THE ELDERLY AND THE DISCRIMINATORY USE OF GENETIC INFORMATION

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Genetic science, the study of the very building blocks of the human body, has progressed to a point where testing can predetermine a person's predisposition to disease. Although such knowledge might provide a boon for medicine, it also presents a threat of discrimination by insurers, especially against the elderly. In this note, Mr. Kyle French explains the science of genetic testing, outlines how insurers analyze risk and use genetic information, demonstrates why the elderly are particularly susceptible to genetic information discrimination by insurers, examines current and proposes future legislation proscribing genetic discrimination, and provides elder law practitioners with useful information for advising clients facing genetic information issues including and beyond insurer discrimination.

I. Introduction

Since the time of Aristotle, doctors have known that certain families carry genetic traits for diseases.[1] Over the centuries, however, limited technical innovation confined scientific progress in genetic research. During this early period, genetic science remained highly theoretical in nature. Today, twentieth-century advances in basic research technology are dramatically pulling down the long-standing barriers in genetic research resulting in a striking shift from basic theoretical study to human application.[2] The secrets held

This note is dedicated to Brandy J. Schmitt and written in memory of my parents who continue to inspire me in all my endeavors.

1. *See* Shannon Brownlee & Joanne Silberner, *The Age of Genes*, U.S. NEWS & WORLD REP., Nov. 4, 1991, at 66.

2. Scientists at the Battelle Memorial Institute identify gene mapping and derivative testing products as the top technology for the year 2005, followed by super materials, compact energy sources, and high-definition TV. *See* Jim Dillon, *Top 10 New Technologies Identified: Battelle Scientists Pick Gene Mapping*, DAYTON DAILY NEWS, Feb. 21, 1995, at 6B.

within our genes are unraveling at a rapid pace,[3] and the increasing availability of genetic information offers promises of improved diagnoses and therapies for genetic disorders. We now know that more than four thousand genetic diseases afflict humans.[4] The distinction between what we currently understand as medical science and genetic science stands to be altered inexorably. Future genetic testing[5] technology will be very different from present-day medical testing.[6] Genetic tests will act as a crystal ball enabling people to look several decades into the future.[7] Basic decisions about individual lifestyles and whether to conceive new life will be fundamentally altered by each person's access to readily available genetic information.

Regrettably, for many genetic diseases, no definitive therapy will be possible when testing becomes available.[8] For some disorders the

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3. *See* David Stipp, *Gene Chip Breakthrough: Microprocessors Have Reshaped Our Economy, Spawned Vast Fortunes, and Changed the Way We Live*, FORTUNE, Mar. 31, 1997, at 56 ("Within a decade it should be possible to put a few of your cells in a gene-chip scanner and quickly analyze your genetic risks for scores of diseases.").

4. *See* Larry L. Deaven, *Mapping and Sequencing the Human Genome*, *in* ARE GENES US? THE SOCIAL CONSEQUENCES OF THE NEW GENETICS 12, 12 (Carl F. Cranor ed., 1994). "Worldwide, genetic diseases affect no less than [five percent] of all newborns. Most are caused by altered genes transmitted at conception, while a lesser share are due to chromosomal abnormalities . . . ." Victor B. Penchaszadeh, *Genetics and Public Health*, 28 BULL. PAN AM. HEALTH ORG. 62, 62 (1994).

5. "No generally accepted term precisely defines 'genetic testing.' The term implies that a piece of human genetic code is examined to determine if the chemical sequence is proper." *Report of the National Association of Insurance Commissioners Genetic Testing Working Group*, 15 J. INS. REG. 7, 9 (1996) [hereinafter *NAIC Report*]. According to the American Council of Life Insurance Medical Section on Genetic Testing, "genetic tests are laboratory tests used to determine the presence or absence of abnormal or defective genes and/or chromosomes. Such tests are direct measures of such defects or abnormalities, as opposed to indirect manifestations of genetic disorders." AMERICAN COUNCIL OF LIFE INS. & HEALTH INS. ASS'N OF AM., REPORT OF THE ACI-HIAA TASK FORCE ON GENETIC TESTING 1 (1991).

> In those states where legislation has been adopted addressing genetic testing, the definition has been relatively restrictive, limiting the definition to those tests which examine the genetic code or direct gene products. In addressing the issue of defining genetic testing, insurers have advocated extremely tight restrictions, limiting such testing to laboratory testing of human DNA or chromosomes. [S]ome advocacy groups have advocated much broader definitions, including a prohibition against inquiring into the applicant's family history or even the ages or health of one's parents as a form of a genetic test.

NAIC Report, *supra*. Unless otherwise specified, genetic testing, when used in this article, also encompasses genetic screening, which is a one-time test used to detect a single trait in an individual.

6. *See* Brownlee & Silberner, *supra* note 1, at 66.

7. *See* Kathleen McAuliffe, *Predicting Diseases*, U.S. NEWS & WORLD REP., May 25, 1987, at 64.

8. *See* COMMITTEE ON ASSESSING GENETIC RISKS, INSTITUTE OF MEDICINE, ASSESSING GENETIC RISKS: IMPLICATIONS FOR HEALTH AND SOCIAL POLICY 38 (Lori B.

lag time between testing and treatment capabilities will be so long that individuals confronted with the choice of whether to be tested will not have any prospect of effective treatment. Under such circumstances, nonmedical benefits and harms will dominate decisions about whether testing should be undertaken, both for individuals and for society.[9] The growing availability of identifiable genetic information about individuals is already profoundly impacting areas far beyond basic medical care and creating an ever-widening number of ethical and legal issues.

Concerns about the improper use of genetic information abound. Information technology and societal attitudes heighten these concerns. Genetic discrimination[10] fears are compounded by worries about how the widespread delineation of genetic profiles could result in a centralization of genetic information in much the same way that credit information is centralized today.[11] Because Deoxyribonucleic Acid (DNA) sequence databases are prone to error, "comparison of an individual's genetic profile to an error-ridden prototype could have the same stigmatizing effect as do false positives on drug tests and tests for the HIV antibody."[12] Some of the most difficult ethical and legal problems associated with genetic testing will arise as insurers increasingly consider applying genetic testing technology to the risk classification of insured and applicants. For example, tests exist that can identify people whose genes are linked to Alzheimer's or Hunting-

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Andrews et al. eds., 1994) (noting that the identification of the underlying defect will significantly accelerate the discovery of future treatments) [hereinafter ASSESSING GENETIC RISKS]; NEIL A. HOLTZMAN, PROCEED WITH CAUTION: PREDICTING GENETIC RISKS IN THE RECOMBINANT DNA ERA 105 (1989) (noting that for many genetic disorders no drug therapy nor diet or lifestyle changes exist to improve markedly the outcome of those born with a genetic predisposition).

9. *See* ASSESSING GENETIC RISKS, *supra* note 8, at 38.

10. Genetic discrimination has been defined as "discrimination against an individual or against members of that individual's family solely because of real or perceived differences from the 'normal' genome in the genetic constitution of that individual." Marvin R. Natowicz et al., *Genetic Discrimination and the Law*, 50 AM. J. HUM. GENETICS 465, 466 (1992). Natowicz "distinguish[es] genetic discrimination from discrimination based on disabilities caused by altered genes" and thereby clarifies the point that genetic discrimination is not based on any notion of the present function of the individual, rather the discriminating party relies on that individual's genotype to assess risk of future dysfunction. *Id.* As discussed later in this note in Part IV, current federal law does not adequately address such discrimination.

11. *See* Catherine M. Valerio Barrad, *Genetic Information and Property Theory*, 87 NW. U. L. REV. 1037, 1047 (1993).

12. *Id.*

ton's disease and certain kinds of breast and colon cancer, but cures for these diseases are still years away.[13]

Elder law practitioners need to understand genetic testing and its associated legal issues. When addressing genetic testing issues, most people focus on testing children or young adults for disease predisposition, but the elderly population is also likely to be subjected to genetic testing for a variety of reasons.[14] Thus, like most citizens, the elderly population is at significant risk for discriminatory application of genetic information.[15] Although recent federal legislation alleviates some genetic discrimination fears, the legislation leaves notable gaps. This note focuses on the discriminatory application of genetic information by insurers against the elderly for diseases which disproportionately affect the elderly.[16] Part II examines the scientific background of genetic testing. Part III identifies why the elderly population is particularly vulnerable to genetic information discrimination and outlines insurer risk analysis and the use of genetic information. Part IV describes past, recent, and current legislative efforts directed toward restricting the use of genetic information for discriminatory purposes. Part V clarifies the legal and personal concerns elder law practitioners need to keep in mind when an elder client presents a genetic information issue.

II. Background

In order to understand fully the legal issues related to genetic information, a brief overview of the science behind genetic testing is necessary. The processes of human genetics are very complex and, in general, not fully understood. Modern genetics is a relatively new

13. *See* Eric Niiler, *Proposal Would Ban Bias Based on Genetic Tests*, THE PATRIOT LEDGER (Quincy, Mass.), Feb. 21, 1996, at 6.

14. *See infra* Part III.

15. *See infra* Part IV.

16. Genetic testing raises a wide variety of issues, many of which are not directly related to the elder context. Because this note focuses on the use of genetic information in the elder context, other sources should be consulted regarding peripheral genetic testing issues. *See* Katheryn D. Katz, *Ghost Mothers: Human Egg Donation and the Legacy of the Past*, 57 ALB. L. REV. 733 (1994) (genetic testing and the use of third-party gametes to produce a child); Marilyn Moysa, *Eugenics Movement Revival?*, MONTREAL GAZETTE, Dec. 31, 1995, at A5 (use of genetic tests to purify selective human characteristics).

area of medical study.[17] Human biochemical genetics[18] was born in 1901 when Archibald Garrod first related a biochemical abnormality to an inherited disease.[19] Less than four decades ago, in 1953, James Watson[20] and Francis Crick discovered the structure of DNA.[21] "The Watson-Crick model of DNA provided a structural framework for asking specific questions about how genetic information is stored, copied, and used."[22] DNA is contained in forty-six thread-like chromosomes, numbered according to size, which are found in every cell in the human body.[23] Genes, the basic units of inheritance, are segments of DNA that produce proteins.[24] The human body carries fifty to one hundred thousand genes.[25] A human gene can vary in size from less than ten thousand base pairs to more than two million.[26] The sequence of the base pairs in the DNA encodes genetic information.[27] The entire human genome[28] consists of approximately three billion base pairs strung along the twenty-four human chromo-

17. *See* Smith v. Ortho Pharms. Corp., 770 F. Supp. 1561, 1570 (N.D. Ga. 1991) (noting that the American Board of Medical Genetics, which serves to certify specialists in different areas of genetics, was not established until 1979).

