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A Conceptual Framework for Genetic Policy: Comparing the Medical, Public Health, and Fundamental Rights Models

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A CONCEPTUAL FRAMEWORK FOR GENETIC POLICY: COMPARING THE MEDICAL, PUBLIC HEALTH, AND FUNDAMENTAL RIGHTS MODELS

LORI B. ANDREWS*

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I. INTRODUCTION

A decade ago, genetics researchers around the globe launched an ambitious scientific endeavor: the Human Genome Project. Fueled by billions of dollars of research funds from the U.S. Congress, by other countries' public coffers, and by venture capital from biotechnology companies around the world, the Human Genome Project's goal was to sequence all genes in the human body¹ in order to facilitate the development of diagnostic tests and treatments for over five thousand diseases² with a genetic basis.³

The Human Genome Project (HGP or the Project) has not been without its detractors, some of whom have labeled it the "Manhattan Project" of biology.⁴ The 1997 film *GATTACA*, which even used a genetic sequence as its title, captured the dark side of the endeavor.⁵ In *GATTACA*, human personal and social decisions about people are made based on their genes.⁶ In the movie, one's deoxyribonucleic acid (DNA), rather than one's education, aptitude, or drive, dictates one's profession and determines one's place in the social structure.⁷ As internationally renowned gene therapy researcher W. French Anderson said of the movie, "This is what the future will look like unless lawyers do something soon."⁸

GATTACA is not just a science fiction fantasy. By the time it was released, numerous companies had already begun collecting genetic information on their employees,⁹ sometimes surreptitiously.¹⁰ Some insurers

1. Victor A. McKusick, *Mapping and Sequencing the Human Genome*, 320 NEW ENG. J. MED. 910, 910-13 (1989). See also LORI ANDREWS, *THE CLONE AGE: ADVENTURES IN THE NEW WORLD OF REPRODUCTIVE TECHNOLOGY* 184 (1999) [hereinafter ANDREWS, *THE CLONE AGE*].

2. See, e.g., VICTOR A. MCKUSICK, *MENDELIAN INHERITANCE IN MAN: CATALOGS OF AUTOSOMAL DOMINANT, AUTOSOMAL RECESSIVE, AND X-LINKED PHENOTYPES* xvi (9th ed. 1990).

3. See McKusick, *supra* note 1.

4. George J. Annas, *Who's Afraid of the Human Genome?*, 19 HASTINGS CENTER REP., July/Aug. 1989, at 19. The Manhattan Project was a gathering of scientists in Los Alamos, New Mexico, in the 1940s to develop the atomic bomb. G. PASCAL ZACHARY, *ENDLESS FRONTIER: VANNEVAR BUSH, ENGINEER OF THE AMERICAN CENTURY* (1997).

5. *GATTACA* (Sony Pictures 1997). See Chris Kridler, "*GATTACA*" Nice Dip in Gene Pool, *BALT. SUN*, Oct. 24, 1997, at 1E.

6. *GATTACA* (Sony Pictures 1997). See Janet Maslin, *The Next Bigotry: Privilege By Genetic Perfection*, *N.Y. TIMES*, Oct. 24, 1997, at 18E.

7. *GATTACA* (Sony Pictures 1997).

8. W. French Anderson, Remarks at the International Conference on Mammalian Cloning (June 26, 1997). See also Sheryl Gay Stolberg, *A Genetic Future Both Tantalizing and Disturbing*, *N.Y. TIMES*, Jan. 1, 2000, at E7.

9. See *infra* note 325 and accompanying text (discussing the American Management

denied insurance to healthy people either because genetic testing indicated they might become ill later in life¹¹ or because they had a relative with a genetic disease.¹²

Despite the potential for abuses with genetics and despite its historical misuse in the eugenics movements in Germany, the United States, and elsewhere,¹³ no comprehensive legal policy exists for regulating genetics. Legal questions abound regarding whether certain genetic services should be forbidden (such as the testing of minor children for late-onset diseases) or should be required (such as mandatory genetic testing by schools, insurers, employers, or public health officials).¹⁴

This Article presents the first attempt to develop a comprehensive legal framework governing the regulation of genetic information in the United States.¹⁵ Part II addresses the need for such legal framework. Part III analyzes three conceptual legal models that have been adopted in the past for regulating medical services: the medical model, the public health model, and the fundamental rights model. Part IV examines the results of medical and social scientific studies on the impact of genetic services. Part V addresses the impact of genetic services. Part VI revisits the three models to determine which is appropriate for genetics. Part VII discusses the legal justification for the fundamental rights model.

II. THE NEED FOR A LEGAL FRAMEWORK

From the beginning, participants in the HGP recognized the detrimental implications and potential for abuse of genetic information. In an extraordinary move, the first director of the project, Nobel Laureate James Watson, allocated three to five percent of the Project's scientific budget to

Association survey, which indicates that thirty percent of medium- and large-sized companies collect genetic information on employees).

10. See, e.g., *Norman-Bloodsaw v. Lawrence Berkeley Lab.*, 135 F.3d 1260 (9th Cir. 1998).

11. See *infra* notes 288-311 and accompanying text (discussing insurance discrimination).

12. See E. Virginia Lapham et al., *Genetic Discrimination: Perspectives of Consumers*, 274 *SCI.* 621, 622 (1996).

13. See, e.g., DANIEL J. KEVLES, *IN THE NAME OF EUGENICS: GENETICS AND THE USE OF HUMAN HEREDITY* (1985).

14. See Lori B. Andrews, *Gen-Etiquette: Are There Moral and Legal Responsibilities to Share Genetic Information Within Families?*, in *GENETIC SECRETS: PROTECTING PRIVACY AND CONFIDENTIALITY IN THE GENETIC ERA* 263 (Mark Rothstein ed., 1997).

15. The pressing need for this Article's analysis is underscored by the announcement in June 2000 that private and public researchers had completed a rough draft of the sequence of the entire human genome. See Rick Weiss & Justin Gillis, *Teams Finish Mapping Human DNA; Clinton, Scientists Celebrate "Working Draft" of Human Genetic Blueprint*, *WASH. POST*, June 27, 2000, at A1.

fund studies of the ethical, legal, and social implications of the Project.¹⁶ These studies provide a basis for determining the most appropriate policies to implement. Although researchers are providing the map to the human genome, it will be up to lawyers and other policymakers to determine where that map will lead.

Everyday, hundreds of policy decisions are made in genetics, such as whether a particular test should be offered, what information should be provided in advance of a test, and who should have access to the results of the test.¹⁷ Some of those decisions are most appropriately made by individuals, health care providers, or business organizations, while others should be addressed by professional or trade organization guidelines or formal laws or regulations. No matter at what level the issues are approached, all decision makers need a framework for the policies they promulgate and a way of predicting the likely impact of their decisions.

Genetic technologies are already embedded in our culture. Prenatal genetic testing, which assesses the health status of a fetus, has been used for nearly three decades, and the range of disorders being diagnosed has expanded exponentially. Prenatal testing is now possible not just for serious disorders,¹⁸ but also for less serious disorders, diseases that are treatable after birth, for disorders that do not manifest until later in life (such as breast cancer or the debilitating neurological disorder, Huntington's disease), and even for conditions that are not medical problems, such as homosexuality.¹⁹ Already, couples have sought genetic testing for Alzheimer's disease in their fetuses, intending to abort even though the child could have seventy or eighty years of a normal life before manifesting any symptoms of the disease.²⁰

Genetic testing has evolved from its focus on reproductive risks to become a major component of general health care. Increasing numbers of healthy people are tested for diseases that will not manifest until later in life, creating a new class of individuals referred to as the asymptomatic ill.²¹ For

16. See ROBERT COOK-DEEGAN, *THE GENE WARS: SCIENCE, POLITICS, AND THE HUMAN GENOME* 161-85 (1994).

17. For example, the four million women who are pregnant each year face the decision of whether to have amniocentesis; 2.5 million do so. National Center for Health Statistics, *Obstetrical Procedures*, at <http://www.cdc.gov/nchs/fastas/obgyn.htm> (last visited May 5, 2001).

18. An example of a disorder that most people consider to be serious is Tay-Sachs disease. Tay-Sachs disease is a fatal neurodegenerative disorder caused by a genetic mutation. It is very common among Ashkenazi Jews. See, e.g., Eleanor C. Landels et al., *Frequency of the Tay-Sachs Disease Splice and Insertion Mutations in the UK Ashkenazi Jewish Population*, 28 *J. MED. GENETICS* 177-80 (1991).

19. See MCKUSICK, *supra* note 2.

20. Bryan Christie, *The Human Map*, *SCOTSMAN*, May 13, 1996, at 14.

21. See, e.g., Bryce A. Lenox, Comment, *Genetic Discrimination in Insurance and Employment: Spoiled Fruits of the Human Genome Project*, 23 *U. DAYTON L. REV.* 189, 196 (1997).

some diseases, having a genetic mutation means that the person will almost certainly develop the disease. But other mutations only slightly increase the possibility that the person will fall ill.²² With such uncertainty, it is difficult for a person to determine how to incorporate this new information into his or her life.

The meaning of genetic tests varies widely. There are single gene disorders for which environmental factors or other genes may increase or decrease the likelihood that the disease will actually express itself.²³ In scientific terms, such mutations are not fully “penetrant,” that is, not everyone with the genetic mutation will manifest the disorder.²⁴ Often the gene indicates only a predisposition to a problem, and it takes an additional intervention, such as a particular environmental exposure, to trigger the condition.²⁵

Even for disorders that are completely penetrant, it is impossible to predict how severe the disease will be or when it will strike. Even though the average age of onset for Huntington’s disease is between thirty and fifty, children as young as two have been symptomatic of the disease, while other people have not manifested symptoms until their late seventies.²⁶ Similarly, some people with genetic mutations, such as the cystic fibrosis mutation, have such a mild manifestation of the disease (or even no symptoms whatsoever) that they never realize they have the disease.²⁷ Others with the same genetic profile may have serious health problems.²⁸

A. The Ethical Differences Between Genetics and Other Medical Realms

Genetics shares many features with other medical fields, but it also has several unique features that raise concerns about its impact on people’s lives. First, genetics often plays a central role in people’s lives. Because genes are usually viewed as immutable and essential to the determination of a person’s identity, information about genetic predispositions may cause a person to

22. Bernadine Healy, *BRCA Genes: Bookmaking, Fortunetelling, and Medical Care*, 336 *NEW ENG. J. MED.* 1448-49 (1997).

23. Robert Wachbroit, *Biotechnology and the Law: Making the Grade: Testing for Human Genetic Disorders*, 16 *HOFSTRA L. REV.* 583, 587-88 (1988).

24. Rhyidian Hapgood, *Essential Genetics for General Practice*, *PULSE*, Jan. 8, 2000, at 44.

25. Wachbroit, *supra* note 23, at 588.

26. Raymund A.C. Roos et al., *Age at Onset in Huntington’s Disease: Effect of Line of Inheritance and Patient’s Sex*, 28 *J. MED. GENETICS* 515-15 (1991).

27. See, e.g., Patrik S. Florencio, *Genetics, Parenting, and Child’s Rights in the Twenty-First Century*, 45 *MCGILL L.J.* 527, 536-37 (2000).

28. See generally D.R. Gill et al., *A Placebo-Controlled Study of Liposome-Mediated Gene Transfer to the Nasal Epithelium of Patients with Cystic Fibrosis*, 4 *GENE THER.* 199 (1997).

change his or her self-perception and may cause others to treat that person differently.²⁹ Second, people may undergo genetic testing or therapy without sufficient advance consideration of its potential effects.³⁰ In most instances, people seek medical services because they are already ill. However, biomedical companies and physicians have an incentive to heavily market predictive genetic testing, and, as a result, healthy people undergoing testing may not consider the psychological, social, and financial impact of learning genetic information about themselves before they agree to genetic testing. As one group of cancer researchers observed with respect to genetic testing, “[S]ociety’s technological capabilities have outpaced its understanding of the psychological consequences.”³¹

The therapeutic gap creates another problem to consider. Many diseases can be diagnosed through genetic testing, but few can be treated successfully. This gap presents enormous social and financial implications because an individual’s health insurer may drop him or her based on a genetic test result.³² It also exposes potentially risky medical implications. While genetic treatment and preventive strategies for asymptomatic individuals are being developed, positive results on a genetic test may lead to interventions that are costly, unnecessary, ineffective, or even harmful.³³ A woman who has a mutation in her breast cancer gene may have both her breasts surgically removed although she would never have developed cancer, for example.

Genetics has another unique feature. Genetic testing of a particular individual also reveals genetic risk information about his or her relatives. A parent and a child have half their genes in common, as do siblings.³⁴ Cousins share one-quarter of their genes, as do grandparents and grandchildren.³⁵ The acquisition and disclosure of genetic information raise new and profound questions of “gen-etiquette,”³⁶ questions about the moral obligations owed to relatives. If a woman learns she has a genetic mutation predisposing her to breast cancer, does she have a moral or even a legal duty to share that information with her sister? What about an estranged cousin?

In the past, genetic testing was generally used like other clinical testing—

29. See *infra* notes 132-201 and accompanying text.

30. Lori Andrews et al., *Informed Consent for Genetic Research on Stored Tissue Samples*, 274 JAMA 1786 (1995) [hereinafter Andrews et al., *Informed Consent*].

31. Andrew Baum et al., *Stress and Genetic Testing for Disease Risk*, 16 HEALTH PSYCHOL. 8, 9 (1997).

32. See insurance discussion *infra* Part V.D.

33. See Andrews et al., *Informed Consent*, *supra* note 30.

34. Stanton Peele & Richard DeGrandpre, *My Genes Made Me Do It*, PSYCHOL. TODAY, July-Aug. 1995, at 50-53, 62-68.

35. *Id.*

36. See Andrews, *supra* note 14.

in situations in which the patient was symptomatic or the patient's family history, age, or ethnic background suggested a particular risk.³⁷ Now genetic testing is suggested for the population at large to predict future diseases.³⁸ The idea seems seductively simple: one can look into the medical crystal ball, see one's future diseases, and try to prevent them. The reality is much more complicated, however. For most complex disorders, the genetic test gives ambiguous results.³⁹ Prevention and treatment strategies are uncertain as well.⁴⁰ Some diseases, such as Huntington's disease, have no known cures and lead to certain debilitation and death.⁴¹ Learning this information may cause a person to give up on his or her future or be alienated from or rejected by social institutions such as professional schools, insurers, or employers.⁴²

Genetic technologies influence our lives in a variety of ways, with profound effects. Yet there is no comprehensive policy framework for regulating such technologies. The genetics policies adopted thus far generally deal with specific, isolated genetics issues, such as the use of a particular type of genetic test (for example, cystic fibrosis carrier screening⁴³ or breast cancer testing⁴⁴) or the subsequent use of test results by a particular type of third party (for example, employers or insurers⁴⁵). The scholarly articles, too, usually focus on a particular application of the technology or a particular legal or ethical issue. Little attempt has been made to create an overall conceptual framework to regulate genetics.

Creating an overall framework would serve several useful functions. Analyzing alternative conceptual frameworks for genetics policy provides an opportunity to understand better the values that undergird professional and public policies in this area by allowing a closer scrutiny of the principles underlying specific policies. It transforms what may seem like an isolated

37. *Id.*

38. *Id.*

39. See generally Jeffrey P. Struewing et al., *The Risk of Cancer Associated with Specific Mutations of BRCA1 and BRCA2 Among Ashkenazi Jews*, 336 NEW ENG. J. MED. 1401 (1997).

40. See, e.g., Francis S. Collins, *BRCA1—Lots of Mutations, Lots of Dilemmas*, 334 NEW ENG. J. MED. 186, 187 (1996).

41. See generally Virginia Morell, *Huntington's Gene Finally Found*, SCI., Apr. 2, 1993, at 28.

42. See discussion *infra* Part V.D.

43. Cystic fibrosis is caused by a disorder of exocrine glands and is thought to be the most common, potentially fatal, genetic disease among Caucasians. Individuals with cystic fibrosis may have a variety of physical abnormalities. The most serious among these is chronic obstructive lung disease. OFFICE OF TECH. ASSESSMENT, U.S. CONG., *HEALTHY CHILDREN: INVESTING IN THE FUTURE* 263 (1988) [hereinafter *HEALTHY CHILDREN*].

44. See National Advisory Council for Human Genome Research, *Statement on Use of DNA Testing for Pre-Symptomatic Identification of Cancer Risks*, 271 JAMA 785 (1994).

45. See, e.g., Karen H. Rothenberg, *Genetic Information and Health Insurance: State Legislative Approaches*, 23 J. LAW, MED. & ETHICS 312 (1995).

individual case (e.g., should Aunt Millie be told that she, too, might have a gene predisposing her to breast cancer?) into a larger category of cases (e.g., to what extent should scientists, physicians, and policymakers facilitate people learning about their genetic make-up?). In addition, by assessing how alternative conceptual frameworks would address genetics issues where policies have not yet been adopted, the enterprise provides a basis for developing more forward-looking policies that can be readily invoked to handle new technologies or new issues, rather than relying on reactive policies to deal only with current crises.⁴⁶

The need for a framework with respect to genetics policy issues was raised by Robert Blank in his book *Regulating Reproduction*, where he noted that “by concentrating on one or several applications, the cumulative impact of reproductive and genetic technologies is obscured.”⁴⁷ Blank observed that the “fragmented [American] policy-making process and its tendency to focus on immediate, conspicuous problems has led to a failure to provide systematic, comprehensive assessment of the technologies or their implications for society.”⁴⁸

When technologies are introduced incrementally and when policies are adopted to deal with a few isolated issues at a time, there is less opportunity to stimulate a social debate about whether society is moving in the direction that people would like to go.⁴⁹ Some commentators criticize what they labeled the “extemporaneous” manner in which genetics policy has been made in the United States.⁵⁰ They argue in favor of using an “evidentiary” approach incorporating an evaluation of research and attention to underlying normative issues.⁵¹ Their focus is on clinical medical research, but it is important to consider research from a wider variety of disciplines, such as anthropology, sociology, philosophy, history, and linguistics.

46. The biomedical policy area is replete with examples of policy that does not get adopted until there is a visible public case and the policy that is adopted is not very helpful because it is narrowly tailored to the facts of that case. In the early 1980s, for example, a number of legislatures considered bills that would have dealt with surrogate motherhood in a comprehensive fashion. *See, e.g.,* LORI B. ANDREWS, *NEW CONCEPTIONS: A CONSUMER'S GUIDE TO THE NEWEST INFERTILITY TREATMENTS, INCLUDING IN VITRO FERTILIZATION, ARTIFICIAL INSEMINATION, AND SURROGATE MOTHERHOOD* 237-41 (1985) (describing proposed Michigan law). However, it was not until after the much-publicized Baby M case that lawmakers began to adopt laws in this area, and the laws were only tailored to the problems raised by the one case. *See* LORI ANDREWS, *BETWEEN STRANGERS: SURROGATE MOTHERS, EXPECTANT FATHERS, & BRAVE NEW BABIES* (1989).

47. ROBERT H. BLANK, *REGULATING REPRODUCTION* 139 (1990).

48. *Id.* at 180.

49. *See* MARQUE-LUISA MIRINGOFF, *THE SOCIAL COSTS OF GENETIC WELFARE* 25-27 (1991).

50. *See* Benjamin S. Wilfond & Kathleen Nolan, *National Policy Development for the Clinical Application of Genetic Diagnostic Technologies*, 270 *JAMA* 2948 (1993).

51. *Id.*

III. THREE PROPOSED CONCEPTUAL FRAMEWORKS

Genetic technologies raise issues that cut to the core of what it means to be human and what it means to be a just and fair society. The significance of those technologies, however, has not been addressed in a systematic way by policymakers in the United States. Instead, a chaotic series of pronouncements by different agencies, medical organizations, health care institutions, and legislatures has addressed narrow issues or isolated subcategories of genetic technologies. The result has been unnecessary duplication of effort, conflicting guidelines, and specialized policies that can cause harm when applied in an inappropriately wide manner.

Concerns about appropriate uses of certain genetic technologies have been addressed by a variety of professional and governmental entities,⁵² including the Institute of Medicine of the National Academy of Sciences, the National Institutes of Health (NIH)/Department of Energy Working Group on the Ethical, Legal, and Social Implications Program of the Human Genome Project,⁵³ the National Bioethics Advisory Commission,⁵⁴ the (now-defunct) Office of Technology Assessment (OTA) of the U.S. Congress,⁵⁵ and professional organizations such as the American Society of Human Genetics⁵⁶ and the American College of Medical Genetics.⁵⁷ These entities have addressed each issue with ad hoc committees meeting for limited periods of time, without a mechanism for situating the subject they are addressing within a larger social context. In addition, these entities are usually reactive, springing into action once a particular technology has been developed. The discovery of the genetic mutation associated with cystic fibrosis, for example, initiated a series of policy deliberations about the use of

52. See *ASSESSING GENETIC RISKS: IMPLICATIONS FOR HEALTH AND SOCIAL POLICY* 290-307 (Lori B. Andrews et al. eds., 1994) [hereinafter *ASSESSING GENETIC RISKS*].

53. See National Action Plan on Breast Cancer & the NIH-DOE Working Group on Ethical, Legal, and Social Implications of Human Genome Research, Genetic Discrimination and Health Insurance: A Case Study on Breast Cancer (July 11, 1995) (presentation at conference in Bethesda, MD) (on file with author) [hereinafter *Conference on Genetic Discrimination and Health Insurance*].

54. See NAT'L BIOETHICS ADVISORY COMM'N, *CLONING HUMAN BEINGS: EXECUTIVE SUMMARY REPORT AND RECOMMENDATIONS OF THE NATIONAL BIOETHICS ADVISORY COMMISSION* (1997).

