screening from degenerating into eugenics. Specifically, prenatal genetic screening technology should be questioned at the national, public policy level before being handed over to the public. At the very least, legislation should be enacted to ensure that prenatal genetic screening is not performed without genetic counseling.

282. One of the most recognized eugenics concerns is that genetic screening will be used for sex selection. See Fletcher & Wertz, supra note 23, at 788 ("An exception to this duty should be made in decisions that involve information about the gender of the fetus, unrelated to genetic diseases, that may lead to abortion.").

283. Consider how leaving genetic testing programs for newborns to state discretion has resulted in a great deal of variance:

These state-run newborn screening programs differ from one another in the source of their authority. In some states, the legislature specifies the tests to be performed. In others, the legislature delegates the authority to develop screening programs to other institutions, most frequently departments of public health. Even when the legislature takes a direct role, the statutes are usually quite simple in structure, occupying at most a few sections. Some states conduct screening programs even though they have no enabling legislation.

The states also vary in whether they allow parents to opt out of screening, and if so, what reasons suffice. In some states, parents can refuse testing only for religious reasons; in others, any reason for objecting will do. Almost no state legislatures require parents to provide their informed consent to screening, despite the formal recognition that screening receives in other medical settings. Clayton, supra note 74, at 98-99 (footnotes omitted).

284. Consider the following suggestion:

Although none of the major issues raised by past genetic screening and counseling cases have been solved, the major factors to be considered before initiating a screening program have been identified: (1) the frequency and severity of the condition; (2) the availability of treatment of documented efficacy; (3) the extent to which detection by screening improves the outcome; (4) the validity and safety of the screening tests; (5) the adequacy of resources to assure effective screening and counseling follow-up; (6) the costs of the program; and (7) the acceptance of the screening program by the community, including physicians and the public. Annas, Monster Mythology, supra note 17, at 641 (footnote omitted).

285. See Conrad, Genetic Counseling, supra note 39, at 41 (addressing the impending explosion of knowledge in human genetics and concluding that "[g]iven our current medical division of labor, genetic counselors are the obvious candidates for the job"). Genetic counselors, who deal with testing laboratories and patients' needs on a daily basis, are most capable of informing patients as to what testing is available and its reliability, where the testing is done, and whether the patient's own test sample is reliable. They also are capable of monitoring research laboratories, ensuring both speed and accuracy, and putting patients in contact with those who have faced similar choices.

To ensure counselor involvement in genetic testing, NIH grants should be accompanied by prohibitions forbidding research laboratories from running their tests for anyone who is not a recognized genetic counselor, geneticist, or physician associated with an established health care facility. See supra note 193 (addressing present NIH guidelines). Moreover, the medical facilities that make genetic counseling services available should be expressly forbidden from running research-stage tests that have not reached an industry-accepted level of accuracy. Such restrictions are justified by the fact that
(2) the genetic counseling is given by those trained in the social sciences;\(^{286}\) (3) those giving the counseling satisfy specific informed-consent requirements;\(^{287}\) and (4) the information presented to satisfy

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[b]biotechnology companies have economic incentives to sell their diagnostic products, but proficiency testing and quality control for laboratories performing DNA analysis remain limited. Given good, well-controlled DNA linkage studies or even direct gene analysis, there are few controlled clinical research studies to confirm the benefit generated by early diagnosis of heritable diseases for which no cure exists.

Elsas, supra note 36, at 827 (footnotes omitted).

286. See supra Parts II.A. & II.B. Who performs the genetic counseling is perhaps as important as whether there is counseling: "Even who does the counseling associated with prenatal diagnosis can influence what a woman does after learning of a fetal chromosome abnormality; rates of induced abortion are higher when obstetricians relate the results of testing than when geneticists do." Lippman, supra note 56, at 36 (footnotes omitted). The role of genetic counselors is to help patients make choices. "Medical geneticists are mediators between other fields in medicine with experience in dealing with ethical problems in human genetics." Fletcher & Wertz, supra note 23, at 748. In contrast, consider scientists' approach to morality:

Scientists, on the other hand, (with the possible exception of some involved in the Human Genome Initiative), tend to think of social policy and ethics as fields that "lag behind" science and cannot "keep up with" scientific progress and advancement. It is almost as if they believe that morality is a field of knowledge "in the charge of unidentified, but presumably rather incompetent experts." Experts in both fields have little experience with each other, and generally only meet in the courtroom or in the congressional hearing room. Scientists often then revert to the old slogan, "What is good for General Motors is good for the country," or more precisely, as James Watson has put it, "Science is good for society."

