COMMENT

INSURANCE, EMPLOYMENT, AND THE GENETIC INFORMATION NONDISCRIMINATION ACT OF 2008

I. INTRODUCTION ................................................................. 126

II. BACKGROUND ...................................................................... 128
    A. THE RISE OF GENETICS .................................................. 128
    B. THE INTERPLAY BETWEEN GENETIC AND MEDICAL
       INFORMATION .................................................................. 130
    C. INSURANCE AND ADVERSE SELECTION ......................... 131
    D. HEALTH INSURANCE, EMPLOYMENT, AND GENETIC
       DISCRIMINATION ......................................................... 135

III. THE GENETIC INFORMATION NONDISCRIMINATION
     ACT OF 2008 ................................................................... 137
     A. DEFINITIONS .................................................................. 138
        1. GENETIC INFORMATION .............................................. 139
        2. GENETIC TEST .......................................................... 141
     B. TITLE I ......................................................................... 143
        A. GENERAL PROVISIONS .............................................. 143
        2. AMENDMENTS TO THE EMPLOYEE RETIREMENT
           INCOME SECURITY ACT OF 1974 .............................. 145
        3. AMENDMENTS TO PUBLIC HEALTH SERVICE ACT AND
           INTERNAL REVENUE CODE ....................................... 147
           a. Public Health Service Act ..................................... 147
           b. Internal Revenue Code of 1986 ............................... 149
        4. AMENDMENTS TO THE SOCIAL SECURITY ACT ........... 150
           a. Title XVIII—Medigap .............................................. 150
           b. Title XI—Application of HIPAA Regulations ............. 151
     C. TITLE II ....................................................................... 152
     D. REMEDIES .................................................................... 158
        1. TITLE I ..................................................................... 158
        2. TITLE II ................................................................... 160

IV. ANALYSIS ........................................................................ 160

V. CONCLUSION ..................................................................... 171
I. INTRODUCTION

The completion of the Human Genome Project represents an important milestone in the field of genetics and will further our ability to understand and care for ourselves. The information this project unlocked promises to open better avenues of disease prediction and prevention. By giving people who might be susceptible to diseases the ability to anticipate their development, steps can be taken to monitor these conditions or prevent them altogether. Additionally, the use of preventive procedures as opposed to remedial treatment will hopefully help to lower the cost of health care in some cases, both for the individual and those providing the care. But as the use of genetic information becomes more commonplace in the practice of medicine, health insurance providers will have access to that information, specifically where there is coverage for the particular testing.

The increased prevalence of genetic information has sparked concern about potential discrimination by health insurance companies.1 Insurance providers are in the business of fair discrimination; these companies use information to determine risks that potential policyholders present. However, genetic testing is still in its early stages; the results are accurate enough to disclose potential diseases, but they are not failsafe proof that the identified diseases will develop. Proponents of genetics legislation argue that genetic discrimination is currently keeping people from undergoing genetic testing (or at least refusing to do so under their insurance coverage) and that this is preventing the development of genetically-based treatment.2 But, insurance companies claim to need this information in order to properly determine risk.3 Without this information, risk assessment remains inaccurate and adverse selection will potentially drive premiums up, causing lower-risk individuals in the same insurance pool to begin subsidizing the cost of those who pose higher risks.4

This tension has crept into the employment setting. Because most health care coverage is provided by employers, increased premiums due to caring for sick employees raise the already enormous cost of providing health care for employees. Increased health insurance premiums result in


2. Rivka Jungreis, Fearing Fear Itself: The Proposed Genetic Information Nondiscrimination Act of 2005 and Public Fears About Genetic Information, 15 J.L. & POL’Y 211, 244-46 (2007) (acknowledging the potential impact on scientific advancement in the field of genetics if fears of genetic discrimination are allowed to continue).

3. Insurance underwriting depends on the assessment of potential risks an applicant poses and classifies that risk according to the probability of its occurrence.