18. Genetics examines the manner by which specific traits are passed from generation to generation and how they are expressed. *See* ASSESSING GENETIC RISKS, *supra* note 8, at 60.

19. *See* D.J. WEATHERALL, THE NEW GENETICS AND CLINICAL PRACTICE 38 (2d ed. 1985).

20. Watson resigned from leading the National Institutes of Health Genome Project on April 10, 1992, over concerns about his investments in biotechnology firms. *See Head of Federal Gene Research Agency Resigns*, L.A. TIMES, Apr. 11, 1992, at A18.

21. *See* James D. Watson & F.H.C. Crick, *Molecular Structure of Nucleic Acids: A Structure for Deoxyribose Nucleic Acid*, NATURE, Apr. 25, 1953, at 737 (announcing the discovery of the DNA double helix).

22. KARL A. DRLICA, DOUBLE-EDGED SWORD: THE PROMISES AND RISKS OF THE GENETIC REVOLUTION 40 (1994) ("Without question, this was the biological discovery of the twentieth century."). In 1962, Watson and Crick shared the Nobel Prize in Medicine or Physiology with Maurice Wilkins for their discovery of the DNA structure. *See* JAMES D. WATSON, THE DOUBLE HELIX (1968) (a personal account of Watson and Crick's discovery of the structure of DNA). Despite Harvard University's controversial refusal to print *The Double Helix*, Watson's book has been read by millions and printed in at least 17 languages. *See* Walter Sullivan, *A Book That Couldn't Go to Harvard*, N.Y. TIMES, Feb. 15, 1968, at 1, 4; Gunter S. Stent, *Preface* to JAMES D. WATSON, THE DOUBLE HELIX at ix (Gunter S. Stent ed., 1968).

23. *See* OFFICE OF TECH. ASSESSMENT, MAPPING OUR GENES, GENOME PROJECTS: HOW BIG, HOW FAST? 24 (1988) [hereinafter MAPPING OUR GENES].

24. *See id.* at 21.

25. *See id.* at 4.

26. *See id.* at 24. A base pair consists of two strands of DNA held together in the shape of a double helix by a weak bond. *See id.* at 201. The size of a genome is generally given as its total number of base pairs. *See id.*

27. *See* Robert A. Weinberg, *The Dark Side of the Genome*, TECH. REV., Apr. 1991, at 44.

somes.[29] Genes are generally located by finding minor genetic variations, called polymorphisms, that occur throughout human DNA and act as markers.[30] Although techniques for detecting genetic disorders have existed for some time, they have expanded dramatically in their scope, accuracy, and speed over the last twenty years.[31]

A. Genetic Research Initiatives

The Human Genome Project is a worldwide effort that ultimately will lead to an understanding of the structure and function of the genetic information contained in each human cell.[32] The Project aims to map the sequence of all three billion base pairs that make up the human genome.[33] Although the Human Genome Project is not a single endeavor, it is the title most commonly used to refer to a large collection of genome programs and projects throughout the world.[34]

In 1988, the U.S. Congress launched the Human Genome Project by appropriating funds to two federal agencies: the Department of Energy and the National Institutes of Health.[35] The Project's objectives include the determination of the complete sequence of human DNA by the year 2003.[36] The Project was both ahead of schedule and

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28. The human genome is the entirety of the biochemical compounds that form the molecular basis for human life. *See* MAPPING OUR GENES, *supra* note 23, at 3.

29. *See id.* at 24 (three billion base pairs along a haploid genome not a diploid which is 46 chromosomes).

30. *See id.* at 27.

31. *See* ASSESSING GENETIC RISKS, *supra* note 8, at 63. "Genetics research has accelerated to the point where several human genes are discovered every week." *Prepare for the Age of Genetics*, FIN. TIMES, Apr. 12, 1996, at 17. "'New disease genes are discovered almost weekly,' Dr. Francis Collins, director of the National Center for Human Genome Research, told a congressional hearing last month. 'Once a disease gene is identified, it is often only a matter of months before a diagnostic test can be made available.'" *Poll Shows Dark Side of Genetic Research*, HOUSTON CHRON., Oct. 25, 1996, at A5.

32. The project also includes major studies on the legal, ethical, and social issues raised by genetic testing. *See* Elke Jordan, *Invited Editorial: The Human Genome Project: Where Did It Come from, Where Is It Going?*, 51 AM. J. HUM. GENETICS 1 (1992).

33. *See id.* at 1.

34. *See* Deaven, *supra* note 4, at 12 n.1. Other genome projects are also being done in France, Japan, and the European Community. *See* Jordan, *supra* note 32, at 5.

35. *See* Deaven, *supra* note 4, at 12.

36. *See* VICTOR A. BERNSTAM, THE HANDBOOK OF GENE LEVEL DIAGNOSTICS IN CLINICAL PRACTICE 4-5 (1992). *But see* Victor A. McKusick, *The Human Genome Project: Plans, Status, and Applications in Biology and Medicine*, *in* GENE MAPPING 18, 18 (George J. Annas & Sherman Elias eds., 1992) (stating that given adequate funding, an estimated $200 million a year for the worldwide effort in 1988 dollars, the Project should be completed by 2005). "The driving motive behind the Human Gen-

under budget as of March 1995.[37] Congress recognized early on the Project's potential importance and impact,[38] and despite recent cuts in funding scientific research,[39] the federal government continues to support the Project.[40] The budget request for the National Center for Human Genome Research for fiscal year 1996 is $166,678,000.[41] By facilitating genetic test development through the identification of the genetic basis for diseases, the Genome Project will play a key role in the genetic testing field by greatly increasing genetic test availability over the next five to ten years.[42] The Project will also generate significant

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ome Initiative is quite simple and direct: the identification and eradication of all genetically based diseases." George P. Smith, II & Thaddeus J. Burns, *Genetic Determinism or Genetic Discrimination?*, 11 J. CONTEMP. HEALTH L. & POL'Y 23, 30 (1994).

37. *See Department of Health and Human Services Appropriations for FY 1996: Hearings Before a Subcomm. of the House Comm. on Appropriations*, 104th Cong. 1445-1528 (1995) (statement of Francis Collins, Director of the National Center for Human Genome Research, Department of Health and Human Services) [hereinafter *Statement of Francis Collins*]. "[T]he HGP [Human Genome Project] has made rapid and significant progress, in some cases exceeding the expectations of participating scientists." National Ctr. for Human Genome Research, *Current Scientific Priorities of the NCHGR Extramural Program* (visited Oct. 8, 1996) <http://www.hgr.nih.gov>.

38. *See, e.g.*, 135 CONG. REC. E1418 (daily ed. Apr. 27, 1989) (statement of Rep. Michael A. Andrews) (calling the Human Genome Project the most important biological project in the history of science). *But see* MAPPING OUR GENES, *supra* note 23, at 185 (in an attempt to mitigate misplaced controversy, the O.T.A. report classified the Human Genome Project as being "relatively modest").

39. *See, e.g., GOP's Proposed Cuts Threaten Science Research, Clinton Says*, BOSTON GLOBE, Oct. 19, 1995, at 10.

40. "[T]he results [of the Genome Project] have been impressive enough that even the penny-pinching Republican Congress voted an 11.2 percent budget increase for genome research in 1996—$170 million, up from $154 million last year and even more than President Clinton requested." Robert S. Boyd, DNA Research Project Shows Great Promise: Genetic Code Is Program Target (on file with author).

41. *See Statement of Francis Collins*, *supra* note 37.

42. *See* ASSESSING GENETIC RISKS, *supra* note 8, at 2.

commercial success.[43] A map of about sixteen thousand human genes can now be seen on the Internet.[44]

B. Genetic Testing

In the past, genetic diagnosis relied on inferences from observations far removed from the gene.[45] Sufficient data was available to draw correct inferences for only a few diseases.[46] Today, recombinant DNA technology[47] and advanced detection test techniques are rapidly pushing genetic medical science into uncharted ethical and legal territory.[48]

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43. *See* Kathleen Day, *Biotech Executives Find Wealth in Their Genes*, WASH. POST, Apr. 8, 1994, at D1; Lawrence M. Fisher, *Profits and Ethics Clash in Research on Genetic Coding*, N.Y. TIMES, Jan. 30, 1994, at 1 ("The Human Genome Project . . . is still more than a decade from completion. But in a rapid blurring of big science and big business, the effort has already created its first millionaires."); Lawrence M. Fisher, *Two Founders of Microsoft Buy Biotechnology Stake*, N.Y. TIMES, May 7, 1994, at 51 ("William H. Gates and Paul G. Allen, co-founders of the Microsoft Corporation, have invested $10 million in Darwin Molecular Technologies, Inc. . . . a biotechnology company that hopes to use DNA sequences in the human genome to create novel drugs for cancer, AIDS and autoimmune disease."). The total market for Deoxyribonucleic Acid (DNA) diagnostics is expected to exceed $700 million by 1998. *See* Paul H. Silverman, *Genetic Analysis*, 25 COM. & GENETIC DIAGNOSTICS, HASTINGS CENTER REP., S15, S15 (spec. supp. 1995). For information on the genetics industry, see Michael J. Malinowski & Maureen A. O'Rourke, *A False Start? The Impact of Federal Policy on the Genotechnology Industry*, 13 YALE J. ON REG. 163 (1996). However, failure of the federal government to enact laws to regulate the industry could cripple the industry's commercial success. *See Genetic Privacy, Discrimination Issues Could Cripple Biotech Industry*, BIOTECHNOLOGY NEWSWATCH, Oct. 7, 1996, at 13, *available in* LEXIS, Health Library, Biotech File.

44. Although genes have been mapped and data published in different forms, scientists said this was an unprecedented effort to provide a map of the location of 16,334 genes identified so far that would be accessible to laypeople and scientists alike. *See* Joanne Kenen, *Gene Map Spurs Research*, REUTERS NORTH AMERICAN WIRE, Oct. 24, 1996, at 1 (on file with author). Dr. Francis Collins, director of the National Center for Human Genome Research, called the map project placing "bookmarks in the book of life." *Id.*

45. *See* HOLTZMAN, *supra* note 8, at 1.