Annas, Monster Mythology, supra note 17, at 651 (footnotes omitted); see also Capron, supra note 110, at 665 ("I don't think these scientists are thinking about mankind at all. I think that they're getting the thrills and the excitement and the passion to dig in and keep digging to see what the hell they can do." (quoting Alfred E. Vellucci, Mayor of Cambridge, Mass.)); Cassell, supra note 51, at 37 ("Doctors who have mastered a technology tend to use it as often as possible—not necessarily for reasons of profit, but because they love their skills and technologies."); cf. Michael Crichton, Jurassic Park (1990) (imagining a future in which scientists extract dinosaur genes from a preserved insect that dined on dinosaur blood, clone dinosaurs, and unleash havoc).

As discussed supra note 139 and the accompanying text, medical doctors who are free to diagnose conditions, which may mean "counseling" patients to the point of pushing them towards a given result, may remove choice from parental decision making. See Gangelhoff, supra note 134, at A1 (A mother who decided to deliver a child who would die of anencephaly describes how doctors pressured her when the condition was discovered prenatally: "They said her baby would have more in common with a fish than a human. They said to expect the girl to be about as smart as a baboon."); cf. Leslie Loddike, Men's Attitudes Toward Poor Wanes During Medical School, Hous. Post, May 19, 1993, at A6 (discussing the "Male View" towards moral problems as analyzing them in terms of rights and rules).

287. The intent of true informed-consent requirements is to provide the patient with enough information so that he or she, rather than his or her physician, is able to determine what treatment is best for him or her, and this is the responsibility of genetic counselors. See supra notes 268-281 and accompanying text. Standardized informed-consent require-
these informed-consent requirements reflects the proven impact of the identified genetic abnormality on the health of children born with that abnormality. Some genetic testing—for example, testing for sex selection, treatable conditions such as hypertension and diabetes, and character traits such as sexual orientation—should be flatly banned on the ground that it is eugenic in nature. In addition, individuals with disabilities should be included in decision making regarding prenatal genetic testing.

Because the practice of prenatal genetic screening presently is highly dependent upon research laboratories and medical tests that are diagnostic in nature, immediate steps can, and should, be taken. Specifically, the Clinical Laboratory Improvement Amendments of...
and the medical devices legislation under which the FDA regulates testing products such as kits, probes, and reagents are means of providing some immediate control. The following measures, all of which have been suggested in some form and to some degree by the Committee on Assessing Genetic Risks, should be carried out under this legislative authority:

- Most genetic tests should be classified as “high complexity” and governed by CLIA88 to assure the highest level of federal oversight of laboratories performing genetic tests.

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288. See 57 Fed. Reg. 7137 (1992) (codified at 42 C.F.R. § 493.1). The CLIA88 provides regulations for laboratories performing an “examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings . . . .” See id. CLIA standards vary according to whether the tests performed are of “moderate” or “high” complexity, and the factors influencing which standards apply include: the knowledge needed to perform the test, the characteristics of the operational steps, the judgment required, and interpretation of the results. Assessing Genetic Risks, supra note 9, ch. 3, at 9. The Committee found that:

Few laboratories performing genetic tests as their sole or principal activity are yet complying with the CLIA88 regulations. Based on the committee’s workshops and other information, it appears that few genetics laboratories have applied for certification from HCFA [Health Care Financing Administration] even though they provide genetic test information for clinical use. Committee staff also surveyed the directors of 12 genetics laboratories in academic centers to ask if their laboratory had applied for certification, and only 1 laboratory indicated that it had.

Id. ch 3, at 10. The fact that the CLIA88 is not being implemented to regulate prenatal genetic screening is significant, for the Committee on Assessing Genetic Risks found that “[a]n increasing number of tests are being marketed as laboratory services by commercial laboratories and a few academic laboratories.” Id. ch. 3, at 2.

289. Investigational Device Exemptions, 21 C.F.R. § 812 (1993); Medical Devices Act of 1976 and Safe Medical Device Amendments of 1990, 21 C.F.R. § 201(h) (1993). Many genetic tests are being made available as kits, and “[b]efore a medical device can be legally marketed for invitro diagnostic use, its sponsor (manufacturer, university, or individual scientist) must obtain premarket approval (PMA).” Assessing Genetic Risks, supra note 9, ch. 3, at 12. Nevertheless, “[o]nly a small proportion of genetic tests in widespread use have been reviewed by FDA . . . .” Id. ch. 3, at 11. Moreover, “FDA is aware of the problem of the use of medical devices that it has not reviewed for marketing and that are not in compliance with its regulations regarding investigational devices.” Id. ch. 3, at 15 (citing the MSAFP test as an example).

