
NOTE

ENDING THE GENETIC DISCRIMINATION BARRIER: REGAINING CONFIDENCE IN PRECONCEPTION, PRENATAL, AND NEONATAL GENETIC TESTING

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*One of the ironies in the current health care coverage crisis is that developing more accurate biomedical information could make things worse rather than better.*¹

INTRODUCTION

Every human being carries approximately five to seven fatal recessive genes² and up to thirty genetic predispositions to various disorders.³ As researchers develop the ability to identify these genetic indicators, more people may be discriminated against by health insurers based on genetic

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1. NIH-DOE WORKING GROUP ON ETHICAL, LEGAL & SOC. IMPLICATIONS OF HUMAN GENOME RESEARCH, NAT'L HUMAN GENOME RESEARCH INST., NIH PUBL. NO. 93-3686, GENETIC INFORMATION AND HEALTH INSURANCE (1993), http://www.nhgri.nih.gov/About_NHGRI/Der/Elsi/itf.html.

2. Alexander M. Capron, *Which Ills to Bear?: Reevaluating the "Threat" of Modern Genetics*, 39 EMORY L.J. 665, 690 (1990).

3. Louise M. Slaughter, *Genetic Information Must Remain Private to Prevent Discrimination*, *Spur Research*, 2 GENETIC TESTING 17, 19 (1998).

information. Over the past ten years, the federal government has supported a research effort to map the entire human genome. This endeavor has yielded the discovery of genetic links to many potentially deadly diseases including breast and colon cancer, cystic fibrosis, and Lou Gehrig's disease.⁴

In September 1999, leaders of the government-funded Human Genome Project announced that they would meet their goal of completing a high-quality human DNA reference sequence by 2003—two years earlier than estimated.⁵ This accelerated schedule enabled the Project to develop a rough draft of the entire human genome in the spring of 2000—one year before the scheduled completion date.⁶

While genetic testing holds great promise for preventing and treating many diseases, it is uniquely suited to improve the problem of genetic birth defects. Newly developed testing and screening programs to detect the probability of genetic conditions before, during, and after birth offer prevention and treatment options to parents that would not be available if the birth defects were detected later. Additionally, recent research indicates that even more options are on the horizon.⁷ These vast improvements in preventing and treating genetic birth defects will not be realized, however, if prospective parents fear that genetic testing will adversely affect their insurance coverage and fail to avail themselves and their babies of timely genetic tests.

While researchers are making remarkable strides in genetics that promise to yield significant clinical benefits, public fear of misuse of genetic information threatens to stymie this effort. Genetic discrimination,⁸

4. See Lynn E. Egan, Note, *Genetic Discrimination in Health Insurance*, 24 J. LEGIS. 237, 238 n.5 (1998).

5. See Human Genome Program, U.S. Dep't of Energy, *HGP Leaders Confirm Accelerated Timetable for Draft Sequence*, HUMAN GENOME NEWS, Oct. 1999, at 1, available at <http://www.ornl.gov/hgmis/publicat/hgn/v10n3/hg10n34col.pdf> [hereinafter Human Genome Program].

6. Press Release, White House Office of the Press Sec'y, President Clinton Announces the Completion of the First Survey of the Entire Human Genome (June 25, 2000), at <http://www.ornl.gov/hgmis/project/clinton1/htm> [hereinafter White House Press Release].

7. See *infra* text accompanying notes 70–75, 98–117.

8. As used in this Note, the term "genetic discrimination" describes the act of differentiating between individuals based on their genetic makeup. Others suggest that the concept of genetic discrimination is inherently faulty because it is based on the idea that there is a "normal" genotype and that variation from that norm is defective. See Susan M. Wolf, *Beyond "Genetic Discrimination": Toward the Broader Harm of Geneticism*, 23 J.L. MED. & ETHICS 345, 350 (1995). Wolf suggests that, in light of the rich heterogeneity associated with the human genome, "geneticism" is a more accurate description of using genetics to "reinforce power relationships in which some dominate and others are subordinated." *Id.*

as the newest form of discrimination in the United States, has not yet spurred comprehensive empirical research on public attitudes toward genetic progress. A recent empirical study conducted to test for breast cancer genes, however, found that one-third of the prospective subjects declined to participate in the study, citing fear that their genetic information would not be kept confidential.⁹

Part I of this Note describes the problem of birth defects and the genetic tests that are available to diagnose or to prevent certain genetic conditions. It includes a discussion of how preconception, prenatal, and neonatal genetic testing can ameliorate the problem of birth defects. Part II describes indicators of the public's fear of genetic discrimination, why genetic information is valuable to health insurance companies, and why it may be injurious to individuals as a result. Part III details how states have responded to the fear of discrimination by enacting legislation. It also evaluates the success of state laws in addressing genetic discrimination. Part IV outlines current and proposed federal legislation and highlights the gaps in protection left by these laws. Finally, Part V argues that comprehensive federal legislation prohibiting insurers' use of genetic information is needed to protect the future of genetic research and the prospects for prevention and treatment that it brings. This federal legislation must engender four ideals as guidelines for reform: 1) a broad definition of genetic information; 2) protection for routine tests and examinations; 3) protection for scientific uses of genetic information; and 4) universal application for all insureds.

I. THE IMPACT OF PRECONCEPTION, PRENATAL, AND NEONATAL GENETIC TESTING ON BIRTH DEFECTS

A. THE PROBLEM OF BIRTH DEFECTS

Every year in the United States, over 120,000 families experience the birth of a baby with a serious birth defect.¹⁰ The implications for such an event are far reaching. In addition to the psychological trauma that accompanies caring for a child with a birth defect, these families must cope with daunting economic realities. These economic implications include

9. See *Genetic Information and Health Care: Hearing Before the S. Labor & Human Res. Comm.*, 105th Cong. 38 (1998) [hereinafter *Senate Hearing*] (testimony of Judith Palkovitz, Vice President of Hadassah Women's Jewish Membership Organization).

10. See Ctrs. For Disease Control & Prevention, U.S. Dep't of Health & Human Servs., *Economic Costs of Birth Defects and Cerebral Palsy—United States, 1992*, 44 MORBIDITY & MORTALITY WKLY. REP. 694, 698 (1995) [hereinafter *Economic Costs of Birth Defects*].

both medical costs for ongoing health care as well as nonmedical costs like special education and rehabilitation.¹¹ For example, the estimated additional lifetime costs for an individual born with cystic fibrosis is \$800,000.¹²

Four of the most common and serious birth defects that have been linked to genetic origins are spina bifida, cystic fibrosis, sickle cell disease, and Tay Sachs disorder. “Spina bifida is the most frequently occurring permanently disabling birth defect. It affects approximately one out of every 1,000 newborns in the United States.”¹³ It is a condition in which the spinal column fails to close early in gestation.¹⁴ Nerve damage caused by spina bifida *in utero* is irreversible but can be minimized by surgery shortly after birth.¹⁵

Cystic fibrosis is “the most common fatal autosomal recessive disease in the American population”¹⁶ and affects one in 2,500 white individuals.¹⁷ Over ten million people (one in thirty-one) in the United States are carriers of the cystic fibrosis gene.¹⁸ The average life span for an individual with cystic fibrosis is thirty years.¹⁹

11. *See id.* at 695.

12. Consensus Dev. Conference, Nat'l Insts. Of Health, *Genetic Testing for Cystic Fibrosis*, 159 ARCHIVES INTERNAL MED. 1529, 1533 (1999).

13. SPINA BIFIDA ASS'N OF AM., FACTS ABOUT SPINA BIFIDA, at http://sbaa.org/html/sbaa_facts.html (2001) [hereinafter FACTS ABOUT SPINA BIFIDA].

14. *See* Phillip R. Reilly, *Biomedical Technology, Ethics, Public Policy, and the Law: Public Policy and Legal Issues Raised by Advances in Genetic Screening and Testing*, 27 SUFFOLK U. L. REV. 1327, 1331 (1993). This failure often leaves the affected child paralyzed in the lower limbs and impairs bladder and bowel functioning. *See id.* Spina bifida is often accompanied by hydrocephalus, a condition in which fluid accumulates in the brain, which will cause brain damage unless alleviated through a drainage process called shunting. *See* NORMAN J. WAITZMAN, RICHARD M. SCHEFFLER & PATRICK S. ROMANO, THE COST OF BIRTH DEFECTS: ESTIMATES OF THE VALUE OF PREVENTION 145, 192–93 (1996).

15. *See* FACTS ABOUT SPINA BIFIDA, *supra* note 13.

16. Capron, *supra* note 2, at 684. An autosomal recessive disease is one which is not sex linked and requires inheritance of carrier genes from both parents. *See* GENE CARE MED. GENETICS CTR., TAY SACHS TESTING, at <http://www.genecare.com/ts.html> (last modified Oct. 6, 2000) [hereinafter GENE CARE].

17. *See* BARRY R. FURROW, SANDRA H. JOHNSON, TIMOTHY S. JOST & ROBERT L. SCHWARTZ, BIOETHICS: HEALTH CARE LAW AND ETHICS 176 (2d ed. 1991) [hereinafter BIOETHICS].

18. *See* CYSTIC FIBROSIS FOUND., FACTS ABOUT CYSTIC FIBROSIS, at <http://www.cff.org/publications03.htm> (revised Mar. 16, 2001). Those affected by cystic fibrosis are unable to transport sodium and chloride away from cells lining organs such as the lungs and pancreas. *See id.* This faulty transport “causes the body to produce an abnormally thick, sticky mucus” in the lungs and pancreas which interferes with the functioning of those organs. *Id.*

19. *See* Wayne W. Grody, *Cystic Fibrosis: Molecular Diagnosis, Population Screening, and Public Policy*, 123 ARCHIVES PATHOLOGY & LABORATORY MED. 1041, 1042 (1999).

Sickle cell disease is an inherited blood disorder that affects one out of every 375 African-American babies.²⁰ Approximately one out of every ten African-Americans carries the sickle cell trait.²¹ Lung tissue damage, stroke, and pain are common symptoms of sickle cell disease.²² The average life expectancy of a person with sickle cell disease is in the mid-forties.²³

Tay Sachs disorder is a fatal neurodegenerative disorder affecting one out of every 3,600 Ashkenazi Jews.²⁴ It often causes blindness and paralysis before death.²⁵ The average life span of those born with Tay Sachs is just three to five years.²⁶

B. BIRTH DEFECTS THAT HAVE GENETIC PREDICTORS

Many serious birth defects have been identified as having genetic origins. These include conditions such as cystic fibrosis, Duchenne's muscular dystrophy, hemophilia, Marfan's syndrome, sickle cell disease, and spina bifida.²⁷ Additionally, many congenital defects have been found to have genetic components as well. These include "pyloric stenosis, cleft lip and palate, congenital dislocated hips and some cardiac defects."²⁸

20. See Doris Hale, Priscilla Davis, Betholyn Gentry & Jess Dancer, *25 Facts on Sickle Cell Disease: A Regional Survey of Public School Nurses*, 89 PERCEPTUAL & MOTOR SKILLS 1043, 1043 (1999). People with sickle cell disease have red blood cells that cannot carry oxygen properly due to the presence of hemoglobin S, rather than hemoglobin A which allows for normal cell functioning. See SICKLE CELL DISEASE ASS'N OF AM., WHAT IS SICKLE CELL DISEASE?, at <http://www.sicklecelldisease.org/whatis.htm>. (last visited Mar. 17, 2001). The red blood cells become malformed and hardened, often blocking small blood vessels, which causes damage to tissues. See Hale et al., *supra*, at 1044.