55. See, e.g., OFFICE OF TECH. ASSESSMENT, U.S. CONG., *HUMAN GENE THERAPY* (1984); OFFICE OF TECH. ASSESSMENT, U.S. CONG., *GENETIC MONITORING AND SCREENING IN THE WORKPLACE* (1990) [hereinafter *GENETIC MONITORING AND SCREENING*].

56. See C. Thomas Cashey et al., *American Society of Human Genetics Statement on Cystic Fibrosis Screening*, 46 *AM. J. HUM. GENETICS* 393 (1990).

57. See AM. COLL. OF MED. GENETICS STORAGE OF GENETICS MATERIALS COMM., *Statement on Storage and Use of Genetic Materials*, 57 *AM. J. HUM. GENETICS* 1499 (1995).

the cystic fibrosis test by professional organizations, the NIH, and the OTA.⁵⁸

These efforts have suffered from several deficiencies. Some groups have been influenced by the governmental or professional organizations that formed them and have not adequately represented the public.⁵⁹ Other committees made guidelines in a vacuum with neither adequate staffing nor a mechanism to collect data to assess the impact of their proposed guidelines. Still others addressed only the physical risks of proposed procedures, not the social values at stake.

Limiting the parameters of inquiry overlooks the fact that studies find that “risk is less significant than moral acceptability in shaping public perceptions of biotechnology.”⁶⁰ Consequently, members of the public “do not find the language of objective risk assessment adequate, arguing that risks are fundamentally moral and political.”⁶¹ Moreover, efforts to date often failed to address the real life situations in which people make decisions about genetics. For example, the OTA report about genetic testing for cystic fibrosis provided elaborate economic formulas about the cost savings to society if women aborted fetuses affected with cystic fibrosis.⁶² However, the formulas ignored data about how women make such decisions and what proportion of women pregnant with fetuses affected with cystic fibrosis would use testing for such purposes.⁶³

A more systematic approach for addressing genetic technologies would be to develop a central set of principles that apply to all such technologies and serve as a starting point in the development of regulatory policy. Any deviation from those principles would then have to be justified by sufficient evidence and analysis. But how can such principles be derived? A promising approach is to analyze the conceptual frameworks that govern the adoption of other medical technologies in the United States to determine which one is the

58. See, e.g., HEALTHY CHILDREN, *supra* note 43. Workshop on Population Screening for the Cystic Fibrosis Gene, *Statement from the National Institutes of Health Workshop on Population Screening for the Cystic Fibrosis Gene*, 323 NEW ENG. J. MED. 70 (1990).

59. See ANDREWS, *THE CLONE AGE*, *supra* note 1, at 184-206.

60. Biotechnology and the European Public Concerted Action Group, *Europe Ambivalent on Biotechnology*, 371 NATURE 845, 845 (1997).

61. *Id.* at 947. The researchers note that this is in keeping with ULRICH BECK, *RISK SOCIETY: TOWARDS A NEW MODERNITY* (1992), and ANTHONY GIDDENS, *THE CONSEQUENCES OF MODERNITY* (1990).

62. OFFICE OF TECH. ASSESSMENT, U.S. CONG., *CYSTIC FIBROSIS AND DNA TESTS: IMPLICATIONS OF CARRIER SCREENING 39-40* (1992) [hereinafter *CYSTIC FIBROSIS AND DNA TESTS*].

63. In its cost-benefit analyses, the OTA Committee assumed in most of the scenarios that one hundred percent of women with affected fetuses would abort. *Id.* This assumption is inconsistent with studies of carrier/carrier couples in which only twenty percent of the couples said they would abort an affected fetus. Dorothy C. Wertz et al., *Attitudes Toward Abortion Among Parents of Children with Cystic Fibrosis*, 81 AM. J. PUB. HEALTH 992, 995 (1991).

most appropriate for genetics.

The diagnosis and treatment of disease have long been the focus of social policy debates. Concerns about access to health care services and their cost, quality, and social impact have led to a variety of professional, institutional, and legal guidelines from medical licensing laws to drug safety regulations. Three different models dominate health care services regulations today: the medical model, the public health model, and the fundamental rights model. Determining the appropriate application of each model depends upon the perceived risks and benefits of the health care service at issue and the aspect of a person's life the service addresses. Choosing the wrong public policy response to genetics could aggravate the negative impacts of genetic services.⁶⁴ Moreover, the policies we develop are a crucial statement about "who we are and what we value."⁶⁵

A. The Medical Model

The medical model is the most common approach to setting policy for health care services in the United States. This model assumes that people will have access to particular health care services, as long as they can afford them and as long as health care providers are willing to offer them. Although this model emphasizes individual patient decisions, the physician is ultimately the gatekeeper for health care services and can be the driving force in recommending such services. Issues such as quality assurance and confidentiality are generally left to the standards of the medical profession.

The underlying premise of the medical model is that physicians can judge which interventions a patient requires. In fact, for many generations, patients were expected to do whatever the doctor ordered. In 1957, a California court introduced for the first time the legal requirement of informed consent into the medical model. Under this doctrine, a physician must give patients sufficient information in advance of a proposed treatment to make a knowing decision about whether to undergo it.⁶⁶ At least twenty-three states have adopted informed consent statutes requiring physicians to give patients certain information before a proposed treatment (and, in some instances,

64. "The imprimatur of public policy can foster beliefs that eventually prove to have little basis in fact," observed geneticist Neil A. Holtzman. Interview with Neil A. Holtzman, MD, MPH, Johns Hopkins University Medical Institutions (Nov. 1, 1998).

65. Message from David Dingwall, Canadian Minister of Health, *in* NEW REPRODUCTIVE AND GENETIC TECHNOLOGIES: SETTING BOUNDARIES, ENHANCING HEALTH (1996) ("New genetic technologies concern the future of our society. How we manage them will be no less than a statement of who we are and what we value.")

66. *Salgo v. Leland Stanford Jr. Univ. Bd. of Trs.*, 317 P.2d 170, 181 (Cal. 1957).

before a diagnostic procedure as well), including the nature of the patient's condition and the risks, benefits, and alternatives to the proposed intervention.⁶⁷

The legal ideal of informed consent is rarely seen in practice, however.⁶⁸ A typical study found "that it was common in the hospitals studied for physicians to fail to inform patients about the nature, purpose, and risks of a planned procedure in a way that would enable them to make meaningful decisions."⁶⁹ In part, physicians' lack of disclosure is due to a profound misunderstanding of what patients actually want to know.⁷⁰ While only thirteen percent of physicians in one study said they would give "a straight statistical prognosis" to patients with advanced lung cancer, eighty-five percent of the public indicated that they wished to have that sort of information.⁷¹ A study on the communication between physicians and patients with cancer showed that seventy-five percent of elderly patients diagnosed with cancer felt that their doctors "created undue worry by not providing them with enough information."⁷² Another study found that forty percent of cancer patients felt they "were not fully informed about their diagnosis, prognosis and treatment."⁷³ Moreover, in most states, the scope of the disclosure is determined by the medical profession itself. Physicians are only "required to disclose that information which other minimally competent physicians would disclose in like or similar circumstances."⁷⁴ In a minority of states, the standard is based on patient needs. Physicians in those states must disclose what a reasonable patient would want to know before making

67. See Lori B. Andrews, *Informed Consent Statutes and the Decisionmaking Process*, 5 J. LEGAL MED. 163 (1984).

68. JAY KATZ, *THE SILENT WORLD OF DOCTOR AND PATIENT* 1 (1984), points out that "disclosure and consent, except in the most rudimentary fashion, are obligations alien to medical thinking and practice."

69. Charles Lidz & Alan Meisel, *Informed Consent and the Structure of Medical Care*, in 2 MAKING HEALTH CARE DECISIONS: THE ETHICAL AND LEGAL IMPLICATIONS OF INFORMED CONSENT IN THE PATIENT-PRACTITIONER RELATIONSHIP 399-405 (President's Commission for the Study of the Ethical Problems in Medicine and Biomedical and Behavioral Research ed., 1982).

70. In one survey, eighty-eight percent of physicians believed "patients want doctors to choose for them the best alternative." In contrast, seventy-two percent of the public said they wanted the decisions to be made jointly. 1 MAKING HEALTH CARE DECISIONS: THE ETHICAL AND LEGAL IMPLICATIONS OF INFORMED CONSENT IN THE PATIENT-PRACTITIONER RELATIONSHIP (President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research ed., 1982).

71. *Id.* at 75.

72. *Behavioral Medicine*, DENVER ROCKY MOUNTAIN NEWS, Sept. 6, 1998, at 1F.

73. *Id.*

74. Mary Anne Bobinski, *Autonomy and Privacy: Protecting Patients from Their Physicians*, 55 U. PITT. L. REV. 291, 343 (1994).

the decision.⁷⁵

Thus, under the medical model, informed consent receives little attention. This lack of attention is thought to be tolerable because people seek medical services when they already have a health problem, and because physicians are thought to be acting in the patient's best interest by providing those services. For example, there is little protest when certain routine, noninvasive blood tests are undertaken without advance explanation.⁷⁶

Medical malpractice suits are the mechanism on which the medical model relies to address concerns about the quality of care. Patients may sue health care providers who fail to meet the "standard of care."⁷⁷ Unlike other areas of law where the standards of behavior are externally imposed, the medical profession itself sets the standard of care in medicine. A physician has a duty to follow the standards set by the majority of the profession (or, at least, a "respectable minority" of the profession).⁷⁸ Even if the profession provides abysmal care for a particular disorder, a physician who meets that low standard is not liable for bad outcomes. Only on extremely rare occasions have courts held that the standards of a particular medical field were so low that a different standard should govern.⁷⁹

The medical malpractice system of quality assurance relies on a particular signaling method for error. It assumes that the patient is able to decide by his or her worsened condition that an error has occurred. When a physician fails to diagnose a cancer and the condition subsequently manifests, the patient is usually aware that an error has been made. When an improper medical or surgical treatment is undertaken, the patient may be aware of the error because of the resulting harm or because of the need for a corrective treatment. Of course, this approach is far from perfect. Patients whose conditions worsen may believe their declining state results from their underlying illness and not realize that it results from the physician's

75. LORI ANDREWS, *MEDICAL GENETICS: A LEGAL FRONTIER* 110 (1987) [hereinafter ANDREWS, *MEDICAL GENETICS*]. The most famous decision using the reasonable patient standard is *Canterbury v. Spence*, 464 F.2d 772 (D.C. Cir. 1972).

76. When a patient's blood is tested in a chemistry profile, a hospital's test for liver disease, kidney disease, and other diseases without explaining each test in detail.

77. BARRY R. FURROW ET AL., *HEALTH LAW: CASES, MATERIALS AND PROBLEMS* (3d ed. 1997).

78. *Id.*

79. *See, e.g., Helling v. Carey*, 519 P.2d 981, 983 (Wash. 1974) (holding that although it is the medical standard to only offer a glaucoma test to patients over the age of forty, "the reasonable standard that should have been followed [in this case, where the plaintiff was under the age of forty] was the timely giving of this . . . test"). This case is only one of a handful of such cases. Moreover, immediately after the case, the Washington legislature tried to avoid future cases by passing a statute, WASH. REV. CODE ANN. § 4.24.290 (West 2001), requiring that plaintiffs in malpractice actions prove that the physician had violated the medical standard of care.

negligence.

Currently, the medical model regulates most genetic services. Under it, physicians are the source of information about genetic tests, although the fast pace of gene discovery may make it difficult for physicians to keep their knowledge current. If genetic tests or services are performed negligently, the only recourse for patients would be a malpractice suit. The harm, however, might not be discovered until years later, past the time within which patients are allowed to bring suit.⁸⁰ An erroneous “normal” result on a genetic cancer test, for example, may not be discovered until after the person developed cancer decades later. Certain side effects of gene therapy on embryos—such as sterility—may not be possible to detect until the child reaches reproductive age.

The medical model is most appropriate in a situation where physicians have a high level of knowledge about the health care service at issue, the service has a clear benefit to the patient, negligence is easily detectable, and use of the service does not have potential to harm the patient physically, psychologically, or socially in a way that might cause the patient to reject the service. Determining whether the medical model should apply requires an assessment of the capability of the medical system to deliver genetic services in a high quality way and the extent to which new genetic services such as testing to predict later-onset disorders require more attention to patient consent than do other medical services.

B. The Public Health Model

A less common approach for regulating health care services is known as the public health model.⁸¹ The public health model attempts to prevent disease through education, the financing of certain health care services, and, in some instances, mandating interventions such as vaccinations.⁸² Generally, public health measures are invoked to prevent imminent, substantial hazards to the population at large through efforts to eradicate infectious disease.⁸³

80. Several cases have already held that the statute of limitations in situations involving genetics runs from the time of the negligent act, rather than from the time the patient learns that the test result was wrong. *Taylor v. Kurapati*, 600 N.W.2d 670 (Mich. Ct. App. 1999); *Weed v. Meyers*, 674 N.Y.S.2d 242 (N.Y. App. Div. 1998). This determination would preclude suit, for example, for a person who was told negligently that he or she did not have a gene mutation for Huntington’s disease and later developed the disease.

81. See, e.g., Patricia A. Baird & Charles R. Scriver, *Genetics and the Public Health*, in *PUBLIC HEALTH & PREVENTIVE MEDICINE* 983 (John M. Last & Robert B. Wallace eds., 13th ed. 1992).

82. See, e.g., Daniel A. Cantor, *Striking a Balance Between Product Availability and Product Safety: Lessons from the Vaccine Act*, 44 AM. U. L. REV. 1853, 1860 (1995).

83. See generally Lawrence O. Gostin & James G. Hodge, Jr., *The “Names Debate”: The Case*

The classic mandate for public health came when health benefits could only be realized through intervention that required participation of the public as a whole. This dictate involved such efforts as the development of sewers, fluoridation of water, certain infectious disease screening programs (such as syphilis testing prior to marriage), and vaccination.⁸⁴

Mandatory intervention, such as vaccination, is used very rarely in health care. The laws that were adopted to require vaccinations, and the U.S. Supreme Court decision that upheld them,⁸⁵ occurred at a time when infectious diseases such as smallpox and typhoid threatened to kill off whole towns. Smallpox had already killed sixty million people in eighteenth century Europe.⁸⁶ The Court likened society's ability to vaccinate people to its ability to draft citizens to defend itself in wartime.⁸⁷ The principle behind the vaccination laws is one of reciprocity:⁸⁸ mandatory vaccination of a particular individual protects other members of the community, while mandatory vaccination of others protects the individual. Historically, courts have not ordered nontherapeutic medical interventions for the benefit of an identifiable third party. For example, no cousin,⁸⁹ father,⁹⁰ or half-sibling⁹¹ has been forced to provide bone marrow to a relative. Nor has a hospital been required to disclose the name of a potential bone-marrow donor to a patient dying of leukemia.⁹²

Another prime tenet of public health has been education. At the founding of the public health field, education focused mainly on information about the prevention of infectious disease. More recently, public health education has been focused on disease prevention through antismoking campaigns,⁹³ proper nutrition messages,⁹⁴ and information for pregnant women.⁹⁵ These

for *National HIV Reporting in the United States*, 61 ALB. L. REV. 679, 705-09 (1998).

84. *Jacobson v. Massachusetts*, 197 U.S. 11, 30-31 (1905) ("The state legislature proceeded upon the theory which recognized vaccination as at least an effective if not the best known way in which to meet and suppress the evils of a smallpox epidemic that imperiled an entire population.").

85. *Id.*

86. Daniel F. Roses, *From Hunter and the Great Pox to Jenner and Smallpox*, 175 SURGERY GYNECOLOGY & OBSTETRICS 365, 366 (1992).

87. *Jacobson*, 197 U.S. at 29.

88. Janet Gallagher, *Prenatal Invasions and Interventions: What's Wrong with Fetal Rights*, 10 HARV. WOMEN'S L.J. 9, 24-25 (1987).

89. *McFall v. Shimp*, 10 Pa. D. & C.3d 90 (1978).

90. *In re George*, 625 S.W.2d 151 (Mo. App. 1981).

91. *Curran v. Bosze*, 566 N.E.2d 1319 (Ill. 1990).

92. *Head v. Colloton*, 331 N.W.2d 870 (Iowa 1983).

93. See, e.g., Lawrence O. Gostin et al., *The Law and the Public's Health: A Study of Infectious Disease Law in the United States*, 99 COLUM. L. REV. 59, 79 (1999).

94. *Id.* at 80.

95. See generally Jennifer Sinton, Note, *Rights Discourse and Mandatory HIV Testing of Pregnant Women and Newborns*, 6 J.L. & POL'Y 187 (1997) (discussing issues surrounding mandatory

educational messages are directed to people who may not perceive themselves as ill and may not seek a physician who would otherwise provide the medical information.

Currently, there is a move to apply the public health model to an increasing number of genetic services. Genetics is “the ultimate public health issue,”⁹⁶ according to Muin Khoury, head of the Center for Disease Control and Prevention’s new Office of Genetics. A range of policies are in place to address genetics within a public health model.⁹⁷ These policies include a variety of efforts to enhance awareness of and to encourage the use of genetic technologies, such as a California regulation requiring obstetricians to offer maternal serum alpha-fetoprotein (MSAFP) testing to pregnant women in order to evaluate whether their fetuses have spina bifida or other neural tube defects.⁹⁸ They also include efforts to make genetic services available to low-income people, such as the public funding of amniocentesis under Medicaid programs in forty-five states.⁹⁹

States have also adopted and, in some cases, repealed laws that required people to use certain genetic services. At the turn of the twentieth century, statutes in more than twenty-five states required the sterilization of institutionalized people thought to have disfavored genetic traits.¹⁰⁰ In the early 1970s, many states passed laws mandating the sickle cell anemia screening of African Americans.¹⁰¹ Both sets of these laws have now been repealed.¹⁰² Currently, state laws mandate the use of genetic services in only one instance: newborn genetic screening. In five states, laws mandate that blood samples be taken of newborns to be tested for genetic disorders such as phenylketonuria (PKU), a genetic disorder that can cause mental retardation if the infant is not treated soon after birth, and congenital hypothyroidism.¹⁰³ In forty other states, parents ostensibly have the right to refuse newborn

HIV testing of pregnant women).

96. *CDC Speaks Out on Gene Testing: Won't Scan Healthy Population*, MEDICAL UTILIZATION MANAGEMENT, May 28, 1998, available at NEXUS, Lexis Library, News Group file.

97. For a summary of some of these approaches, see Lori B. Andrews, *Public Choices and Private Choices: Legal Regulation of Genetic Testing*, in JUSTICE AND THE HUMAN GENOME PROJECT (Marc A. Lappé & Timothy F. Murphy eds., 1994).

98. CAL. CODE REGS. tit. 17, § 6527 (2000).

99. CYSTIC FIBROSIS AND DNA TESTS, *supra* note 62, at 28. Currently, there is varied coverage of genetic testing and counselling by state Medicaid programs. For example, forty-five state Medicaid programs cover amniocentesis and twenty-six state Medicaid programs cover DNA analysis. *Id.*

100. PHILIP REILLY, THE SURGICAL SOLUTION: A HISTORY OF INVOLUNTARY STERILIZATION IN THE UNITED STATES 94 (1991).

101. ANDREWS, MEDICAL GENETICS, *supra* note 75, at 18.

102. *Id.* at 15, 18.

103. *See id.* at 238.

screening,¹⁰⁴ but most of them are not told that they have such a right so testing is de facto mandatory.

Under the public health model, the classic case for the use of the educational component occurs when there is widespread consensus that a particular lifestyle choice (e.g., smoking, unprotected sexual intercourse, lack of prenatal care) is dangerous and that making certain information available will help avert the danger by encouraging people to change their behavior. The mandatory intervention aspect of the public health model is most appropriately applied to prevent the transmission of serious diseases to large numbers of people. Determining whether genetics should be handled within the public health model requires assessments of the seriousness of a disorder, of whether prevention can adequately be achieved, and of whether prevention itself is an appropriate goal. While society might achieve near-consensus about the appropriateness of vaccination to prevent measles, it is unlikely there would be support for mandatory prenatal diagnosis and abortion as a way to prevent particular genetic diseases.

C. The Fundamental Rights Model

A third approach, the fundamental rights model, is applied to health care services that are central to our notions of ourselves, such as reproductive services. The fundamental rights model attempts to ensure that a health care service takes place only voluntarily, with extensive information given in advance, and only when quality assurance mechanisms exist. In these situations, governmental restrictions on health care services require greater justification according to the courts. Decisions about reproduction can logically apply a fundamental rights approach because such decisions provide important ways of expressing ourselves and have a vast impact on our lives. The decision whether or not to have a child expresses an individual's personal beliefs and has a significant impact on his or her lifestyle. Certain U.S. Supreme Court decisions, for example, recognize that a woman's ability to employ contraception methods and to undergo an abortion allows her to pursue other important means of personal development, such as education and employment.¹⁰⁵ Under the fundamental

104. *Id.*

105. *See, e.g.,* Planned Parenthood of Southeastern Pa. v. Casey, 505 U.S. 833 (1992). The U.S. Supreme Court in *Casey* said:

[F]or two decades of economic and social developments people have organized intimate relationships and made choices that define their views of themselves and their places in society, in reliance on the availability of abortion in the event that contraception should fail. The ability of women to participate equally in the economic and social life of the Nation has been facilitated by

rights approach, use of a particular health care service (such as sterilization or abortion) must be voluntary and uncoerced.¹⁰⁶ In addition, an individual is entitled to have access to necessary information before undergoing the service. Under a federal law, for example, in vitro fertilization (IVF) clinics must disclose their success rates.¹⁰⁷ In several states, lengthy disclosures must be made about the medical and psychological backgrounds of proposed surrogate mothers.¹⁰⁸

The fundamental rights model allows for enhanced regulation of quality assurance when the usual tort incentives to behave nonnegligently do not operate with enough force in a particular field. This is particularly true with respect to reproductive technologies where the harm from an error might not be discovered until the next generation.¹⁰⁹ In addition, reproductive technologies do not have the same signaling system with regard to malpractice, as compared to other areas of medicine. When a patient is ill and undergoes surgery where negligence occurs, the patient's condition can worsen. When a healthy couple experiences negligence in an in vitro fertilization process, however, their own physical health does not generally suffer. Because IVF has only about a twenty-eight percent success rate,¹¹⁰ the couple may not realize or be able to prove that negligence has occurred. They may think, or be led to believe, that they are just in the unlucky seventy-two percent. Consequently, some states have adopted statutes to regulate the qualifications of the personnel who perform IVF¹¹¹ and to require that clinics disclose success rates.¹¹²

their ability to control their reproductive lives.