46. *See id.*

47. Recombinant DNA technology allows genes to be split up in pieces and then reformed in a new combination. *See id.* Only with the application of recombinant DNA techniques to human genetic diseases did research to develop practicable methods of gene therapy become possible. *See* JAMES D. WATSON ET AL., RECOMBINANT DNA (2d ed. 1992) (describing advances in genetic research). *See generally* W. French Anderson, *Human Gene Therapy*, 256 SCI. 808, 809 (1992); Judith Areen, *Regulating Human Gene Therapy*, 88 W. VA. L. REV. 153, 170 (1985); LeRoy Walters, *The Ethics of Human Gene Therapy*, 320 NATURE 225, 225-27 (1986).

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> During 1994 and 1995, major new advances were announced in the search for cancer-causing genes. Genes responsible for a portion of breast, colon, ovarian, prostate, and other cancers were discovered. In addition to the previously discovered tumor suppressor gene, the

Genetic testing services include services offered by specialized genetics centers, pediatricians, obstetricians, family physicians, internists, and specialists in the course of their regular practice.[49] Current tests use blood or urine samples to test for chemical properties of certain genes.[50] However, genetic tests are seldom perfect predictors of risk because genetic discoveries are not limited to disease-causing genes, but also include genes that belie a predisposition or susceptibility to a particular disease.[51] The actual development of most diseases is a result of a combination of factors, such as other genes and the environment.[52] The DNA Committee of the Pacific Northwest Regional Genetics Network suggests that a disease test should be moved from the research test list to the clinical test list when at least seventy percent of matings are expected to be informative.[53]

> ataxia telangiectasia mutated ("ATM") gene was discovered in 1995. Both of these genes have been associated with numerous forms of cancer. Work also has been proceeding on the identification of genes associated with other multifactorial disorders, such as heart disease, diabetes, asthma, and rheumatoid arthritis, as well as various neuropsychiatric conditions and behaviors.

Mark A. Rothstein, *Preventing the Discovery of Plaintiff Genetic Profiles by Defendants Seeking to Limit Damages in Personal Injury Litigation*, 71 IND. L.J. 877, 881 (1996).

49. *See* ASSESSING GENETIC RISKS, *supra* note 8, at 65. Genetic screening is distinguishable from genetic testing. Genetic screening is defined as the use of various genetic tests to evaluate populations or groups of individuals independent of a family history of a disorder or symptoms. *See id.* Tests to spot genetically related diseases could balloon into a multibillion dollar business early in the next century. *See* Susan Moffat, *DNA Use a Shot in Arm for Biotech*, L.A TIMES (San Diego County ed.), Jan. 18, 1992, at D1. Currently, the medical market is moving rapidly to put tests into the hands of doctors. For example, on October 30, 1996, doctors could begin ordering a comprehensive genetic test to predict breast cancer. The test, manufactured by Myriad Genetic Laboratories Inc., will cost $2,400 and for the first time promises to detect every known mutation on two genes that can cause inherited breast or ovarian cancer. Previous tests have detected only a handful of mutations. People with faulty genes are thought to have about an 85% chance of eventually getting breast cancer and a 44% chance of ovarian cancer. *See Breast Cancer Genetic Testing: Gene Test Offered as Ethics Debate Continues*, CANCER WKLY. PLUS, Nov. 11, 1996, *available in* LEXIS, Market Library, IACNWS File.

50. *See* OFFICE OF TECH. ASSESSMENT, GENETIC TESTS AND HEALTH INSURANCE: RESULTS OF A SURVEY 15-16 (1992) [hereinafter SURVEY].

51. *See* Jon Beckwith, *The Human Genome Initiative: Genetics' Lightning Rod*, 17 AM. J.L. & MED. 1, 5 (1991). "The imprecision surrounding genetic prognostication is related to several important genetic concepts. These include the mode of inheritance, whether it is a single gene or multifactorial (complex) disorder, the degree of penetrance of the disorder, the variable expressivity of the disorder, allelic heterogeneity, allelic expansion, and genomic imprinting." Rothstein, *supra* note 48, at 882-83 (noting "[c]urrent genetic technology can, at best, assign a broad range of risk. The only true test is the test of time.").

52. *See id.*

53. *See* BERNSTAM, *supra* note 36, at 3.

C. Public Support

A 1992 March of Dimes survey polled one thousand people in the United States regarding their views about genetic testing and gene therapy. Although those surveyed did not completely understand all the issues, 79% expressed their willingness to undergo gene testing and therapy if necessary, and 88% said they would have their children genetically tested and undergo gene therapy in order to prevent or cure a genetic disease that would usually be fatal if undetected.[54] Recent news stories about genetic tests have even resulted in families prone to breast cancer offering bribes to be included in medical studies or to be moved up in a testing queue.[55]

Public support for genetic testing does come with reservations about information disclosure. Approximately 75% of those polled in the March of Dimes survey expressed concerns that genetic testing and therapy be undertaken only in accordance with "strict regulations."[56] More than 50% of those surveyed stated their belief that when a genetic disease is discovered, someone needs to be apprised of this fact. Of those, approximately 33% believed an employer should be advised of the genetic disease, 58% concluded insurers should be informed, and 98% concluded one's spouse or fiancé should be told.[57]

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54. *See* Howard Markel, *The Stigma of Disease: Implications of Genetic Screening*, 93 AM. J. MED. 209 (1992); Sandy Rovner, *Many Americans Say Gene Therapy Okay*, WASH. POST, Sept. 29, 1992 (Health Magazine), at 5.

55. *See* Marilyn Chase, *Genetic Testing Needs Clear Plans for How to Handle Treatment*, WALL ST. J., Feb. 26, 1996, at B1. Public interest in genetics is not limited to testing. Recent reports revealed parents are requesting genetically engineered human growth hormones for their children because they want their children to grow tall. *See* Kendra Hogue, *Local Doctor/Lawyer Explores Potential of Genes*, BUS. J. (Portland), Mar. 17, 1995, at 22.

56. *See* Rovner, *supra* note 54, at 25.

57. *See id.* A December 1993 poll of 500 adult Americans taken by Yankelovich Partners for TIME/CNN found a marked ambivalence among the respondents regarding genetic research and its applications. *See* Philip Elmer-Dewitt, *The Genetic Revolution*, TIME, Jan. 17, 1994, at 48. For example, 49% said they would not take a genetic test that could tell them what diseases they were likely to suffer later in life, while 50% said they would like to know. *See id.* Most respondents strongly opposed the uses of human genetic engineering except for the purpose of curing disease or enhancing agricultural production. *See id.* Fifty-eight percent thought altering human genes was against the will of God. *See id.* Ninety percent said it should be illegal to allow insurance companies to use genetic tests in order to decide whom to insure. *See id.*

III. Analysis: Elder Vulnerability to Genetic Discrimination

A. Genetic Information and the Elderly

There are at least three major reasons why genetic testing issues are especially relevant to the elderly population: (1) the use of genetic tests to aid in disease diagnosis; (2) the probability of increased use of Health Maintenance Organizations (HMOs) by the elderly; and (3) the estate planning benefit derived from disease predisposition knowledge.

1. LATE STAGE DISEASE DIAGNOSIS

Because doctors currently use genetic tests as a diagnosis tool, the population segment most affected by chronic disease, the elderly, face an increased probability of being genetically tested in comparison to the general population.[58] An elderly patient's likelihood of being tested is also enhanced by recent genetic discoveries in diseases which disproportionately affect the elder population.

Contemporary breakthroughs in the genetic origins of Alzheimer's disease illustrate this point. Over four million Americans suffer from Alzheimer's disease, and countless others are at risk of developing this common form of dementia—the fourth leading cause of death in the nation with one hundred thousand deaths a year.[59] Scientists can now identify specific genes linked to early-onset Alzheimer's disease.[60] In 1992, Dr. Allen Roses at Duke University Medical School discovered that two copies of genes known as Apo-E genes are associated with a ninety percent chance of getting Alzheimer's by age eighty.[61] A kit used to detect Alzheimer's genetic predisposition is widely available to doctors and is used in at least eight major diagnostic labs.[62] Several biotechnology companies now

58. For example, Genica Pharmaceuticals Corp. of Worchester, Massachusetts, only offers its Alzheimer's genetic testing kits to doctors as an aid in symptom diagnosis. *See* Jamie Talan, *The Fuss over the Alzheimer's Test*, NEWSDAY, Sept. 27, 1995, at B4; *see also* HOLTZMAN, *supra* note 8, at 1 (noting genetic tests will initially be used for diagnosis in those whose health is already impaired).

59. *See* Tom Paulson, *Seattle Team Finds Genetic Clue to Disease: Hope for Alzheimer's Victims*, SEATTLE POST-INTELLIGENCER, Aug. 18, 1995, at A1.

60. *See id.*

61. *See* Talan, *supra* note 58, at B4.

62. *See id.*

promote the test's use and availability in major medical journals like any other common pharmaceutical product.[63]

2. MEDICARE REFORM

Medicare recipient participation in HMOs increases the probability of elder genetic testing. The impetus for health care reform includes the demand to create more effective cost containment than the current prospective government payment system now provides.[64] Economic experts believe that high medical costs endanger global competitiveness and the nation's long-term economic stability. Health care costs in the United States increased from over $600 billion in 1990 ($2566 per person) to nearly $900 billion in 1993 ($3380 per person).[65] Compared to other developed countries with similar constellations and disease rates, U.S. health care costs were dramatically higher during this period.[66]

It is widely recognized that health care reform cannot be brought about without addressing the Medicare program[67] because Medicare covers over ninety-eight percent of persons age sixty-five or older.[68] HMOs are rapidly emerging as a primary means to contain costs while expanding medical coverage to all Americans.[69] A new system based on current Medicare reform proposals will likely encourage eld-

63. *See id.* ("Genica Pharmaceuticals Corp. of Worchester, Mass., has been selling Apo-E tests, which cost about $200 each, since January 1994. As of September 1995, the company has sold 750 Alzheimer's test kits.").

64. *See* Alison Barnes, *The Policy and Politics of Community-Based Long-Term Care*, 19 NOVA L. REV. 487, 489 (1995).

65. *See* Sally T. Burner et al., *National Health Expenditures Projections Through 2030*, 14 HEALTH CARE FINANCING REV. 1, 29 (1992).