21. See Hale et al., *supra* note 20, at 1044.

22. See SICKLE CELL DISEASE ASS'N OF AM., FREQUENTLY ASKED QUESTIONS, at <http://www.sicklecelldisease.org/whatis.htm> (last visited Mar. 17, 2001).

23. *Id.*

24. See Frederic Golden, *Good Eggs, Bad Eggs*, TIME, Jan. 11, 1999, at 56, 58. Tay Sachs is "caused by a deficiency of the enzyme Hexosaminidase A." GENE CARE, *supra* note 16. While babies born with Tay Sachs experience normal development for the first few months after birth, they begin experiencing severe physical and mental deterioration shortly thereafter. *Id.*

25. GENE CARE, *supra* note 16.

26. *Id.*

27. See Carole Kenner & Stephanie Amlung, *Neonatal Nursing and the Genetics Revolution!*, 13 J. PERINATAL & NEONATAL NURSING 90, 95 (1999).

28. *Id.* at 94.

C. GENETIC TESTING AND THE HUMAN GENOME PROJECT

Every nonreproductive cell in the human body contains twenty-three chromosome pairs.²⁹ Each of the forty-six chromosomes contains approximately 4,000 genes.³⁰ Chromosomes are comprised of four bases that pair up in three billion various sequences to form the double helix structure called deoxyribonucleic acid (DNA).³¹ The base pairs' sequencing contains genes that direct the proteins in the human body.³² "A mutation in one gene may lead to a number of defects in the corresponding protein, which sometimes results in a genetic abnormality."³³ Researchers estimate that each human has from 24,000 to 100,000 genes.³⁴

The Human Genome Project (Project) is the United States' contribution to the Human Genome Initiative, a global scientific effort to learn more about the human genome.³⁵ Today, countries such as France, Germany, Japan, China, and the United Kingdom actively participate in the Project.³⁶ Under the direction of the National Institutes of Health and the Department of Energy, the goals of the Human Genome Project are:

29. BIOETHICS, *supra* note 17, at 167. See also Jennifer M. Jendusa, Note, *Pandora's Box Exposed: Untangling the Web of the Double Helix in Light of Insurance and Managed Care*, 49 DEPAUL L. REV. 161, 169 (1999).

30. BIOETHICS, *supra* note 17, at 167.

31. Jendusa, *supra* note 29, at 167.

32. See *id.* at 168.

33. *Id.* at 169.

34. Traditionally, textbooks have suggested that humans have as many as 100,000 genes. See, e.g., BARRY R. FURROW, THOMAS L. GREANEY, SANDRA H. JOHNSON, TIMOTHY S. JOST & ROBERT L. SCHWARTZ, HEALTH LAW: CASES, MATERIALS & PROBLEMS 838, 1002 (3d ed. 1997) [hereinafter HEALTH LAW]. In February 2001, Celera Genomics, the leading private human genome research organization, published early analysis of the human genome draft estimating the number of human genes at between 24,000 and 40,000. J. Craig Venter et al., *The Sequence of the Human Genome*, 291 SCIENCE 1304, 1320 (2001) (report authored by 263 research scientists from fourteen private-sector and educational organizations). The leading public consortium of human genome researchers published similar estimates the same week finding that humans have approximately 31,000 genes. Int'l Human Genome Sequencing Consortium, *Initial Sequencing and Analysis of the Human Genome*, 409 NATURE 860, 900 (2001). While these findings are consistent with one another, they remain controversial because they suggest that humans may have only a third more genes than the "rather unsophisticated" roundworm. John-Michel Claverie, *What If There Are Only 30,000 Human Genes?*, 291 SCIENCE 1255, 1255 (2001). Researchers at the International Human Genome Sequencing Consortium explain that the complexity of humans is not due to sheer numbers of genes; rather, human genes are "spread out over much larger regions of genomic DNA, and they are used to construct more alternative transcripts. This may result in perhaps five times as many primary protein products in the human as in the worm or fly." Int'l Human Genome Sequencing Consortium, *supra*, at 901.

35. Jendusa, *supra* note 29, at 168, 172 (the human genome comprises all human genes "collectively as packaged in chromosomes").

36. Human Genome Program, *supra* note 5.

to identify all the approximate 30,000 genes in human DNA, determine the sequences of the three billion chemical base pairs that make up human DNA, store this information in databases, develop tools for data analysis, . . . and address the ethical, legal, and social issues . . . that may arise from the project.³⁷

The Project was originally estimated to take fifteen years to complete: from 1990 to 2005.³⁸ The original estimated budget was three billion dollars.³⁹

In September 1999, leaders of the Project announced accelerated deadlines including a plan to complete a draft of the human genome by the spring of 2000 which, in turn, would enable the creation of a high-quality human DNA reference sequence by 2003.⁴⁰ On June 25, 2000, President Clinton announced the early completion of the working draft.⁴¹

Two sources have been particularly valuable in promoting the accelerated progress. First, by sponsoring cloning projects, the Department of Energy was able to generate resources to increase support for the development of tools that eliminate redundant sequencing.⁴² Second, “the commercialization of a new generation of automated capillary DNA sequencing machines” has further encouraged progress.⁴³ Throughout the Project, leaders have maintained a policy of displaying all sequence information in publicly accessible databases within twenty-four hours of assembly.⁴⁴

The advances of the Human Genome Project provide researchers with the knowledge to promote an understanding of how genes contribute to disease. Jennifer Jendusa has outlined three categories of potential benefits from the Human Genome Project:

First, the HGP is expected to create information about genetic endowments through the creation of a complete map of the human genome. This will likely result in the capability to identify an individual’s predisposition to genetic diseases. Second, the HGP may help to create intervention procedures to prevent and treat an increasing number of genetic problems. Third, the HGP is expected to produce the

37. HUMAN GENOME PROJECT INFORMATION, at <http://www.ornl.gov/hgmis> (last modified Feb. 14, 2001) (emphasis omitted).

38. *See id.*

39. Jendusa, *supra* note 29, at 172.

40. Human Genome Program, *supra* note 5.

41. White House Press Release, *supra* note 6.

42. Human Genome Program, *supra* note 5.

43. *Id.*

44. *See id.*

ability to create or enhance desirable characteristics within an individual.⁴⁵

Thus, the Human Genome Project provides hope that many of the genetic disorders humans struggle with today may soon be identified earlier, spurring the development of prevention and treatment options.

D. HOW GENETIC TESTING CAN IMPROVE THE ODDS

1. *Genetic Testing*

The scientific advances achieved through the Human Genome Project and other research initiatives provide the foundation for creating genetic tests. Today, genetic centers in the United States offer DNA tests for various genetic disorders.⁴⁶ Genetic testing is used for several purposes: 1) predisposition testing; 2) carrier screening; and 3) DNA profiling for forensic purposes.⁴⁷

The goal of predisposition testing is to determine whether the individual is likely, although not certain, to develop a genetic condition. Predisposition tests are conducted on asymptomatic individuals⁴⁸ and are available for conditions such as heart disease, diabetes, colon cancer, depression, and schizophrenia.⁴⁹

Carrier screening is conducted on a healthy population in order to determine whether individuals carry genes for certain inherited genetic disorders.⁵⁰ Individuals found to be carriers of autosomal recessive disorders will never develop the condition but their children may be at risk if both parents are carriers. Conditions such as hemophilia, Duchenne's muscular dystrophy, sickle cell anemia, cystic fibrosis, and Tay Sachs can only be inherited when both parents are carriers.⁵¹

"Finally, DNA profiling results when testing is used in a forensic capacity to identify an individual by matching a sample of his or her DNA with criminal evidence."⁵² Genetic testing in the forensic setting allows

45. Jendusa, *supra* note 29, at 175.

46. See Golden, *supra* note 24, at 56.

47. See Kimberly Nobles, Note, *Birthright or Life Sentence: Controlling the Threat of Genetic Testing*, 65 S. CAL. L. REV. 2081, 2083-88 (1992).

48. Adrienne Asch, *Genetics and Employment, More Disability Discrimination*, in THE HUMAN GENOME PROJECT AND THE FUTURE OF HEALTH CARE 158, 161 (Thomas H. Murray et al. eds., 1996).

49. *Id.*

50. *Id.*

51. Egan, *supra* note 4, at 238 n.8.

52. Jendusa, *supra* note 29, at 171.

law enforcement officials to compile enough genetic information to identify an individual with up to a one in three billion level of certainty.⁵³

The ability of genetic testing to predict disease accurately is variable. The development of some diseases requires many contributing factors, so a genetic test that positively identifies a predisposing gene for one factor does not guarantee that the individual will ever become symptomatic.⁵⁴ Additionally, the validity of genetic testing is often questionable:

In the United States, the Task Force on Genetic Testing recommends requiring organisations developing new genetic tests to submit protocols for establishing the clinical validity (including sensitivity and positive predictive value) and utility of the tests to institutional review boards, equivalent to local research ethics committees in the United Kingdom.⁵⁵

The Food and Drug Administration (FDA) oversees genetic testing kits that are marketed as products; however, the FDA has chosen not to exercise its right to review tests that are offered as services.⁵⁶

With advanced research, the ability to develop genetic tests for inherited disorders increases. Unfortunately, there is often a therapeutic gap between the development of genetic tests and the ability to prevent or to treat the genetic condition indicated.⁵⁷ Since the 1960s, however, advanced knowledge of genetics has provided promising prevention or treatment options that continue to improve today.

2. *Prevention: Preconception Genetic Testing*

One way to use genetic-testing results to increase the number of healthy birth outcomes is to take precautions that will help prevent the conception of babies with birth defects. Genetic information is helpful for couples involved in reproductive decisionmaking.⁵⁸ Couples can undergo carrier screening in order to determine if one, or both, partners carry a defective gene that may be passed on to future children.⁵⁹ Testing can also inform carriers of the probability that their children would inherit the genetic disorder.⁶⁰ If both partners find that they are carriers, they face

53. This level of certainty assumes no laboratory error. Nobles, *supra* note 47, at 2087–88.

54. See Neil A. Holtzman & David Shapiro, *The New Genetics: Genetic Testing and Public Policy*, 316 BRITISH MED. J. 852, 852 (1998).