Id. at 856.

106. *See, e.g.*, 42 U.S.C. § 300a-5 (1994); 42 C.F.R. §§ 50.203-205, 441.250-259 (1999). Family planning sterilizations performed with federally assisted funding are permissible only after obtaining noncoerced, voluntary, and informed consent from competent patients. Health care providers in federally assisted family planning projects are prohibited from performing sterilizations on individuals from whom they did not obtain informed consent. The federal guidelines include specific provisions that must be met when acquiring informed consent prior to the procedure. The federal requirements exist to ensure that people who undergo sterilization procedures do so voluntarily and knowingly.

107. 42 U.S.C. § 263a-1(a) (1994). Virginia has a similar law. VA. CODE ANN. § 54.1-2971.1 (2000).

108. *See, e.g.*, VA. CODE ANN. § 20-160 (2000).

109. For example, if a new fertilization technique leads to sterilization in offspring, it will not be discovered until the next generation.

110. Based on live births per retrieval for fresh, nondonor cycles IVF was 27.7% successful in 1997. U.S. DEP'T OF HEALTH & HUMAN SERVICES, CENTERS FOR DISEASE CONTROL & PREVENTION ET AL., 1997 ASSISTED REPRODUCTIVE TECHNOLOGY (ART) SUCCESS RATES, NATIONAL SUMMARY AND FERTILITY CLINIC REPORTS fig. 8, at 17, available at <http://www.cdc.gov/nccdphp/drh/art97/pdf/ART97.pdf> (Dec. 1999).

111. *See, e.g.*, LA. REV. STAT. ANN. § 9:128 (2000).

112. *See, e.g.*, VA. CODE ANN. § 54.1-2971.1 (2000).

The fundamental rights approach has an additional role: protecting certain groups of patients from discrimination. The U.S. Constitution guarantees equal protection of laws;¹¹³ therefore, government-funded entities cannot discriminate against patients based on race, gender, religion, or ethnic status.¹¹⁴ Additional federal and state statutes provide further protection. The Americans with Disabilities Act, for example, prohibits employers, health care providers, and other groups from discriminating against patients based on their disability.¹¹⁵ Some state human rights statutes prohibit discrimination against people based on race, gender, and marital status.¹¹⁶ City ordinances, too, may provide additional protections, such as prohibition against discrimination based on sexual preference.¹¹⁷ In some instances, the fundamental rights approach also serves as a justification for requiring public funding for additional genetics services for people who cannot afford them.¹¹⁸

The fundamental rights approach has been applied to certain genetics services, most often those involving reproduction. In *Lifchez v. Hartigan*, a federal court struck down a state statute banning embryo and fetal research because it prohibited couples from using experimental forms of prenatal testing (such as chorionic villi sampling, which was considered experimental at the time) to learn genetic information about the fetus.¹¹⁹ The court held that because people have a fundamental right to privacy when making reproductive decisions,¹²⁰ they also have a fundamental right to certain information needed to make those decisions.¹²¹ Legislatures in six states have mirrored this fundamental rights policy by allowing experimental genetic

113. U.S. CONST. amend. XIV, § 1.

114. 42 U.S.C. § 2000d (1994).

115. *See, e.g.*, 42 U.S.C. § 12182(a) (1994).

116. Under the Illinois Human Rights Act, for example, an employer may not discriminate unlawfully. 775 ILL. COMP. STAT. 5/2-102(a) (1998).

117. Under the City of Chicago Human Rights Ordinance, employers may not discriminate against employees or applicants based on race, color, sex, age, religion, disability, national origin, ancestry, sexual orientation, marital status, parental status, military discharge status, or source of income. CHICAGO, IL, ORDINANCES, § 2-160-030 (1998).

118. Under the existing fundamental rights analysis with respect to abortion, the U.S. Supreme Court has taken the position that federal constitutional law does not require the public funding of abortion. *See Webster v. Reprod. Health Serv.*, 492 U.S. 490 (1989). However, some state legislatures have enacted laws funding abortion for poor women and some courts have held that the state constitution requires funding of abortion to enable women to exercise their fundamental right to privacy to make reproductive decisions. *See, e.g., Moe v. Sec'y of Admin. & Fin.*, 417 N.E.2d 387, 399-400 (Mass. 1981).

119. 735 F. Supp. 1361 (N.D. Ill. 1990).

120. *Lifchez*, 735 F. Supp. at 1376.

121. *Id.* at 1377.

screening of embryos.¹²²

The fundamental rights approach applies well to situations in which health care providers may lack necessary information or may be unduly influenced by their personal feelings. It is considered to be the most appropriate approach when the decision to use or to refuse a particular health care service has an impact on how the individual is viewed and treated by social institutions. The fundamental rights model is also used if traditional malpractice law is inadequate to assure quality.

IV. USING EMPIRICAL DATA ABOUT THE IMPACT OF GENETIC SERVICES TO DEVELOP POLICY

Genetic testing generates information unparalleled in scope compared to other areas of medicine. People can learn that, decades later, they will suffer from an untreatable disorder,¹²³ that they have an increased risk of cancer,¹²⁴ or that their children have a one-in-four chance of dying of a serious disorder in childhood.¹²⁵ The impact of this knowledge has a profound effect on people's lives by challenging their self-image,¹²⁶ by altering their cultural and social identity,¹²⁷ and by changing their relationships with family and friends,¹²⁸ and by causing them to think about their life, health, and responsibilities in new ways.

Medical and social scientific studies provide data on the effects of genetic technologies, and these studies can be used to analyze the potential impact of adopting policies based on a particular conceptual framework. The studies show that learning about one's genetic information can have a negative impact on one's self-concept, can significantly change the way one experiences pregnancy, can change one's personal relationships, and can lead to stigmatization and discrimination by others.¹²⁹

The dizzying assortment of available genetic services raises challenges for people as individuals and as members of a larger community. In the near future, every person will be faced with the question of whether he or she should undergo genetic testing. In some instances, people will even find—as

122. MASS. GEN. LAWS ANN. ch. 112, § 12J (West 2001); MICH. COMP. LAWS §§ 333.2685-92 (West 2000); N.H. REV. STAT. ANN. § 168-B:15(II) (2000); N.D. CENT. CODE § 14-02.2-01(3) (2000); R.I. GEN. LAWS § 11-54-1(c) (2001); UTAH CODE ANN. § 76-7-310 (2000).

123. For example, one may have advance knowledge of Huntington's disease.

124. For example, genetic testing can reveal an increased risk of breast cancer.

125. For example, one may test for recessive genetic diseases.

126. See *infra* Part IV.A.

127. See *infra* Part IV.B.

128. See *infra* Part IV.C.

129. See *infra* notes 132-201 and accompanying text.

hundreds of people have already found—that they have been tested without their knowledge or consent.¹³⁰ Third parties such as insurers, employers, and courts may be making decisions about a person based on his or her genes.¹³¹

A. Self-Concept

The information that is generated through the use of genetic technologies has an impact on a person's emotional well-being and self-concept.¹³² An individual's carrier status for a recessive disease will have no effect on his or her health, and although he or she may objectively understand that fact, carriers tend to have more negative feelings about their future health than the general population.¹³³ In an eight-year follow-up study on individuals who had been screened for Tay-Sachs carrier status when in high school, forty-six percent recalled that they were upset at the time of their result,¹³⁴ and approximately twenty percent remained worried six to eight years later.¹³⁵ Genetic information can affect people's reproductive behavior, including their willingness to conceive a child,¹³⁶ to continue a pregnancy,¹³⁷ or to use alternative reproduction technologies, such as gamete or embryo donation or adoption to become a parent.¹³⁸ It can change the way women experience both pregnancy and motherhood.¹³⁹ The existence of prenatal diagnostic technologies also changes concepts about what type of children are "normal" and worthy of a mother's unconditional love. A poll found that twelve

130. See, e.g., *Norman-Bloodsaw v. Lawrence Berkeley Lab.*, 135 F.3d 1260 (9th Cir. 1998).

131. See *supra* Part V.D for a discussion of genetic discrimination.

132. See, e.g., Mark Lipkin, Jr. et al., *Genetic Counseling of Asymptomatic Carriers in a Primary Care Setting*, 105 ANNALS INTERNAL MED. 115 (1986). There are also speculative philosophical writings about how genetic technologies might change self-concept. See, e.g., Dan W. Brock, *The Human Genome Project and Human Identity*, 29 HOUS. L. REV. 7 (1992).

133. Theresa M. Marteau, *Psychological Implications of Genetic Screening*, in 28 BIRTH DEFECTS: ORIGINAL ARTICLE SERIES 185, 186-87 (1992). Although Tay-Sachs carriers viewed their current health status no differently than noncarriers, carriers' perception of future health and risk of illness was significantly more negative than noncarriers. *Id.*

134. Susan Zeeman et al., *A Private View of Heterozygotes: Eight-Year Follow-Up Study on Carriers of the Tay-Sachs Gene Detected by High School Screening in Montreal*, 18 AM. J. MED. GENETICS 769, 772 (1984).

135. *Id.*

136. See Nancy Wexler, *Clairvoyance and Caution: Repercussions from the Human Genome Project*, in THE CODE OF CODES: SCIENTIFIC AND SOCIAL ISSUES IN THE HUMAN GENOME PROJECT 211-43 (Daniel J. Keveles & Leroy Hood eds., 1992).

137. See Mitchell S. Golbus et al., *Prenatal Genetic Diagnosis in 3000 Amniocenteses*, 300 NEW ENG. J. MED. 157 (1979).

138. See Michael K. McCormack et al., *Attitudes Regarding Utilization of Artificial Insemination by Donor in Huntington's Disease*, 14 AM. J. MED. GENETICS 5-13 (1983).

139. See Barbara Katz Rothman, *The Tentative Pregnancy: Then and Now*, 8 FETAL DIAGNOSIS & THERAPY 60 (1993); Tjeerd Tymstra, *Prenatal Diagnosis, Prenatal Screening, and the Rise of the Tentative Pregnancy*, 7 INT'L J. TECH. ASSESSMENT IN HEALTHCARE 509 (1991).

percent of Americans would consider aborting a fetus predisposed to severe untreatable obesity.¹⁴⁰

Presymptomatic genetic testing for late-onset disorders can be even more problematic because the results may signal future health risks for an individual. In a preliminary study of BRCA1 testing for a predisposition for breast cancer, a substantial number of women with the mutation experienced psychological distress.¹⁴¹ Learning that one has a BRCA1 or BRCA2 mutation can create a schism between a woman and her body. After DNA testing revealed she had a BRCA1 mutation, one person said, "It felt as if there was a time bomb ticking away inside me."¹⁴²

The psychological impact of learning that one has the gene for an untreatable disorder such as Huntington's disease can be significant. Huntington's disease is a dominant disorder where the children of at-risk individuals have a fifty percent chance of inheriting the disease.¹⁴³ Huntington's disease is a genetically-linked illness, striking in middle age and progressively destroying the brain's neurons.¹⁴⁴ The disease retards one's motor skills, slowly causes confusion, irritability, depression, dementia, and movement disorders, and eventually kills the individual.¹⁴⁵ "uicide is now a question of when, not if," a woman told her psychologist after learning that she had the genetic mutation associated with Huntington's disease.¹⁴⁶ The suicide rate is nearly four times higher among people with Huntington's disease than among the general population of whites in the United States.¹⁴⁷

140. Dorothy C. Wertz et al., *Attitudes Toward Abortion Among Parents of Children with Cystic Fibrosis*, 81 AM. J. PUB. HEALTH 992, fig. 2, at 994 (1991).

141. Robert T. Croyle et al., *Psychological Responses to BRCA1 Mutation Testing: Preliminary Findings*, 16 HEALTH PSYCHOL. 63, 69 (1997).

142. Jo Revell, *Why I Had a Mastectomy Before Cancer Was Diagnosed*, EVENING STANDARD, Dec. 1, 1993, at 12. Jenny Wilson had a preventive mastectomy after cancer struck her twin sister and six other close relatives. Similarly, after her mother, grandmother, and aunt got breast cancer, Cheryl Corin-Bonder said, "I looked in the mirror every day and I couldn't stand my breasts. I felt they would kill me. I wanted to save my life, and I didn't care what anyone thought." Carol Ann Campbell, *Cheating Cancer Fear Drives Some to Surgery Before Disease Hits*, BERGEN REC., May 15, 1994, at A1. Dr. T.S. Ravikumar, codirector of the Comprehensive Breast Care Cancer Center in New Brunswick, estimates that several hundred American women have preventive mastectomies every year. *Id.* at A8.

143. Simeon Margolis, *Diagnosing, Predicting Huntington's Disease*, BALTIMORE SUN, Dec. 19, 1995, at 5E.

144. *Id.*

145. Peter Gorner, *Out of the Shadow a New Genetic Test Can Foretell Agonizing Death: Would You Take It?*, CHI. TRIB., Aug. 4, 1988, at C1. At any given time, about 25,000 Americans are suffering from Huntington's disease, but 150,000 others live knowing that they have a fifty percent chance of having inherited the gene and may develop the disease. *Id.*

146. LORI B. ANDREWS, *FUTURE PERFECT: CONFRONTING DECISIONS ABOUT GENETICS* 34 (2001) [hereinafter ANDREWS, *FUTURE PERFECT*].

147. Lindsay A. Farrer, *Suicide and Attempted Suicide in Huntington's Disease: Implications for*

Even when people are prepared for bad news as a result of testing, they may still be shocked by the reality of it. A woman who expected that she had a faulty Huntington's disease gene nonetheless stated after she received the results, "I feel like someone has died. Part of me has died, the hopeful part."¹⁴⁸ The woman experienced depression that became increasingly problematic.¹⁴⁹

Even when the results of genetic testing reveal that a person does not have a genetic mutation, the results may cause psychological harm. Some people experience "survivor's guilt" similar to that of soldiers whose buddies have died in war; they wonder why they have been spared when other family members have tragically inherited the gene.¹⁵⁰ Of people who undergo genetic testing for Huntington's disease and learn that they do not have the gene, ten percent experience severe psychological problems as a result.¹⁵¹ Many people whose parents have Huntington's disease assume that they have inherited the gene.¹⁵² They may live their lives as if they will die of the disease in their fifties. They may have chosen not to pursue a particular career or relationship because they believe they will get the disease. Learning they do not have the gene radically changes their self-image.¹⁵³ One woman said, "If I'm not at risk—who am I?"¹⁵⁴

One man, with a fifty percent risk for Huntington's disease, lived his life in preparation for an early death.¹⁵⁵ He spent money, rather than saving it, and ran up huge loans and credit card bills.¹⁵⁶ He did not commit to a long-term relationship with a girlfriend because he did not want to get married and risk passing on the gene to a child.¹⁵⁷ Then he was tested and learned he did not have the gene associated with Huntington's disease.¹⁵⁸ He was just a

Preclinical Testing of Persons at Risk, 24 AM. J. MED. GENETICS 305, 308 (1986).

148. Maurice Bloch et al., *Predictive Testing for Huntington's Disease in Canada: The Experience of Those Receiving an Increased Risk*, 42 AM. J. MED. GENETICS 499, 504 (1992).

149. *Id.*

150. See Kimberly A. Quaid et al., *Knowledge, Attitude and Decision to be Tested for Huntington's Disease*, 36 CLINICAL GENETICS 431 (1989); Nancy Wexler, *Genetic Jeopardy and the New Clairvoyance*, 6 PROGRESS IN MED. GENETICS 277, 298 (1985).

151. Marlene Huggins et al., *Predictive Testing for Huntington Disease in Canada: Adverse Effects and Unexpected Results in Those Receiving a Decreased Risk*, 42 AM. J. MED. GENETICS 508, 508 (1992).

152. If one of their parents has the disorder, there is a fifty percent chance they will inherit the genetic mutation and get the disorder themselves. ALICE WEXLER, *MAPPING FATE: A MEMOIR OF FAMILY, RISK, AND GENETIC RESEARCH* (1996).

153. See Huggins et al., *supra* note 151, at 512.

154. *Id.* at 510.

155. *Id.* at 512.

156. *Id.*

157. *Id.* at 511-12.

158. *Id.*

normal, healthy man who might need to start thinking about a mortgage rather than “living hard, dying young, and leaving a beautiful corpse.”¹⁵⁹ The test results precipitated a downward spiral, culminating in embezzlement from his company to pay his bills.¹⁶⁰

B. Cultural and Social Identity

Genetic information influences the expectations of tested individuals and can also transform their cultural past. Nowhere is the latter more clear than in Iota, Louisiana, a place where, according to the New Orleans historical archives, no one of Jewish descent set foot in New Orleans until the late nineteenth century.¹⁶¹ In actuality, in 1720, a German Jew named Johann Adam Edelmeirer crossed the ocean and settled in Louisiana.¹⁶² In addition to his worldly goods, it is now assumed that he brought with him the genetic mutation for the devastating disorder known as Tay-Sachs disease,¹⁶³ common to three percent of Ashkenazi Jews.¹⁶⁴ Once in Louisiana, Edelmeirer probably hid his Jewish origins because of a 1724 regulation requiring that all Jews leave the territory within three months upon penalty of confiscation of their persons and property.¹⁶⁵ These facts might not have been unearthed were it not for the recent advent of genetic testing. Just a few years ago, Cajun Catholic and fundamentalist families who were descendants of Edelmeirer, learned that they carried the Tay-Sachs mutation, commonly considered a “Jewish” mutation.¹⁶⁶

The psychological and social upheaval caused by this kind of information can be enormous, yet these scenarios will continue to be repeated as tested individuals receive genetic information linked to an ethnic and racial background about which they were unaware.¹⁶⁷ In addition to the psychological changes in self-image, there may be dramatic changes in social standing and even in personal finances. For example, a person who is socially considered a Native American, yet does not meet what researchers claim is the typical genetic profile of a Native American, may be deprived of

159. *Id.*

160. *Id.*

161. Laurie Garrett, *A Hidden Killer in Cajun Country*, NEWSDAY, Nov. 26, 1990, at 4.

162. *Id.*

163. *Id.*

164. *Id.*

165. *Id.*

166. See generally Benedict Carey, *Chance of a Lifetime*, 8 HEALTH 90 (1994).

167. Some researchers claim they have discovered genetic markers related to race. Gail Vines, *Genes in Black and White*, NEW SCIENTIST, July 8, 1995, at 34.

certain land rights and educational scholarships.¹⁶⁸

In Orthodox Judaism, rabbis with the highest status are thought to be descendants of Aaron, the older brother of Moses, who was the first of the Cohanim, the Jewish priesthood that predated the rabbis.¹⁶⁹ In Orthodox and some conservative congregations, these descendants are the only rabbis who can perform particular religious duties.¹⁷⁰ Researchers have now found a genetic pattern on the Y chromosome that they believe is shared by the descendants of the Cohanim.¹⁷¹ Such a test could in the future be used to remove rabbis from the high priesthood if their DNA does not measure up.

C. Relationships with Spouses and Potential Spouses

Genetic information also affects relationships with spouses and potential spouses. For centuries, people have chosen mates based on their potential to produce healthy children. Genetic testing can directly and indirectly affect such choices. It can also have a profound impact on intimate relationships.

Currently, in the Orthodox Jewish community of New York, where arranged marriages are still common, genetic information is increasingly being taken into consideration at the matchmaking stage. People who are of Ashkenazi Jewish descent have a one in twenty-five chance of having a Tay-Sachs genetic mutation.¹⁷² If two such carriers marry, each child would have a one in four chance of having the devastating disease.¹⁷³ A child with Tay-Sachs appears normal at birth but later loses motor functions, suffers massive neurological deterioration and seizures, and is likely to die by age six.¹⁷⁴ A program in New York known as Chevra Dor Yeshorim, which means "Association of an Upright Generation,"¹⁷⁵ offers Tay-Sachs carrier screening to Orthodox Jewish adolescents. Before a marriage is arranged, the matchmaker calls the program with the identification numbers of the two individuals involved.¹⁷⁶ If they both carry the gene for Tay-Sachs, the two individuals are not matched for marriage.¹⁷⁷ One rabbi has proclaimed, "It is

168. Eric T. Juengst, *The Perils of Genetic Genealogy*, 10 CENTERVIEWS 1, 3-5 (1996); Arthur L. Caplan, *Handle with Care: Race, Class, and Genetics*, in JUSTICE AND THE HUMAN GENOME PROJECT, *supra* note 97, at 30.