66. According to the United Nations 1994 Human Development Report, the United States spent 13.3% of its gross domestic product (GDP) on health care. *See* Paul Spector, *Failure by the Numbers*, N.Y. TIMES, Sept. 24, 1994, at 19. By comparison, Canada spent 9.9%; Japan, 6.8%; and the United Kingdom, 6.6% of its GDP. *See id.*

67. *See* Susan Dentzer, *Separating Smoke and Substance: Questions and Answers about the Political Battle over How to Reform the Medicare Program*, U.S. NEWS & WORLD REP., Sept. 25, 1995, at 57 ("Both Democrats and Republicans agree that Medicare's growth can and should be slowed for the sake of the nation's fiscal health."); Donna K. Thiel & Christopher L. White, *What Happens to Medicare and Medicaid Under the Clinton Reform Plan?*, HEALTH SPAN, Nov. 1993, at 15, *available in* WL 10 No. 10 PH-HTHSP15.

68. Barnes, *supra* note 64, at 498.

69. *See* Susan J. Stayn, Note, *Securing Access to Care in Health Maintenance Organizations: Toward a Uniform Model of Grievance and Appeal Procedures*, 94 COLUM. L. REV. 1674, 1677 (1994). For historical perspective on the federal government's role in the emergence of HMOs, see KAREN DAVIS ET AL., HEALTH CARE COST CONTAINMENT 134, 140 (1990); JOSEPH L. FALKSON, HMOS AND THE POLITICS OF HEALTH SYSTEM REFORM 1 (1980).

erly citizens to join HMOs.[70] Over three and a half million Medicare beneficiaries have already joined HMOs.[71]

HMOs are classified as health care providers.[72] Although HMOs are technically not health insurers, they provide similar benefits to members and are generally not distinguished from insurers by consumers.[73] Additionally, HMOs operate on the same market principles as insurers. HMO decision-making processes raise access-to-care concerns because HMOs and practitioners share significant financial incentives to limit costly treatment when determining whether to authorize and recommend medical services.[74] The Health Care Financing Administration (HCFA), which administers Medicare, is no longer actively encouraging beneficiaries to join HMOs, in part because of quality-of-care concerns.[75] HCFA's reversal of position[76] should be cause for some concern given President Clinton's and states' efforts to move Medicare recipients from Medicare to HMOs, especially because Medicare HMO patients have much more well-developed federal avenues for recourse against access problems than do other HMO members.

A 1992 insurance industry study about attitudes towards the application of genetic information revealed that HMOs are likely to use genetic information as a factor in determining insurability. More than twenty-five percent of the HMOs surveyed would be somewhat likely or very likely to alter claims payment practices as new genetic tests

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70. *See* T.J. Sullivan, *Current Developments in Tax Exempt Health Care*, C968 A.L.I.-A.B.A. 221, 235 (1994) (nearly all of the health reform proposals under consideration encourage growth in HMO participation). *See generally* Dentzer, *supra* note 67, at 57. Although now dead, the Clinton administration's 1994 national health-care reform legislation contained a provision which prohibited the discriminatory use of genetic information. *See* Seth Shulman, *Preventing Genetic Discrimination*, TECH. REV., July 1995, at 16.

71. *See* Dentzer, *supra* note 67, at 57.

72. For a short, nontechnical discussion of HMOs, see EMPLOYEE BENEFIT RESEARCH INST., FUNDAMENTALS OF EMPLOYEE BENEFIT PROGRAMS 115-25 (1983). *See also* Stayn, *supra* note 69, at 1677-79.

73. *See* EMMET J. VAUGHAN, FUNDAMENTALS OF RISK AND INSURANCE 76 (5th ed. 1989).

74. *See* Stayn, *supra* note 69, at 1677.

75. *See* Robert Pear, *Medicare to Stop Pushing Patients to Enter H.M.O.'s*, N.Y. TIMES, Dec. 27, 1993, at A1 (quoting HCFA Administrator Bruce C. Vladeck: "I don't want to get into a big marketing campaign until we can tell beneficiaries that quality is really good, that every H.M.O. is doing a good job by our beneficiaries.").

76. *Id.* at A1 (noting that HCFA aggressively promoted HMOs for Medicare patients during the Reagan and Bush administrations).

come in line.[77] Eighty-seven percent of the HMOs conducted an economic analysis of genetic testing as part of applicant screening. Seventy-four percent of the HMOs agreed strongly or agreed somewhat that it is fair for insurers to use genetic test information and that insurers should have the option of determining how to use genetic information in determining risks.[78]

The structure of HMO operations presents many opportunities to limit coverage to genetically predisposed patients. HMOs reduce their costs by exercising special control over patients' access to doctors.[79] Enrollees who desire treatment or a second opinion from a specialist must first secure permission from their primary care physician. Also, in contrast to traditional insurance plans and Medicare, which generally rely on retrospective review, HMOs decide whether to reimburse care prospectively and concurrently. Discriminatory application of genetic information by HMOs would be logical because HMOs provide an incentive to their network doctors to undertreat through their reimbursement structure. Although HMO cost-conserving strategies are designed to maximize the efficiency and cost effectiveness of health care services, these strategies also create the potential for undertreatment based on genetic dispositions without the patient's knowledge or acquiescence.[80]

3. ESTATE AND FAMILY PLANNING

Beyond the obvious medical diagnosis benefits, there are sound legal reasons for elder genetic testing. Many elderly people undergo genetic testing to aid them in estate planning.[81] Knowledge about predisposition to dementia-related diseases is likely to impact how people handle their estate planning. It should not be surprising that genetic testing is often motivated by legal reasons rather than medical reasons because most genetic tests lead to few opportunities for cura-

77. *See* SURVEY, *supra* note 50, at 29.

78. *See id.* at 32.

79. *See* Stayn, *supra* note 69, at 1679.

80. Although federal laws enable Medicare recipients to appeal HMO treatment decisions, very few recipients use the laws, and the grievance system is generally viewed as an ineffective deterrent against HMO coverage abuses. *See id.* at 1695.

81. *See Parkinson's Disease Research: Hearings Before the House Comm. on Commerce*, 104th Cong. (1995), *available in* 1995 WL 437451 (testimony of John Hardy relating specifically to Alzheimer's disease genetic tests); Talan, *supra* note 58, at B4 (stating that genetic testing information can help Alzheimer's families alleviate anxiety and adequately plan ahead).

tive treatment of genetic conditions.[82] Elderly people with genetically related illnesses may also consider testing for the sole purpose of providing information about disease predisposition to their family members. However, genetic information discrimination fears of both an elderly client and his or her family could preclude information dissemination within a family and subsequent testing for predisposition.

B. Discriminatory Application of Genetic Information by Insurers

The revelation of genetic information to third parties concerns most people. More than four out of five subjects in a recent survey involving three hundred interviews said the risk of losing insurance was important or very important when deciding whether to be genetically tested.[83] More than one-third felt that the risk of losing one's insurance was medium or high if they were found to be a genetic disease carrier.[84]

1. LACK OF PROTECTION

People fail to realize that they may have little control over genetic test results. Controlling genetic information dissemination is difficult because a person's genetic information can be obtained through routine and minimally evasive medical procedures. Because DNA is present in all nucleated body cells, including blood, it can be easily extracted from tissue and stored for an indefinite period.[85] At least three routine medical practices make blood samples readily available to insurers. First, few people know that hospitals are required to store genetically testable blood samples from millions of Americans. Every time a baby is born in this country, doctors take blood samples to test for certain diseases[86] that need to be diagnosed early if the affected

82. *See* ASSESSING GENETIC RISKS, *supra* note 8, at 149.

83. *See Human Genome Project: Hearings Before the Subcomm. on Energy*, 103d Cong. 102 (1994) (testimony of Ellen Wright Clayton) [hereinafter *Clayton*].

84. *Id.*

85. *See* OFFICE OF TECH. ASSESSMENT, GENETIC MONITORING AND SCREENING IN THE WORKPLACE 78 (1950) [hereinafter MONITORING]; *see also* Niiler, *supra* note 13, at 6 ("samples taken during a routine blood test could be analyzed years later to determine a person's predisposition to a certain disease").

86. *See* ASSESSING GENETIC RISKS, *supra* note 8, at 1-5 (noting that there are at least 10 genetic conditions for which states screen newborns and that although the scope of such screening varies by state, every state tests newborns for at least two types of genetic disorders). For example, at the New England Regional Newborn Screening Center in Jamaica Plain, babies are tested for eight childhood diseases. *See* Niiler, *supra* note 13, at 6.

child is to be healthy.[87] Some states require these samples to be held for years.[88] Second, life insurers often require an applicant to provide blood samples as a screening tool for detecting AIDS and other fatal diseases.[89] Third, whenever a person has some tissue surgically removed, the hospital's pathology lab must retain some of the tissue for as long as twenty years in some states.[90] Blood and tissue samples represent a powerful and easily accessible repository of genetic information.[91]

Inadequate protection of personal health information is another reason why genetic information is easily obtained and transferred. According to the Institute of Medicine Board on Health Care Services Chair, medical information is protected by a "patchwork of largely inadequate, uncoordinated, and sometimes contradictory state laws."[92] On April 1, 1992, a report submitted to the House Committee on Government Operations declared that neither law nor technology gives individuals adequate protective control over their personal records.[93] The routine availability to insurance carriers of identifiable genetic information about individuals involves policy problems "more complex than the traditional privacy concerns presented by credit records, bank records, or even medical records."[94]

2. INSURER RISK CLASSIFICATION

Risk classification is a fundamental part of the insurance system because insurers operate in a private and voluntary market.[95] Insurers

87. Arguably, mandatory screening of newborns has not been shown to be essential to achieve desired public health benefits. *See* R. R. Faden et al., *A Survey to Evaluate Parental Consent as Public Policy for Neonatal Screening*, 72 AM. J. PUB. HEALTH 1347 (1982).

88. *See id.*

89. *See Genetic Discrimination Protecting Privacy of Information on Genes*, THE RECORD (Northern New Jersey), Feb. 2, 1996, at 6 ("Once they [insurers] have the blood, there is no legal restraint on what they can do with it."). According to New Jersey State Senator Jack Sinagra (R-Middlesex), insurer use of blood test for genetic information "is probably one of the greatest risks of discrimination that could hit the average citizen in the future." *Id.*

90. *See Clayton*, *supra* note 83.