290. The Committee on Assessing Genetic Risk has expressly acknowledged that federal legislative authority is not being implemented to oversee the quality of genetic testing. Assessing Genetic Risks, supra note 9, exec. summ. at 9; see also id. ch. 3. This is true despite the fact that, in July 1992, congressional hearings were held to highlight unresolved laboratory issues in human genetics. See id. ch 3, at 3 (discussing these hearings).

291. See id. ch. 3.

292. As suggested by the Committee on Assessing Genetic Risks, to satisfy FDA data requirements for safety and effectiveness,

[f]or rare diseases, the FDA could grant the applicant “provisional premarket approval,” a designation under which the test could be made more widely available
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All research laboratories—whether they be situated in academic health centers or elsewhere—that conduct research but perform genetic tests as a service also should be governed by CLIA88 and be subjected to the same criteria, standards, and regulation as commercial genetic testing laboratories;

- Prenatal genetic testing should be banned unless it is performed with the involvement of a qualified genetic counselor;
- All genetic tests should either be designated as investigational devices—thereby subject to institutional review board approval and FDA regulation—or be submitted to the FDA for full premarket approval;
- Similarly, the manufacturers and users of new genetic screening tests, including state laboratories and health departments, should be made to comply with the FDA's regulations for investigational devices;
- Because of the nature of genetic tests and the fact that people may rely upon them to the extent of aborting wanted pregnancies, they should be subject to a standard of close to zero chance of error;
- To ensure quality and testing proficiency, testing for rare diseases should be centralized in a few laboratories that would accept specimen referrals; and
- All laboratories performing genetic screening should be compelled to report their activities.293

Conclusively, subjecting the practice of prenatal genetic screening, which presently is being carried out to a large extent through research laboratories, to existing FDA regulations and CLIA88 would at least ensure some minimum level of public accountability. In light of the impact of prenatal genetic screening technology on parental choice and the societal importance of these choices, we should accept nothing less.

Conclusion

Before the end of this decade, extensive prenatal genetic screening will be a standard component of prenatal health care. The techno-

while making the manufacturer responsible for obtaining additional postmarket data until sufficient data are available to warrant full "premarket" approval.

*Id. exec. summ. at 11.*

293. In fact, ultimately, we should encourage the commercialization of the prenatal genetic screening tests that prospective parents will rely upon in order to ensure the accountability and the level of reliability that can be achieved through centralization of testing. Unfortunately, it appears that such a movement is currently being discouraged. See Richard Saltus, Plan to Market Tests for Cancer Gene Is Hit, BOSTON GLOBE, Mar. 10, 1994, at 3 (reporting a warning issued as a statement by the National Institutes Advisory Council for Human Genome Research that "it is premature to offer DNA testing or screening for cancer predisposition outside a carefully monitored research environment") (this statement is also published in the March issue of the Journal of the American Medical Association).
logical capability to detect genetic abnormalities that have been identified as causative of hundreds of health impairments is already here, and it is being expanded dramatically even as this Article goes into print. More importantly, the technology is being relied upon by prospective parents, many of whom will undergo late-term abortions of their wanted pregnancies based upon the information prenatal genetic screening offers.

With the technological capability to know information about the health of fetuses before viability comes an obligation—whether arising from procreative liberty, legal liability, or society’s failure to accept children with serious health impairments and offer them adequate assistance—to let prospective parents know about the health of their fetuses. However, because genetic screening creates the option of late-term abortion, and because presently this is generally the only option other than delivery for prospective parents whose fetuses are found to carry genetic abnormalities, policy makers must ensure that it is practiced with caution. Prospective parents who undergo prenatal genetic testing must understand the limitations of the technology, and an effort must be made to ensure that the late-term abortion option created through genetic screening is not abused.

Although extensive prenatal genetic screening is already a reality, important policy choices have not been made. This Article has identified many of those choices. Its message is theoretically simple: In light of the fact that prospective parents are a vulnerable group living within a competitive society that places an extraordinary value on “perfection,” we are in danger of allowing an incredible opportunity to expand parental choice to degenerate into a eugenic nightmare.

This danger is captured in The Twilight of the Golds, a play written by Jonathan Tollins that ran on Broadway during the fall of 1993.294 It is the story of a family thrown into turmoil when genetic testing of a woman’s fetus reveals that her child will most likely be gay. The social danger of such genetic testing capability is captured in the words of the character David Gold, who says, “Every human being is a tapestry. You pull one thread, one undesirable color, and the art unravels. You end up staring at the walls.” Prenatal genetic screening enables us to identify these “colors.” Although the wonders of prenatal genetic screening should be welcomed, they should also be subjected to public scrutiny and approached with caution, lest the tapestry of future generations be unravelled.