169. Denise Grady, *Who is Aaron's Heir? Father Doesn't Always Know Best*, N.Y. TIMES, Jan. 19, 1997, at 4.

170. *Id.*

171. *Id.*

172. Beverly Merz, *Matchmaking Scheme Involves Tay-Sachs Problem*, 258 JAMA 2636 (1987).

173. *Id.*

174. *Id.*

175. *Id.*

176. *Id.*

177. *Id.*

the obligation of every parent, without exception, to turn to Chevra Dor Yeshorim, and heed their advice, before finalizing a match for his or her child.”¹⁷⁸

Most people, however, do not consciously seek a partner based on his or her genetic pedigree. Nevertheless, such information is becoming increasingly available, thereby creating complicated interpersonal questions. If a person has a gene for colon cancer, should he or she be obligated to warn a potential spouse? What happens when the recipient who believed such information would not make a difference in the relationship finds that he or she is beginning to view the loved one differently?

Men are more likely than women to say they would alter marriage plans if they learned that their potential spouse was the carrier of a recessive genetic disorder. Eight years after participating in Tay-Sachs testing,¹⁷⁹ ninety-five percent of female carriers (compared to sixty-nine percent of male carriers) responded that they would not alter marriage plans upon discovering their partner or intended partner was also a carrier.¹⁸⁰ Another study of Tay-Sachs testing found that twenty-five percent of carriers and six percent of carriers’ spouses felt that knowing their own or their spouse’s carrier status would have affected their marriage decision.¹⁸¹

What people say they *will* do is not always what they actually do. A study of sickle cell anemia testing in Orchemenos, Greece, provided information on actual behavior.¹⁸² Although people who are carriers of the sickle cell gene are healthy themselves, if they procreate with another carrier, each of their children has a twenty-five percent chance of having sickle cell anemia.¹⁸³ The health care providers in Greece thought that the testing they offered would decrease the number of affected children by causing people to make more “rational” reproductive decisions (i.e., if a carrier and a noncarrier have a child together, there is no chance that the child will be affected with the disorder).¹⁸⁴ What actually happened, however, was that sickle cell carriers were stigmatized.¹⁸⁵ As a result, the birth rate of affected children did not decrease because, in some instances, only a carrier would

178. *Id.*

179. Zeesman et al., *supra* note 134.

180. *Id.* at 773.

181. Barton Childs et al., *Tay-Sachs Screening: Social and Psychological Impact*, 28 AM. J. HUM. GENETICS 550-52 (1976).

182. See George Stamatoyannopoulos, *Problems of Screening and Counseling in the Hemoglobinopathies*, in BIRTH DEFECTS: PROCEEDINGS OF THE FOURTH INTERNATIONAL CONFERENCE 268 (Arno G. Motulsky & F.J.G. Ebling eds., 1974).

183. ASSESSING GENETIC RISKS, *supra* note 52, at 61.

184. Stamatoyannopoulos, *supra* note 182, at 268.

185. *Id.* at 273.

marry another carrier.¹⁸⁶ Similarly, in a maple syrup urine disease testing program among the Bedouin tribe, male carriers married outside the tribe, and female carriers were stigmatized and considered to be unmarriageable.¹⁸⁷

Genetic knowledge of carrier status may significantly impact couples' relationships. In the Orchemenos study, twenty percent of the parents of noncarriers and ten percent of the parents of carriers advise[d] their children to avoid marrying a carrier.¹⁸⁸ Seven percent of noncarriers avoided marrying a carrier, and some terminated their engagement when they learned the potential spouse had the sickle cell gene.¹⁸⁹ Of the sickle cell carriers in the study, twenty-five percent concealed their status from their potential spouse.¹⁹⁰ Twenty percent of the carriers broke off their engagement when they learned their prospective spouse was also a carrier.¹⁹¹ Likewise, follow-up on twenty-one couples who received Huntington's disease testing revealed that six had divorced, with three couples specifically attributing the divorce to the testing.¹⁹²

Genetic knowledge can also strain a couple's relationship short of terminating it. People who learned they were likely to suffer from Huntington's disease experienced a significant decline in their level of satisfaction with their primary relationship during the two-year follow-up period after receiving the test results.¹⁹³ If a person is found to have a genetic mutation associated with a serious genetic disease, his or her partner will

186. *Id.* at 274.

187. Mairi Levitt, *A Sociological Perspective on Genetic Screening*, in *THE ETHICS OF GENETIC SCREENING* 157 (Ruth Chadwick et al. eds., 1999).

188. *Id.* at 274.

189. *Id.*

190. *Id.*

191. *Id.*

192. L.B. Jakobsen et al., *Psychological Consequences of Presymptomatic Genetic Testing*, 119 *TIDSSKR NOR LAEGEFØREN* 1913, 1913-16 (1999).

193. A Canadian study assessed changes in relationships for individuals participating in predictive testing for Huntington's disease by administering questionnaires before they received their test results and then again seven to ten days, and six, twelve, eighteen, and twenty-four months thereafter. The study included 217 individuals, "53 individuals received an increased risk . . . , 96 individuals received a decreased risk . . . , 33 individuals . . . [received] an uninformative result . . . ," and 35 individuals ultimately decided not to participate in testing. T. Copley et al., *Significant Changes in Social Relations After Predictive Testing for Huntington Disease*, 55 *AM. J. HUM. GENETICS* ser. 1707, at A291 (1994). There were no differences between groups as far as gender, employment status, marital status, or number of children. However, the mean age of the decreased risk group was significantly older than the mean age of the other groups. *Id.* A U.S. study of individuals participating in predictive testing for Huntington's disease found similar results. Nineteen couples participated in testing. Five of the couples received increased risk results. "The analysis of follow-up data indicates that high-risk individuals and couples are significantly more distressed [even up to] 12 months after testing than low-risk individuals and couples." Kimberly A. Quaid & Melissa K. Wesson, *The Effects for Predictive Testing for Huntington Disease on Intimate Relationships*, 55 *AM. J. HUM. GENETICS* ser. 1728, at A294 (1994).

naturally worry about the children they have created together. Partners of individuals with Huntington's disease can develop resentment and hostility over the fact that the disease may have been transmitted unknowingly to their children.¹⁹⁴

Even when neither spouse has a mutated gene, the genetic testing can still impact the couple's relationship. For example, one woman was disappointed when she was tested for Huntington's disease and learned she did not have the mutation.¹⁹⁵ She thought that if she learned she had the gene and would die soon, she would have had the courage to leave her husband.¹⁹⁶ In another case, a man suffered from clinical depression when his wife learned she did not have the Huntington's disease mutation.¹⁹⁷ He had arranged his life and his retirement in such a way that he could care for her when she fell ill.¹⁹⁸ He was a workaholic before he retired and planned a "second career" as his wife's caretaker.¹⁹⁹ When they discovered that she did not have the mutation, he felt as if he had lost his job and his purpose.²⁰⁰

When a person encounters a problem in life, he or she often turns to a partner for comfort. In the case of genetic testing, however, the partner might be having a troubling reaction, different from that which the tested individual is experiencing. While married individuals are typically more emotionally well-adjusted than unmarried people, research on Huntington's disease testing found that married persons who tested positive for the disease were less well-adjusted than unmarried persons who tested positive for the disease. Johns Hopkins researchers note that "[u]nlike single persons, married positives have the added psychological stress of knowing that they are 'causing' distress in someone close to them." Alternatively, positives may have been affected by their spouses' reaction to the news.²⁰¹

The use of genetic services can cause a person to lose his or her internal moorings and to view himself or herself in a different way. It can also make conditional some of the previous unconditionals in relationships, creating fault lines in the very foundation of one's life.

194. See Mary B. Hans & Arnulf H. Koeppen, *Huntington's Chorea: Its Impact on the Spouse*, 168 J. NERVOUS & MENTAL DISEASE 209 (1980).

195. Huggins et al., *supra* note 151, at 511.

196. *Id.*

197. *Id.* at 513.

198. *Id.* at 513-14.

199. *Id.* at 514.

200. *Id.* at 513-14.

201. *Id.*

V. USE OF GENETIC SERVICES

Depending on their personalities, backgrounds, and life experiences, individuals may react in a variety of ways to the offer of genetic testing and the information generated by a test. Geneticists may fail to appreciate the complex factors that influence a person's response to genetic services and merely assume that people will invariably find it beneficial to learn genetic information whether it brings good news or bad. Such an assumption is illustrated by the predictions that genetic services will become a part of normal health care. For example, cystic fibrosis (CF), a disorder of the exocrine glands that causes chronic obstructive lung disease, is "the most common potentially fatal genetic disease in the white population."²⁰² Asymptomatic carriers of this recessive disorder have one gene with a CF mutation.²⁰³ If two carriers produce a child together, the child has a twenty-five percent chance of being affected by cystic fibrosis.²⁰⁴ No known cure exists, and the average life expectancy is currently thirty years.²⁰⁵ Nevertheless, some individuals lead normal lives without even realizing they have two genes with the mutation.²⁰⁶

When scientists first discovered the cystic fibrosis gene, they assumed that virtually all whites of reproductive age would rush to be tested. Some analysts suggested that once testing became widely available, each genetics health care provider in the United States would spend at least sixteen weeks per year counseling individuals about cystic fibrosis testing.²⁰⁷ In an initial survey, eighty-four percent of patients in obstetrics and gynecology clinics indicated their "interest in being tested for CF carrier status before pregnancy."²⁰⁸ When CF testing was offered free of charge in a series of pilot studies to the general population, however, less than one percent of the people offered the test actually took it.²⁰⁹ In another study, less than four percent of people responded to a free offer of cystic fibrosis carrier testing

202. HEALTHY CHILDREN, *supra* note 46, at 263.

203. Jean L. Marx, *The Cystic Fibrosis Gene Is Found*, 245 SCIENCE 923 (1989).

204. *Id.*

205. See Melissa A. Rosenfeld & Francis S. Collins, *Gene Therapy for Cystic Fibrosis*, 109 CHEST 241 (1996).

206. Suzanne P. Tomlinson, *Policy Commentary: Genetic Testing for Cystic Fibrosis: A Personal Perspective*, 11 HARV. J.L. & TECH. 551, 559 (1998).

207. Benjamin S. Wilfond & Norman Fost, *The Introduction of Cystic Fibrosis Carrier Screening into Clinical Practice: Policy Considerations*, 70 MILBANK Q. 629, 639-40 (1992).

208. Jeffrey R. Botkin & Sonia Alemagno, *Carrier Screening for Cystic Fibrosis: A Pilot Study of the Attitudes of Pregnant Women*, 82 AM. J. PUB. HEALTH 723, 724 (1992).

209. Ellen Wright Clayton et al., *Lack of Interest by Nonpregnant Couples in Population-Based Cystic Fibrosis Carrier Screening*, 58 AM. J. HUM. GENETICS 617-627 (1996).

mailed from their HMOs.²¹⁰ Even when they were approached for free CF carrier status screening at their doctor's office, only approximately twenty-four percent underwent testing.²¹¹

Geneticists also expected widespread interest with respect to testing for late-onset disorders. When they identified a genetic marker for Huntington's disease in 1983,²¹² and when they localized the gene itself in 1993,²¹³ scientists assumed that at-risk individuals would flock to be tested. Geneticists predicted a benefit to individuals who received Huntington's disease testing,²¹⁴ believing that those who tested negative for the genetic mutation associated with Huntington's disease would be overjoyed at the results. They also assumed that people who tested positive for the gene associated with Huntington's disease would, at some level, value the information because it would allow them to make financial provisions for their future illness, such as purchasing insurance, or to make lifestyle changes, such as not having children.

The initial surveys of at-risk individuals seemed to support the geneticists' beliefs. The majority of at-risk individuals said they would undergo Huntington's disease testing if a test were available.²¹⁵ When the test actually became available, however, fewer than fifteen percent of at-risk individuals chose to undergo the testing.²¹⁶ Similarly, many people with relatives affected with breast cancer said that they would undergo genetic testing if it were available.²¹⁷ Once they learned more about the uncertainties and risks in testing, however, fewer women than expected pursued such

210. Ellen S. Tambor et al., *Offering Cystic Fibrosis Carrier Screening to an HMO Population: Factors Associated with Utilization*, 6 AM J. HUM. GENETICS 626-637 (1994).

211. *Id.*

212. See James F. Gusella et al., *A Polymorphic DNA Marker Genetically Linked to Huntington's Disease*, 306 NATURE 234 (1983).

213. See The Huntington's Disease Collaborative Research Group, *A Novel Gene Containing a Trinucleotide Repeat that is Expanded and Unstable in Huntington's Disease Chromosomes*, 72 CELL 971 (1993).

214. Some researchers assumed that Huntington's Disease testing would be beneficial because testing would resolve the uncertainty, no matter what the result. But in some cases, "uncertainty can also reduce distress." Baum et al., *supra* note 31, at 12.

215. Seymour Kessler, *Psychiatric Implications of Presymptomatic Testing for Huntington's Disease*, 7 AM. J. ORTHOPSYCHIATRY 212, 212-13 (1987).

216. David Craufurd et al., *Uptake of Presymptomatic Predictive Testing for Huntington's Disease*, 2 LANCET 603, 604 (1989). See also Maurice Bloch et al., *Predictive Testing for Huntington's Disease: II. Demographic Characteristics, Life-Style Patterns, Attitudes, and Psychosocial Assessments of the First Fifty-One Test Candidates*, 32 AM. J. MED. GENETICS 217, 222 (1989).

217. See Robert T. Croyle & Caryn Lerman, *Interest in Genetic Testing for Colon Cancer Susceptibility: Cognitive and Emotional Correlates*, 22 PREVENTIVE MED. 284 (1993).

testing.²¹⁸

The low testing rate is one indication of the complexities of the decision to use genetic technologies. The ambivalent reactions that people have to their test results further indicate that genetic technologies are not an unalloyed benefit. Though scientists assume that if the public is educated about new genetic technologies, they will be more supportive of them, this is often not the case. The more that people know about basic biology, the less optimistic they are about the potential benefits of biotechnology and genetic engineering.²¹⁹ The more that women know about the limited predictive value of breast cancer testing, the less likely it is that they will take the test.²²⁰

A. The Impact of Genetic Testing on Preventive Activities

Genetic testing is often thought to be beneficial even for people who test positive as a way to motivate them to undertake health surveillance or prevention activities. People may even think that the information will help them cope when the disease manifests. Various studies, however, have found that these benefits do not necessarily occur after genetic testing.²²¹ In fact, evidence exists that the stress created by genetic information can actually lessen the likelihood that the individual will engage in surveillance strategies and will monitor himself or herself for early signs of the disease.²²² Even if the person does engage in preventive strategies, the physiological and psychological harm from increased stress may offset any benefit that comes from increased surveillance.²²³

In addition, knowing one's risk of disease prior to onset does not necessarily help the individual to cope with the disease once it manifests. A study found that carriers who coped with the initial results of Huntington's disease testing became depressed or suicidal and showed disturbed

218. See Gail Geller et al., *Informed Consent and BRCA1 Testing*, 11 NATURE GENETICS 364, 364 (1995).

219. Biotechnology and the European Public Concerted Action Group, *Europe Ambivalent on Biotechnology*, 387 NATURE 845, 845 (1997).

220. See Geller et al., *supra* note 218.

221. See, e.g., Andrew Baum et al., *Stress and Genetic Testing for Disease Risk*, 16 HEALTH PSYCHOL. 8, 10 (1997) (citations omitted).

222. *Id.* at 17. The authors note that a study of 140 women with family histories of breast cancer "found that breast cancer worries were associated with poorer adherence with mammography screening." *Id.* at 16 (citing Caryn Lerman et al., *Factors Associated with Repeat Adherence to Breast Cancer Screening*, 19 PREVENTIVE MED. 279 (1990)). Another study found that the women at highest risk of breast cancer performed fewer self-examinations and those with close relatives diagnosed with breast cancer were less likely to undergo mammograms. Caryn Lerman et al., *Psychological Side Effects of Breast Cancer Screening*, 10 HEALTH PSYCHOL. 259 (1991).

223. Baum et al., *supra* note 221, at 109-11.

functioning once the symptoms manifested.²²⁴

Moreover, when a treatment such as prophylactic surgery based on presymptomatic testing is offered to a presymptomatic individual, the treatment carries physical and psychological risks. As the first woman with the BRCA1 breast cancer gene mutation who underwent a prophylactic mastectomy said, “I had wonderful counselling beforehand but nothing prepared me for the feeling of loss [and] of mutilation. A woman’s breasts are very much tied up with the image she has of herself and however perfect the reconstruction you are aware they are not your own. It was far more emotionally traumatic than I had expected.”²²⁵

B. Quality Assurance Problems in Genetics Services

For most medical services, individuals rely on their physicians for advice, and society relies on the scientific community for their assessments of the risks and benefits of those services. This paradigm does not necessarily work well for genetic services, however. The commercial push to introduce tests has led to premature testing.²²⁶ In addition, since genetic services in the reproductive context may involve the termination of affected fetuses, physicians’ personal moral views may color their supposedly neutral medical advice.²²⁷

Relying on physicians to disseminate new genetic information presents problems. Not all medical schools offer courses in genetics. A 1995 survey found that only sixty-eight percent of 125 American medical schools required students to take a genetics course.²²⁸ In some of those schools, the “course” was only four hours long.²²⁹ An interdisciplinary federal advisory task force observed that “genetics is not being taught adequately to all medical students” and urged that the schools’ “clinical departments pay greater attention to genetic issues.”²³⁰

Researchers discover many new genes each month and move the genes rapidly into use in clinical diagnosis by physicians who are not adequately prepared to advise patients about the appropriate use and interpretation of

224. Aad Tibben et al., *Presymptomatic DNA Testing for Huntington Disease: Identifying the Need for Psychological Intervention*, 48 AM. J. MED. GENETICS 137, 140 (1993).

225. Revill, *supra* note 142.

226. Healy, *supra* note 22.

227. ANDREWS, *FUTURE PERFECT*, *supra* note 146, at 123-24.

228. PROMOTING SAFE AND EFFECTIVE GENETIC TESTING IN THE UNITED STATES: FINAL REPORT OF THE TASK FORCE ON GENETIC TESTING 65 (Neil A. Holtzman & Michael S. Watson eds., 1998) [hereinafter FINAL REPORT OF THE TASK FORCE ON GENETIC TESTING].

229. *Id.* at 65.

230. *Id.*

their test results. In an assessment of the genetics knowledge of nearly two thousand primary care physicians, the average respondent had only a seventy-four percent correct response rate.²³¹ In another study, residents in obstetrics and gynecology departments received a mean score of sixty-nine percent on a genetic examination.²³² In addition, a study showed that one-third of physicians surveyed erroneously interpreted the results of genetic testing for colorectal cancer.²³³

Some of the current problems of inadequate genetic education by physicians may be alleviated by referring patients to genetic counselors²³⁴ who are knowledgeable about the etiology of genetic disorders and the risks and benefits of testing. However, there are only approximately two thousand genetic counselors in the United States,²³⁵ most of whom are disproportionately located in certain geographic areas (i.e., New England, Chicago, and California).²³⁶ Even where counselors are available, physicians vary in their willingness to refer patients to genetic counselors. More pediatricians and obstetricians-gynecologists than primary care physicians, internists, and psychiatrists offer some form of genetic counseling.²³⁷

Even if physicians are knowledgeable about genetics, they may disseminate inaccurate information to patients because the tests themselves are faulty, because laboratories run them incorrectly, or because the results are difficult to interpret. A 1999 study of 245 molecular genetic testing labs found that thirty-six labs (fifteen percent) scored lower than seventy percent on a quality-control scale.²³⁸ The researchers conducting the study highlighted the need for improved personnel qualifications and laboratory practice standards.²³⁹

231. Karen J. Hofman et al., *Physicians' Knowledge of Genetics and Genetic Tests*, 68 ACAD. MED. 625 (1993).

232. M.A. Kershner et al., *Knowledge of Genetics Among Residents in Obstetrics and Gynecology*, 51 AM. J. HUM. GENETICS A16 (1992).

233. Francis M. Giardiello et al., *The Use and Interpretation of Commercial APC Gene Testing for Familial Adenomatous Polyposis*, 336 NEW ENG. J. MED. 823, 824-25 (1997).

234. "Genetic counseling is the process by which individuals and families come to learn and understand relevant aspects of genetics; it is also the process for obtaining assistance in clarifying options available for their decision making and coping with the significance of personal and family genetic knowledge in their lives." ASSESSING GENETIC RISKS, *supra* note 52, at 148.

235. Katherine A. Schneider & Kathy J. Kalkbrenner, *Career Information*, at <http://www.nsgc.org/pss98.asp> (last visited Apr. 7, 2001).

236. ASSESSING GENETIC RISKS, *supra* note 52, at 203.

237. Neil A. Holtzman, *Primary Care Physicians as Providers of Frontline Genetic Services*, 8 FETAL DIAGNOSTIC THERAPY 213, 216-18 (1993).

238. Judy Peres, *Genetic Testing Can Save Lives—But Errors Leave Scars*, CHI. TRIB., Sept. 26, 1999, at C1, available at LEXIS, Nexis Library, News Group File. See also Margaret M. McGovern et al., *Quality Assurance in Molecular Genetic Testing Laboratories*, 281 JAMA 835 (1999).