55. *Id.*

56. *Id.* at 852–53.

57. See *id.* at 853–54.

58. See BIOETHICS, *supra* note 17, at 171.

59. Nobles, *supra* note 47, at 2085–86.

60. See *id.*

several preventive options in order to avoid having an affected child, including adoption, seeking donated eggs or sperm, or remaining childless.⁶¹ “The optimal time for population screening for autosomal recessive disorders is early in adulthood, before marriage, when individuals are able to make mature decisions about testing.”⁶²

One example of the benefit that carrier screening has had in reducing the inheritance of genetic disorders is the reduction in incidents of Tay Sachs disease. Tay Sachs is a fatal neurological disorder that causes an affected child “to suffer horribly and die by age five of the disease.”⁶³ The disease affects one in 3,600 Ashkenazi Jews.⁶⁴ Since the 1970s, screening programs have been available to this population and have contributed to reducing the incidence of Tay Sachs by up to ninety-five percent.⁶⁵ The Orthodox Jewish community has embraced a screening program known as the Dor Yeshorim concept where young adults are screened and carrier status is kept confidentially at the Dor Yeshorim office.⁶⁶ Before a couple considers marriage, they call the Dor Yeshorim office to determine whether they are compatible as a couple in terms of their carrier status.⁶⁷

Similarly, the incidence of beta-thalassemia, a fatal genetic disorder common in some areas of the Mediterranean basin, has been reduced by carrier screening programs. The disease interferes with normal hemoglobin production and is not curable.⁶⁸ Public health efforts to screen for carriers and educate them as to the dangers of marrying other carriers has contributed to a “marked decline” in the incidence of the disease.⁶⁹ Preconception screening is particularly helpful for fatal diseases or other serious disorders for which treatment options are currently limited.

New technology offers couples in which both individuals are carriers of genetic disorders even more options. “If couples know they carry genes for life-threatening illnesses that they don’t want to pass on to the next generation, they can opt for a remarkable procedure called pre-implantation

61. *Id.*

62. Feige Kaplan, *Tay-Sachs Disease Carrier Screening: A Model for Prevention of Genetic Disease*, 2 GENETIC TESTING 271, 279 (1998).

63. Reilly, *supra* note 14, at 1332.

64. Golden, *supra* note 24, at 58.

65. *Id.*

66. See Mark Levin, *Screening Jews and Genes: A Consideration of the Ethics of Genetic Screening Within the Jewish Community: Challenges and Responses*, 3 GENETIC TESTING 207, 210 (1999).

67. *Id.*

68. See Reilly, *supra* note 14, at 1332.

69. *Id.*

genetic diagnosis (PGD).⁷⁰ PGD is an additional genetic-testing step interjected in the more commonly used *in vitro* fertilization process.⁷¹ *In vitro* fertilization involves mixing eggs from the mother and sperm from the father in a laboratory setting.⁷² This process forms embryos that can then be inserted into the mother's uterus, intending that at least one embryo will implant in the uterine wall and result in a normal pregnancy. With the PGD procedure, the embryos are analyzed before they are inserted into the uterus.⁷³ The fertilized eggs undergo rigorous DNA analysis that reveals whether the embryo has inherited defective genes from the mother and father.⁷⁴ When the analysis indicates that an embryo is affected, that embryo is not implanted.⁷⁵

PGD is not widely used yet. While the technology has proven quite successful since its development over ten years ago, the cost of \$20,000 per screening keeps many couples from availing themselves of this option.⁷⁶ Infertile couple or those who have experienced multiple miscarriages, however, may find PGD an attractive option in their pursuit of having a healthy child.⁷⁷ Furthermore, a recent study indicates that an improved method of performing PGD limits misdiagnosis and yields successful pregnancy rates comparable to those of routine *in vitro* fertilization.⁷⁸ The study found that the improved method of conducting PGD is "accurate, reliable, and safe for introduction into clinical practice as an alternative to prenatal diagnosis."⁷⁹

Sex selection is another preventive procedure. Couples who may be at risk for Duchenne's muscular dystrophy or hemophilia, which only affect males, can opt for *in vitro* fertilization in order to select a female embryo. A technique for distinguishing sperm that create female embryos from those that create male embryos is a recent development growing out of the Human Genome Project.⁸⁰ Sex selection techniques during the *in vitro*

70. Golden, *supra* note 24, at 58.

71. *Id.*

72. *Id.*

73. *Id.*

74. *Id.*

75. *Id.*

76. *See id.*

77. *Id.*

78. *See* Y. Verlinsky, S. Rechitsky, O. Verlinsky, V. Ivachnenko, A. Lifchez, B. Kaplan, J. Moise, J. Valle, A. Borkowski, J. Nefedova, E. Goltsman, C. Strom & A. Kuliev, *Prepregnancy Testing for Single-Gene Disorders by Polar Body Analysis*, 3 GENETIC TESTING 185, 189 (1999).

79. *Id.* at 189-90.

80. Kenner & Amlung, *supra* note 27, at 91.

fertilization process avoid implanting male embryos and, thereby, eliminate the risk of having a child affected by these sex-linked disorders.⁸¹

Finally, a simple B-vitamin called folic acid has recently been linked to preventing neural tube defects.⁸² Women who learn they are predisposed to having children with neural tube defects like spina bifida and anencephaly can work with their physicians to use folic acid supplements to improve their chances of having a healthy baby.⁸³

3. *Treatment: Prenatal Genetic Testing*

In addition to prophylactic techniques implicated by preconception genetic testing, prenatal genetic testing allows doctors to treat affected fetuses *in utero* in an effort to minimize or to prevent the manifestation of genetic conditions. Prenatal testing may involve several of the following processes: 1) serum-alpha-fetalprotein testing; 2) amniocentesis; or 3) chorionic villus sampling.

Serum-alpha-fetalprotein testing is the most common prenatal testing process; it involves sampling the mother's blood for the presence of excess proteins that may indicate a fetus affected with spina bifida, Down syndrome, or neural tube defects.⁸⁴ Amniocentesis involves withdrawing amniotic fluid from the placenta,⁸⁵ and chorionic villus sampling involves withdrawing fluid containing actual fetal cells from part of the placenta.⁸⁶ These two procedures provide increased accuracy in predicting the presence of a genetic disorder. Due to the invasive nature of amniocentesis and chorionic villus sampling, they are generally only performed on women who are at high risk of having a baby with these types of genetic conditions.⁸⁷

Until recently, prenatal genetic testing has only been useful for parents wishing to avoid the birth of an affected child through abortion. However, advanced technology has created additional options for parents who learn

81. See Golden, *supra* note 24, at 58. Obviously, the ethical implications of sex selection for nontherapeutic purposes are serious. In the context of this Note, sex selection is discussed solely to offer an example of a therapeutic method for couples who are carriers of sex-linked disorders.

82. See Martha M. Werler, Carol Louik & Allen A. Mitchell, *Achieving a Public Health Recommendation for Preventing Neural Tube Defects with Folic Acid*, 89 AM. J. PUB. HEALTH 1637, 1637 (1999).

83. All women of childbearing age are recommended to take 400 micrograms of folic acid daily to prevent birth defects of the brain and spine. See *id.* at 1637.

84. Golden, *supra* note 24, at 57.

85. Nobles, *supra* note 47, at 2087 n.38.

86. *Id.* at 2087.

87. *Id.*

that their fetus has a genetic condition. Two innovative treatment options have been developed that may help prevent or minimize the manifestation of genetic conditions: fetal surgery and fetal therapy.

Fetal surgery is a procedure in which doctors can surgically correct some congenital defects discovered through genetic testing or screening in order to ameliorate adverse effects.⁸⁸ For example, spina bifida can be corrected through fetal surgery at about seven months' gestation. Fetuses affected by spina bifida have part of the spine exposed, which causes two problems: 1) the spinal cord develops abnormally; and 2) the spine is exposed to the intrauterine environment for a prolonged period.⁸⁹ Research at the Vanderbilt University Medical Center has shown that amniotic fluid causes serious damage and neurologic lesions to the spinal cord late in pregnancy.⁹⁰ Surgery to cover the exposed spine during pregnancy can prevent nerve damage and help the baby enjoy normal development.⁹¹ Even though the surgery is still experimental, early detection through genetic testing creates the option of fetal surgery so that the disabling hole in the fetus' spinal cord caused by spina bifida can be surgically closed before birth. An unexpected benefit of fetal surgery is that fewer individuals require shunting for hydrocephalus than among those who have surgery shortly after birth.⁹²

A second treatment technique, fetal therapy, is a process in which doctors treat metabolism errors such as vitamin or carboxylase deficiencies by injecting supplements through the placenta to improve the fetus' condition.⁹³ Similarly, fetuses diagnosed as having phenylketonuria (PKU), can be spared the mental retardation that results from leaving PKU untreated.⁹⁴ PKU is a genetic condition in which the baby cannot digest phenylalanine, "a normal (indeed, essential) component of the human diet."⁹⁵ Treatment options begin *in utero* for PKU babies by adding a metabolic supplement to the mother's diet to ameliorate the condition.⁹⁶

88. See Golden, *supra* note 24, at 58.

89. *Groundbreaking Fetal Surgery at VUMC*, INSIGHTS INTO SPINA BIFIDA, Nov./Dec. 1998, at <http://www.sbaa.org/docs/insights/vumc4.pdf>.

90. *Id.*

91. *See id.*

92. *Id.* Hydrocephalus and shunting are discussed *supra* note 14.

93. *See* Kenner & Amlung, *supra* note 27, at 91.

94. *See id.*

95. Capron, *supra* note 2, at 686.

96. *See* Kenner & Amlung, *supra* note 27, at 91. Additional treatment is necessary at the neonatal stage and is discussed *infra* Part I.C.4.

Prenatal testing also enables the obstetrician to make better-informed decisions regarding the birth process. For example, scalp sampling and vacuum extraction are commonly used during the normal birthing process. Prenatal diagnosis of hemophilia in a fetus enables the physician to avoid using these techniques and, thereby, avoid injuring the baby at birth.⁹⁷

4. *Treatment: Neonatal Genetic Testing*

In addition to the benefits of early intervention before birth, genetic testing enables doctors to intervene and to improve the future for babies born with treatable genetic defects.⁹⁸ “Mandatory neonatal screening is already in place for diseases such as PKU, sickle cell anemia, congenital hypothyroidism, galactosemia, and congenital adrenal hypoplasia because early intervention for these diseases can have a profound effect on outcome.”⁹⁹ For example, all newborns throughout the United States are now tested for PKU.¹⁰⁰ Testing for PKU began over thirty years ago in an effort to prevent the mental retardation that occurs when the disease is left untreated.¹⁰¹ By diagnosing those with PKU early, a simple diet change can prevent retardation.¹⁰²

Increased genomic research may yield new treatment options for patients suffering from certain genetic conditions. An experimental treatment called gene therapy has garnered increased attention for its ability to replace faulty genes with normal ones.¹⁰³ Gene therapy involves one of two processes. In the first process, cells with malfunctioning genes are removed, the faulty genes are extracted, and then normal genes are added in a process called “gene insertion.”¹⁰⁴ The other form of gene therapy

97. See Elena A. Gates, *Prenatal Genetic Testing: Does It Benefit Pregnant Women?*, in WOMEN & PRENATAL TESTING 183, 185 (Karen H. Rothenberg & Elizabeth J. Thomson eds., 1994).