91. *See id.*

92. *Protesting Medical Records Confidentiality: Hearings on the Medical Record Confidentiality Act of 1995 Before the Comm. on Labor & Human Resources*, 104th Cong. (1995).

93. *See* H.R. REP. NO. 102-478 (1992) [hereinafter POLICY].

94. *Id.*

95. *See* Kenneth S. Abraham, *Efficiency and Fairness in Insurance Risk Classification*, 71 VA. L. REV. 403, 403 (1985) ("The heart of any insurance system is its method of classifying risks and setting prices.").

use underwriting to determine whether, and on what basis, they will accept an application for insurance.[96] "The primary goal of underwriting is the accurate prediction of the costs of death (how much an insured has paid in premiums before the insured dies versus the face value of the policy) and sickness (how much the insured has paid in premiums versus the cost of medical care for diseases the insured will contract)."[97] The threshold premise that insurance prices function in accord with supply and demand is the key to understanding insurer behavior.[98] "Like other products, as the cost of insurance rises, demand for it generally decreases."[99] In a competitive market, the insurer who can develop the most efficient risk classification system—one that classifies and prices risks most accurately—will compete successfully for premium dollars.[100] This is because the insurer can, through classification, offer low-cost users lower prices.[101] This does not mean that insurers will go to any lengths to obtain additional information regarding expected losses. Additional information may be expensive and time consuming to collect and may result in a marginal improvement in the efficiency of the classification that is not justified by the expense.[102] What it does suggest is that insurers in a competitive market stand to gain from the creation of an accurate classification system.[103] Thus, the market in which insurers operate "is affected by the quality of the classification system that determines price (premium), the probability of a covered event occurring and the expected loss, and the risk aversion of the purchaser."[104]

However, insurers and persons of average or low risk have powerful incentives to reduce the effects of adverse selection:

> If the insurer cannot distinguish high- and low-risk individuals he must offer them the same premium. Low-risk individuals are

96. Underwriting is "[t]he process of selecting risks and classifying them according to their degrees of insurability so that the appropriate rates may be assigned." MERRITT CO., GLOSSARY OF INSURANCE TERMS 201 (Thomas E. Green ed., 1980).

97. T.H. Cushing, *Should There Be Genetic Testing in Insurance Risk Classification?*, 60 DEF. COUNS. J. 249, 253 (1993).

98. *See* Maria O'Brien Hylton, *Insurance Risk Classifications after McGann: Managing Risk Efficiently in the Shadow of the ADA*, 47 BAYLOR L. REV. 59, 70 (1995).

99. *See* Abraham, *supra* note 95, at 407.

100. *See* Hylton, *supra* note 98, at 70.

101. "The more refined (and accurate) an insurer's risk classifications, the more capable it is of 'skimming' good risks away from insurers whose classifications are less refined." Abraham, *supra* note 95, at 408.

102. *See* Hylton, *supra* note 98, at 70.

103. *Id.*

104. *Id.*

> worse off and high-risk individuals better off compared with the situation in which the insurer knows the risk class of insureds. The insurer has an incentive to identify low-risk individuals since he could increase his expected profits by offering a policy to low risks at a premium below the pooled premium but greater than the low risks' accident probability.[105]

Would an insurer want to use genetic testing? According to one American insurance company's position, several conditions should be met before insurers use a medical test for insured classification:

> (1) The test must supply information in addition to information otherwise available from other sources (e.g., from the medical history questionnaire). (2) The disease of interest must have serious morbidity and/or mortality implications. (3) The disease must be common enough to ensure that the test is predictive and that the cost can be justified. (4) The test must be predictive of disease (or absence of disease) and reliable. (5) The test must be understood, accepted, and used by the medical profession. (6) Laboratories must be able to readily perform the test. (7) The test must be affordable and able to provide results quickly. (8) The test must be risk-free.[106]

Due to recent scientific breakthroughs genetic testing now meets the insurer's criteria because the tests supply inexpensive risk-free information about terminal disease disposition that is otherwise unavailable with a high degree of probability. Despite general industry denials, evidence demonstrates that insurers are currently using genetic information to discriminate.[107] A genetic discrimination study, prepared by Paul R. Billings, M.D. and cited by the NIH-DOE ELSI Working Group in their report entitled *Genetic Information and Health Insurance*, cites a number of insurance coverage discrimination cases that resulted from insurer knowledge about an individual's genetic predisposition.[108] According to the Council for Responsible Genetics

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105. Hugh Gravelle, *Insurance Law and Adverse Selection*, 11 INT'L REV. L. & ECON. 23, 25 (1991).

106. OFFICE OF TECH. ASSESSMENT, MEDICAL TESTING AND HEALTH INSURANCE 121 (1988) [hereinafter MEDICAL TESTING].

107. Health insurance companies do not deny that they want to know what potential policy holders know about their risk potential. *See* Laurel Shackelford, *The Genetic Roadmap: A Promise of Hope or a Threat?*, THE COURIER-JOURNAL (Louisville, Ky.), Apr. 7, 1996, at 2D. Insurance carriers are not demanding that people get gene testing, at least not so far, but once a person gets mapped prospective insurers want to know the road signs. *See id.*

108. 141 CONG. REC. S17096-97 (daily ed. Nov. 15, 1995) (statement of Sen. Hatfield) (the study found 100 people who were denied insurance benefits because of genetic risks, and a survey of families with inherited diseases found 31% had been denied coverage even if members of their families were not actually ill).

(CRG), a "genetic underclass" is being created by insurers who use genetic tests to deny coverage.[109]

In a recent survey of over three hundred members of U.S. support groups for genetic diseases, "25% reported being refused life insurance and 22% had been refused health insurance," say Washington researchers.[110] Eighteen percent of respondents did not tell insurers about their genetic background, and seventeen percent did not tell their employers.[111] Although the survey was not a scientific sample, it appeared to confirm long-held fears about the side effects of genetic research.

There are at least three theories about the impact of genetic testing on the insurance industry:

> (1) Overall, genetic analysis will mean fewer people will have access to health insurance because such tests identify or refine cost risks for the insurer; (2) Genetic assays could rule out an individual's risk for a disorder and hence increase access to health care coverage. That is, making use of genetic information would allow insurers to better assess risk, with the result that individuals at elevated risk will pay more (or be denied access), but people with low risk will pay less; and (3) As the number of identified genes increases, so will the number of people who will be identified as at risk, which could spread risk. The ultimate impact of genetic tests, then, will depend, in part, on the practices and attitudes of insurers toward tests for genetic disorders, as well as the morbidity and mortality associated with particular conditions.[112]

To the extent that a person's personal genetic record reveals the likelihood of future disease, it will be possible to estimate with greater precision the risk of insuring that person.[113] Those with greater risk of disease are less desirable subjects of insurance.[114] Thus, most com-

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109. *See* David Ballingrud, *Gene Testing Raises Fears of Insurance Discrimination*, ST. PETERSBURG TIMES, June 4, 1995, at 14A (CRG is a nonprofit group that monitors social issues in biotechnology.).

110. *Health Notes: Survey Finds People Upset About Genetic Discrimination*, UPI, Oct. 28, 1996, *available in* LEXIS, Nexis Library, UPI file.

111. *See id.*

112. SURVEY, *supra* note 50, at 1.

113. *See* POLICY, *supra* note 93.

114. These individuals are more likely to seek insurance and may seek to keep the results of their genetic tests out of the hands of insurers. *See* John Murray, *Ethical Issues in Human Genome Research*, 5 FED'N AM. SOC. FOR EXPERIMENTAL BIOLOGY 55, 57 (1991); Talan, *supra* note 58, at B4 (noting that the temptation may exist for insurers to use the Apo-E Alzheimer's test to avoid insuring people who have a genetic predisposition, even though they may never develop the disease).

mentators believe that use of genetic testing information by insurers will increase the number of uninsured.[115]

When fighting against recent state legislation that would have restricted insurer genetic information use, the American Council of Life Insurance insisted that insurers be allowed access to the results of tests performed at the request of the person seeking insurance.[116] In arguing for the use of genetic testing, insurers rely on the traditional fair discrimination market perspective theory of insurance.[117] Applicants for health or life insurance are said to "adversely select" against an insurer when, without informing the insurer of any health problem, they seek coverage based on their knowledge that they are in poor health.[118] If an insurer underassesses certain risks, it will not have sufficient funds to pay all the claims made in the future, unless it overcharges people who represent little or no risk.[119] Without sufficient funds to meet contractual obligations, insurers will go bankrupt and leave many insured without coverage. On the other hand, because of the free market nature of the insurance industry, if an insurer overassesses the risks and sets premiums too high, prospective customers will purchase from other insurers.[120] Because genetic tests yield imperfect disposition information, the threat of genetic discrimination compromises quality medical care, and genetic conditions exist at a fairly stable incidence in our society and are arguably already accounted for in actuarial tables, laws are needed to prevent the improper use and dissemination of genetic information.[121]

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115. *See, e.g.*, Carol Lee, Comment, *Creating a Genetic Underclass: The Potential for Genetic Discrimination by the Health Insurance Industry*, 13 PACE L. REV. 189, 222 (1993).

116. *See id.*

117. *See* Cushing, *supra* note 97, at 253. Insurers also argue that genetic testing is appropriate given the sharply escalating costs of health care. *Id.*

118. *See* MEDICAL TESTING, *supra* note 106, at 3.

119. *See id.*

120. *See id.*

121. *See* Wendy L. McGoodwin, *Genetic Testing: A Tool for Doctors, Not for Insurers*, 15-1 J. INS. REG. 71, 71 (1996).

IV. Current Regulations of Insurer Use of Genetic Testing Information

Before the turn of the century, insurance was not considered interstate commerce[122] and thus was left completely to the domain of state regulation. In light of the dramatic growth of the insurance industry during the early part of the century, the Supreme Court decided that insurance is subject to congressional regulation under the Commerce Clause.[123] Responding to the Court's decision, the insurance industry proposed and obtained the passage of the federal McCarran-Ferguson Act,[124] which mandated state control of insurance regulation.[125]

A. Federal Regulations

Although many nations are moving to regulate genetic testing information,[126] the U.S. federal government has enacted few restrictions on the use of genetic information.[127] On April 24, 1991, Representative John Conyers, Jr. (D-Mich.) introduced legislation to safeguard the privacy of individuals who submit to genetic testing.[128]

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122. *See* Paul v. Virginia, 75 U.S. 168 (1869) (holding that issuing a policy of insurance is not a transaction of interstate commerce), *overruled by* United States v. South-Eastern Underwriters Ass'n, 323 U.S. 811 (1944).