239. McGovern et al., *supra* 238, at 127.

Moreover, it is more difficult to maintain the quality of genetic tests than many other medical tests.²⁴⁰ A genetic test for a late-onset disease that is performed negligently may not be discovered for however many years it takes the disease to manifest. Because most genetic testing results are negative outside of high-risk families, laboratory personnel may be less than vigilant.²⁴¹ Tests may be performed in specialized laboratories far from where the sample is collected, thereby increasing the risk of mix-ups between samples.²⁴² Because the DNA test may not predict all disease-causing mutations, false-negative testing results may arise.²⁴³ The meaning of the test may depend on an analysis of test results in other family members.²⁴⁴ The test may produce probabilistic data which most physicians are not adept at interpreting.²⁴⁵ Because certain diseases such as inherited breast cancer are incompletely penetrant, a positive test result may not necessarily mean the individual will get the disease.²⁴⁶

Although errors have occurred in newborn screening,²⁴⁷ in karyotyping,²⁴⁸ in interpretation of linkage studies,²⁴⁹ in predictive cancer testing,²⁵⁰ and in Tay-Sachs screening,²⁵¹ only a small minority of states have special licensing requirements for laboratories undertaking genetic tests.²⁵² These requirements vary widely. New York has a rigorous program for quality assurance,²⁵³ while Maryland merely requires that genetic laboratories perform satisfactorily in external proficiency testing programs approved by the Secretary of Health and Mental Hygiene.²⁵⁴

Unfortunately, some state statutes impede, rather than encourage, quality in genetic services by prohibiting traditional malpractice suits for certain

240. ASSESSING GENETIC RISKS, *supra* note 52, at 127.

241. *Id.* at 117.

242. *Id.* at 133.

243. *Id.* at 117.

244. *Id.* at 127.

245. *Id.*

246. *See id.* at 130.

247. *See* Candy Holtzman et al., *A Descriptive Epidemiology of Missed Cases of Phenylketonuria and Congenital Hypothyroidism*, 78 PEDIATRICS 553 (1986). There are more than five percent false negatives in newborn screening. ASSESSING GENETIC RISKS, *supra* note 52, at 133 (citations omitted).

248. *See* Jerry Vockley et al., "Pseudomosaicism" for 4p—in Amniotic Fluid Cell Culture Proven to be True Mosaicism After Birth, 39 AM. J. MED. GENETICS 81 (1991). *See also* Martinez v. Long Island Jewish Hillside Med. Ctr., 512 N.E.2d 538 (N.Y. 1987).

249. ASSESSING GENETIC RISKS, *supra* note 52, at 123.

250. Francis M. Giardiello et al., *supra* note 233. *See also* Susan Gilbert, *Doctors Often Misread Results of Genetic Tests, Study Finds*, N.Y. TIMES, Mar. 26, 1997, at C8.

251. *See* Curlender v. Bio-Science Laboratories, 165 Cal. Rptr. 477 (Cal. Dist. Ct. App. 1980).

252. ASSESSING GENETIC RISKS, *supra* note 52, at 118.

253. N.Y. PUB. HEALTH LAW § 57 (McKinney 2000).

254. MD. CODE ANN., HEALTH-GEN. § 17-211 (2000).

genetic services. Seven states have passed statutes prohibiting couples from suing their physicians or laboratories for negligent prenatal genetic testing if they claim that they would have aborted the fetus if the test had been properly performed.²⁵⁵

Federal statutes address the quality of genetic services, but they are often not followed. Under the Medical Devices Amendments of 1976²⁵⁶ and the Safe Medical Devices Act of 1990,²⁵⁷ the Food and Drug Administration (FDA) has the authority to scrutinize the components of genetic testing kits that are marketed in interstate commerce.²⁵⁸ Before such kits can be sold, the FDA requires proof of safety and efficacy in a premarket approval process.²⁵⁹ However, the Assessing Genetic Risks Committee of the Institute of Medicine notes that “[o]nly a small proportion of genetic tests in widespread use have been reviewed by FDA; these include tests for hypothyroidism, . . . (PKU), and [maternal serum alphafetoprotein] MSAFP.”²⁶⁰

Why have so few tests been reviewed by the FDA? The academic, government, hospital, and commercial laboratories are not marketing tests but, are instead, using their own components, known in the trade as “home brews.”²⁶¹ The FDA has not aggressively regulated “home brews” even though they are used in tests sold to patients who use the results to make crucial decisions. In fact, the FDA has admitted that it does not exercise its authority to regulate these “home brew” genetic testing services.²⁶² Moreover, a 1995 survey found that an alarming number of organizations developing or offering “home brew” genetic tests have never contacted the FDA regarding such services. Of the forty-three biotech companies and 215 not-for-profit organizations surveyed less than sixteen percent had contacted the FDA.²⁶³

Even when the FDA has assessed a particular genetic test in its premarket approval process, problems may arise in assuring the quality of the test when it is used for other purposes. Maternal serum alphafetoprotein (MSAFP)

255. Note, *Wrongful Birth Actions: The Case Against Legislative Curtailment*, 100 HARV. L. REV. 2017, 2019 (1987). These statutes were the result of lobbying efforts of right to life groups. See Jennifer Mee, Note, *Wrongful Conception: The Emergence of a Full Recovery Rule*, 70 WASH. U. L.Q. 887, 896-97 (1992).

256. P.L. No. 94-295, 90 Stat. 539 (codified as amended 21 U.S.C. §§ 360c-k, 379, 379a (1994); 42 U.S.C. § 3512 (1994)).

257. P.L. No. 101-629, 104 Stat. 4511 (codified as amended 21 U.S.C. §§ 360l, 383 (1994)).

258. 21 U.S.C. §§ 360s, l (1994).

259. 21 U.S.C. § 360c (1994).

260. ASSESSING GENETIC RISKS, *supra* note 52, at 128.

261. *Id.* at 132.

262. *Id.*

263. FINAL REPORT OF THE TASK FORCE ON GENETIC TESTING, *supra* note 228, at 30.

testing was scrutinized for its ability to predict the likelihood of neural tube defects in a fetus.²⁶⁴ Subsequently, the test has also been used to predict whether a fetus has Down syndrome, even though the test has neither been specifically approved nor assessed by the FDA for that purpose.²⁶⁵

The genetics industry itself has expressed widespread concern about the poor quality of genetic services. In one survey, sixty-seven percent of the eighty-one biotechnology companies and seventy-five percent of the 245 nonprofit organizations polled agreed that “FDA policies, or lack of policies, hinder the development of safe and effective genetic test kits or other products.”²⁶⁶ The vast majority (over eighty-four percent) of both types of organizations indicated that there were genetic testing laboratories that lacked adequate quality assurance programs.²⁶⁷

The Clinical Laboratory Improvement Act of 1967 (CLIA) could potentially improve the quality of genetic tests.²⁶⁸ This statute, which was tightened considerably in response to widespread errors in Pap smear tests, covers the hundreds of thousands of laboratories in the United States that provide tests “for the diagnosis, prevention, or treatment of any disease . . . or the assessment of the health of, human beings.”²⁶⁹ Therefore, CLIA applies only to labs that provide to patients or doctors information upon which a health care decision will be made.²⁷⁰ It excludes research labs that do not provide identified test results to patients or doctors.²⁷¹ CLIA requires labs to participate in proficiency testing programs in which blood and other samples are sent to the labs to determine if the labs can get accurate results.²⁷² CLIA also requires lab inspections.²⁷³

The problem with CLIA is that labs have to identify themselves for CLIA certification.²⁷⁴ Few genetic labs have applied for certification.²⁷⁵ Many researchers at university genetics laboratories that provide test results to patients and doctors fail even to realize they are covered by this law.²⁷⁶ Moreover, “in many large academic hospitals, the central lab is not even

264. ASSESSING GENETIC RISKS, *supra* note 52, at 79.

265. *Id.* at 129.

266. FINAL REPORT OF THE TASK FORCE ON GENETIC TESTING, *supra* note 228, tbl. 7, at 124.

267. *Id.*

268. ASSESSING GENETIC RISKS, *supra* note 52, at 124.

269. 42 U.S.C. § 263a(a) (1994). *See also* ASSESSING GENETIC RISKS, *supra* note 52, at 124-25.

270. *See* 42 U.S.C. § 263a(a) (1994). *See also* ASSESSING GENETIC RISKS, *supra* note 52, at 126.

271. *See supra* note 270.

272. 42 U.S.C. § 263a(f)(1)(D),(3) (1994). *See also* ASSESSING GENETIC RISKS, *supra* note 52, at 125.

273. 42 U.S.C. § 263a(g)(1) (1994).

274. ASSESSING GENETIC RISKS, *supra* note 52, at 126.

275. FINAL REPORT OF THE TASK FORCE ON GENETIC TESTING, *supra* note 228, at 126.

276. *Id.*

aware of all the labs [in its own institution] that provide services.”²⁷⁷

In its overall inspection program, the federal government found that eighty to eighty-four percent of the physician office labs inspected had problems under CLIA, and eleven percent had serious problems.²⁷⁸ Additionally, CLIA lacks any special requirement for laboratories offering DNA-based genetic testing, so a lab need only demonstrate general, good laboratory practices.²⁷⁹ Because genetic testing is more complex than much of the other testing offered, there is reason for concern about the quality of information patients receive from genetic testing.²⁸⁰ For example, a 1995 survey found that “commercial laboratory directors . . . were aware of poor quality laboratories who were offering services.”²⁸¹ Because of the lack of reliable information available on the quality of standards in labs performing genetic tests, patients and providers may never know the identities of the poor quality labs. In fact, even the commercial laboratory directors themselves indicated that “information on the quality of laboratories spreads by word of mouth.”²⁸²

C. Impact of Genetics on Cultural Values and Social Institutions

Genetic information has the potential to change the nature of our social fabric by influencing our ideas about individual and social responsibility and by challenging basic societal concepts such as free will and equality. If most people choose to have prenatal diagnosis and to abort fetuses with certain disabilities, society may be less willing to provide services to people with those types of disabilities by viewing them as having erroneously slipped through the net of prenatal screening. Some physicians and lawyers are already claiming that people should have a duty to learn their genetic status and to make lifestyle choices about where to live, what type of job to take, what type of insurance to purchase, and even whether to bear a child based on that information. A medical article urged parents whose children have a genetic propensity toward skin cancer to quit their jobs and move to a rainy city like Seattle.²⁸³ The journal *Food Technology* predicted that, in the future,

277. *Id.*

278. *HCFAs to Complete First Round of POL Inspections by May 1995*, BNA HEALTH CARE DAILY, Oct. 7, 1994.

279. FINAL REPORT OF THE TASK FORCE ON GENETIC TESTING, *supra* note 228, at 115. On May 4, 2000, the Department of Health and Human Services proposed new rules that would create a CLIA specialty dealing with genetics. 65 Fed. Reg. 25,928-934 (proposed May 4, 2000).

280. See ANDREWS, *FUTURE PERFECT*, *supra* note 146, at 114.

281. FINAL REPORT OF THE TASK FORCE ON GENETIC TESTING, *supra* note 228, at 115.

282. *Id.*

283. Frederick Hecht & Barbara Kaiser McCaw, *Chromosome Instability Syndromes*, in

kitchen computers will generate diets individualized to people's genetic profiles.²⁸⁴ In addition, some physicians and lawyers claim that it should be a crime to give birth to a child with a serious genetic disorder that could have been discovered prenatally.²⁸⁵

Certain groups utilize genetics rationales in lobbying for social policies. Recently, an organization seeking school tax reductions argued against special education programs on the grounds that, because such disabilities are genetic, "responsibility should fall to the medical system, not to the schools."²⁸⁶ Philanthropic organizations are also beginning to make predictions based on genetics. An article in a philanthropy journal, relying on the controversial book *The Bell Curve*, argued that because some people are genetically predestined to be low achievers, it is probably not worth spending foundation money to try to enhance their opportunities.²⁸⁷

D. Stigmatization and Discrimination

Genetic information influences people's relationships with third parties, such as insurers and employers.²⁸⁸ While individuals might want to know their own genetic makeup in order to make important life decisions, such information can also be used against them.

Among people in families with a known genetic condition, thirty-one percent have been denied health insurance coverage for some service or treatment because of their genetic status, whether or not they were actually

GENETICS OF HUMAN CANCER 105, 114 (John J. Mulvihill et al. eds., 1977).

284. Fergus Clydesdale, *Present and Future of Food Science and Technology in Industrialized Countries*, FOOD TECH., Sept. 1989, at 134, cited in Dorothy Nelkin, *The Social Dynamics of Genetic Testing: The Case of Fragile-X*, 10 MED. ANTHROPOLOGY Q. 537, 546 (1996).

285. See, e.g., Margery W. Shaw, *Conditional Prospective Rights of the Fetus*, 5 J. LEGAL MED. 63, 111 (1984).

286. Dorothy Nelkin, *Behavioral Genetics and Dismantling the Welfare State*, in BEHAVIORAL GENETICS: THE CLASH OF CULTURE AND BIOLOGY 156, 165 (Ronald A. Carson & Mark A. Rothstein eds., 1999).

287. Criticizing such an approach, geneticist Benno Müller-Hill points out:

The scientific prediction of a person's limitations, and thus his possible fate, has a very dangerous component in that it may lead the individual to inaction and despair. It may also lead the population at large to believe that, as there is no real chance, money should not be wasted to counteract genetic limitations. It could be forgotten that these limitations are also set by environmental factors.

Benno Müller-Hill, *The Shadow of Genetic Injustice*, 362 NATURE 491, 492 (1993).

288. For more information about how insurers have responded to information about people's genetic status, see CYSTIC FIBROSIS AND DNA TESTS, *supra* note 62; Paul R. Billings et al., *Discrimination as a Consequence of Genetic Testing*, 50 AM. J. HUM. GENETICS 476 (1992). See also Neil A. Holtzman, PROCEED WITH CAUTION: PREDICTING GENETIC RISKS IN THE RECOMBINANT DNA ERA 195 (1989); Larry Gostin, *Genetic Discrimination: The Use of Genetically Based Diagnostic and Prognostic Tests by Employers and Insurers*, 17 AM. J.L. & MED. 109, 119 (1991).

sick.²⁸⁹ When Kim Roembach-Ratliff learned through prenatal testing that her child had spina bifida, her insurer refused to provide coverage, claiming that the disease should be treated as a preexisting condition. “If we had found out in the delivery room that he had it, he would have been covered,” she said. “This genetic information was used against us.”²⁹⁰ Similarly, when a pregnant woman underwent cystic fibrosis testing and her fetus was diagnosed as being affected, her health maintenance organization informed her that it would not pay for the health care costs of the child if she chose not to abort. In that case, however, the decision was reversed after a public outcry.²⁹¹

A health insurance company told a woman whose mother had breast cancer that she could obtain health care coverage, but not for any treatment of breast cancer.²⁹² In another case, a newborn diagnosed with PKU was covered under her father’s health insurance at the time, but when he changed jobs eight years later, he was told that his child was ineligible for coverage under his new group plan because of her diagnosis, even though her treatment had been completely successful and she was developmentally normal and healthy.²⁹³

Some people have lost their health insurance as a result of their participation in genetics research, including a man who underwent screening for adenomatous polyposis colon cancer as part of a research study.²⁹⁴ Because health insurance companies can exclude people with preexisting disorders, genetic testing provides an enormous loophole whereby numerous diseases can be classified as preexisting because they have their roots in a person’s genes.²⁹⁵ Whether or not a person wishes to risk insurance discrimination determines whether or not they will seek genetic information. Among high-risk individuals offered colon cancer testing, seventy-two percent of those with insurance decided to receive their results, while forty-three percent of uninsured individuals decided not to.²⁹⁶

289. E. Virginia Lapham et al., *Genetic Discrimination: Perspectives of Consumers*, 274 *SCI.* 621, 622 (1996). In another study, fourteen percent of genetic counselors surveyed reported that their counselees had difficulty obtaining or retaining health insurance due to genetic testing results. *ASSESSING GENETIC RISKS*, *supra* note 52, at 270.

290. Stephanie Armour, *Could Your Genes Hold You Back?*, *USA TODAY*, May 5, 1999, at 1B.

291. See *CYSTIC FIBROSIS AND DNA TESTS*, *supra* note 62, at 33.

292. CONFERENCE ON GENETIC DISCRIMINATION AND HEALTH INSURANCE, *supra* note 53 (testimony of Mary Jo Ellis Kahn).

293. Billings et al., *supra* note 288, at 478.

294. Lori Andrews, *Body Science*, 83 *A.B.A. J.* 44, 47 (1997).

295. There are some limitations for using genetic testing as a loophole under group health insurance plans, due to the federal Health Insurance Portability and Accountability Act, discussed *infra* Part IV.C.

296. *Don't Break It to Me, Doc* (May 5, 1999), at <http://www.wired.com/news/technology/>

The chilling irony of genetic testing is that, even in rare cases where a treatment exists, people may be afraid to get tested for the disorder because their insurer might drop them entirely or an employer may refuse to hire them based on their test results.²⁹⁷ Such is the case with hemochromatosis, a chronic, fatal disease in which too much iron builds up in the blood.²⁹⁸ It can be treated easily by periodic withdrawals of blood.²⁹⁹ Although his father and uncle both had the disease, a graduate student chose not to be genetically tested for it because he was worried about his job prospects.³⁰⁰ In another case, a man was tested for hemochromatosis and was treated successfully, but his insurer still dropped him on the grounds that he might stop taking the treatment and develop the costly disease.³⁰¹ Similarly, relatives of people with Huntington's disease have been refused health insurance.³⁰² "People with von Hippel-Lindau (VHL) disease, a rare hereditary condition that can cause brain and kidney tumors, often find it hard to obtain health insurance because of the expensive surgeries they might need."³⁰³ Parents of children at risk for VHL³⁰⁴ or for polycystic kidney disease³⁰⁵ often avoid having their children tested for the mutations because they fear the children will become uninsurable.

Insurance in the United States is based on concepts of risk spreading and risk sharing.³⁰⁶ When most people's future health risks are unknown, the future health care costs of a group can be predicted on an aggregate actuarial basis, and the costs can be spread across the whole group.³⁰⁷ As genetic technologies began to identify which currently healthy people will later develop particular diseases, insurance companies began to charge exorbitant amounts to people predicted to be at genetic risk or to deny them coverage entirely.³⁰⁸ At first glance, such a policy seems reasonable, for it is akin to

0,1282,19500,00.html (last visited May 15, 2001).

297. Bob Groves, *New Privacy Fight is All in the Genes*, REC., July 18, 1999, at N04.

298. *Id.*

299. *Id.*

300. *Id.*

301. Wendy McGoodwin, Council for Responsible Genetics, Address at the ABA Annual Meeting (Aug. 1997).

302. Tim Beardsley, *Vital Data*, SCI. AM., Mar. 1996, at 100, 102.

303. *Id.* at 103.

304. *See id.* (interview with William C. Dickson, research management chair of the VHL Family Alliance).

305. *See id.* (interview with Gregory G. Germino, a researcher at Johns Hopkins University School of Medicine).

306. Meredith A. Jagutis, *Insurer's Access to Genetic Information: The Call for Comprehensive Federal Legislation*, 82 MARQ. L. REV. 429, 432 (1999).

307. *Id.*

308. Karen Ann Jensen, *Genetic Privacy in Washington State: Policy Considerations and a Model Genetic Privacy Act*, 21 SEATTLE U. L. REV. 357, 368 (1997). At one company, the job interviewer

charging higher rates to people who smoke. As dozens of genes are identified each week, however, the absurdity of this approach becomes apparent. Because each of us has between eight and twelve genetic defects,³⁰⁹ everyone could potentially become uninsurable. Alternatively, if everyone were charged an amount equal to their future medical costs, insurance would lose all of its risk-spreading benefits.

The genetic revolution thus calls into question the current structure of health care financing in the United States, which is one of only two industrialized nations (the other being South Africa) that does not provide its citizens with universal access to health care.³¹⁰ Even if the United States is not willing to introduce such an approach, the challenges raised by genetic services suggest that careful consideration should be given to the possibility of going back to a community rating system, whereby the costs of private health care insurance are spread over the entire population of a larger geographic area. A handful of states have already implemented this approach.³¹¹

Just as insurance discrimination might occur based on genetic information, so might employment discrimination. A survey of U.S. geneticists revealed that many would share the patient's genetic information with employers *without the patient's consent*.³¹² Physicians are increasingly being put into the role of "double agents" with conflicting loyalties to the patient and to the patient's school, employer, potential insurer, relative, or child.³¹³

There are numerous examples of employment discrimination based on genetic information. In the early 1970s, some employers discriminated against African American employees and job applicants who were carriers of

learned the applicant's father had Alzheimer's disease. "I have single parents here,' he reportedly told her, 'and I don't want their premiums to go up.'" Armour, *supra* note 290.

309. See ANDREWS, *FUTURE PERFECT*, *supra* note 146, at 134-35.

310. ASSESSING GENETIC RISKS, *supra* note 52, at 20.

311. "A community rating system effectively spreads the risks of health care utilization over a substantial portion of the population, which creates a more equitable distribution of the financial burden." Katy Chi-Wen Li, *The Private Insurance Industry's Tactics Against Suspected Homosexuals: Redlining Based on Occupation, Residence and Marital Status*, 22 AM. J.L. & MED. 477, 500 (1996). At least eight states have enacted laws that require community rating in some instances of health insurance. ARK. CODE ANN. § 23-98-110 (Michie 1999); FLA. STAT. ANN. § 627.6699 (West 1996); LA. REV. STAT. ANN. § 22:228.6 (West 1995); 1997 N.H. LAWS 344; N.Y. COMP. CODES R. & REGS. tit. 11, § 360.1-12 (2000); N.C. GEN. STAT. § 58-50-130 (1999); VT. STAT. ANN. tit. 18, § 4080b (2001); WASH. REV. CODE ANN. §§ 48.43.005, 48.46.064, 48.46.066 (West 1999).

312. J.J. MULVIHILL ET AL., *ETHICS AND HUMAN GENETICS: A CROSS-CULTURAL PERSPECTIVE* 419, 440 (Dorothy C. Wertz & John C. Fletcher eds., 1989).