4. See infra Part II.C.
decreased profits. Employers are aware of this correlation, and genetic information and testing can provide a vehicle to properly screen potential and current employees in order to save on the bottom line. However, employers are subject to myriad regulations preventing discrimination and argue that they are already prevented from discriminating on the basis of genetic information.\(^5\)

In response to the issues surrounding genetic information, Congress enacted the Genetic Information Nondiscrimination Act of 2008 ("GINA").\(^6\) This bill places restrictions on the ability of the health insurance providers to access the genetic information of its policyholders and creates a cause of action against employers who improperly use such information.\(^7\) GINA was enacted as part of the Paul Wellstone Mental Health Parity and Addiction Equity Act of 2007\(^8\) and represents an attempt by Congress to neutralize fears about genetic discrimination.\(^9\)

This comment explores the Genetic Information Nondiscrimination Act of 2008 and its potential consequences on insurers and employers. It discusses the important balance this legislation attempts to strike between competing interests of privacy and health insurance, and the likelihood of success it will have in the larger task of changing the genetic landscape. Part II of this comment will discuss the science that led to the current advancements in genetics and develop the contours of the impasse facing insurance companies, employers, and individuals regarding the use (or misuse) of genetic information. Part III describes the mechanics of GINA and documents the developed changes through the course of earlier-proposed legislation. Part IV will address the implications and difficulties

---

5. Employers are already regulated by the Occupational Safety and Health Administration, Title VII of the Civil Rights Act of 1964 through the EEOC, the Department of Labor, and other organizations established for enforcing worker's entitlements. Additionally, insurance provided by employers subjects the providing employers to ERISA, COBRA, and HIPAA regulations.


8. See Emergency Economic Stabilization Act of 2008, Pub. L. No. 110-343, 122 Stat. 3765 (2008). The Wellstone Mental Health Parity and Addiction Equity Act was enacted as part of the Stabilization Act. See id. at Division C. This Act, of which GINA is a part, requires health insurance companies to offer benefits for mental illnesses and substance-related disorders under group health plans. Id.

the legislation creates in its attempt to prevent genetic discrimination, but suggests alternatives that could address some of these concerns.

II. BACKGROUND

A. THE RISE OF GENETICS

In February of 1953, two young scientists—James D. Watson and Francis Crick—suggested the first accurate structural model of deoxyribonucleic acid ("DNA").10 DNA is the double-helical structured nucleic acid containing the genetic instructions that dictate the development and functioning of all living organisms.11 The discovery of this structure revolutionized the field of genetics and led to other important discoveries.12 For instance, the discovery of chain-termination DNA sequencing in 1977 enabled scientists to determine nucleotide sequences of DNA.13 Also, the discovery of the polymerase chain reaction in 1983 allowed for the isolation and amplification of particular segments of DNA.14 In an effort to fully understand the dynamics of DNA and its effects on development and disease, a multinational research venture known as the Human Genome Project was formally initiated in October 1990.15 The purpose behind this

10. See James Watson & Francis Crick, Molecular Structure of Nucleic Acids; A Structure for Deoxyribose Nucleic Acid, 171 Nature 737, 737-38 (1953). Though Watson and Crick are the best known pioneers of the discovery of DNA, Rosalind Franklin was instrumental in providing the X-ray diffraction images and information about the base pairings that lead to the creation of the current model. See Brenda Maddox, Rosalind Franklin: The Dark Lady of DNA 169-70 (New York, Harper Collins 2002). Also, Maurice Wilkins was the first person who, after undertaking X-ray diffraction analysis, suggested the helical structure. See Maurice Wilkins et al., Molecular Structure of Deoxypentose Nucleic Acids, 171 Nature 738, 738-40 (1953).


The Genetic Information Nondiscrimination Act of 2008

The project was to map out, sequence, and analyze all the genes in the human body. On April 14, 2003—fifty years after the structural discovery of DNA—the entire sequencing of the human genome was completed. In short, we are only beginning to unlock the full impact of the Human Genome Project and its benefits on understanding human development.

On the whole, genetics research concerns itself with the genome. The genome is the entire deoxyribonucleic composition of an organism and every cell contains the entirety of this information. The entire genome is composed of genes. Genes are the basic unit for determining the particular characteristics and functions of each cell in an organism, and thus, the organism itself. These are the instructions for the production of proteins that perform certain functions in an organism's cells, and will determine the nature and placement of the cells in the organism as a whole. Because genes are instrumental in the development of almost all characteristics of an individual, genes can potentially disclose predispositions for certain diseases.

Genetic testing is the scientific technique that can identify specific genes and detect changes in a person's genetic material. Currently, there are approximately 1,000 different genetic tests available. Genetic markers have been identified for such diseases as Huntington's disease, sickle-cell


18. See Dep't of Energy Office of Sci., Human Genome Project Information: About the Human Genome Project, Oct. 15, 2008, http://ornl.gov/sci/techresources/Human_Genome/project/about.shtml (last visited Feb. 17, 2009). The genome is typically housed in the chromosomes, which are tightly-wound bundles of genetic information contained in the cell. Id. There is, however, an exception. See infra note 19.