98. See Bartolomé Jaime Roig, *Preventing Congenital Defects: New Perspectives*, in 1 THE HUMAN GENOME PROJECT: LEGAL ASPECTS 121, 124 (1996).

99. Lori A. Whittaker, *The Implications of the Human Genome Project for Family Practice*, 35 J. FAM. PRAC. 294, 297 (1992).

100. TASK FORCE ON HEALTH RECORDS & GENETIC PRIVACY OF THE HOUSE COMM. ON COMMERCE, 105TH CONG., PRIVACY, CONFIDENTIALITY AND DISCRIMINATION IN GENETICS 48 (Comm. Print 1997) (statement of Arthur L. Beaudet, Chairman of the Department of Molecular and Human Genetics, Baylor College of Medicine).

101. *Id.* at 49.

102. *Id.* at 48–49.

103. See BIOETHICS, *supra* note 17, at 172. Medical ethicists agree that gene therapy should only be conducted on somatic (nonreproductive) cells rather than germ line (reproductive) cells because the generational gene pool consequences of germ line gene therapy are unknown. See Whittaker, *supra* note 99, at 298.

104. BIOETHICS, *supra* note 17, at 172.

involves introducing healthy cells in order “to produce needed cell-growth factor or perform a beneficial cellular function.”¹⁰⁵

“One of the most promising gene therapy experimental efforts to date involves delivering therapeutic genes to the lungs of patients with [cystic fibrosis].”¹⁰⁶ In 1989, scientists discovered the gene that causes cystic fibrosis.¹⁰⁷ The first experimental dose of a gene therapy treatment was given to a cystic fibrosis patient in 1993, when doctors administered healthy cells that actually repaired the defective cystic fibrosis cells.¹⁰⁸ The treatment remains experimental today as scientists work to improve methods of delivering healthy genes to defective cells. One effective method involves using modified viruses as vehicles for inserting healthy genes into cystic fibrosis cells.¹⁰⁹ While gene therapy has been successfully administered only in a limited number of cases,¹¹⁰ some researchers suggest that contributions from the Human Genome Project may serve as the foundation for developing “new gene therapies that may cure diseases that now commonly lead to morbidity and mortality.”¹¹¹

Neonatal genetic testing can even decrease the incidence of untreatable genetic disorders. Duchenne Muscular Dystrophy (DMD) is a common fatal genetic disorder that affects males.¹¹² Generally, symptoms of the disorder do not express themselves until the affected child is about four years old¹¹³ and the average age at diagnosis is 4.9 years.¹¹⁴ DMD symptoms include weakness and deterioration of the muscles; most boys become wheelchair bound by age eleven and die in their late teens or early twenties.¹¹⁵ Early symptoms are often mistaken for laziness or

105. *Technological Advances in Genetics Testing: Implications for the Future: Hearing Before the Subcomm. on Tech. of the House Comm. on Sci.*, 104th Cong. 103 (1996) (statement of Alan Goldhammer, Ph.D., Director of Technical Affairs, Biotechnology Industry Organization).

106. Allyn L. Taylor, *Globalization and Biotechnology: UNESCO and an International Strategy to Advance Human Rights and Public Health*, 25 AM. J.L. & MED. 479, 487 n.65 (1999).

107. See CYSTIC FIBROSIS FOUND., *GENE THERAPY AND CYSTIC FIBROSIS* (2000), at <http://www.cff.org/facts.htm>.

108. *See id.*

109. *Id.*

110. See Ahmad S. Islam, *Genetic Tests for Congenital Diseases and the Prospects of Gene Therapy*, INDEPENDENT (London), Feb. 13, 1999, LEXIS, News Library, News Group File.

111. Taylor, *supra* note 106, at 487.

112. A. Drousiotou, P. Ioannou, T. Georgiou, E. Mavrikiou, G. Christopoulos, T. Kyriakides, M. Voyasianos, A. Argyriou, & L. Middleton, *Neonatal Screening for Duchenne Muscular Dystrophy: A Novel Semiquantitative Application of the Bioluminescence Test for Creatine Kinase in a Pilot National Program in Cyprus*, 2 GENETIC TESTING 55, 55 (1998).

113. *Id.* at 55.

114. *Id.* at 56.

115. *Id.* at 55.

clumsiness.¹¹⁶ Even though the symptoms are not expressed for several years, neonatal tests are available and could alert parents and other relatives to the dangers of conceiving additional children. In fact, one study estimates that thirteen to eighteen percent of all DMD cases could be avoided by using neonatal tests.¹¹⁷

II. THE PROBLEM OF GENETIC DISCRIMINATION IN HEALTH INSURANCE COVERAGE

A. PUBLIC PERCEPTION OF GENETIC DISCRIMINATION

Despite the growing number of reasons to use genetic testing at the preconception, prenatal, and neonatal stages of reproduction, the threat of discrimination in insurance coverage may hamper decisions to undergo genetic testing.¹¹⁸ In a recent speech to the American Association of the Advancement of Science, President Bill Clinton discussed the implications of this problem:

The fear of misuse of private genetic information is already very widespread in our nation. Americans are genuinely worried that their genetic information will not be kept secret, that this information will be used against them. As a result, they're often reluctant to take advantage of new breakthroughs in genetic testing—making a point I think we cannot make too often—if we do not protect the right to privacy, we may actually impede the reach of these breakthroughs in the lives of ordinary people, which would be a profound tragedy.¹¹⁹

Moreover, the threat of discrimination itself impedes efforts to determine the scope of the problem: “We may not be able to measure how many people have been denied health insurance until we know how many people have not taken the genetic testing to begin with, and that does cost lives because people are not doing what they need to do early enough.”¹²⁰

Because the public's reasons for failing to take advantage of genetic tests are difficult to measure, little reliable empirical evidence is available

116. *Id.* at 56.

117. *Id.*

118. See Islam, *supra* note 110; Burk Burnett, Note, *Genetic Discrimination: Legislation Required to Keep Genetic Secrets*, 21 SETON HALL LEGIS. J. 502, 510, 513 (1997).

119. President William J. Clinton, Remarks on Signing an Executive Order to Prohibit Discrimination in Federal Employment Based on Genetic Information (Feb. 8, 2000), in 36 WEEKLY COMP. PRES. DOC. 241, 243 (Feb. 14, 2000) [hereinafter Clinton Remarks].

120. *Senate Hearing, supra* note 9, at 11 (testimony of Senator Patty Murray).

to document the phenomenon.¹²¹ However, the National Institutes of Health recently conducted a study in which women were invited to participate in a research program to determine the presence of the breast cancer gene. One third of invited subjects declined to participate out of fear that the results may not remain private and could result in discrimination.¹²²

Genetic discrimination poses three potential problems. First, by deterring genetic testing, it undermines the value that those tests contribute to saving babies from genetic birth defects. Second, public fear of discrimination stymies the growth of genetic research and threatens to hinder the development of genetic tests. Finally, it makes gaining and maintaining insurance coverage more difficult for families and individuals who may need it most.

1. *Leaving Genetic Tests Unused*

The primary problem with genetic discrimination in health insurance coverage is that it may deter individuals from undergoing genetic testing, thereby denying them the benefit of early knowledge. Initially, the commercial genetic testing market was expected to be a burgeoning new industry capable of generating \$100 million per year.¹²³ However, biotechnology companies involved in the market have been disappointed by a guarded public response. Individuals interviewed about the underlying reasons for the lackluster response have “stated that fear of discrimination played a key role in their decision not to take a test, even where they believed it could provide critical medical information.”¹²⁴ A 1995 study of attitudes toward genetic testing indicated that over eighty-five percent of respondents were very concerned or somewhat concerned that their genetic information may not be kept confidential and that insurers or employers would gain access to the information.¹²⁵

Offshore genetic testing markets, however, have capitalized on American skepticism. Some Israeli oncology clinics that provide genetic testing have noted a new type of medical tourism developing: U.S. citizens travel to Israel to undergo genetic testing, believing that their results will be

121. See *Senate Hearing, supra* note 9, at 11 (testimony of Senator Patty Murray).

122. *Id.* at 38 (testimony of Judith L. Palkovitz).

123. *Id.* at 37.

124. *Id.*

125. *Id.* at 9 (testimony of Senator Olympia Snowe).

beyond the reach of U.S. insurance companies.¹²⁶ In fact, a 1998 Israeli newspaper ran an article entitled “Come to Israel—test your genes.”¹²⁷

Even individuals who have firsthand knowledge of the importance of genetic testing for preventive health care fear discriminatory implications. A 1996 study of genetic support-group members found that nine percent of members refused to undergo genetic testing solely because of a fear of discrimination.¹²⁸ “This fear eliminates the opportunities of individuals to learn that they are not at increased risk for the genetic disorder in the family or to make lifestyle changes to reduce the risks or seriousness of the condition.”¹²⁹ Eighteen percent of members reported that they withheld genetic information from insurance companies out of fear of discrimination.¹³⁰ Furthermore, eighty-three percent indicated that “they would not want their insurers to know if they were tested and found to be at high risk for a genetic disorder.”¹³¹

2. Arresting Genomic Research

The second problem associated with genetic discrimination in health insurance coverage relates to its stunting effect on the continued growth of genomic research. Dr. Francis Collins, director of the National Human Genome Research Institute at the National Institutes of Health, recently expressed his concern that the great scientific strides may not lead to improved health benefits if paralyzed by public fears:

[We cannot access the benefits of research] if we decide to let the specter of health insurance discrimination continue to hang like a pall over these exciting developments, frightening patients from participating in research or taking advantage of genetic tests as they become available in the regular practice of medicine. If we do not act, the potential that this exciting field will be stillborn is very real.¹³²

In 1996, genetic researchers in Boston requested the help of Jewish leaders to encourage members of the Boston Jewish community to

126. *Id.*

127. *Id.*

128. See E.V. Lapham, C. Kozma & J.O. Weiss, *Genetic Discrimination: Perspectives of Consumers*, 274 *SCIENCE* 621, 621 (1996).