123. United States v. South-Eastern Underwriters Ass'n, 322 U.S. 533 (1944).

124. 15 U.S.C. §§ 1011-1015 (1994).

125. Section 1011 of the McCarran-Ferguson Act states that "the continued regulation and taxation by the several States of the business of insurance is in the public interest, and that silence on the part of the Congress shall not be construed to impose any barrier to the regulation or taxation of such business by the several States." *Id.* § 1011. Section 1012(a) further declares that "[t]he business of insurance, and every person engaged therein, shall be subject to the law of the several States which relate to the regulation or taxation of such business." *Id.* § 1012(a). Section 1012(b) states that "[n]o Act of Congress shall be construed to invalidate, impair, or supersede any law enacted by any State for the purpose of regulating the business of insurance, . . . unless such Act specifically relates to the business of insurance." *Id.* § 1012(b).

126. *See* Charles F. De Jager, Note, *The Development of Regulatory Standards for Gene Therapy in the European Union*, 18 FORDHAM INT'L L.J. 1303 (1995); Charles Arthur, *Dorrell Rejects New Laws to Cover Genetic Testing*, INDEPENDENT (London), Feb. 29, 1996, at 6 (decision by Britain's Secretary of Health, Stephan Dorrell, not to cover genetic testing under any new legislation).

127. In fact, the government's collection of genetic information is more prolific than most people realize. For example, the Pentagon has been collecting samples of DNA from all military personnel and civil servants since 1993 and storing them for up to 75 years for the purpose of remains identification. *See* Laura Myers, *Pentagon Sets Relaxed DNA Rules Necessity of Samples Faces Court Challenge*, ATLANTA J. & CONST., Apr. 12, 1996, at A13. Facing a legal challenge to collecting DNA samples, the Pentagon altered its policy to allow military personnel to have their specimens destroyed once they complete their service. *See id.*

128. H.R. 2045, 102d Cong. (1991).

The Human Genome Privacy Act proposed to safeguard individual privacy of genetic information from the misuse of records maintained by agencies, their contractors, or their grantees for the purpose of research, diagnosis, treatment, or identification of genetic disorders, and to provide to individuals access to records concerning their genome which are maintained by agencies for any purpose.[129] Although Congress held hearings on the bill,[130] the legislation never left the House Committee on Government Operations.[131]

On September 3, 1996, President Clinton signed into law the Health Insurance Portability and Accountability Act of 1996 (HIPA).[132] As the first federal law addressing genetic discrimination, HIPA takes the initial steps toward regulating genetic discrimination in two ways. First, the new law prohibits insurers from denying health insurance coverage to individuals under a group plan for more than twelve months for a "preexisting" medical condition. Included in the definition of preexisting condition is genetic information. Second, the new law prohibits health insurers and employers from denying coverage to an employee or dependent based on an individual's health status, including an individual's genetic information.

As the first step toward a uniform federal approach to genetic testing issues, the law is a positive step in the right direction. However, HIPA contains many serious problems and shortcomings. HIPA will not prevent insurance companies from charging higher premiums to a group health plan as a whole. Thus, although an insurance company cannot discriminate because of an individual's genotype, the company could charge more to the entire group. Escalation of charges could rise to the point that continuation of the whole plan would be cost prohibitive. HIPA also does not prohibit insurers from limiting coverage for a particular condition, and it does not cover life and disability insurance. A large number of people, including the uninsured and the self-employed, do not come under HIPA's protection.

The key to HIPA's enforcement is also the Act's most significant problem. HIPA uses the term "genetic information" but fails to define what it encompasses. For the elderly this is the most troubling aspect

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129. *See id.*

130. *See Domestic and International Data Protection Issues: Hearings Before the Government Info., Justice & Agric. Subcomm. of the House of Representatives Comm. on Gov't Operations*, 102d Cong. (1991).

131. *See* Smith & Burns, *supra* note 36, at 52.

132. Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (1996).

of the new law because it is unclear whether the term is confined to genetic test results or includes information conveyed to relatives about predisposition.

The gaps left open by HIPA could best be covered by legislation aimed at regulating the use and dissemination of genetic information. In 1995, the Senate considered a bill to establish limitations on the disclosure and use of genetic information. The bill was never enacted, but similar bills were introduced in 1996 and 1997.[133] Introduced by Senators Mark Hatfield (R-Or.) and Connie Mack (R-Fla.), the Genetic Privacy and Nondiscrimination Act of 1995[134] sought to establish initial limitations with respect to the disclosure and use of genetic information with the goal of balancing the need to protect the rights of the individual against society's interests.[135] The Act was modeled on the Genetic Privacy Act passed by the Oregon legislature, and it also drew on recommendations made by the NIH-sponsored ELSI Working Group and the National Action Plan on Breast Cancer.[136] When introducing the bill, Senator Hatfield noted that "there are currently no Federal laws governing the use of genetic information."[137]

The bill had four major provisions.[138] First, the bill prohibited the disclosure of genetic information[139] by anyone without the specific written authorization of the individual. Second, the legislation prohibited employers from seeking to obtain or use genetic information of an employee or prospective employee in order to discriminate against that person. Third, the legislation prohibited health insurers from using genetic information to reject, deny, limit, cancel, refuse to renew, increase the rates of, or otherwise affect health insurance. This

133. Genetic Confidentiality and Nondiscrimination Act of 1996, S. 1898, 104th Cong., 2d Sess. (1996); Genetic Privacy and Nondiscrimination Act of 1997, H.R. 341, 105th Cong., 1st Sess. (1997); Genetic Confidentiality and Nondiscrimination Act of 1997, S. 422, 105th Cong., 1st Sess. (1997).

134. S. 1416, 104th Cong. (1995). On November 29, 1995, an identical bill was introduced in the House. *See* H.R. 2690, 104th Cong. (1995) (introduced by Rep. Stearns).

135. The purpose of the Genetic Privacy Act of 1995 is to establish some initial limitations with respect to the disclosure and use of genetic information with the goal of balancing the need to protect the rights of the individual against society's interests. *See* S. 1416.

136. *See* 141 CONG. REC. S17096 (daily ed. Nov. 15, 1995) (statement of Sen. Hatfield).

137. *Id.* at S17097 (statement of Sen. Hatfield).

138. *See* S. 1416.

139. "Genetic information" is defined as "the information about genes, gene products, or inherited characteristics that may derive from an individual or a family member." S. 1416 § 3(4).

prohibition was in line with changes under consideration with regard to health insurance and preexisting condition exclusions. And fourth, the bill required the recently established National Bioethics Advisory Commission to submit to Congress its recommendations on further protections for the collection, storage, and use of DNA samples and genetic information obtained from those samples, and appropriate standards for the acquisition and retention of genetic information in all settings.

On March 7, 1996, Senator Dianne Feinstein (D-Cal.) introduced the Genetic Fairness Act of 1996.[140] The bill would prohibit an insurer offering health care coverage from terminating, restricting, limiting, canceling, refusing to renew, or varying the rates of coverage, or from denying coverage or otherwise discriminating against an individual or member of the individual's family on the basis of genetic information[141] or a request for or receipt of genetic services.[142] In addition, an insurer offering health care coverage could not require an applicant or an insured to be the subject of a genetic test or to be subjected to questions relating to genetic information. Given the failure of the Human Genome Privacy Act and the passage of HIPA, both pending bills face an uncertain future.[143]

B. State Regulations

After the McCarran-Ferguson Act was made law, the National Association of Insurance Commissioners (NAIC)[144] recognized the need for uniform state laws. Despite the NAIC's continuing efforts to promote model regulations, state insurance regulation is highly frag-

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140. S. 1600, 104th Cong. (1996).

141. "Genetic information" is defined as "information about genes, gene products, or inherited characteristics that may be derived from an individual or a family member." *Id.*

142. "Genetic services" are defined as "health services provided to obtain, assess, and interpret genetic information for diagnostic and therapeutic purposes, and for genetic education and counseling." *Id.*

143. On November 15, 1995, the Senate bill was referred to the Senate Labor and Human Resources Committee. Senator Pete Domenici (R-N.M.) recently told a group of biotechnology and pharmaceutical industry executives that he hopes that the 105th Congress will reach conclusions about "what we are to set as national standards regarding gene confidentiality and discrimination." *Genetic Privacy, Discrimination Issues Could Cripple Biotech Industry*, BIOTECHNOLOGY NEWSWATCH, Oct. 7, 1996, at 13, *available in* LEXIS, Health Library, Biotech File.

144. "The insurance industry formed the National Association of Insurance Commissioners in 1871 to promote uniformity in insurance regulation and to protect insurance policyholders." Lee, *supra* note 115, at 210 n.180.

mented and nonuniform.[145] Although all fifty states have enacted legislation requiring fair and equitable treatment of insured parties in the insurance underwriting process,[146] few states have specific laws restricting the use of genetic information.[147] Prior to 1986, state laws prohibiting genetic discrimination were very limited in scope. However, since 1990, with the start of the Human Genome Project, ten states have enacted laws that protect against genetic discrimination for most genetic conditions.[148] Additionally, at least nine states have passed laws making it a crime for insurers or employers to discriminate against someone because of their genetic makeup,[149] and twenty other states are considering genetic discrimination legislation.[150]

In 1992, Wisconsin became the first state to ban the use of genetic testing in health insurance underwriting.[151] Wisconsin law prohibits "[a]n insurer, or a county, city, village or school board that provides health care services for individuals on a self-insured basis" from requesting or requiring an individual or family member to obtain a genetic test or to reveal if a genetic test was taken or any results of such a test.[152] In addition, health insurers are prohibited from denying insur-

145. *See id.*

146. *See* Herman T. Bailey et al., *The Regulatory Challenge to Life Insurance Classification*, 25 DRAKE L. REV. 779, 782 (1976).

147. Oregon, Colorado, California, Wisconsin, Ohio, Minnesota, and New Hampshire have genetic privacy acts that require patient permission to release any genetic information and prohibit health insurers from discriminating based on the tests. *New Genetic Tests Raise Privacy Issues*, PHOENIX GAZETTE, Sept. 27, 1995, at A7 [hereinafter *New Genetic Tests*].