19. MATT RIDLEY, GENOME: THE AUTOBIOGRAPHY OF A SPECIES IN 23 CHAPTERS 8 (N.Y. Harper Perennial 2006). However, Ridley notes that the presence of mitochondrial DNA is an exception to this rule. Id. at 9.


21. Id. at 521.


anemia, cystic fibrosis, Tay-Sachs disease, and a litany of others.25

In application, genetic testing can be separated into two broad categories: genetic screening and genetic monitoring.26 Genetic screening is the process whereby an individual's genetic make-up is analyzed to determine if they possess genes causing particular diseases or are carriers of the gene.27 This type of genetic testing is most closely affiliated with health insurance because of the diagnostic and medical treatments that can result from genetic screening.28 On the other hand, genetic monitoring is a method of genetic testing that occurs on a periodic basis, mainly for individuals engaged in professions where exposure to harmful or hazardous chemicals is frequent.29 Here, genes are monitored for mutations or changes that typically result from overexposure.30

B. THE INTERPLAY BETWEEN GENETIC AND MEDICAL INFORMATION

The most problematic issue created by the rise of genetic information is its effect on what is considered medical information.31 Genetics was generally limited to the study of a limited number of specific diseases.32 Genetics dealt mainly with the relatively rare single gene or chromosomal disorder.33 The Human Genome Project has advanced the science of

29. See Watterson, supra note 27, at 431. OSHA has established a list of potentially hazardous chemicals and has established regulations that include genetic monitoring. See generally U.S. DEP'T OF LABOR OCCUPATIONAL SAFETY & HEALTH ADMIN., SCREENING AND SURVEILLANCE: A GUIDE TO OSHA STANDARDS (2000), available at http://www.osha.gov/Publications/osha3162.pdf (identifying some of the procedures required for working with particularly hazardous chemicals).
31. See Sonia M. Suter, The Allure and Peril of Genetics Exceptionalism: Do We Need Special Genetics Legislation?, 79 WASH. U. L.Q. 669 (Fall 2001) (arguing that there is no distinction between medical and genetic information and that the attempts at genetic legislation will create class inequalities because of environmental factors).
33. See Jon Emery & Susan Hayflick, The Challenge of Integrating Genetic Medicine into
genetics, and the advancement in this area is impacting the medical profession. No longer limited to Mendelian disorders, genetics has expanded to identify multifactor disorders and has helped to develop the interplay between different genes and their mutative capabilities. Because of this broadened role, genetics is beginning to play a potentially important part in early disease identification and treatment.

This is where the problem lies. Where genetics was once its own specialized area, the contributions of the Human Genome Project have started to move genetics and the information it provides into the general practice of medicine. On one hand, some believe genetic information is a unique and special type of information because of its ability to show the possible manifestation of disease. Those who subscribe to this view argue that the use of this information as a risk assessment tool is too prejudicial because the development of identified conditions is uncertain, and as such, special protections are needed. On the other hand, critics of this view state that there is no difference between genetic information and other medical information. Those who see no difference between genetic and medical information label the call for special protection as "genetics exceptionalism." The classification of genetic information has proven to be a steep hurdle in attempting to solve what one commentator has identified as the "genetic/medical fair/unfair discrimination dilemma."

Primary Care, 321 BRITISH MED. J. 1027, 1027 (Apr. 28, 2001) (acknowledging that traditional genetics dealt with specific conditions).


35. See id.

36. See, e.g., Bruce Korf, Integration of Genetics into Clinical Teaching in Medical School Education, 4 GENETICS IN MED. 33S, 33S-38S (Supp. Nov./Dec. 2002) (noting three particular areas where genetics is beginning to play an important role in medical practice).

37. See Jungreis, supra note 2, at 224-26.


41. Holmes, supra note 12, at 503.
C. INSURANCE AND ADVERSE SELECTION

The business of insurance is mainly about two things: risk and loss. Insurance companies issue policies to individuals and organizations to insure against certain losses that might occur in the future. Insurers engage in three primary functions: risk transfer, risk pooling, and risk allocation. Risk transfer deals with the transfer of risk from an individual or organization to the insurance company. The insurance company then takes this assumed risk to engage in risk pooling. An insurer takes the risks associated with insuring individual policyholders and pools them with risks of other policyholders that are independent. By doing this, these pools become diversified. This diversification makes the individual losses that are covered by the insurance company more predictable. Finally, insurance companies allocate risks of the pool through charging premiums. The insurer will quantify the risks posed by individual policyholders and allocate contributions accordingly.