129. *Id.*

130. *Id.*

131. *Id.*

132. *Senate Hearing*, *supra* note 9, at 14 (testimony of Dr. Francis Collins, Director of the National Human Genome Research Institute at the National Institutes of Health).

participate in genetic research.¹³³ The community leaders chose not to become involved, expressing concern that public policy does not adequately protect research participants from genetic discrimination.¹³⁴

Rabbi Tendler, [an] ethicist at Yeshiva University, said he would discourage Jews from participating in research or genetic testing until protections are passed. “There’s so much promise that I always walk gingerly when it means holding back any aspect of research,” he said. “Yet, you have to weigh the risk against the benefit.”¹³⁵

3. *Keeping Health Insurance Out of Reach*

The third problem with genetic discrimination in health insurance coverage is that, ironically, it may make it difficult for individuals who need it most to receive coverage. Although there is no empirical evidence of widespread discrimination, public fear is created by publicized accounts of genetic discrimination. The survey of genetic support-group members found that twenty-five percent of respondents believed that they or a family member were refused health insurance due to a genetic disorder.¹³⁶ The survey also found that forty-seven percent of respondents who were asked about genetic and disability information in the insurance application were denied enrollment.¹³⁷ Furthermore, a group of genetic counselors and primary care physicians reported that “550 people . . . were denied jobs or denied health insurance as a result of a genetic predisposition to an illness.”¹³⁸

Some families who do wish to avail themselves of the perinatal advantages related to genetic testing have faced increased difficulty obtaining insurance to cover the health care they need. One California couple with a history of cystic fibrosis sought coverage for a prenatal cystic fibrosis screening of their unborn child. While their health insurer agreed to pay for the screening, the company threatened that if the test indicated that the child had cystic fibrosis “and the couple chose not to terminate the

133. Sheryl G. Stolberg, *Concern Among Jews Is Heightened as Scientists Deepen Gene Studies*, N.Y. TIMES, April 22, 1998, at A24.

134. *See id.*

135. *Id.*

136. Lapham et al., *supra* note 128, at 621. The reliability and methodology of this study have been challenged by a health insurance industry representative. *See* L. Carl Volpe, *Genetic Testing and Health Insurance Practices: An Industry Perspective*, 2 GENETIC TESTING 9, 10 (1998). Specifically, a low response rate and lack of independent verification of insurance denials may undermine the result. *See id.*

137. *See* Lapham et al., *supra* note 128, at 621.

138. *Senate Hearing, supra* note 9, at 5 (testimony of Senator Olympia Snowe).

pregnancy, the insurance company would not provide health care coverage for the child.”¹³⁹ Ultimately, the insurer acquiesced when the couple threatened to sue.¹⁴⁰

Throughout the 1990s, Dr. Paul Billings documented cases of genetic discrimination in insurance coverage. He noted one case in which a couple had a child with PKU. Despite the simple and inexpensive regimen associated with treating PKU,¹⁴¹ the couple’s insurance company refused to cover anyone in the family.¹⁴² While few reports of actual discrimination have been documented since the 1996 passage of the Health Insurance Portability & Accountability Act,¹⁴³ these well-publicized stories fuel public fear of discrimination.

Because the United States does not guarantee health care coverage for all of its citizens, the threat of losing private insurance is very serious. For families with children affected by birth defects or other genetic conditions, health insurance is vital. The financial burden of caring for such a child can be financially devastating for any family.

Medicaid is the only federally funded health insurance program available to children and people of childbearing age.¹⁴⁴ Medicaid, however, is not a meaningful safety net for many Americans who are deemed uninsurable by private insurers. States promulgate eligibility requirements for Medicaid within the confines of federal regulations.¹⁴⁵ The primary requirement for Medicaid eligibility is economic need. This hurdle alone often makes public health insurance unattainable for many families who find acquiring affordable private insurance difficult based on their genetic records.

In addition to economic need, prospective beneficiaries must qualify under certain categories. First, federal law requires that all pregnant women within 133% of the poverty line be covered, and thirty states opt to cover women up to 185% of the poverty line.¹⁴⁶ Second, in all states,

139. Whittaker, *supra* note 99, at 296.

140. *Id.*

141. Treatment of PKU is discussed *supra* Part I.D.4.

142. Golden, *supra* note 24, at 59.

143. Health Insurance Portability & Accountability Act of 1996 (HIPAA), Pub. L. No. 104-191, 110 Stat. 1936 (codified as amended at scattered sections of 18, 26, 29, and 42 U.S.C.). HIPAA is discussed in detail *infra* Part IV.A.2.

144. While specialized programs are available to veterans, American Indians, and those serving in the armed forces, Medicaid is the only generally applicable public health program. See HEALTH LAW, *supra* note 34, at 838, 865–83.

145. *See id.*

146. *Id.* at 866.

Medicaid covers children up to age six if they are in families with incomes below 133% of the poverty line.¹⁴⁷ While this is important coverage for poor families, middle-class families unable to acquire private insurance are left without redress. Middle-class families without insurance are not likely able to bear the expense of caring for a child with a birth defect. For example, the estimated additional lifetime costs associated with having a serious birth defect are \$503,000 for cerebral palsy, \$451,000 for Down syndrome, and \$294,000 for spina bifida.¹⁴⁸ Furthermore, despite Medicaid coverage, the United States has over thirteen million uninsured children.¹⁴⁹

B. HEALTH INSURANCE UNDERWRITING AND GENETIC TESTING

1. *Health Insurance and the Medical Underwriting Process*

The underlying goal of health insurance is to spread the risk of uncertain health care costs over a large group in order to minimize the concentration of loss in a few individuals.¹⁵⁰ Because even uncertain events, like the incurrence of medical expenses, establish a pattern of regularity among large groups, insurers are able to predict costs of a group and establish premiums of contributions to cover those costs.¹⁵¹ Health insurers sometimes use a process called medical underwriting in order to provide health insurance in a fiscally solvent context. Medical underwriting is the “examination of individuals for the purpose of selecting risks and pricing policies.”¹⁵² Insurance companies generally engage in underwriting activities by investigating the prospective insured’s medical history, medical records, current physical condition, family medical history, and any other information that may help predict how costly the individual will be to insure.¹⁵³ They then use that information in order to determine whether to issue a health insurance policy and, if so, the price of that policy.

Insurers use the underwriting process to limit liability for the prospective insured’s medical expenses in several ways. First, the insurer

147. *Id.*

148. *Economic Costs of Birth Defects*, *supra* note 10, at 695.

149. HEALTH LAW, *supra* note 34, at 867.

150. *See id.* at 786.

151. *See id.*

152. Deborah A. Stone, *The Implications of the Human Genome Project for Access to Health Insurance*, in THE HUMAN GENOME PROJECT AND THE FUTURE OF HEALTH CARE 133, 144 (Thomas H. Murray et al. eds., 1996).

153. *See id.* at 138–44.

may choose not to offer a policy to that individual. Second, the insurer may offer a policy but exclude coverage for a specific medical problem that the insurer suspects is likely to arise in the future.¹⁵⁴ Finally, the insurer may include a provision in the policy that excludes preexisting conditions. Such provisions would enable the insurer to deny payment for a claim related to a condition that existed, or was diagnosed or treated, prior to the commencement of the policy.¹⁵⁵

Insurers generally use underwriting to varying degrees depending on the type of insured. There are three types of health-insured groups in the United States: 1) individuals who purchase private health insurance negotiated individually; 2) individuals who are insured as part of a group plan negotiated or self-funded by their employers; and 3) individuals who are insured through government programs.

Underwriting is almost always used for applicants in the individual market.¹⁵⁶ For individual applicants, there is not a group involved to pool risks and spread costs, making insurers more cautious about the potential costs of future health care for that individual. The individual market comprises ten to fifteen percent of all health insurance that is purchased in the United States¹⁵⁷ and covers about 14.5 million Americans.¹⁵⁸ Insurance industry representatives state that the process of underwriting enables insurers to offer coverage at “reasonable rates” to approximately seventy to eighty percent of individuals who apply.¹⁵⁹

The underwriting process, however, is not solely confined to the individual market. Over one-third of those insured through employer-based groups belong to a group of twenty-five or fewer employees.¹⁶⁰ Insurers commonly engage in the underwriting process for these small groups, because a single employee’s serious health problems may be too costly to spread over a small group. Some insurers even use individual medical underwriting for all groups of insureds, regardless of size.¹⁶¹

154. *See id.* at 145–46.

155. *See id.* at 147. The definition of a preexisting condition varies according to the definition in the particular insurance policy contract.

156. *See id.* at 144.

157. *See id.*

158. *See* HEALTH LAW, *supra* note 34, at 786.

159. *Senate Hearing, supra* note 9, at 52 (testimony of Joanne Denise, representative of the National Association of Health Underwriters).

160. *See* Stone, *supra* note 152, at 144–45.

161. *See id.* at 145.

2. *The Value of Genetic Testing Information to Insurers*

One mechanism that disrupts the loss spreading function of health insurance is adverse selection. Adverse selection occurs when “people who expect to need health services are more likely than others to purchase insurance, and are also likely to seek coverage for the specific services they expect to need.”¹⁶² Thus, insurance industry experts suggest that those with poorer health are more likely to seek and maintain higher insurance levels than those with better health.¹⁶³ When insurance premiums go up, healthier insureds are more likely to leave the insurance pool while less healthy insureds have incentives to remain. Thus, adverse selection tends to result in a downward spiral where the risk-spreading pool shrinks and the risks are more concentrated among those with higher health expenses.¹⁶⁴

Private health insurers fear that without the ability to engage in traditional medical underwriting, consumers may use genetic testing results to engage in adverse selection.¹⁶⁵ For example, if a woman learns that she carries the sickle cell gene, she is more likely to seek and maintain health insurance coverage. Conversely, if she learns that she is not a carrier, she is more likely to drop her health insurance coverage. This type of behavior alters the integrity of normal coverage patterns disabling insurance companies from predicting the level of funding needed adequately to insure plan participants. Health insurers also fear that if individuals can gain genetic test results without disclosing them to their prospective insurer, the insurer is at an informational disadvantage and will be forced to make insuring decisions without access to all relevant information.

The effects of adverse selection not only harm insurance companies, but other insureds as well. To remain fiscally solvent, insurance companies must spread health-care costs associated with medically needy individuals to other insureds, thereby raising health insurance premiums. Higher premiums minimize the number of individuals who can afford health insurance. Health insurance industry representatives suggest that “[i]n states where individual health policies are guaranteed issue with no health questions, premiums have increased dramatically, and carriers have fled the market.”¹⁶⁶

162. HEALTH LAW, *supra* note 34, at 788–89.

163. *Id.* at 789.

164. *Id.*

165. *Senate Hearing*, *supra* note 9, at 52 (testimony of Joanne Denise, representative of the National Association of Health Underwriters).