148. *See* CAL. CIV. CODE § 56.17 (Deering 1997); CAL. INS. CODE §§ 10123.3, 10123.31, 10123.35, 10140, 10140.1, 10140.5, 10143, 10146, 10147, 10148, 10149, 10149.1, 11512.95, 11512.96, 11512.965 (Deering 1997); CAL. HEALTH & SAFETY CODE §§ 1374.7, 1374.9 (Deering 1997); COLO. REV. STAT. § 10-3-1104.7 (1997); FLA. STAT. ch. 760.40 (1997); GA. CODE ANN. §§ 33-54-1 to -8 (1997); MINN. STAT. § 72A.139 (1997); MONT. CODE ANN. § 33-18-206 (1997); N.H. REV. STAT. ANN. §§ 141-H:1 to :6 (1997); OHIO REV. CODE ANN. §§ 1742.42, 1742.43, 3901.49, 3901.491, 3901.50, 3901.501 (Anderson 1997); OR. REV. STAT. §§ 659.700, 659.705, 659.710, 659.715, 659.720, 746.135 (1997); WIS. STAT. § 631.89 (1997); Richard A. Bornstein, Note, *Genetic Discrimination, Insurability and Legislation: A Closing of the Legal Loopholes*, 4 J.L. & POL'Y 551, 589 (1996).

149. *See* ARIZ. REV. STAT. ANN. § 20-448D (1997); CAL. HEALTH & SAFETY CODE § 1374.7 (Deering 1997); CAL. INS. CODE § 10143 (Deering 1997); FLA. STAT. ch. 760.40 (1997); MD. CODE ANN., INS. § 223 (1997); MINN. STAT. § 72A.139 (1997); MONT. CODE ANN. § 33-18-206 (1997); N.J. STAT. ANN. § 10:5-5 (1997); 1995 Or. Laws ch. 680, § 2(1)(c); WIS. STAT. § 631.89 (1997). Other states have enacted laws that only preclude impermissible employer use of genetic information. *See, e.g.*, IOWA CODE § 729.6 (1997); KAN. STAT. ANN. § 40-2404 (1997).

150. *See* Myers, *supra* note 127, at A13.

151. *See* WIS. STAT. § 631.89 (1997).

152. *Id.* § 631.89(2)(a), (b).

ance or setting premiums based on whether an individual has obtained a genetic test or on the results of such a test.[153] A March 17, 1995, bill proposed to repeal and amend certain sections of the Wisconsin statute in order to expand the definition of "genetic test."[154] Under the revision, genetic tests would include the physical examination of an individual or an examination of the individual's family history to determine if there is a genetic disorder or predisposition to a genetic disease.[155]

California prohibits insurance companies from using genetic information to determine coverage eligibility and set rates.[156] California's statute is one of the strongest genetic testing laws in the United States due to its coverage and the "breadth" of its definition of genetic characteristics.[157] A recently passed law expanded statutory protection by forbidding insurers from testing without the person's written informed consent.[158]

Both Montana and Arizona law prevent insurers from refusing to consider applicants on the basis of a genetic condition.[159] Additionally, basing an applicant's rejection or rates on a genetic condition constitutes unfair discrimination unless the applicant's medical condition and history, and either claims experience or actuarial projections establish that substantial differences in claims are likely to result from the genetic condition.[160]

Similarly, Maryland law states that "an insurer may not refuse to insure or make or permit any differential in ratings, premium payments, . . . solely because the applicant or policyholder has . . . any genetic trait which is harmless within itself, unless there is actuarial justification for it."[161] Thus, in Maryland, Montana, and Arizona, an

153. *See id.*

154. "Genetic test" is currently defined in Wisconsin as "a test using [DNA] extracted from an individual's cells in order to determine the presence of a genetic disease or disorder or the individual's predisposition for a particular genetic disease or disorder." *Id.* § 631.89(1).

155. *See* A.B. 227, 92d Leg. Sess., 1995-96 Reg. Sess. (Wis. 1995).

156. CAL. INS. CODE § 10143 (Deering 1997).

157. *See* Sally Lehrman, *New California Law Prohibits Genetic Discrimination by Health Insurers*, BIOTECH. NEWSWATCH, Oct. 17, 1994, at 1, *available in* LEXIS, Health Library, Biotech File.

158. *See* CAL. INS. CODE § 10148(a) (Deering 1997).

159. *See* ARIZ. REV. STAT. ANN. § 20-448(D) (West 1997); MONT. CODE ANN. § 33-18-206(3) (1997).

160. *See* ARIZ. REV. STAT. ANN. § 20-448(E) (West 1997); MONT. CODE ANN. § 33-18-206(4) (1997).

161. MD. CODE ANN., INS. § 223(a)(3) (1997).

insurer can use genetic information in assessing risk if it can provide actuarial justifications supporting such use.

Florida law provides that genetic tests "may be performed only with the informed consent of the person to be tested, and the results . . . are the exclusive property of the person tested, are confidential, and may not be disclosed without the consent of the person tested."[162] The person tested must be sent notice if the genetic information is used in a decision to grant or deny insurance.[163] In early 1995, a bill that would have expanded protection against discrimination by barring insurers from requiring genetic testing was introduced, but it made little headway.[164]

Added to state law in 1992, Iowa's genetic testing statute only protects against employment related uses of genetic information. Iowa does not protect against insurance discrimination.[165]

In July 1995, Oregon passed "the nation's strictest genetic privacy act."[166] The law states that "the 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."[167] Under the law, "an insurance provider may not use genetic information to reject, deny, limit, cancel, refuse to renew, increase the rates of, affect the terms and conditions of or otherwise affect any policy for hospital or medical expenses."[168] The Oregon law also contains general provisions on acquiring and using genetic information by prohibiting the acquisition of genetic information without a person's informed consent,[169] generally prohibiting genetic information retention,[170] requiring the prompt destruction of DNA samples after the purpose for which a sample was obtained has been accomplished,[171] and prohibiting the disclosure of genetic information except as specifically provided.[172]

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162. FLA. STAT. ch. 760.40(2)(a) (1997).
163. *See* FLA. STAT. ch. 760.40(3) (1997).
164. *See* Ballingrud, *supra* note 109, at 14A.
165. *See* IOWA CODE § 729.6 (1997).
166. *See New Genetic Tests*, *supra* note 147, at A7.
167. OR. REV. STAT. § 659.705(1)(c) (1997).
168. *Id.* § 746.135(3). This provision applies only to insurance policies issued or renewed on or after the act's effective date. *See id.* § 680.10.
169. *See* Act effective Sept. 9, 1995, ch. 680, § 3(1), 1995 Or. Laws Spec. Sess. 2064, 2065.
170. *See id.* § 4, 1995 Or. Laws Spec. Sess. at 2065.
171. *See id.*
172. *See id.* § 5, 1995 Or. Laws Spec. Sess. at 2065.

These state laws collectively reflect a trend giving greater protection to individuals in the area of health insurance. In some instances, the laws extend to the protection of genetic information and the regulation of genetic testing. The trend of affording greater protections to individuals for health insurance is consistent with social policy considerations.

C. Preventing Discriminatory Application of Genetic Information

The prospect of refusing to provide insurance to individuals because of a genetic trait is inequitable and contrary to public policy.[173] First, carriers of defective genes may never develop symptoms that affect their ability to function.[174] In the 1970s, insurers discriminated against individuals who tested positive for the sickle cell trait, even when those people were only carriers of the trait and unlikely to show symptoms of the disease.[175] More importantly, however, such disparate treatment and resulting risk minimization vitiate the purpose of traditional private insurance as a risk-spreading mechanism.[176]

A prohibition on the use of genetic information would provide the most protection against insurer discrimination. Additionally, such prohibition would eliminate the incentive for individuals to avoid genetic testing recommended by physicians or conducted for research purposes out of fear that they would lose or not be able to acquire health insurance.[177]

The financial impact on insurers would be mitigated because most genetic tests only establish susceptibility to disease and not certainty of affliction.[178] Also, by having a uniform ban enacted at the federal level, all insurance companies would be similarly situated in the competitive marketplace.

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173. *See* Cushing, *supra* note 97; Kimberley Nobles, Note, *Birthright or Life Sentence: Controlling the Threat of Genetic Testing*, 65 S. CAL. L. REV. 2081, 2090 (1992).

174. *See* Nobles, *supra* note 173, at 2090.

175. *See* Benjamin S. Wilfond & Norman Fost, *The Cystic Fibrosis Gene: Medical and Social Implications for Heterozygote Detection*, 263 JAMA 2777, 2778 (1990).

176. *See* Nobles, *supra* note 173, at 2090.

177. *See* Nancy E. Kass, The Ethical, Legal and Social Issues Concerning the Use of Genetic Tests by Insurers: Toward the Development of Appropriate Public Policy 30 (1992) (unpublished manuscript on file with the National Institute of Health, National Center for Human Genome Research), *cited in* Lee, *supra* note 115, at 210 n.180.

178. *See supra* Part II.

Arguably, the Constitution may afford some protection against the discriminatory use of genetic information.[179] However, adequate and uniform discrimination protection can only be achieved through federal law. Although Oregon and California law may indicate that states will be enacting more restrictions on the use of genetic information,[180] given the rapid pace of genetic science, state restrictions are generally weak and few in number. Congress could amend the Americans with Disabilities Act (ADA)[181] to cover people genetically predisposed to disease, and concerns about federal use of genetic information could be addressed by amending the federal Privacy Act.[182] However, the dynamic nature of genetic science and the particular societal interests in the proper use of genetic information require the establishment of a special genetic legal regime. Although HIPA was a positive step in the correct direction, federal laws explicitly addressing genetic information and the regulation of genetic testing need to be enacted.

New laws should forbid insurers and employers from discriminating based on a comprehensive definition of genetic information or on the refusal to submit to a genetic test. Because classifying a particular genetic trait as predispositionary is not universally agreed upon, it is important to forbid insurer discrimination based on the entire field of genetic information.

Existing property and privacy rights regimes could form the principal foundations for new federal laws. The recognition of a fun-

179. *See* Smith & Burns, *supra* note 36, at 23 (examining safeguards from discrimination based on genotype arguably afforded to individuals under the Equal Protection Clause of the 14th Amendment to the Constitution).

180. In the absence of federal law, states could continue to pass increasingly restrictive use laws. However, under the doctrine of preemption, federal law takes precedence over any inconsistent state law. *See* JOHN E. NOWAK ET AL., CONSTITUTIONAL LAW § 9.1, at 311 (4th ed. 1991).