Where risk pooling is done through actuarial analysis, risk allocation is done through the process of underwriting. Actuarial analysis evaluates the risks and potential loss exposure of a general pool or type of insurance policy. Actuaries use objective standards that are closely connected to the potential costs associated with coverage and that will protect the solvency


43. KENNETH S. ABRAHAM, INSURANCE LAW AND REGULATION 2 (Foundation Press 4th ed. 2005).

44. Id. at 4-5.

45. Id. Risk transfer typically involves the transfer of risk from a party that is risk-adverse to the insurance company who, from an economic standpoint, is risk-neutral. Id. Risk aversion is the concept of preferring a larger probability of small loss in comparison to a small probability of a large loss. Id. For instance, someone who is risk adverse would prefer a 10% chance of losing $1,000 as opposed to 1% chance of losing $100,000. An insurance company is typically considered risk-neutral, in that they make no distinction between a higher probability of a small loss or a lower probability of a large loss if the economic costs of each respective loss is the same. Id. In the given example, the insurance company would insure against the risk in either case, because the values of each loss are the same: $100.

46. ABRAHAM, supra note 43, at 4-5.

47. Id.

48. Id.

49. Id.

50. Id.

51. See Bureau of Labor Statistics, U.S. Dep’t of Labor, Career Guide to Industries: Actuaries, Mar. 18, 2008, http://www.bls.gov/oco/ocos041.htm (last visited Feb. 17, 2009). Actuaries are not limited to health insurance industry, but 6 out of 10 actuaries are employed in the insurance industry. Id. Actuaries assess the risk of events that might occur and will create policies that will minimize the financial impact on the companies for whom they are performing actuarial analysis. Id.
of the insurance company.\textsuperscript{52} In short, actuaries set premiums for particular policies, where underwriting is the balancing of risk factors posed by a particular policyholder in order to determine whether an individual qualifies for the policy.

In order to make business profitable while offering proper coverage, insurance companies engage in fair discrimination.\textsuperscript{53} In the health insurance sector, insurers request information about an individual's medical history, current medical health, habits, propensities, and even family history.\textsuperscript{54} This information is requested in order to accurately determine whether the applicant should be part of the risk pool.

However, the effective functioning of insurance is threatened by a phenomenon called adverse selection. Adverse selection is when "the variation of expected outcomes within a risk class is too great[.]",\textsuperscript{55} This occurs:

When insurers charge each party the same price for coverage, then high-risk parties elect to be insured in greater proportion than low-risk parties, [resulting in more claims] and insurers are forced to raise the price of coverage. As a result, some of the comparatively low-risk parties that had previously been insured decline to purchase coverage [at an increased premium] or purchase less of it, and the insurer is forced to raise prices again [in order to cover the claims], thus restarting the cycle of adverse selection.\textsuperscript{56}

Generally, adverse selection occurs because applicants withhold information about their health when applying for health insurance.\textsuperscript{57} As a result of their failure to fully disclose this information, policyholders who

\begin{itemize}
\item \textsuperscript{52} \textit{Actuarial Standards Bd., Actuarial Standards of Practice: Risk Classification} 5 (Dec. 2005), \textit{available at} http://www.actuarialstandardsboard.org/pdf/asop012_101.pdf.
\item \textsuperscript{53} Holmes, supra note 12, at 534-35.
\item \textsuperscript{55} \textit{Actuarial Standards Bd.}, supra note 52, at 5.
\item \textsuperscript{56} \textit{Abraham}, supra note 43, at 6.
\item \textsuperscript{57} Mark J. Browne & Helen I. Doerpinghaus, \textit{Information Asymmetries and Adverse Selection in the Market for Individual Medical Expense Insurance}, 60 J. Risk & Ins. 300, 300 (1993). Adverse selection is one element of what has been deemed the problem of imperfect information. \textit{See Abraham}, supra note 43, at 6. The other phenomenon is moral hazard, and typically occurs when a tangible object is insured. \textit{See id.} Once insurance is obtained, the insured does not seek to protect the insured object and is not concerned with its well-being, because it is insured. \textit{Id.}
\end{itemize}
pose less risks end up subsidizing the costs of those who pose higher risks.\textsuperscript{58} This continues until all the low risk policyholders are driven out of the pool and the balance between risk and premiums is destroyed, creating a financial loss for the insurance company.\textsuperscript{59}