166. *Id.*

III. THE STATES RESPOND TO GENETIC DISCRIMINATION

A. CURRENT STATE LEGISLATION

A majority of states concede that the use of genetic information by health insurers must be regulated. To date, thirty-nine states have enacted “some form of genetic discrimination legislation.”¹⁶⁷ Legislation in twenty states prohibits health insurers from denying coverage based on genetic information.¹⁶⁸ Nineteen states prohibit insurers from using genetic information in the determination of health insurance premiums.¹⁶⁹ Furthermore, fourteen states prohibit insurers from using genetic information as the basis for canceling or refusing to renew health insurance policies.¹⁷⁰

While many of the states’ goals in addressing genetic discrimination are the same, the processes they use to achieve those goals are disparate. The primary difference between the various state legislative efforts to address genetic discrimination is the way the states define the genetic information to be protected. Most state definitions fall into one of two categories: 1) that which confines protected genetic material to the results of laboratory tests of human DNA or chromosomes;¹⁷¹ and 2) that which protect all genetic information whether derived from family history or other indicators.¹⁷² The effects of these and other distinctions are best exemplified through a brief description of three states’ approaches to limiting genetic discrimination in health insurance coverage.

1. Georgia’s Narrow Protections

The Georgia state assembly explicitly recognized the intent of its genetic testing law as preventing health insurers from “using information derived from genetic testing to deny access” to health insurance coverage.¹⁷³ The Georgia law prohibits conducting genetic testing for any

167. Jeremy A. Colby, Note, *An Analysis of Genetic Discrimination Legislation Proposed by the 105th Congress*, 24 AM. J.L. & MED. 443, 463–64 (1998).

168. See Meredith A. Jagutis, Comment, *Insurer’s Access to Genetic Information: The Call for Comprehensive Federal Legislation*, 82 MARQ. L. REV. 429, 438–39 (1999).

169. See *id.* at 439.

170. See *id.*

171. See, e.g., GA. CODE ANN. § 33-54-2 (1996).

172. For example, in New Jersey, genetic information is defined as “information about genes, gene products or inherited characteristics that may derive from an individual or family member.” N.J. STAT. ANN. § 17B:30-12(e)(2) (West Supp. 2000).

173. GA. CODE ANN. § 33-54-1(4) (1996).

nontherapeutic or diagnostic reason.¹⁷⁴ It also protects the confidentiality of such tests by requiring written consent before testing,¹⁷⁵ as well as before releasing the results to anyone other than the tested individual.¹⁷⁶ The Georgia statute defines genetic testing narrowly so that only information gained from a test of human DNA or chromosomes is protected.¹⁷⁷ This statute also explicitly prohibits insurers from using genetic testing results for any nontherapeutic purpose.¹⁷⁸ Finally, Georgia attempts to ensure that this law will not hinder continued scientific research by explicitly authorizing genetic testing in that arena.¹⁷⁹

This narrow definition creates unusual discrepancies in coverage under Georgia law. For example, if a couple undergoes genetic testing to determine whether they are carriers of the sickle cell gene, their test results are protected under Georgia law and insurers would be prohibited from using the results for underwriting purposes. However, if this same couple had a child with sickle cell disease, an insurer could presume that both the mother and father are carriers of the gene and could use that information for any purpose, including medical underwriting.¹⁸⁰

2. *New Jersey's Broad Protections*

New Jersey's Genetic Privacy Act has been heralded as one of the most comprehensive state laws in addressing genetic discrimination.¹⁸¹ The statute explicitly recites the policy basis for the law: "[T]he improper collection, retention or disclosure of genetic information can lead to significant harm to the individual, including stigmatization and discrimination in areas such as employment, education, health care and insurance."¹⁸² The New Jersey statute prevents insurance companies from using "genetic information" or discriminating based on a potential insured's effort to keep test results confidential or refusal to undergo testing.¹⁸³ New Jersey adopted a broad definition of genetic information

174. *Id.* § 33-54-3(a).

175. *See id.*

176. *See id.* § 33-54-3(b).

177. *Id.* § 33-54-2(1).

178. *Id.* § 33-54-4.

179. *See id.* § 33-54-6.

180. *See Senate Hearing, supra* note 9, at 21–22 (testimony of Dr. Francis Collins).

181. *See* Kourtney L. Pickens, Comment, *Don't Judge Me by My Genes: A Survey of Federal Genetic Discrimination Legislation*, 34 TULSA. L.J. 161, 171 (1998).

182. N.J. STAT. ANN. § 10:5-44(c) (West Supp. 2000).

183. Pickens, *supra* note 181, at 171.

including any “information about genes, gene products or inherited characteristics that may derive from an individual or family member.”¹⁸⁴

Such a broad definition of genetic information has been criticized for unduly restraining insurance companies from relying on sources that have been a basic part of the underwriting process for generations.¹⁸⁵ For example, genetic indicators from family history or even a routine medical test may be off-limits to insurers under this type of broad definition because it may yield information about genes or inherited characteristics.¹⁸⁶

3. *Oregon’s Property Conception*

Similar to the New Jersey statute, Oregon law creates broad protections for genetic information. One unique aspect of the Oregon law is that it grants individuals a personal property right over their genetic information.¹⁸⁷ While this provision stands to expand individual rights to genetic testing confidentiality, it poses certain risks for scientific research.

Before the current version of New Jersey’s Genetic Privacy Act was passed and signed by New Jersey’s Governor in November of 1996, an earlier version was passed and offered to the Governor for her signature in June of that year.¹⁸⁸ The Governor vetoed that bill due to concerns about property rights in genetic information because an individual could “demand royalties from a new product resulting from a clinical study” in which the individual’s genetic information was used.¹⁸⁹ The Governor expressed her concerns that litigation related to these questions could interfere with continued scientific research and clinical innovation.¹⁹⁰ Such concerns have limited the number of states using personal property rights to convey individual protection over genetic information.

B. PROBLEMS ASSOCIATED WITH STATE LEGISLATION

1. *Inconsistent Approaches*

While this diverse set of state-level approaches enjoys varying degrees of success in addressing the problem of genetic discrimination in insurance

184. N.J. STAT. ANN. § 10:5-44(e)(2) (West Supp. 2000).

185. *Senate Hearing*, *supra* note 9, at 64–65 (testimony of Mary Nell Lehnhard, Senior Vice President for Policy and Representation at Blue Cross/Blue Shield Association).

186. *Id.* at 64.

187. OR. REV. STAT. § 659.715 (1997).

188. *See Jendusa*, *supra* note 29, at 199.

189. *Burnett*, *supra* note 118, at 529.

190. *Jendusa*, *supra* note 29, at 200.

coverage, its coverage of disparate types of genetic information fails to offer insureds any consistent form of protection upon which they can rely.¹⁹¹ The first step in promoting the use of genetic testing to decrease the severity and incidence of genetic birth defects is building confidence in the health-care consumer. The state-level patchwork of laws fails adequately to fulfill a reasonable insured's expectations for protection and in many states offers no protection at all.

While the states should be applauded for their quick response to the problem of genetic discrimination and the public's perception of it, some commentators believe that the hasty approach created state statutes without foresight, suggesting that much of this state legislation will soon be obsolete.¹⁹² Because the field of genomic research is so dynamic, legislation addressing genetic discrimination must be broad enough to protect anticipated changes without constraining scientific research.

2. Federal ERISA Preemption

In addition to the inconsistency associated with state legislation, the Employee Retirement and Income Security Act of 1974 (ERISA)¹⁹³ exempts some employee benefit plans from state regulation.¹⁹⁴ Section 1144(a) of ERISA preempts state laws that "relate to" employee benefit plans.¹⁹⁵ This broad preemption is subject to ERISA's "Savings Clause," which provides that ERISA does not preempt state laws that regulate insurance.¹⁹⁶ However, the Savings Clause is further subject to the "Deemer Clause," which provides that state laws regulating insurance cannot deem a *self-funded* employee benefit plan to be an insurance plan.¹⁹⁷ Thus, under the Deemer Clause, all self-funded employee benefit plans are exempted from state insurance regulations.¹⁹⁸ The Supreme Court has interpreted § 1144(a) as evidencing congressional intent to subject employee benefit plans to a "uniform body of benefits law"¹⁹⁹ and, thereby, to "minimize the administrative and financial burden of complying with

191. *See id.* at 203.

192. *See id.*

193. 29 U.S.C. §§ 1001–1461 (1994).

194. *Id.* § 1144(a).

195. *Id.*

196. *Id.* § 1144(b)(2)(A).

197. *Id.* § 1144(b)(2)(B).

198. *Id.*

199. *N.Y. State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 656 (1995).

conflicting directives among States or between States and the Federal Government.”²⁰⁰

Seventy percent of Americans who acquire health insurance in the private sphere are covered through employment-related group benefit plans.²⁰¹ Self-funded plans comprise thirty-nine percent of the beneficiaries of those employment-related group plans that are exempt from state insurance regulation.²⁰² Thus, for the 125 million Americans insured through these self-funded plans,²⁰³ state laws offer no protection from genetic discrimination.

The preemption provision in ERISA “has created a strong incentive for companies to self-insure. The incentive increases as State-mandated benefits proliferate.”²⁰⁴ In fact, evidence suggests that some employers may strategically use ERISA in order to avoid unfavorable or burdensome state insurance regulations.²⁰⁵ For example, the Fifth Circuit upheld an employer’s right to alter the entire self-funded employee benefit package in response to one beneficiary’s claims.²⁰⁶ In *McGann v. H & H Music Co.*, the plaintiff was an employee suffering from AIDS who made claims for AIDS treatment against the employer’s commercial health plan.²⁰⁷ In response to McGann’s claims, the employer switched from a commercial health plan to a self-funded plan and limited AIDS treatment benefits to \$5,000, while all other medical care claims had a \$1,000,000 maximum.²⁰⁸ Like AIDS, genetic diseases can be costly to treat and are thus attractive targets for exclusions from health plan benefits for insurers seeking to reduce costs.

Thus, ERISA renders state protections from genetic discrimination powerless for many insureds. Furthermore, inconsistent application of state laws fails to provide the foundation for consistent public expectations of protection, making state law inadequate to address the problem of public fears of genetic discrimination in insurance coverage.

200. *Id.*

201. HEALTH LAW, *supra* note 34, at 781.

202. *Id.*

203. *See Senate Hearing, supra* note 9, at 33 (testimony of Christine Brunswick, Vice President of the National Breast Cancer Coalition).

204. HEALTH LAW, *supra* note 34, at 785.

205. *See Egan, supra* note 4, at 243.

206. *See McGann v. H & H Music Co.*, 946 F.2d 401 (5th Cir. 1991).

207. *Id.* at 403.