313. DOROTHY NELKIN & LAWRENCE TANCREDI, *DANGEROUS DIAGNOSTICS: THE SOCIAL POWER OF BIOLOGICAL INFORMATION* 164 (1989).

the sickle cell anemia gene even though carrier status has no impact on an individual's health or ability to perform his or her job.³¹⁴ The only significance of sickle cell carrier status is that the carrier has a twenty-five percent chance of having a child with sickle cell anemia if he or she procreates with another carrier.³¹⁵ More recently, a healthy carrier of the gene for Gaucher's disease was denied a government job based on his carrier status.³¹⁶ Another man was given restricted benefits and denied a promotion and job transfer because he and his son carry the gene for neurofibromatosis.³¹⁷ A computer scientist was refused a job when his preemployment physical revealed that he had Klinefelter's syndrome, a sex chromosome disorder occurring in one out of every 450 men.³¹⁸ The syndrome can cause sterility but does not impact one's ability to work.³¹⁹ A social worker was fired when her employer learned her mother had died of Huntington's disease.³²⁰ Another man claimed that he was not seriously ill during a preemployment physical.³²¹ He had a genetic form of kidney disease but was asymptomatic.³²² Nevertheless, the man's potential employer withdrew the job offer on the ground that he had "lied".³²³

According to a 1999 survey of one thousand large and mid-size companies, over half of all new hires are subjected to medical examinations and "dozens of firms don't inform applicants or employees about the types of tests being done."³²⁴ Thirty percent of the companies surveyed obtain genetic information on their employees through testing or family histories, and seven percent use such information for hiring and promotion decisions.³²⁵

Some employers test workers without their knowledge or consent.

314. ANDREWS, *MEDICAL GENETICS*, *supra* note 75, at 18.

315. John A. Robertson, *Genetic Selection of Offspring Characteristics*, 76 B.U. L. REV. 421, 441 (1996).

316. Billings et al., *supra* note 288, at 478.

317. Jon Matthews, *Bias Based on Genetic Testing Techniques*, SACRAMENTO BEE, May 7, 1995, at A3.

318. Groves, *supra* note 297.

319. Klinefelter Syndrome and Associates, *Sex Chromosome Variations—About 47XXY*, at <http://www.genetic.org/ks/scvs/47xxy.htm> (last visited Apr. 7, 2001).

320. Groves, *supra* note 297.

321. *Id.*

322. *Id.*

323. *Id.*

324. *Genetic Discrimination: The Next Civil Rights Issue*, AMERICAN HEALTH LINE, May 6, 1999, available at LEXIS, Nexis Library, News Group File. See also Armour, *supra* note 290.

325. 1999 AMA SURVEY ON WORKPLACE TESTING: MEDICAL TESTING: SUMMARY OF KEY FINDINGS 2, available at <http://www.amanet.org/research/medico/index.htm> (last visited May 17, 2001). An earlier study, a 1989 survey of companies by the Office of Technology Assessment of the U.S. Congress found that one in twenty companies conducted genetic screening or monitoring in the workplace. GENETIC MONITORING AND SCREENING, *supra* note 55, at 22.

Employees sued Lawrence Berkeley Laboratories, a University of California, Berkeley, laboratory funded by the U.S. Department of Energy.³²⁶ The suit alleged that the lab had tested African American employees for the sickle cell gene without their knowledge or consent during routine physicals and had secretly maintained the information in their files.³²⁷ A federal district court sided with the employer, finding that the practice did not invade the employees' privacy because they had agreed to undergo physical exams and give medical histories even though the employees had not been told about the genetic testing.³²⁸ The judge found that given the "overall intrusiveness" of the physical exams and the "large overlap" between the medical histories and the tests, any additional privacy intrusions due to the challenged tests were minimal.³²⁹

However, the Court of Appeals for the Ninth Circuit disagreed with the district court and held that an employer may not test employees for "highly sensitive" medical and genetic information without the employees' consent.³³⁰ The court stated that such "illicit"³³¹ testing, if proved at trial, would be an invasion of privacy in violation of the California Constitution and the U.S. Constitution, and because of its differential impact on blacks and women, it would amount to job discrimination in violation of Title VII.³³² Judge Stephen Reinhardt, writing for the unanimous three-judge panel, wrote: "One can think of few subject areas more personal and more likely to implicate privacy interests than that of one's health or genetic makeup."³³³ Judge Reinhardt also added that "it goes without saying that the *most basic* violation possible involves the performance of unauthorized tests—that is, the non-consensual retrieval of previously unrevealed medical information that may be unknown even to plaintiffs."³³⁴ The court rejected the argument that the workers had effectively consented to the tests by agreeing to undergo the medical exam, filling out medical questionnaires, and giving blood and urine samples.³³⁵ The court held that none of these acts was the same as authorizing a genetic test.³³⁶ The court allowed the job

326. *Norman-Bloodsaw v. Lawrence Berkeley Lab.*, 135 F.3d 1260 (9th Cir. 1998).

327. The judge also indicated that the intrusion was not actionable since the workers' employment apparently had not been affected by the test. *Id.* at 1266.

328. *Id.*

329. *Id.* at 1269.

330. *See id.* at 1268.

331. *Id.* at 1269.

332. *Id.* at 1275.

333. *Id.* at 1269.

334. *Id.*

335. *Norman-Bloodsaw*, 135 F.3d at 1269.

336. *Id.* at 1270.

discrimination claims to proceed, finding that the allegations “fall neatly into a Title VII framework.”³³⁷ Because only women were tested for pregnancy and only African Americans were tested for the sickle cell trait, the court stated that “the employment of women and blacks at Lawrence was conditioned, in part on allegedly unconstitutional invasions of privacy to which white and/or male employees were not subjected.”³³⁸ Further, Judge Reinhardt noted that even if different testing requirements based on sex, race, and pregnancy were unconstitutional, they would still be a valid basis for a Title VII discrimination claim.³³⁹

The availability of genetic technologies also changes people’s relationships with legal institutions. Courts are increasingly asked to mandate genetic testing, not for medical treatment, but to serve as the basis for a decision in a lawsuit. Judges have begun to accept—and even require—genetic information in a variety of cases. For judges with a complex, busy caseload, the idea that genetic information may provide legal guidance is seductive. Consequently, the use of genetic testing to answer legal questions is growing, without sufficient thought to the social context or social impact. Through DNA testing, a fifteen-year-old child may find out that her biological father is a man she has never met. Giving that man visitation rights simply because of a genetic bond proven through DNA testing, however, may be terribly disruptive.

In a South Carolina case, a judge actually ordered a woman to undergo Huntington’s disease testing in order to terminate her parental rights.³⁴⁰ This may foreshadow genetic battles in custody cases where divorcing spouses each seek genetic testing on the other in order to see which one is less likely to get cancer or heart disease and thus more likely to live longer. Such an evidentiary quest may put quantity of time with the child above quality since the quality of a parental relationship is more difficult to measure and prove than the presence or absence of a particular gene. Under this approach, the child may not actually end up with the “better” parent.

An even more explosive area of genetic testing may be in cases involving personal injury.³⁴¹ Currently, if an injured individual wins a case involving medical malpractice, an auto accident, or other tort, he or she is awarded

337. *Id.* at 1272.

338. *Id.*

339. *Id.*

340. Berkeley County Dept. of Social Services v. David Galley and Kimberly Galley, No. 92-DR-08-2699 (Moncks Corner, S.C., Apr. 19, 1994).

341. See Mark A. Rothstein, *Preventing the Discovery of Plaintiff Genetic Profiles by Defendants Seeking to Limit Damages in Personal Injury Litigation*, 71 IND. L.J. 877 (1996).

damages based on statistics about the life expectancy of a person that age.³⁴² Savvy defendants may begin to require genetic testing of plaintiffs to prove that there is a genetic reason that the plaintiff may die earlier than expected, so that the defendant will have to pay less in damages. When a chemical company was sued by parties on behalf of a child allegedly damaged by the company's toxins, the company persuaded a judge to order genetic testing on the boy in an attempt to prove that his problem was genetic and not due to exposure.³⁴³ Ruth Hubbard and Elijah Wald argue that, in suits against tobacco companies, the companies may be able to avoid liability if they blame the cancers on the plaintiff's genetic "susceptibilities".³⁴⁴

Plaintiffs' lawyers are now beginning to order genetic testing on their clients in order to stave off defendants' claims that the client's condition was not due to their negligence.³⁴⁵ In one such case, the medical malpractice defendant claimed that a child's mental retardation was the result of Oritz-Frias Syndrome, a genetic disorder. When testing revealed the condition was not genetic, the defendant settled for \$1.75 million.³⁴⁶

The implications of such legal maneuvers are profound. What if unforeseen genetic mutations are found when a plaintiff's lawyer orders genetic tests on a child? Although possibly irrelevant to the case, they could have a potentially lasting impact on the child, the child's parents, and the child's treatment by teachers, insurers, and future employers.

In the coming years, anyone who brings a personal injury claim or custody claim may be forced to undergo genetic testing. Given the enormous psychological and social impact of genetic information, many people who have been injured may be deterred from suing if there is a risk that a judge will force them to learn their genetic makeup. In the South Carolina suit, the woman who did not want to be tested for Huntington's disease³⁴⁷ faced a painful choice: either learn whether or not she was predisposed to an

342. *Id.* at 878 n.1.

343. Meg Fletcher, *Genetic Testing Ordered in Product Liability Case*, BUS. INS., Aug. 1, 1994, at 1, available at NEXIS, Lexis Library, News Group File.

344. RUTH HUBBARD & ELIJAH WALD, *EXPLODING THE GENE MYTH: HOW GENETIC INFORMATION IS PRODUCED AND MANIPULATED BY SCIENTISTS, PHYSICIANS, EMPLOYERS, INSURANCE COMPANIES, EDUCATORS, AND LAW ENFORCERS* (1993). Rebecca Pentz has pointed out that tobacco companies "claim that smoking only causes cancer in those with a genetic susceptibility—implying that if we just fix the genes there is no need to stop buying and using their product." Rebecca D. Pentz, *Commentary on "Ethical Issues in Genetic Engineering, Screening and Testing,"* by P. Michael Conneally 1-2 (Nov. 1996) (paper for Conference on Culture and Biology, Galveston, Texas).

345. Don Babwin, *Meet the New Building Block of Legal Life: Genetics*, ILL. LEGAL TIMES, Jan. 1999, at 1, available at NEXIS, Lexis Library, News Group File.

346. *Id.* (citing *Dewey v. Zack*, 651 N.E.2d 643 (Ill. App. Ct. 1995)).

347. ANDREWS, *FUTURE PERFECT*, *supra* note 146, at 144.

untreatable disease or give up the chance to seek custody of her child.³⁴⁸ She “decided to disappear—even though it would mean not seeing her child—rather than be tested.”³⁴⁹

This legal trend is a contributing factor of the growing genetic determinism taking place today. Dorothy Nelkin and Susan Lindee draw attention to the way genetics is increasingly being used to explain behavior.³⁵⁰ They note that since 1983, when the category behavioral genetics first appeared in the *Reader’s Guide to Periodic Literature*, hundreds of articles on that topic have appeared and “among the traits attributed to heredity have been mental illness, aggression, homosexuality, exhibitionism, dyslexia, addiction, job and educational success, arson, tendency to tease, propensity for risk taking, timidity, social potency, tendency to giggle or to use hurtful words, traditionalism, and zest for life.”³⁵¹ They also show how these ideas have influenced popular culture in the form of novels, movies, soap operas, and advertisements.³⁵²

Nelkin and Lindee discuss why such explanations are readily accepted by the public by explaining that they can “relieve personal guilt by implying compulsion, an inborn inability to resist specific behavior.”³⁵³ In addition, they can relieve societal guilt and excuse social services cutbacks by deflecting attention away from social and economic influences on behavior.³⁵⁴

VI. APPLICATION OF SOCIAL SCIENTIFIC INFORMATION TO THE EXISTING LEGAL MODELS

The serious impact of genetic technologies and genetic information necessitate the regulation of this field. The results of various empirical studies indicate the importance of personal autonomy over whether individuals are subject to genetic testing and who has access to those results. They also indicate the need for better quality assurance mechanisms to achieve these goals.

348. *Id.*

349. *Id.*

350. DOROTHY NELKIN & M. SUSAN LINDEE, *THE DNA MYSTIQUE: THE GENE AS A CULTURAL ICON* 82 (1995).

351. *Id.*

352. *Id.*

353. *Id.* at 145.

354. *Id.*

A. *The Medical Model*

Under the medical model, there are problems with relying on physicians to disseminate new genetic information. Physicians might not offer a test because of their own personality traits. A study by Neil Holtzman and his colleagues at Johns Hopkins found that a particular personality trait, tolerance for ambiguity, influenced whether physicians would offer patients genetic testing.³⁵⁵ In addition, the physician's gender can affect what services he or she offers. Surveys of medical students revealed that eighty-five percent of male medical students (compared to seventeen percent of female medical students) would not offer artificial insemination to a couple in which the man was at-risk for Huntington's disease, despite the fact that half the at-risk men claim they are willing to use donor sperm.³⁵⁶ A physician's religious beliefs or political views may also influence whether or not he or she informs patients of the availability of genetic services. When Vanderbilt researchers tried to recruit pediatricians to offer free cystic fibrosis carrier screening to the general population, the pediatricians refused because of their personal beliefs regarding abortion.³⁵⁷ The physicians did not want to tell couples that such testing was available because couples made up of carriers might choose to abort an affected fetus following prenatal diagnosis.³⁵⁸ Consequently, people often learn about genetic services from sources other than physicians. In a study of 520 women who had undergone amniocentesis, only thirty-six percent had first learned about the procedure from their obstetrician.³⁵⁹ Meanwhile, a similar percentage, thirty-six percent, first learned about the procedure from the media.³⁶⁰

Even when a physician offers the test, he or she may provide incorrect information to the patient. In a study of obstetricians in Rochester, New York, thirty-eight percent of ob-gyns surveyed incorrectly believed that one needed to have an affected relative in order to have a child with cystic fibrosis, and forty-three percent believed that CF only affected children of a

355. See Gail Geller et al., *Measuring Physicians' Tolerance for Ambiguity and its Relationship to Their Repeated Practices Regarding Genetic Testing*, 31 MED. CARE 989 (1993).

356. Sandra Leiblum & Christopher Barbrack, *Artificial Insemination by Donor: A Survey of Attitudes and Knowledge in Medical Students and Infertile Couples*, 15 J. BIOSOCIAL SCI. 165, tbl. 3, at 170 (1983).

357. Ellen Wright Clayton, CF Pilot Study, Presentation at Cystic Fibrosis Grantee Meeting, National Institutes of Health, Bethesda, MD (Sept. 8-10, 1993).

358. See *id.*

359. Margaret M. McGovern et al., *Acceptability of Chorionic Villi Sampling for Prenatal Diagnosis*, 155 AM. J. OBSTETRICS GYNECOLOGY 25, 27 (1986).

360. *Id.*

particular sex.³⁶¹ In a Johns Hopkins study, ninety-nine percent of geneticists but approximately fifty-six percent of ob-gyns knew, that when only one parent was a carrier, there was almost no chance of having a CF child.³⁶² In another study, twenty percent of the sickle cell carriers had the “misconception that sickle cell trait is a mild disease,” due to misinformation they received from their doctors.³⁶³

Physicians may coerce or mislead people into undergoing genetic testing because of their own beliefs about the type of information people should want or the kind of children who should be born, or even because of their own fear of legal liability if they failed to test someone. Even the language that physicians and genetic counselors use about testing exerts a subtle coercion. For example, patients who undergo genetic testing are described as “brave and courageous.” Even the decision to have a prophylactic mastectomy is described as “courageous.”³⁶⁴ People who decide not to have genetic testing are described as “avoiders”.

Under the medical model, only cursory attention is paid to informed consent. Genetic testing is now sometimes undertaken on behalf of people, particularly pregnant women, without their advance notice or informed consent.³⁶⁵ For example, obstetricians routinely test pregnant African American women for the gene for sickle cell anemia without informing them in advance or asking for their consent.³⁶⁶ Only when bad results indicate that the woman is a sickle cell anemia carrier is she informed.³⁶⁷

The problem of informed consent is exacerbated by multiplex testing, whereby numerous genetic tests can be performed on a single tissue sample.³⁶⁸ As a result, people will be offered prenatal testing for a greater range of disorders in situations in which there is no family history or other personal familiarity with the disorder. How health care providers describe the disorders will influence whether people will choose to undergo testing and

361. Peter T. Rowley et al., *Cystic Fibrosis Carrier Screening: Knowledge and Attitudes of Prenatal Care Providers*, 9 AM. J. PREVENTION MED. 261, 265 (1993).

362. Neil A. Holtzman, *Primary Care Physicians as Providers of Frontline Genetic Services*, 8 FETAL DIAGNOSTIC THERAPY 213, 216 (1993).

363. Stamatoyannopoulos, *supra* note 182, at 273.

364. Professor Michael Baum, who diagnosed Jenny Revill (the first woman in Britain to have a prophylactic mastectomy) called her surgical decision “courageous”. Revill, *supra* note 142. Nonetheless, Jenny says “nothing prepared me for the loss. . . . It was far more emotionally traumatic than I had expected.” *Id.*

365. For an example of a research protocol in which sickle cell anemia screening was undertaken without informed consent, see Peter T. Rowley et al., *Do Pregnant Women Benefit From Hemoglobinopathy Carrier Detection?*, 565 ANN. N.Y. ACAD. SCI. 152 (1989).

366. *Id.*

367. *Id.*

368. ASSESSING GENETIC RISKS, *supra* note 52, at 177-78.

whether women will choose to abort their fetuses based on the results. The fact that many tests will be undertaken on a single sample has led some physicians to decide against specifically informing patients about the genetic disorders being tested for before multiplex testing. Information, education, and counseling would be provided only *after* the individual tested positive for a genetic disorder.³⁶⁹

It does not seem appropriate to apply the medical model to genetic technologies, which can profoundly impact our self-image, intimate relationships, and childbearing plans. The model does not provide assurances that the information people receive is accurate. The medical model's treatment of quality assurance, or subsequent malpractice liability, is inadequate protection because errors in late-onset genetic disease testing may not be discovered until decades later. Even with respect to errors that may be discovered in the short term (such as failure to offer prenatal diagnosis that result in the birth of an affected child), litigation is not sufficient. Some judges have stated that unless patients tell doctors that they are in a high-risk group for a particular genetic disease, the doctors do not have to tell them about testing for that disease.³⁷⁰ Such an approach puts too heavy an onus on patients for them to decipher much genetic meaning out of their family history. Moreover, some types of malpractice suits in the genetic realm are prohibited by statute. Wrongful life suits are barred in nine states,³⁷¹ and wrongful birth suits are not allowed in seven states.³⁷² In the latter states, the physicians and labs cannot be sued for negligence if the couple carried to term a pregnancy they would have terminated regardless of the results.

B. The Public Health Model

Some genetics researchers and professionals, as well as some legal commentators, insist that genetic testing and treatment should be governed by a public health model. Other commentators may fail to realize that they

369. Sherman Elias & George Annas, *Generic Consent for Genetic Screening*, 330 NEW ENG. J. MED. 1611, 1612 (1994).

370. See, e.g., *Munro v. Regents of the Univ. of Cal.*, 263 Cal. Rptr. 878 (Cal. Ct. App. 1989).

371. See CAL. CIV. CODE § 43.6 (Deering 2001); IDAHO CODE § 5-334 (Michie 2000); IND. CODE ANN. § 34-12-1-1 (Michie 2000); ME. REV. STAT. tit. 24, § 2931 (West 2000); MINN. STAT. ANN. § 145.424 (West 2000); MO. REV. STAT. § 188.130 (1999); N.D. CENT. CODE § 32-03-43 (2000); 42 PA. CONS. STAT. ANN. § 8305 (West 2000); S.D. CODIFIED LAWS § 21-55-2 (Michie 2000); UTAH CODE ANN. § 78-11-24 (2000).

372. IDAHO CODE § 5-334 (Michie 1990); MINN. STAT. ANN. § 145.424(2) (West 1998); MO. ANN. STAT. § 188.130 (West 1996); N.C. GEN. STAT. § 14-45.1(e) (1993) (providing that doctors cannot be sued for refusing to participate in procedures that could result in abortion); 42 PA. CONS. STAT. ANN. § 8305(a) (West 1998); S.D. CODIFIED LAWS § 21-55-2 (Michie 1987); UTAH CODE ANN. § 78-11-24 (1996 & Supp. 2000).

are evoking a public health model when they make policy recommendations or discuss genetic obligations using language associated with public health. For example, language advocating the “prevention” of a genetic disease, analogies to infectious disease, and prevention directed toward contraception and abortion use language of the public health model.³⁷³ The “impropriety” of allowing affected children to be born is also suggested in articles that discuss the financial cost of genetic disorders to society by providing figures relating to the annual costs of care per patient.³⁷⁴

An increasing number of articles advocate a public health approach to genetics and various commentators argue that people have a duty to learn their genetic status. Dr. B. Meredith Burke states that teens should be required to have genetic tests when they become sexually active.³⁷⁵ Allowing minors to refuse genetic testing, says Burke, “downplays the moral and legal obligation to protect an innocent bystander,” namely, the fetus.³⁷⁶

There are other policies that could be adopted to further the public health model application. One is the imposition of tort liability for not sharing genetic information with relatives or for not undergoing genetic testing. A California case, *Curlender v. Bio-Science Laboratories*, suggested that a child born with Tay-Sachs, a genetic disease, could bring suit against her parents for not undergoing prenatal screening and aborting her.³⁷⁷ Some commentators go further and suggest that people should be criminally liable for not making use of genetic services. Lawyer and physician Margery Shaw, for example, recommends that states adopt policies to prevent the birth of children with genetic diseases.³⁷⁸ She suggests that the prevention of genetic disease is so important that couples who decide to give birth to a child with a serious genetic disorder should be criminally liable for child abuse.³⁷⁹

In many instances, the analysis of why the public health model is appropriate is very superficial. For example, researchers who wish to use patients’ blood samples without their permission to obtain breast cancer incidence data claim that their actions are appropriate because breast cancer

373. George Cunningham, Maternal Serum Alpha-Fetoprotein Screening in California (unpublished manuscript, on file with author).