181. 42 U.S.C. §§ 12101-12213 (1994). The ADA prevents employers from discriminating against individuals who have or have had a history of a disability that involves a mental or physical impairment that limits a major life activity. *See id.* Although untested, the Equal Employment Opportunity Commission (EEOC) recently declared that it is a violation of the ADA for employers to base personal decisions on genetic predispositions. *See* Paul F. Gerhart, *Employee Privacy Rights: Introduction and Overview*, 17 COMP. LAB. L.J. 1 (1995) (the EEOC Compliance Manual, released on March 15, 1995, defined the term "disability" under the ADA and stated that using genetic test results to deny employment would be considered illegal discrimination); *EEOC Says Firms Can't Use Gene Tests to Discriminate*, WALL ST. J., Apr. 10, 1995, at C17.

182. Privacy Act of 1974, 5 U.S.C. § 552a (1994). The Privacy Act restricts the type of information that the federal government may collect. *Id.* Thus, it provides that the government may retain only the minimal amount of records possible.

damental privacy right regarding an individual's genetic material is crucial to extending protection to those individuals with abnormal genotypes. Protections requiring informed consent before testing and subsequent use of genetic information, along with strong confidentiality protections, are the best ways to secure genetic privacy. Any genetic test should require the person's consent and disclosure of the results to the individual.[183] Thus, privacy protections afforded to other forms of sensitive information would be extended to genetic information.

Genetic information also should be extended property rights protections. Genetic information should not be releasable to third parties without consent, and DNA samples used to obtain genetic information should be destroyed at a tested individual's discretion.

Tough criminal sanctions against genetic discrimination need to be imposed. Low fine amounts would be little deterrent. Enforcing genetic discrimination laws should not depend on the willingness of victims to file civil suits against the violators. The difficulty in identifying and documenting nonovert discriminatory practices makes a private attorney general approach inappropriate. The insurance industry is already subject to extensive federal oversight which enables careful monitoring of insurer practices.

However, any general legislative effort needs to achieve protection without negatively stigmatizing the value of genetics. Ensuring universal access to the wide opportunities of genetic services will allow persons "to act on the perception that it is good to want to know about genetic risks."[184] Accordingly, when the benefits of genetic diagnosis and treatment become more evident over time, genetic information will, in turn, become far less threatening and stigmatizing.[185]

Continuing efforts to reform health care provide an excellent opportunity to create federal genetic information protection. However, reforms in the Medicare area which propose shifting the elderly into more HMOs especially need to recognize that, absent federal protections, significant incentives exist within the managed care market to exploit genetic information to the detriment of elder health care. Fi-

183. The newly emerging science of pre-implantation genetic screening poses special disclosure issues and should be covered under a new federal law. *See* Vicki G. Norton, Comment, *Unnatural Selection: Non-therapeutic Genetic Screening and Proposed Regulation*, 41 UCLA L. REV. 1581 (1994).

184. John C. Fletcher & Dorothy C. Wertz, *Ethics, Law, and Medical Genetics: After the Human Genome Is Mapped*, 39 EMORY L.J. 747, 759 (1990).

185. *See id.*

nally, in addition to legislation, all new genetic tests should be subject to the Food and Drug Administration's (FDA) approval.[186] Some firms are currently marketing tests without FDA approval.[187]

V. Genetics and the Elder Law Practitioner

There are many ethical and legal issues regarding genetic science, and it is my hope that this note will help an important and often overlooked group in dealing with these issues—the legal practitioner. In preparing for this note, I was surprised to find few, if any, publications addressing what practitioners need to know about genetics in order to handle genetic issues raised by their clients. As noted above, elder law practitioners are likely to confront genetic issues in practice. The following points place the above material in the context of resolving client genetic issues.

Medicare coverage of all laboratory tests, including genetic tests, is limited to those that (1) are performed in a laboratory certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA);[188] (2) are approved by the Food and Drug Administration (FDA), when required by the Medical Devices Act;[189] (3) are ordered and/or received by persons authorized by state law; and (4) are medically necessary for the diagnosis or treatment of a beneficiary's illness or injury.[190] "Thus, Medicare does not generally pay for routine screening tests, or for experimental tests or procedures that are not

186. The government has not yet decided whether or how to regulate genetic testing. A federally funded task force has been writing recommendations that could help decide the question by spring 1997. *See Breast Cancer Genetic Testing: Gene Test Offered as Ethics Debate Continues*, CANCER WKLY. PLUS, Nov. 11, 1996, *available in* LEXIS, Market Library, IACNWS File.

187. *See* Shackelford, *supra* note 107, at 2D.

188. 42 U.S.C. § 263a (1994). Under CLIA, over 100,000 labs (regardless of type, location, or participation in Medicaid or Medicare) that perform any of an estimated 10,000 medical tests on human specimens must be inspected and licensed by the federal government every two years. *See* Suzanne V. Cocca, *Who's Monitoring the Quality of Mammograms? The Mammography Quality Standards Act of 1992 Could Finally Provide the Answer*, 19 AM. J.L. & MED. 313, 330 (1993) (citing Diane M. Gianelli, *Gentler Lab Regulations*, AM. MED. NEWS, Sept. 14, 1992, at 1, 14-15). CLIA took effect on September 1, 1992, and requires that all labs meet federal quality standards for testing, record keeping, quality control, personnel, and proficiency testing. *Id.*

189. 21 U.S.C. § 321 (1994).

190. *See Genetic Testing: Hearing on the Role of Government in Genetic Testing Before the House Science Comm. on Tech.*, 104th Cong. (1996) (statement of Bruce C. Vladeck, Adm'r, Health Care Financing Admin.), *available in* 1996 WL 10831054.

widely recognized as medically necessary for the diagnosis or, treatment of a particular medical condition."[191]

In the absence of a specific national coverage policy, coverage decisions about genetic tests are made by the Health Care Financing Administration's (HCFA) local carriers.[192] Each carrier has some discretion, within parameters set by HCFA, to judge whether a particular genetic test would be considered medically necessary for a particular purpose within their geographic area.[193]

> Some long-established types of genetic testing have been covered under Medicare for some time. For example, since 1979 Medicare has covered cytogenetic studies for the diagnosis or treatment of genetic disorders in a fetus. Other examples of diagnostic genetic tests generally covered by Medicare include alfa fetoprotein testing (for spina bifida), chloride tests or sweat tests (for cystic fibrosis), and some hematologic tests (such as hemoglobin electrophoresis for sickle cell anemia).[194]

Lawyers should play a critical role in counseling individuals considering whether or not to be tested. Although physicians are unlikely to know or understand the legal consequences associated with genetic testing, lawyers advising clients about genetic testing should be sure that their clients also seek the advice of a physician.[195] Regrettably, a current lack of clinical methods for counseling patients and families who are considering genetic testing makes the elder lawyer's role in genetic counseling[196] all the more critical.[197] Also, even if spe-

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191. *Id.*

192. "Local carriers" are insurance companies that contract with HCFA to process Medicare claims. *See id.*

193. *See id.*

194. *Id.*

195. Where consultation with a professional in another field is itself something a competent lawyer would recommend, the lawyer should make such a recommendation. At the same time, a lawyer's advice at its best often consists of recommending a course of action in the face of conflicting recommendations of experts. *See* MODEL RULES OF PROFESSIONAL CONDUCT Rule 2.1 cmt. (1983). The reaction to news about genetic predisposition could be catastrophic—even, in some cases, leading to consideration of suicide. *See* Talan, *supra* note 58, at B4.

196. Genetic counseling is the process by which individuals and families come to learn and understand relevant aspects of genetics. It is also the process for obtaining assistance in clarifying options available for their decision making and coping with the significance of personal and family genetic knowledge in their lives. *See* ASSESSING GENETIC RISKS, *supra* note 8, at 148.

197. *See Hearings Before the Comm. on Labor, Health & Human Servs. & Educ.*, 104th Cong. (1995), *available in* 1995 WL 120636 (testimony of Suzanne Hurd, acting director of the National Institute of Nursing Research) (noting that methods need to be developed and evaluated to help patients and their families choose whether and when to undergo genetic screening, given the possibility of abruptly pessimistic, unresolved results).

cialized genetics professionals are considered the best providers of genetic counseling services, there simply will be too few genetics professionals to meet the growing demand for services.[198]

Practitioners need to be aware that how genetic information is viewed within families can be a source of conflict and concern for their client. Elderly clients may wish to get a test in order to pass along any information about predisposition and links between particular genes and disease manifestation to family members. Concerns about genetic information disclosure can affect people's willingness to have genetic tests and, even if they do have tests, may result in a desire not to share heritability information with other family members for fear that they might then lose their insurance.[199] A recent study of families at risk for cystic fibrosis demonstrated that some families refuse to share information about heritability with family members who are at risk.[200] Relatives of elder clients may feel entitled to pressure clients to have tests or to learn more about their relatives' genetic test results.[201]

Understanding state and federal laws about the use and dissemination of genetic information can help a practitioner alleviate or validate a client's perceptions regarding discrimination-based fears about genetic test information. Clients need also to be told about the possible personal and family legal consequences of genetic testing so that they can think about what the information may mean for them before they decide whether or not to accept testing.

As genetic science continues to push beyond the ability of federal and state laws to provide protection against discrimination, elder law attorneys will play an increasingly critical role in protecting one of our society's most vulnerable groups as genetic testing continues to become more prevalent among the nation's elderly.

198. *See* ASSESSING GENETIC RISKS, *supra* note 8, at 148. Genetic counselor Barbara Bernhardt of Johns Hopkins University says there are only 1,400 board-certified genetic counselors in the United States, and fewer who specialize in cancer. *See* Chase, *supra* note 55, at B1.

199. *See id.*

200. *See* Joanna H. Fanos & John P. Johnson, *Perception of Carrier Status by Cystic Fibrosis Siblings*, 57 AM. J. HUMAN GENETICS 431 (1995).

201. *See id.*

VI. Conclusion

As the science of genetics advances, genetic tests are expected to become more comprehensive and less expensive. The temptation to discriminate will only grow. Efforts by the medical community to deal with concealing genetic test subjects have yet to result in a cohesive approach toward dealing with the legal fallout and medical uncertainty of this new technology.

The best way to address discriminatory problems associated with genetic testing is to enact broader federal laws regulating the use and disclosure of genetic information. Additionally, elder law practitioners need to play a critical role in protecting their clients against genetic information discrimination.