208. *Id.*

IV. THE FEDERAL APPROACH TO LIMITING GENETIC DISCRIMINATION IN INSURANCE COVERAGE

A. CURRENT FEDERAL LEGISLATION

1. *The Americans with Disabilities Act*

Some commentators suggest that the Americans with Disabilities Act (ADA)²⁰⁹ may address the problem of genetic discrimination in insurance coverage despite the fact that it was passed in 1990 without the specific intent to prevent insurance discrimination.²¹⁰ Title III of the ADA provides that:

No individual shall be discriminated against on the basis of disability in the full and equal enjoyment of the goods, services, facilities, privileges, advantages, or accommodations of any place of public accommodation by any person who owns, leases (or leases to), or operates a place of public accommodation.²¹¹

The title also offers an illustrative list of places of public accommodation which includes an insurance office.²¹²

The term “disability” is defined in the ADA as “(A) a physical or mental impairment that substantially limits one or more of the major life activities of such individual; (B) a record of such an impairment; or (C) being regarded as having such an impairment.”²¹³ While the issue of whether a genetic predisposition or carrier status fits within the definition of “disability” has not been litigated yet, the Equal Employment Opportunity Commission (EEOC) commented regarding when genetic status would be considered a substantial impairment. The EEOC definition is circular in that a genetic predisposition to an illness is only a disability when the individual is discriminated against based on that genetic predisposition.²¹⁴

An asymptomatic genetic predisposition, however, has been held to constitute “a bodily disorder or disease” for the purposes of making a prophylactic surgery “medically necessary” and thus covered by health

209. 42 U.S.C. §§ 12101–12213 (1994).

210. See Egan, *supra* note 4, at 243.

211. 42 U.S.C. § 12182(a) (1994).

212. See *id.* § 12181(7).

213. *Id.* § 12102(2)(A)–(C).

214. See Pickens, *supra* note 181, at 173.

insurance.²¹⁵ In *Katskee v. Blue Cross/Blue Shield*, the plaintiff's physician recommended removal of her uterus, ovaries, and fallopian tubes due to her genetic predisposition to breast and ovarian cancer called breast-ovarian carcinoma syndrome.²¹⁶ The health insurer claimed that the surgery was not medically necessary under the terms of the policy because it was not in response to an "illness," as left undefined in the policy.²¹⁷ The Nebraska Supreme Court determined that, even though the plaintiff's present condition was physically undetectable, it constituted an illness under the plain meaning of the plaintiff's health insurance policy making any treatment for her condition medically necessary under the policy terms.²¹⁸

Not only must genetic anomalies be considered a disability to achieve protection under the ADA, but health insurance must be considered a place of public accommodation. While this issue is not settled yet, a recent U.S. District Court case in Minnesota involving disability insurance suggests that the ADA was intended to apply to access to insurance coverage.²¹⁹ In *Winslow v. IDS Life Insurance Co.*, the district court followed the First Circuit²²⁰ in determining that a place of public accommodation is not limited to actual physical structures.²²¹ The court found that the defendant's policy of denying access to disability insurance based on the plaintiff's mental health condition "is founded on a disability-based discrimination violative of the ADA."²²²

Even if the ADA applies to individuals with genetic anomalies seeking protection from health insurance discrimination, the ADA allows plans to "refuse to insure, or refuse to continue to insure, or limit the amount, extent, or kind of coverage available to an individual, or charge a different rate for the same coverage" if the disparate treatment is "based on sound actuarial principles or is related to actual or reasonably anticipated experience."²²³ These aspects of the ADA create problems for individuals seeking protection from genetic discrimination. For example, prospective parents learning that they are carriers of a genetic condition will likely be

215. *Katskee v. Blue Cross/Blue Shield*, 515 N.W.2d 645, 648 (Neb. 1994).

216. *Id.* at 647.

217. *Id.* at 648-49.

218. *See id.* at 651.

219. *See Winslow v. IDS Life Ins. Co.*, 29 F. Supp. 2d 557 (D. Minn. 1998).

220. *See Carparts Distrib. Ctr., Inc. v. Automotive Wholesaler's Ass'n of New England, Inc.*, 37 F.3d 12, 19 (1st Cir. 1994). The Sixth Circuit, however, reached the opposite conclusion in *Parker v. Metropolitan Life Insurance Co.*, holding that "a public accommodation is a physical place." 121 F.3d 1006, 1010-11 (6th Cir. 1997).

221. *Winslow*, 29 F. Supp. 2d at 563.

222. *Id.* at 567.

223. *Id.* at 566. *See also Egan, supra* note 4, at 244.

protected from discrimination since carrier status is not likely actuarially to create anticipated expenses because carriers will never achieve symptoms. The ADA, however, cannot stop the insurer from refusing to insure the couple's baby. Furthermore, the insurer may be able to deny coverage for the woman's pregnancy since it is likely to be associated with expensive complications. These undesirable prospects may provide a disincentive for couples attempting to use genetic testing in order to prevent genetic birth defects.

Additionally, because the ADA was not designed to address genetic discrimination in health insurance, individuals seeking protection under this law must "shoe-horn" their circumstances into the terms and concepts of the ADA. Defining genetic anomalies as disabilities remains unsettled, and access to health insurance does not clearly fall into the category of access to places of public accommodation. Due to the unsettled nature of this law, it provides inadequate protection for individuals seeking preconception, prenatal, and neonatal genetic testing.

Finally, employers with fewer than fifteen employees are exempted from ADA compliance.²²⁴ This exemption leaves insureds in employee group-benefit plans unprotected when the group is small.²²⁵ Additionally, the ADA provides no protection for those insured in the individual market.

2. *The Health Insurance Portability & Accountability Act of 1996: "An Important First Step"*

Unlike the ADA, which does not explicitly address genetic discrimination, the Health Insurance Portability & Accountability Act of 1996 (HIPAA)²²⁶ provides explicit restrictions on the use of genetic information in the health insurance arena.²²⁷ First, HIPAA does not allow group health plans or health insurers offering group coverage to treat genetic information as a preexisting condition, which would enable the insurer to exclude that condition from coverage.²²⁸ If the genetic condition associated with the genetic information has been diagnosed, however, then insurers can consider it to be a preexisting condition and exclude it from coverage.²²⁹

224. See 42 U.S.C. § 12111(5)(A) (1994).

225. Pickens, *supra* note 181, at 173.

226. Health Insurance Portability & Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (codified as amended at scattered sections of 18, 26, 29, and 42 U.S.C.).

227. See 29 U.S.C. §§ 1181(b)(1)(B), 1182(a)(1)(F), 1182(b)(1) (Supp. II 1996).

228. *Id.* § 1181(b)(1)(B).

229. See *id.*

Second, group health plans cannot deem an applicant ineligible for enrollment in the group plan based on genetic information or health status.²³⁰ Furthermore, HIPAA prevents group health plans from charging higher premiums based on genetic information than the plan charges other “similarly situated individual[s] enrolled in the plan.”²³¹ These protections are explicitly limited by provisions of HIPAA that assert that group plans are not required to offer any certain type of benefits and are not prohibited from placing caps on benefits as long as they are consistently applied to all similarly situated enrollees.²³² Additionally, HIPAA explicitly provides that health insurers are not constrained by this law in the amount they may charge employers for group coverage.²³³

In addition to protecting genetic information in group health plans, HIPAA provides special protections for newborns and pregnancies.²³⁴ Group health plans may not enforce preexisting condition exclusions against pregnancy-related conditions or for newborns during the month following birth.²³⁵ Finally, HIPAA provides limited protection for insureds in the individual market. It requires health insurers to renew individual coverage at the option of the insured, except in cases of fraud, nonpayment of premiums, or other terminating events.²³⁶ There are no limitations, however, on the premiums that may be charged under the renewed policy.

HIPAA has been praised by the health insurance industry as an appropriate and helpful way of addressing genetic discrimination in insurance coverage.²³⁷ For example, for individuals who undergo genetic carrier screening and find they are the carriers of Tay Sachs, this part of their medical record cannot be used to deny them eligibility to enroll in a group health plan. Additionally, a pregnant woman who learns through prenatal genetic testing that her baby has spina bifida cannot be excluded from her group health plan for having a preexisting condition. Furthermore, a newborn covered under a group health plan and testing positive for PKU can undergo treatment for PKU without the parents being worried about the treatment being excluded as a preexisting condition.

230. *See id.* § 1182(a)(1)(A), (F).

231. *Id.* § 1182(b)(1).

232. *See id.* § 1182(a)(2)(A), (B).

233. *See id.* § 1182(b)(2)(A).

234. *See id.* § 1181(d)(1), (3).

235. *See id.*

236. *See* 42 U.S.C. § 300gg-42 (Supp. II 1996).

237. *See, e.g., Senate Hearing, supra* note 9, at 70–71 (prepared statement of the Health Insurance Association of America).

However, while advocates for consumers of health insurance regard HIPAA as “an important first step,”²³⁸ additional protection of genetic information is required in order to limit discrimination.²³⁹ The largest population that HIPAA leaves unprotected is insureds in the individual market. For the 14.5 million Americans who acquire health insurance through nongroup plans,²⁴⁰ their genetic information can be used by insurers to raise premiums and cut benefits. For example, if a woman in the individual market undergoes genetic testing and finds that she is a carrier of sickle cell disease, her individual market insurer can access her genetic testing results and place a low cap on pregnancy related claims or exclude pregnancy health care altogether. If this woman is in the middle class, she will not be eligible for Medicaid as a safety net and could find herself with no coverage for prenatal care.

Furthermore, for uninsured individuals applying for health insurance in the individual market, insurers can access their genetic information and deny eligibility to enroll based on that information. For a pregnant couple who learns through prenatal genetic testing that their baby will be born with a genetic birth defect, the individual market insurer can refuse to insure the baby.

Even for those insured in group plans, HIPAA leaves some important gaps in protection. HIPAA allows group health plans to respond to the genetic information of one group member by raising premiums for the entire group.²⁴¹ Similarly, group health plans can exclude coverage for certain conditions or place claims limits on particular conditions, “provided it is not directed at certain individuals.”²⁴² Thus, despite the protections HIPAA provides group health plan enrollees, some parents may find that their attempt to prevent genetic birth defects through genetic testing is used against them to raise premiums or to deny certain benefits.

B. PROPOSED FEDERAL LEGISLATION: THE GENETIC INFORMATION NONDISCRIMINATION IN HEALTH INSURANCE ACT OF 1999

In the first session of the 106th Congress, Congresswoman Louise Slaughter introduced a bill to the House of Representatives that would

238. Clinton Remarks, *supra* note 119, at 243.

239. See, e.g., *Senate Hearing*, *supra* note 9, at 1–2 (testimony of Senator James Jeffords, Chairman of the S. Comm. on Labor & Human Res.).