374. See, e.g., Peter T. Rowley et al., *supra* note 361, at 261 (noting average cost for a patient with cystic fibrosis is \$10,000 and total direct costs may be \$300,000,000); Benjamin S. Wilfond & Norman Fost, *The Cystic Fibrosis Gene: Medical and Social Implication for Heterozygote Detection*, 263 JAMA 2777, 2781 (1990) (estimating the average annual cost \$7,500 and lifetime costs at least \$200,000).

375. B. Meredith Burke, *Genetic Testing for Children and Adolescents*, 273 JAMA 1089 (1995).

376. *Id.*

377. 165 Cal. Rptr. 477, 488 (Cal. Ct. App. 1980).

378. Shaw, *supra* note 285.

379. *Id.*

is a “public health threat.”³⁸⁰ However, the mere fact that a disease affects numerous people,³⁸¹ and is thus a major societal concern, does not mean that it is a public health threat. Most often, that term applies to imminently dangerous disorders that are highly contagious and put the public at risk.

Many commentators have argued that genetic testing should have a role in public health education. With respect to antismoking campaigns, for example, it is thought that people who know they have a genetic mutation that predisposes them to lung cancer would be more likely to quit smoking. The rationale is that genetic testing translates a general risk into an individualized risk, thus increasing the person’s fear and making it more likely that he or she will change his or her behavior. The problem, however, is that genetic information has such a powerful impact that it can make people too fearful to undertake preventive efforts. This is exactly what happened in a study that incorporated genetic information into a smoking cessation program.³⁸² People who learned that they were at higher risk for lung cancer were no more likely to quit smoking than people who did not have that genetic information.³⁸³ However, the people who had the genetic information were more depressed and fearful.³⁸⁴ The researchers concluded that the use of genetic testing may cause their plans to backfire: “Distress could lead some smokers to deny or to underestimate their smoking problem, which would increase resistance to behavioral change. Distress could also promote smoking to achieve the mood-enhancing effects of nicotine.”³⁸⁵

In many ways, the traditional public health model does not meet the task of providing education about genetics.³⁸⁶ The goals of public health educators are to change behavior to prevent disease, and to change attitudes and values leading to behavior changes. This is not the proper way to approach genetics.³⁸⁷ Many genetic disorders cannot be prevented; what is being prevented is the birth of children with these disorders. There is far less societal consensus on the appropriateness of aborting (or not conceiving)

380. See, e.g., Marc Landy & Kyle D. Dell, *The Failure of Risk Reform Legislation in the 104th Congress*, 9 DUKE ENVTL. L. & POL’Y F. 113, 127 (1998).

381. However, even though many women suffer from breast cancer, only five to ten percent of women with breast cancer have a hereditary form of the disease. *Scientists Report New Lead in the Genetics of Breast Cancer*, U.S. NEWSWIRE, Sept. 29, 1995, available at NEXIS, Lexis Library, News Group File.

382. Caryn Lerman et al., *Incorporating Biomarkers of Exposure and Genetic Susceptibility Into Smoking Cessation Treatment: Effects on Smoking-Related Cognitions, Emotions, and Behavioral Change*, 16 HEALTH PSYCHOL. 87, 96 (1997).

383. *Id.*

384. *Id.*

385. *Id.* (references omitted).

386. *Id.* at 94.

387. *Id.*

affected fetuses than there is on the goals of quitting smoking, preventing heart attacks, or eradicating infectious diseases.

Nor is there a clear justification for the public health approach of *mandating* genetic services. Currently, states use the public health model to mandate the use of genetic services by requiring newborn genetic screening.³⁸⁸ But there is less need to mandate testing now than in the late 1960s when newborn screening programs began. If a genetic disorder can be diagnosed in children and prevented or treated during childhood, there is reason to believe that in today's litigious climate, private physicians will offer genetic testing, thereby lessening the need for state interference.

Moreover, mandatory screening does not meet its public health goal. The government argument that it has a right to test children without parental consent to help the children is undercut by the fact that test results are rarely used.³⁸⁹ Most states do not provide funding for the necessary treatments, so poorer children do not receive them.³⁹⁰ In addition, since the public health model does not require parents to be informed about the test and consent to it, there is less accountability in the system, since parents will not know to check if the test has actually been done. By mandating testing and eliminating the requirement that health care professionals inform patients about the test, there is also a missed opportunity to educate people about genetics in general. Such information could help them in other decision-making situations.

It is possible that states may begin mandating genetic testing of adults: in particular, the genetic testing of pregnant women. Currently, a growing number of pregnant women receive genetic information about their fetuses' well-being through fetal blood sampling, chorionic villi sampling, amniocentesis, maternal serum alphafetoprotein screening, and other technologies.³⁹¹ However, the information is obtained at some risk to the fetus itself.³⁹² On the other hand, fetal cell sorting provides information about the fetus without creating a physical risk to the fetus or the pregnant

388. See *supra* notes 98-99, 103-04 and accompanying text.

389. Ellen Wright Clayton, *Screening and the Treatment of Newborns*, 29 Hous. L. Rev. 85, 104 n.84 (1992).

390. See *id.* at 129-30.

391. In the State of New York alone, 25,000 women per year are screened for fetal genetic abnormalities. Kimberly Nobles, *Birthright or Life Sentence: Controlling the Threat of Genetic Testing*, 65 S. Cal. L. Rev. 2081, 2087 (1992). Michael Malinowski notes that "[o]ne 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." Michael Malinowski, *Coming into Being: Law, Ethics, and the Practice of Prenatal Genetic Screening*, 45 HASTINGS L.J. 1435, 1453 (1994).

392. See, e.g., *Chorionic Villus Sampling and Subsequent Abortion*, 50 AM. FAMILY PHYSICIAN 1368 (1994); Golbus et al., *supra* note 137.

woman.³⁹³ A “simple” blood test is performed on the woman.³⁹⁴ Geneticists utilize complex procedures to capture minute amounts of fetal blood cells circulating in the woman’s blood.³⁹⁵ They undertake prenatal diagnosis on these cells to determine whether the fetus has Down syndrome,³⁹⁶ cystic fibrosis,³⁹⁷ Tay-Sachs disease,³⁹⁸ or other disorders. If states begin to mandate such screening, the purpose would be to guide the reproductive decisions of the couples who receive the information.

The advent of fetal cell sorting raises an important policy issue regarding women’s control over prenatal testing. Because the procedure does not create a *physical* risk to the fetus or the woman, there may be a trend toward undertaking the testing without the woman’s consent. In fact, some of the researchers developing this technique suggested that it could be used to screen large populations of women.³⁹⁹ A group of researchers noted that:

because the . . . procedure requires sampling of maternal blood rather than amniotic fluid, it could make widespread screening in younger women feasible Widespread screening is desirable because the relatively large number of pregnancies in women below 35 years old means that they bear the majority of children with chromosomal abnormalities despite the relatively low risk of such abnormalities in pregnancies in this age group.⁴⁰⁰

Some medical commentators have suggested taking a public health approach to the issue of genetic privacy by allowing physicians to breach a patient’s confidentiality and warn the patient’s relatives that they may also have a particular mutant gene, or imposing tort liability on people for not sharing genetic information with relatives. The commentators rely on public health precedents that allow doctors to warn third parties about their patients’

393. For a description of the technology, see Sherman Elias et al., *First Trimester Diagnosis of Trisomy 21 in Fetal Cells from Maternal Blood*, 340 LANCET 1033 (1992). See also Jane Chuen & Mitchell S. Golbus, *Prenatal Diagnosis Using Fetal Cells from the Maternal Circulation*, 159 W. J. MED. 308 (1993); Richard Saltus, *Noninvasive Way is Cited to Deter Down Syndrome in Fetuses*, BOSTON GLOBE, Nov. 12, 1992, at 8.

394. Elias et al., *supra* note 393.

395. *Id.*

396. Down syndrome is caused by extra genetic material on chromosome 21, which results in various malformations and mental retardation. Committee on Genetics, *Health Supervision of Children with Down Syndrome*, 93 PEDIATRICS 855 (1994).

397. See *supra* text accompanying note 43 (description of cystic fibrosis).

398. See *supra* text accompanying note 18 (description of Tay-Sachs disease).

399. Leonard A. Herzenberg et al., *Fetal Cells in the Blood of Pregnant Women: Detection and Enrichment by Fluorescence-Activated Cell Sorting*, 76 PROC. NAT’L ACAD. SCI. U.S.A. 1453, 1455 (1979).

400. *Id.*

violent proclivities⁴⁰¹ or infectious diseases.⁴⁰² The case of genetic disease, however, differs from that of violence and infectious disease. There are already established social policies aimed at preventing violence or the spread of infectious diseases. Criminal laws prohibit violence, and public health laws require reporting infectious diseases and preventing their spread. Thus, breach of doctor-patient confidentiality under such circumstances furthers an established social policy. In contrast, society's position on genetic disease is not so clear cut. For example, no laws have been adopted to prevent the birth of children with genetic disorders.

The legal cases involving infectious disease and violence could be interpreted as offering no precedent for a privilege or duty for health care providers to breach doctor-patient confidentiality to warn relatives of a genetic risk. In the genetics context, the patient is not the cause of the relative's potential genetic mutation.⁴⁰³ Warning siblings or cousins about genetic risks will not prevent them from having the genetic mutation that has already been programmed at conception, although it might prevent a particularly risky gene-environment interaction.⁴⁰⁴ Although warning the relatives about their genetic risk may prevent them from conceiving a child with the same gene, such a future occurrence is not the type of serious, imminent harm required in cases mandating disclosure by physicians to third parties.

Even if the state has a valid, compelling interest in furthering the birth of healthy children, mandating prenatal screening and mandatory disclosure of genetic status to relatives arguably does not further that interest. Since treatment for the screened-for disorders is generally not available, testing encourages the abortion of affected fetuses and deters carriers from having more children, rather than promoting the birth of healthy children.⁴⁰⁵ Because the state cannot show that the policy improves the health of potential children, it will likely argue that such a policy advances a state interest in

401. See, e.g., *Tarasoff v. Regents of Univ. of Cal.*, 551 P.2d 334 (Cal. 1976).

402. See, e.g., *Simonsen v. Swenson*, 177 N.W. 831 (Neb. 1920).

403. In the infectious disease cases, there was no duty to warn if the third party would have gotten the disease anyway. See *Britton v. Soltes*, 563 N.E.2d 910 (Ill. App. Ct. 1990); *Skilling v. Allen*, 180 N.W. 916 (Minn. 1921).

404. For example, a person with a genetic disposition to lung cancer might choose not to smoke.

405. The outcome of the legal analysis would change very little even if treatment were available. If the disorder at issue could be treated after birth, then testing the newborn infant would be a less restrictive alternative with respect to the woman than prenatal testing. If the disorder needed to be treated while the fetus was *in utero*, the case for prenatal testing would be stronger, but would still fail since the treatment would likely be more intrusive than the blood test and invade the woman's bodily integrity and interfere with her right to privacy. Since the woman would be able to refuse the treatment under *In re A.C.*, 573 A.2d 1235 (D.C. Cir. 1990), and *In re Baby Boy Doe*, 632 N.E.2d 326 (Ill. App. Ct. 1994), the state could not show that the testing would assure that the fetus was treated in the end.

saving money by discouraging the birth of children with genetic disorders. However, a state interest in saving money should not override a woman's right to refuse medical intervention.⁴⁰⁶ In particular, the potential burden on the state in caring for children has not been proven to be a compelling interest in other contexts.⁴⁰⁷

State-mandated genetic testing for diseases that are not readily treatable devalues people with disorders for which tests are available. By compelling fetal cell sorting, for example, the government would be directly influencing the type of children born in our society. Such interference smacks of government-initiated eugenics. Government control of the traits of children is inappropriate, despite arguments that it would "upgrade" some characteristics of the population.⁴⁰⁸

There are other dangers in misusing the public health approach. Interventions may be adopted before their risks have been assessed adequately. In the past, well-meaning genetics programs were adopted prematurely and caused unintended yet significant harm.⁴⁰⁹ In the late 1960s, state public health departments began mandatory screening of all infants for PKU which is a genetic disorder that can cause mental retardation if the child is not put on a special low phenylalanine diet shortly after birth.⁴¹⁰ Because the program was implemented without adequate research or monitoring of the children treated, some infants who did not have PKU died or suffered

406. The U.S. Supreme Court has not found the goal of protecting the public treasury to be superior to that of protecting individual rights. A person's right to travel is recognized as more important than the drain on the welfare system of the state to which he or she moves. *See, e.g.,* *Edwards v. California*, 314 U.S. 160 (1941).

407. For example, in *People v. Dominguez*, 64 Cal. Rptr. 290 (Cal. Ct. App. 1967), a pregnant, unmarried woman with two children was convicted of second degree robbery. A condition of her probation was that she would not become pregnant without being married so that the state taxpayers would be spared the burden of caring for illegitimate children. *Id.* at 292. Because the court did not view the state interest in saving money as overriding a woman's interest in childbearing, it is unlikely that the state's interest would have much weight in a genetic testing situation. *See id.* at 293. Moreover, it is also unclear whether the state could prove through a cost-benefit analysis that screening saves a sufficient amount of money to justify infringing upon individual choice. For example, the overall costs of screening and providing counseling and other services for all pregnant women might exceed the costs of supporting affected children. With respect to cystic fibrosis, "[i]t has been estimated that if a national [carrier] screening program were introduced, it would cost \$2.2 million for each case of cystic fibrosis avoided." Benjamin P. Sachs & Bruce Korf, *The Human Genome Project: Implications for the Practicing Obstetrician*, 81 *OBSTETRICS & GYNECOLOGY* 458, 459 (1993).

408. *See* Lori B. Andrews, *Prenatal Screening and the Culture of Motherhood*, 47 *HASTINGS L.J.* 967, 999 (1996) (discussing affect of parents' liberty interest in childrearing decisions on the traits of the children).

409. *See* Neil A. Holtzman, *Dietary Treatment for Inborn Errors of Metabolism*, 21 *ANN. REV. MED.* 335 (1970).

410. *Id.*

irreversible damage when put on the special diet.⁴¹¹

Some prior public health uses of genetic services have ignored the social and psychological impacts of genetic technologies. The laws establishing mandatory sickle cell anemia carrier status screening programs in the 1970s did not provide adequate counseling or sufficient confidentiality protections.⁴¹² The people identified by testing as carriers of the sickle cell gene were stigmatized and discriminated against in insurance and employment.⁴¹³

The empirical data about the potential negative impacts of genetic testing on people's emotional well-being, self-concept, personal relationships, and relationships with insurers and employers would argue against requiring people to learn their genotype against their will. Prevention, the traditional public health goal, does not readily apply to many genetic diseases. Consequently, when the Royal College of Physicians of London listed "prevention" as one of the aims of clinical genetics,⁴¹⁴ geneticist Angus Clarke attacked the idea of making prevention a specific goal:

If we include such prevention of genetic disorders amongst our aims, we immediately abandon the non-directive nature of genetic counselling in favour of a genetic public health policy, or eugenics. It is impossible to maintain a sincerely non-directive approach to counselling about a genetic disorder whilst simultaneously aiming to prevent that disorder: the opportunities for insider dealing are too great Its very name clearly conveys the impression that any birth of a child with a genetic disorder represents a medical failure, at least until proved otherwise. This public espousal of prevention, with the unfortunate choice of name, will ensure that the College's initiative is seen as eugenic⁴¹⁵

The public health approach to genetic services may also raise problems with quality assurance. Some state public health departments have found that as legislatures add more and more tests to the newborn screening mandate, they barely have enough money to test for each disorder, let alone design programs for quality assurance.⁴¹⁶ Although the Centers for Disease Control

411. *Id.*

412. See PHILIP REILLY, GENETICS, LAW, AND SOCIAL POLICY 62-86 (1977).

413. *Id.*

414. THE ROYAL COLLEGE OF PHYSICIANS OF LONDON, PRENATAL DIAGNOSIS AND GENETIC SCREENING: COMMUNITY AND SERVICE IMPLICATIONS (1989).

415. Angus Clarke, *Is Non-Directive Genetic Counselling Possible?*, 338 LANCET 998, 999 (1991).

416. See ASSESSING GENETIC RISKS, *supra* note 52, at 133.

and Prevention (CDC) has, at times, established admirable quality assurance programs for state public health departments, the CDC budget has at other times been insufficient to offer such quality programs.⁴¹⁷ Quality assurance under a public health approach is thus subject to political budget setting and is not a secure way to ensure adequate quality.

C. The Fundamental Rights Model

Under the fundamental rights approach, people are entitled to more information about medical services than under the medical model or public health model. Invoking this approach in the genetic context, a number of court cases dealt with physicians' failure to advise pregnant women over age thirty-five of the availability of prenatal testing, such as amniocentesis. The women in these cases had subsequently given birth to an affected child.⁴¹⁸ The physicians were held liable for not informing pregnant women about the availability of genetic testing even though, under a medical model, the medical standard of care at the time did not require physicians to give such information.

Currently, the fundamental rights approach has been limited to genetics research and genetics services in the reproductive context. However, this approach could be expanded to include decisions about other types of genetics services. It could be argued that genetic information is so central to one's own identity that decisions about whether or not to obtain such information and the potential uses of such information should be deemed a fundamental rights issue even when reproduction is not involved. An additional rationale for protecting genetics services under a fundamental rights model is that it has implications for one's freedom of association, a constitutionally protected right.⁴¹⁹ Information about a person's genetic status may influence whether someone wants to marry, employ, or otherwise associate with another person.

Under the fundamental rights approach, individuals would be entitled to extensive information about the genetics services that could be provided to them in the nonreproductive context (such as information about the availability of testing for genes associated with cancer), as well as in the reproductive context. Such an entitlement would be an incentive for physicians to learn about the technologies involved in genetic testing. The

417. *Id.*

418. *See, e.g.,* *Becker v. Schwartz*, 386 N.E.2d 807, 808 (N.Y. 1978).

419. *See generally* Kenneth L. Karst, *The Freedom of Intimate Association*, 89 *YALE L.J.* 624 (1980).

idea of educating physicians to deter negligent conduct has been used as a rationale in wrongful life and wrongful birth cases.⁴²⁰

In addition, participation in genetics services would be voluntary under the fundamental rights model. Concerned by the various psychological and social risks of genetic testing, various blue ribbon panels of government, ethics organizations, and entities such as the Institute of Medicine have recommended such approach.⁴²¹ In *Reproductive Genetic Testing: Impact Upon Women*, for example, the NIH Workshop recommended that “[r]eproductive genetic services should be *meticulously* voluntary.”⁴²²

Under a fundamental rights model, there would be equal protection under the law and a person’s genetic status would not be a permissible basis for discrimination by societal institutions. Currently, in the United States, policymakers have not adequately tackled the issues of genetic privacy and genetic discrimination. Six states have statutes prohibiting general genetic testing in general without informed consent,⁴²³ but they provide tenuous protection due to the exceptions to the statutes. In five of the six states, the police can gain access to tissue samples for genetic information.⁴²⁴ Four of the six state statutes have exceptions allowing researchers access to genetic samples without the individual’s knowledge or consent.⁴²⁵ The laws that have been adopted in recent years to protect against genetic discrimination in insurance also have loopholes. Thirty-four states prohibit denying people health insurance based on certain types of genetic information.⁴²⁶ Of these,

420. *Berman v. Allan*, 404 A.2d 8, 14 (N.J. 1979).

421. ASSESSING GENETIC RISKS, *supra* note 52, at 276.

422. *NIH Workshop Statement*, 8 FETAL DIAGNOSIS & THERAPY 6, 7 (1993) (emphasis added).

423. DEL. CODE ANN. tit. 16, § 1221(a) (2000); FLA. STAT. ch. 760.40 (2000); NEV. REV. STAT. ANN. § 629.151 (Michie 2000); N.M. STAT. ANN. § 24-21-4 (Michie 2000); N.Y. CIV. RIGHTS § 79-4(2) (McKinney 2001); VT. STAT. ANN. tit. 18, § 9332 (2001).

424. DEL. CODE ANN. tit. 16, § 1221(b)(1) (2000); FLA. STAT. ANN. ch. 760.40(2)(a) (2000); NEV. REV. STAT. ANN. § 629.151(1) (Michie 2001); N.M. STAT. ANN. § 24-21-3(c)(1) (Michie 2000); VT. STAT. ANN. tit. 18, § 9332(3) (2001).

425. DEL. CODE ANN. tit. 16, § 1221(b)(5) (2000); NEV. REV. STAT. ANN. § 629.151(4) (Michie 2001); N.M. STAT. ANN. § 24-21-3(c)(9) (Michie 2000); VT. STAT. ANN. tit. 18, § 9332(5)(d) (2001).