240. See HEALTH LAW, *supra* note 34, at 786.

241. Pickens, *supra* note 181, at 174.

242. *Id.*

specifically address genetic discrimination in health insurance.²⁴³ The proposed Genetic Information Nondiscrimination in Health Insurance Act of 1999 (GINHIA) would make several important changes to current federal law. Primarily, it would amend ERISA to prohibit group health plans from using genetic information to make decisions about policy renewal, benefits levels, and premiums.²⁴⁴ It would also amend ERISA to expose group health plans to liability for compensatory, consequential, and punitive damages for violating the above prohibitions.²⁴⁵ Additionally, GINHIA would amend the Public Health Service Act to extend the same protections to the individual market that are extended to the group market through the ERISA amendments.²⁴⁶ This proposed federal legislation defines genetic information as “information about genes, gene products, or inherited characteristics that may derive from an individual or a family member of the individual.”²⁴⁷

While this proposal does an admirable job of filling in gaps left by HIPAA, the broad definition of genetic information could be interpreted as prohibiting insurers from accessing routine blood tests or physical examinations conducted for reasons other than obtaining genetic information.²⁴⁸ Additionally, the bill does not provide for specific protections of using genetic information in scientific research. Without explicit protections for this benign use of genetic information, scientific research could be hindered.

V. GUIDELINES FOR REFORM

A. EVALUATING THE STATUS QUO

In evaluating the current state and federal level of protection against health insurance discrimination, it is apparent that a majority of health insurance consumers enjoy significant protections today. One hundred twenty-five million Americans enjoy the group health plan protections under HIPAA.²⁴⁹ Many of those not protected by HIPAA, such as

243. H.R. 306, 106th Cong. (1st Sess. 1999). A few months later, Senator Daschle introduced a similar bill to the Senate that addresses genetic discrimination in employment as well as health insurance. *See* S. 1322, 106th Cong. (1st Sess. 1999).

244. *See* H.R. 306, 106th Cong. § 2 (1st Sess. 1999).

245. *See id.*

246. *Id.* § 3.

247. *Id. passim.*

248. *See* Jagutis, *supra* note 168, at 437.

249. *See supra* note 203 and accompanying text.

individuals in nongroup plans, live in states that provide some sort of protection from genetic discrimination.²⁵⁰

The problem with this “patchwork” of protections is highlighted by the arguably inordinate level of public fear²⁵¹ associated with the potential for misuse of genetic information. Allowing different levels of protection while leaving major gaps undermines a consistent expectation of protection and replaces it with an expectation of misuse. While public education efforts emphasizing current protections may calm American skepticism, a well-publicized incident of denied benefits involving one of the millions of families left unprotected by the status quo will fuel public fear once more. Therefore, more aggressive action in the form of comprehensive federal legislation prohibiting health insurers’ use of genetic information is necessary to counteract prevailing public skepticism.

B. COMPREHENSIVE FEDERAL LEGISLATION

The fundamental problem with the status quo is that genetic information can be used by health insurers for nontherapeutic purposes. Any meaningful reform must recognize and address the need “to ensure that people in all health plans, not just group plans, will have the full confidence that the fruits of genetic research will be used solely to improve their care and never to deny them care.”²⁵² Genetic research, and the resulting tests and treatments developed from it, are conducted in order to promote the therapeutic goal of avoiding or minimizing the severity of genetic conditions. Allowing insurers access to genetic-testing results permits discriminatory underwriting decisions based on the assumption that the genetic condition indicated will manifest itself in a medically costly way. The business of insurance is inherently discriminatory and such discrimination helps keep premiums low and coverage widely available. As the advances in the prevention and early treatment of genetic birth defects demonstrate, however, genetic-testing results help doctors minimize or avoid the costs of genetic birth defects. Therefore, protecting genetic information will likely promote the goals of both genetic researchers and clinicians as well as insurers.

250. See *supra* note 167 and accompanying text.

251. Conversely, Dr. Francis Collins, director of the National Human Genome Research Initiative at the National Institutes of Health, says the following about addressing patient fears: “I cannot, as a physician talking to a patient who has those concerns, tell her that I think she is overreacting, because she is not.” *Senate Hearing, supra* note 9, at 21.

252. Clinton Remarks, *supra* note 119, at 243.

Health insurers argue that allowing individuals access to their genetic testing results while prohibiting insurers from using them sets the stage for insurers being adversely selected into insolvency. This argument has serious implications for the health care coverage crisis because putting insurers in a position in which they are forced to raise premiums or leave the market altogether will make it more difficult for individuals to acquire or to maintain health insurance coverage. However, the argument rests on a fundamentally flawed assumption that the insurers will be forced to accept a new population of medically needy individuals. In reality, insurers are currently insuring a population ripe with genetic defects. The insureds in this pool will either stay healthy or become ill *regardless* of whether insurers know the genetic plan. Prohibiting health insurers' use of genetic information and thereby promoting consumer use of genetic tests will theoretically improve the probability that insureds stay healthy and enable them to take steps to prevent or to minimize a genetic illness that would have manifested itself inevitably. These implications may actually save insurers money over the long term.

Therefore, an effective reform policy involves establishing a federally mandated minimum level of protection upon which health insurance consumers can rely. Comprehensive federal legislation prohibiting health insurers' use of genetic information will provide a consistent foundation upon which the American public can rebuild confidence in preconception, prenatal, and neonatal genetic testing decisions. This confidence is the necessary first step in enabling parents to seize the therapeutic power of genetic research in order to improve the health of America's babies.

The state and federal approaches provide valuable lessons regarding what effective legislation should include. Four ideals should be engendered in federal legislation prohibiting insurers' use of genetic information: 1) a broad definition of genetic information; 2) protection for routine tests and examinations; 3) protection for scientific uses of genetic information; and 4) universal application for all insureds.

1. *Define Protected Genetic Information Broadly*

Federal legislation attempting to prohibit genetic discrimination in health insurance coverage should clearly define the type of genetic information to be protected. A broad definition that includes information derived from family members is a more appropriate definition than one limiting genetic information to information derived from tests of DNA and chromosomes. The broad definition is superior in that it eliminates inconsistent applications of the law for similarly situated individuals. For

example, a couple who learns that they are carriers of an autosomal recessive gene through genetic testing will receive the same protection as a couple who learns that they are carriers by having a child with the recessive disorder. The broad definition can best further the purpose of protecting information about conditions that are not currently, and may never be, symptomatic.

A potential problem with a broad definition is that it would force insurers who currently use family genetic information in their underwriting process to eliminate that criterion. Insurers anticipate that this could increase risks and, therefore, force premiums to rise. Genetic testing, however, enables insureds to make better-informed decisions to help prevent the manifestation of genetic diseases in themselves and their offspring. These preventive steps are cost beneficial; therefore, insurers are unlikely to face increased risk if they are denied access to genetic information.

2. *Protect Routine Tests*

In order to prevent problems associated with the broad definition, federal legislation should expressly protect the use of routine tests and examinations that are not conducted with the purpose of discovering genetic information but that yield such information inadvertently. Without explicit protections for routine tests and examinations, courts may interpret federal legislation to prohibit such routine work. While prohibiting insurers from accessing genetic information would not interfere with traditional underwriting methods, eliminating routine tests may interfere with and have unknown implications for the insurance industry.

Expressly protecting routine tests would help placate insurers' fears that traditional underwriting methods would be challenged. Consequently, it would minimize any new level of risk insurers would be required to accept because it would narrowly tailor protections to genetic information. Routine tests are a legitimate tool insurers can use to monitor appropriate use of diagnostic tools to control costs without denying needed care. Cost control leads to lower premiums, which in turn enable larger groups of people to afford health insurance.

3. *Protect Scientific Research*

Comprehensive federal legislation must provide explicit protections for scientific research into genetic information. In the effort aggressively to protect all genetic information from third parties in order to limit genetic

discrimination, benign uses of genetic information may often be limited as well. This could have a chilling effect on scientific research if the legislation does not explicitly protect scientific uses of anonymous genetic information. Unlike the insurance industry's use of genetic information that may be used to deny health care coverage, the research community helps discover and develop therapeutic uses for genetic information. These efforts should steadfastly be protected so that individuals can once again feel comfortable participating in scientific research and so researchers will not be constrained by new legislation.

A provision that explicitly protects scientific uses of genetic testing information while denying insurers access to the same information will likely signal insurance consumers to support scientific uses because they are beneficial. Such a provision will encourage the American public to participate in genomic research without fear that the information will be misused. This encouragement is an important step in continuing the benefits that genomic research provides.

4. *Universal Application*

Any health policy reform must apply not only to group health plans, but to insurance coverage purchased in the individual market as well. Universal application must be respected in order to restore public confidence in both the genetic testing currently available as well as support for genomic research underway. Despite the considerable protections for group health plans that exist today, American skepticism of genetic testing persists. While the forces behind this skepticism have not been formally evaluated, some individuals may worry that they will find themselves in the individual market eventually.

Thus, even individuals once protected in the group market will find decisions they made to undergo genetic testing years earlier can be used against them by individual market insurers. Additionally, a few well-publicized cases of genetic discrimination in the individual market can undermine the confidence even of those with greater protections in the group market. Therefore, consistent protection requires consistent application to all insureds and prohibitions of all insurers from using genetic information for nontherapeutic purposes.

Universal application will likely lead to increased public confidence in genetic-testing protections due to fewer anecdotes of individuals losing benefits or coverage due to genetic testing results. Imposing the federal legislation on insurers in the individual market may require these insurers

to accept increased risks because they would have less information upon which to deny benefits or coverage. Any increased risk, however, will likely be offset by increased prevention measures that informed insureds are enabled to make due to information yielded by genetic tests.

CONCLUSION

With great success comes greater responsibility. The goals so handily realized by the Human Genome Project offer a wealth of hope for health care in the twenty-first century. However, in order to protect the potential associated with improved knowledge of the human genome, the government that initiated and funded the Project must also assure the American public that the knowledge will be used to improve health, not as another means of discrimination.

No one stands in a better position to benefit from scientific advances than America's future generations. While genetic birth defects continue to haunt American families today, genetic testing offers two things that have previously been nonexistent—hope and options. The only way to realize the potential for improving the health of babies is to promote genetic testing at the preconception, prenatal, and neonatal stages of development. Instead of realizing the full potential of genetic advances in perinatal health care, genetic discrimination and the public fear of misuse of genetic information stunt the growth of these advances. In fact, U.S. Representative Cliff Stearns has dubbed genetic discrimination “the civil rights issue of the twenty-first century.”²⁵³

While states have attempted to respond and federal legislation has offered an important first step, prevailing public fear of discrimination suggests that these measures are inadequate. Comprehensive federal legislation that prohibits insurers from using these test results is the best response to parents who need reassurance that their health insurance coverage will not be adversely affected by attempts to improve their chances of having a healthy baby.

253. David L. Gollaher, *Genetic Discrimination: Who Is Really at Risk?*, 2 GENETIC TESTING 13, 13 (1998) (quoting Press Release, Stearns Welcomes President's Interest in Promoting Genetic Privacy (May 19, 1997)).