426. Twenty-nine states prohibit denial of insurance based on certain genetic information. *See* ALA. CODE § 27-53-2(b) (2000); ARIZ. REV. STAT. § 20-448(D) (2000); CAL. INS. CODE § 10140(b) (Deering 2001); COLO. REV. STAT. § 10-3-1104.7(1)(d) (2000); DEL. CODE ANN. tit. 18, § 2317(b) (2000); FLA. STAT. § 627.4301(2)(a) (2000); GA. CODE ANN. § 33-51-4 (2000); HAW. REV. STAT. ANN. § 431:10A-118(a)(1) (Michie 2000); 410 ILL. COMP. STAT. 513/20 (2000); IND. CODE ANN. § 27-8-26-7 (Michie 2000); KAN. STAT. ANN. § 40-2259(b)(3) (2000); KY. REV. STAT. ANN. § 304.12-085(2)(a) (Michie 2001); LA. REV. STAT. ANN. § 22:213.7(B)(1)(a) (West 2000); MD. CODE ANN., INS. § 27-909(c)(1) (2001); MINN. STAT. § 72A-139(3) (2000); MONT. CODE ANN. § 33-18-206(3) (2000); N.H. REV. STAT. ANN. § 141-H:2(II) (2000); N.J. STAT. ANN. § 17B:30-12(1)(e) (West 2001); N.M. STAT. ANN. § 24-21-4(b) (Michie 2000); N.C. GEN. STAT. § 58-3-215(c)(2) (2000); OHIO REV. CODE ANN. § 1751.64(B)(4) (Anderson 2001); OKLA. STAT. ANN. tit. 36, § 3614.1(C)(2) (West 2000); OR. REV. STAT. § 746.135(3) (1999); S.C. CODE ANN. § 38-93-20(A)(1) (Law. Co-op. 2001);

thirty states also prohibit conditioning the provisions of coverage on genetic information,⁴²⁷ and twenty-seven states prohibit the use of a person's genetic information to set rates.⁴²⁸ But most of these laws do not protect people from discrimination based on genetic information about their relatives. In twenty-six of the thirty-four states, insurers can easily circumvent the reach of the laws by basing their decisions on family histories.⁴²⁹ In addition, in most states, insurers can get around the laws by discriminating against people based not on their test result, but on the fact that they previously requested genetic services. Only twelve states prohibit such discrimination.⁴³⁰ Moreover, because of federal preemption under a statute known as the Employee Retirement Income Security Act (ERISA),⁴³¹ the state prohibitions on genetic discrimination do not cover self-funded insurance plans. Yet at least sixty-five percent of all companies and eighty-two percent of companies with more than 5,000 employees are self-insured.⁴³²

TENN. CODE ANN. § 56-7-2703 (2000); TEX. INS. CODE ANN. § 21.73 Sec. 3(a) (Vernon 2000); VT. STAT. ANN. tit. 18, § 9334 (2001); VA. CODE ANN. § 38.2-508.4(B)(1) (Michie 2000); WIS. STAT. § 631.89(2)(c) (2000). Four states prohibit insurers from requiring genetic tests. ME. REV. STAT. ANN. tit. 24-A, § 2159(C)(2) (West 2000); MO. REV. STAT. § 375.1306 (1999); NEV. REV. STAT. ANN. § 689A.417(1)(a) (Michie 2001); WIS. STAT. § 631.89(2)(a) (2000). In addition, Nebraska has established a commission to review genetic discrimination in insurance. NEB. REV. STAT. § 71-8102 (2000).

427. For a list of the twenty-nine states that prohibit such conditioning, see *supra* note 426.

428. See ALA. CODE § 27-53-2(b) (2000); ARIZ. REV. STAT. § 20-448(F) (2000); CAL. INS. CODE § 10143 (Deering 2000); HAW. REV. STAT. ANN. § 431:10A-118(a)(1) (Michie 2000); 410 ILL. COMP. STAT. 513/20 (2000); IND. CODE ANN. § 27-8-26-5(3) (Michie 2000); KAN. STAT. ANN. § 40-2259(b)(4) (2000); KY. REV. STAT. ANN. § 304.12-085(1) (Michie 2001); LA. REV. STAT. ANN. § 22:213.7(b)(1) (West 2001); ME. REV. STAT. ANN. tit. 24-A, § 2159C(2) (West 2000); MD. CODE ANN., INS. § 27-909(c)(1) (2000); MINN. STAT. § 72A-139(4) (2000); MO. REV. STAT. § 375.1303 (1999); MONT. CODE ANN. § 33-18-206(4) (2000); NEV. REV. STAT. ANN. § 689A.417(1)(c) (Michie 2001); N.H. REV. STAT. ANN. § 141-H:4(IV) (2000); N.M. STAT. ANN. § 24-21-4(b) (Michie 2000); N.C. GEN. STAT. § 58-3-215(c)(1) (2000); OHIO REV. CODE ANN. § 1751.64(B)(2) (Anderson 2001); OKLA. STAT. ANN. tit. 36, § 3614.1(C)(2) (West 2000); OR. REV. STAT. § 746.135(3) (1999); S.C. CODE ANN. § 38-93-20(A)(1) (Law. Co-op. 2001); TENN. CODE ANN. § 56-7-2703 (2000); TEX. INS. CODE ANN. § 21.73 Sec. 3(a) (Vernon 2000); VA. CODE ANN. § 38.2-508.4(B)(6) (Michie 2000); WIS. STAT. § 631.89(2)(d) (2000).

429. Only eight states prohibit considering information from a relative in determining rates. See HAW. REV. STAT. ANN. § 431:10A-118(a)(1) (Michie 2000); KAN. STAT. ANN. § 40-2259(b)(4) (2000); LA. REV. STAT. ANN. § 22:213.7(b)(1) (West 2000); MINN. STAT. § 72A-139(4) (2000); NEV. REV. STAT. ANN. § 689A.417(c)(2) (Michie 2001); N.H. REV. STAT. ANN. § 141-H:4(IV) (2000); TENN. CODE ANN. § 56-7-2703 (2000); WIS. STAT. § 631.89(2)(d) (2000).

430. See FLA. STAT. ANN. § 627.4301(2)(b) (2000); KY. REV. STAT. ANN. § 304.12-085(2)(b) (Michie 2001); LA. REV. STAT. ANN. § 213.7(B)(1) (West 2000); ME. REV. STAT. ANN. tit. 24-A, § 2159-C(2) (West 2000); MINN. STAT. § 72A-139(3) (2000); MO. REV. STAT. § 375.1303(1)(3) (1999); NEV. REV. STAT. ANN. § 689A.417(1)(b) (Michie 2001); N.H. REV. STAT. ANN. § 141-H:2(II) (2000); N.M. STAT. ANN. § 24-21-4(A) (Michie 2000); TENN. CODE ANN. § 56-7-2703 (2000); VA. CODE ANN. § 38.2-508.4(b) (Michie 2000); WIS. STAT. § 631.89(2)(b) (2000).

431. 29 U.S.C. § 1144(a) (1994).

432. Eric Zicklin, *More Employers Self-Insure Their Medical Plans Survey Finds*, BUS. AND

The Health Insurance Portability and Accountability Act of 1996 protects individuals from losing coverage when they change jobs.⁴³³ Under the Act, a new employer's group health plan cannot deny coverage or apply preexisting condition exclusions for more than twelve months for any condition diagnosed or treated in the preceding twelve months.⁴³⁴ In addition, group health plans cannot establish eligibility for enrollment on the basis of health status, medical history, or genetic information.⁴³⁵

The law is insufficient, however. It does not prohibit genetic discrimination against people seeking insurance under individual plans and denied or charged exorbitant premiums for coverage.⁴³⁶ Moreover, the law does not prohibit group insurers from charging higher rates to a whole group based on genetic information about a particular individual.⁴³⁷

In the employment context, sixteen states prohibit conditioning employment on genetic testing.⁴³⁸ However, only a few states prohibit employment discrimination based on family history.⁴³⁹ At the federal level, the Americans with Disabilities Act (ADA) prohibits employers with fifteen or more employees from refusing to hire or otherwise discriminate against people with disabilities or who are regarded as having disabilities (unless the disability impedes their ability to do the job in question).⁴⁴⁰ The ADA protects people whose disabilities have already manifested, yet are otherwise qualified to do the job.⁴⁴¹ But there are questions about whether a genetic predisposition without any symptoms should be considered a disability. After much equivocating, the Equal Employment Opportunities Commission (EEOC) provided guidance about how the ADA would apply to an

HEALTH, Apr. 1992, at 74, available at NEXIS, Lexis Library, News Group File.

433. 42 U.S.C. § 300gg (Supp. II 1996).

434. *Id.*

435. *Id.* § 300gg(b)(1)(B).

436. *Id.*

437. *Id.*

438. See ARIZ. REV. STAT. § 41-1463(B)(4) (2000); CONN. GEN. STAT. § 46a-60(11)(B) (1999); DEL. CODE ANN. tit. 19, § 711(a) (2000); IOWA CODE § 729.6(2)(b) (2000); ME. REV. STAT. ANN. tit. 5, § 19302 (West 2000); MO. REV. STAT. § 375.1306(1) (1999); N.H. REV. STAT. ANN. § 141-H:3(I)(b) (2000); N.J. STAT. ANN. § 10:5-12(a) (West 2001); N.Y. EXEC. LAW § 296(1) (McKinney 2001); N.C. GEN. STAT. § 95-28.1A (2000); OKLA. STAT. ANN. tit. 36, § 3614.2(C)(1) (West 2000); OR. REV. STAT. § 659.036(1) (1999); R.I. GEN. LAWS § 28-6.7-1(a)(2) (2001); TEX. LAB. CODE ANN. § 21.402(a) (Vernon 2000); VT. STAT. ANN. tit. 18, § 9333(a) (2001); WIS. STAT. § 111.372(1)(b) (2000).

439. DEL. CODE ANN. tit. 19, § 711(e) (2000); ME. REV. STAT. tit. 5, § 19302 (West 2000); N.J. STAT. ANN. § 10:5-12(a) (West 2001); N.Y. EXEC. LAWS § 292 (21-d) (McKinney 2001) (prohibiting discrimination based on offspring's test); N.C. GEN. STAT. § 95-28.1A (2000).

440. 42 U.S.C. §§ 12101-17 (1994).

441. *Id.*

individual who is presymptomatic for a genetic disease.⁴⁴² According to the EEOC, it is illegal for an employer to discriminate against a person based on genetic information relating to illness, disease, or other disorders.⁴⁴³ As an example, the EEOC indicated that an employer may not refuse to hire an individual simply because the person's genetic profile reveals an increased susceptibility to colon cancer.⁴⁴⁴ Again, this interpretation may not go far enough. It does not specifically address a case in which someone is denied a job because he or she is a carrier of a recessive disorder, such as cystic fibrosis, and the potential employer does not want to pay the health care costs of potential affected children. Also, it does not prevent employers from performing genetic tests on employees, as was done in the *Lawrence Berkeley Laboratory* case. In that case, the California constitution had a particularly strong privacy provision, thus allowing the appellate court to condemn the procedure.⁴⁴⁵ In other states, employers may be legally able to test employees without their consent. In contrast, the fundamental rights approach would require greater protections. For example, the fundamental rights approach mandates disclosures about quality. In Virginia, IVF clinics must disclose their success rates.⁴⁴⁶ In other states, lengthy disclosures must be made about the medical and psychological backgrounds of proposed surrogate mothers.⁴⁴⁷

A reason for the need for stronger regulation in the genetics area is that genetic testing is more prone to error than other scientific tests. Additionally, genetic testing can have such a profound impact on people and their most important life decisions and relationships, it should only be undertaken with advance knowledge and assurances of quality.

The fundamental rights model would provide appropriate protections for people using genetic services, in contrast to the medical model and the public health model. The fundamental rights model would require that participation in genetic services was voluntary and that participants maintain control over their genetic information. Since the medical benefits of genetic testing are in many instances unproven, and there are potential psychological and social risks in genetic testing, the need for assurance that patients will make voluntary and informed decisions about participating in testing is particularly

442. U.S. EQUAL EMPLOYMENT OPPORTUNITY COMM'N, COMPLIANCE MANUAL SECTION ON THE DEFINITION OF THE TERM "DISABILITY" § 902.8(a) (1995).

443. *Id.*

444. *Id.*

445. *Norman-Bloodsaw v. Lawrence Berkeley Lab.*, 135 F.3d 1260 (9th Cir. 1998).

446. VA. CODE ANN. § 54.1-2971.1 (Michie 2000).

447. *See, e.g.*, N.H. REV. STAT. ANN. §§ 16B-13:13, B:18 (2000); VA. CODE ANN. § 20-160 (Michie 2000).

significant. The fundamental rights model would also require enhanced regulation to ensure quality assurance since the usual tort incentives for behaving nonnegligently are not operating with as great a force in genetics as they are in other medical areas.

VII. LEGAL JUSTIFICATION FOR THE FUNDAMENTAL RIGHTS MODEL

The medical model and the public health model would, in a de facto or de jure manner, require people to undergo certain forms of genetic testing. In contrast, the fundamental rights model would prevent people from being tested genetically without their consent. In addition, for people who undergo such services, only the fundamental rights model would be concerned with the impact of a third party's use of an individual's genetic information and would provide adequate assurance of quality. Consequently, in protecting voluntariness in testing, control over the use of one's own genetic information, and accuracy of test results, the fundamental rights model most closely comports with people's needs.

Implementing the fundamental rights approach would require a careful consideration of the appropriate measures for protecting voluntariness, transmitting sufficient information for informed consent, and maintaining quality assurance. Existing legal doctrines would support many of these measures. New laws would be necessary in only a few instances, such as the protection against genetic discrimination.

The common law right of bodily integrity⁴⁴⁸ and the right to refuse medical interventions⁴⁴⁹ could be used as the basis to forbid unauthorized genetic testing. If the testing is part of a state or federal program, additional constitutional protections come into play to protect the right to refuse the intervention such as privacy protection of certain personal information, protections against unreasonable searches and seizures, protections of bodily integrity, and protections of reproductive decision making and decisions regarding childrearing.⁴⁵⁰

Medical information is protected as private, in part because of the psychological, social, and financial risks of its disclosure.⁴⁵¹ Common law

448. See, e.g., *Union Pac. Ry. Co. v. Botsford*, 141 U.S. 250, 251 (1891); *Fosmire v. Nicoleau*, 551 N.E.2d 77, 80-81 (N.Y. 1990).

449. *Matter of Conroy*, 486 A.2d 1209 (N.J. 1985).

450. Equal protection concerns might be raised as well. Such testing might be considered discriminatory based on pregnancy or sex. See, e.g., *Geduldig v. Aiello*, 417 U.S. 484 (1974).

451. See *Doe v. Borough of Barrington*, 729 F. Supp. 376 (D.N.J. 1990).

Society's moral judgment about the high-risk activities associated with the disease, including sexual relations and drug use, make the information of the most personal kind. Also, the privacy

privacy protections exist for certain types of medical information,⁴⁵² as do federal constitutional protections.⁴⁵³ Some mandatory genetic testing would provide medical information about the woman or fetus to third parties (e.g., laboratory personnel or physicians), which could arguably be a breach of privacy if misused.⁴⁵⁴ Such testing would also violate the privacy right not to know medical information about oneself.⁴⁵⁵ In addition, the right of informed consent also includes a right to refuse medical information that is offered by physicians.⁴⁵⁶

An individual could assert a Fourth Amendment right⁴⁵⁷ to refuse the collection of blood or other tissue for a genetic test that was mandated by law or undertaken by a government institution, such as a state university medical school. Mandatory blood testing is considered a search and seizure that must comply with Fourth Amendment standards which balance the nature and quality of the intrusion against the strength of the given state interest.⁴⁵⁸ Under such an analysis, mandatory testing of an arrested individual's blood for HIV infection has been found unconstitutional under the Fourth Amendment.⁴⁵⁹ Similarly, mandatory HIV testing of state employees working with developmentally disabled clients was enjoined as an unreasonable search and seizure under the Fourth Amendment because the

interest in one's exposure to the AIDS virus is even greater than one's privacy interest in ordinary medical records because of the stigma that attaches with the disease.

Id. at 384. Genetic information raises a similar risk of stigma and discrimination.

452. See ANDREWS, *MEDICAL GENETICS*, *supra* note 75, at 190-94 (discussing common law actions for breach of medical privacy including actions based on the tort of privacy, breach of contract, malpractice, and breach of fiduciary duty).

453. See, e.g., *Whalen v. Roe*, 429 U.S. 589, 599-600 (1977); *Doe v. City of New York*, 15 F.3d 264 (2d Cir. 1994).

454. It has long been recognized that a blood sample contains more medical information than a traditional medical record. As Fred Bergmann of the National Institutes of Health stated:

The genetic counselor takes a history and puts it in the computer bank. He also takes a blood sample and puts it in the deep freeze. And from the point of view of confidentiality, I would suggest that there is much more information in the deep freeze than in the computer bank, and I think that point should be appreciated by the lawyers and everyone else.

Harold P. Green, *Mechanisms for Public Policy Decision-Making*, in *ETHICAL ISSUES IN HUMAN GENETICS: GENETIC COUNSELING AND THE USE OF GENETIC KNOWLEDGE* 411 (Bruce Hilton et al. eds., 1973) (statement of F. Bergmann).

455. Michael L. Closen, *Mandatory Disclosure of HIV Blood Test Results to the Individual Tested: A Matter of Personal Choice Neglected*, 22 *LOY. U. CHI. L.J.* 445, 454-57 (1991); Martha A. Field, *Pregnancy and AIDS*, 52 *MD. L. REV.* 402, 409-13 (1993).

456. Lori B. Andrews, *Informed Consent Statutes and the Decisionmaking Process*, 5 *J. LEGAL MED.* 163, 215-16 (1984). See also, e.g., *Cobbs v. Grant*, 502 P.2d 1, 12 (Cal. 1976).

457. See, e.g., Harold J. Krent, *Of Diaries and Data Banks: Use Restrictions Under the Fourth Amendment*, 74 *TEX. L. REV.* 49, 50-51 (1995).

458. *Schmerber v. California*, 384 U.S. 757, 771-72 (1966) (holding that a blood test was permissible as a "minor intrusion").

459. *Barlow v. Ground*, 943 F.2d 1132, 1137 (9th Cir. 1991).

employees' privacy interests outweighed the state's interest in preventing clients from contracting AIDS from employees.⁴⁶⁰

Not only is an individual's body considered private territory, protected by constitutional law and tort law, the information generated through the use of genetic technologies is private as well. Yet, despite all the precedents protecting individual medical decision making, proponents of mandatory genetic testing (such as mandatory fetal cell sorting for pregnant women) might argue that the process only creates a minimal burden on an individual and thus should not be viewed as an infringement of a person's constitutional rights. The view of a blood test as creating minimal burden is present in some Fourth Amendment cases.⁴⁶¹ Moreover, the cases holding that pregnant women have a right to refuse Cesarean sections turned, in part, on the fact that such operations are extremely physically invasive. In *In re A.C.*, for example, the court held that it was improper to order a Cesarean section on an unconsenting woman, but stated: "Our discussion of the circumstances, if any, in which the patient's wishes may be overridden presupposes a major bodily invasion. We express no opinion with regard to the circumstances, if any, in which lesser invasions might be permitted . . ."⁴⁶²

However, even though some courts have viewed blood tests as insignificant, there is reason to believe that genetic tests using blood samples are different because the federal government treats them as different. While certain other blood tests used in federally funded research may be exempt from full review by the Institutional Review Board because they are viewed as entailing "minimal risks,"⁴⁶³ the federal Office of Protection from Research Risks has indicated that genetic tests using blood samples present greater than minimal risks due to the harmful psychological and social risks for tested individuals, including "stigmatization, discrimination, labelling, and potential loss of or difficulty in obtaining employment or insurance."⁴⁶⁴

Recognizing people's right to refuse genetic testing is in keeping with a vast body of legal decisions. Cases dealing with informed consent,⁴⁶⁵ fiduciary duty,⁴⁶⁶ the disposal of body parts,⁴⁶⁷ tissue transplantation,⁴⁶⁸ and

460. *Glover v. E. Neb. Cmty. Office of Retardation*, 867 F.2d 461 (8th Cir. 1989).

461. *See, e.g., Schmerber*, 384 U.S. at 771-72.

462. *In re A.C.*, 573 A.2d 1235, 1246 n.10 (D.C. Cir. 1990). *See also In re Baby Boy Doe*, 632 N.E.2d 326, 333 (Ill. App. Ct. 1994).

463. 45 C.F.R. § 46.110 (1999).

464. OFFICE FOR PROTECTION FROM RESEARCH RISKS, NAT'L INST. OF HEALTH, PROTECTING HUMAN RESEARCH SUBJECTS: INSTITUTIONAL REVIEW BOARD GUIDEBOOK 5-45 (1993).

465. *See, e.g., Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479 (Cal. 1990).

466. *Id.*

467. *See, e.g., Browning v. Norton Children's Hosp.*, 504 S.W.2d 713 (Ky. 1974).

468. *See, e.g., Curran v. Bosze*, 566 N.E.2d 1319 (Ill. 1990).

relatives' rights to make decisions about a deceased person's organs⁴⁶⁹ and tissues all create constraints on what researchers may do with tissue and what information they owe to their subjects and subjects' relatives. Taken together, legal precedent indicates that patients are entitled to certain information before blood and tissue removal and testing.

VIII. CONCLUSION

The policy model we choose to oversee genetic testing and its resulting genetic information will be the caretaker of our values. Society faces the vexing question of how the fruits of genetic research should be used everyday. The task of developing policy in this field is similar to that of writing science fiction. We must envision our society under competing policy approaches. Studies of the actual impact of genetic services on individuals, groups, and society at large help us to evaluate the alternative futures that genetics may bring and guide individuals and society through the choices raised by genetics.

469. See, e.g., *Brotherton v. Cleveland*, 923 F.2d 477 (6th Cir. 1991).