For instance, imagine two people, A and B. A is a smoker. B is not. Both A and B apply for the same health insurance policy, but A withholds the fact that he smokes. Smokers are typically charged higher premiums because they have a higher risk of health problems. Here, A and B will pay the same amount for the insurance policy, though A poses a higher risk than B. The problem begins when A gets sick. Though initial sickness is likely covered, if A continues to be sick, then there is not enough money in the insurance pool to cover A’s health costs, and the company will raise the premiums of those policyholders in the risk pool to cover the additional expenses. Thus, B will pay a higher premium and essentially subsidize the cost of A. Eventually, the premium will increase until B terminates coverage, leaving the insurance company to pay the difference between A’s premium and the increased cost of A’s sickness. Though a rather cursory explanation of both the insurance industry and adverse selection, it suffices in order to highlight the conundrum with which federal legislators are faced.

Essentially, the insurance industry claims it needs to use genetic testing results to make actuarial determinations in order for the process of risk classification to be more predictable and to prevent adverse selection.\textsuperscript{60} The industry has implied that there is no difference between genetic and other medical information, particularly in the way it is considered by the actuarial and underwriting process.\textsuperscript{61} The drawback is that genes are not

\begin{itemize}
\item \textsuperscript{58} See Mark Pauly & Sean Nicholson, \textit{Adverse Consequences of Adverse Selection}, 24.5 J. HEALTH POL. POL’Y & L. 921, 927 (1999) (stating that severe adverse selection will deter low-risk individuals from remaining in a managed care plan when it becomes evident that low-risk policyholders are subsidizing high-risk policyholders, evidenced by a sharp increase in premiums).
\item \textsuperscript{59} See ABRAHAM, supra note 43, at 6.
\item \textsuperscript{60} Holmes, supra note 12, at 538. Professor Holmes concludes that because the insurance industry is in the business of risk classification, any information that can identify potential risks proves actuarially useful. \textit{Id.}
\item \textsuperscript{61} \textit{Id.} at 554. Professor Holmes points out that all test results, whether genetic or not, are required to meet the same standards before they will be used in risk classification:
\begin{itemize}
\item (1) the test must supply information in addition to information otherwise available from other sources (e.g., from a medical questionnaire),
\item (2) the disease of interest must have serious morbidity and/or mortality implications,
\item (3) the disease must be common enough to ensure that the test is predictive and that the cost can be justified,
\item (4) the test must be predictive of disease (or absence of disease) and reliable,
\item (5) the test must be understood, accepted and used by the medical profession,
\item (6) laboratories must be able to readily perform the test,
\item (7) the test must be affordable and able to provide results quickly,
\item (8) the test must be risk free.
\end{itemize} \textit{Id.} (quoting T.H. Cushing, \textit{Should There Be Genetic Testing in Insurance Risk Classification}?
flawless predictive markers for the development of diseases. Individuals are afraid of allowing health insurance providers to use genetic information for fear of discrimination based on genes. Scholars have defined genetic discrimination in the health insurance context as "the denial of rights, privileges or opportunities on the basis of information obtained from genetically-based diagnostic and prognostic tests." Genetic information could possibly be used to initially decline coverage for people with genetic predispositions for certain diseases. Also, people are afraid that insurers could use genetic test results that disclose certain genetic markers to exclude coverage under pre-existing condition exclusions or to increase premiums.

Thus, some individuals who stand to benefit from undergoing certain genetic testing are declining to do so for fear that the results could endanger their health insurance coverage. Also, people have begun paying for genetic testing out-of-pocket in order to keep the information from reaching insurers. However, because people do not disclose the results of genetic testing to their insurers, the underwriting process is undercut, foreshadowing poignant effects on health insurance premiums and the potential solvency of the insurance company.

But the possible answer is just as problematic. Restricting the use of genetic information in order to quell the public fear of genetic discrimination makes the underwriting and actuarial processes remain inaccurate. Furthermore, premiums will still increase as a result of imperfect information, even when the information available to cure the

Arguments For and Against the Use of This New Technology May Be "Right" and Some Form of Universal Health Care May Be the Result, 60 DEF. COUNS. J. 249, 252 (1992)). Most genetic testing, because of its novelty and the multifactoral nature of genetic diseases, will likely fail the fourth requirement.

62. See Abigail L. Rose et al., Attitudes and Misconceptions About Predictive Genetic Testing for Cancer Risk, 8 CMTY. GENETICS 145, 148 (2005) (noting that although genetic markers for cancer indicate the possibility of cancer development, the presence of a genetic marker is not dispositive).

63. See Jungreis, supra note 2, at 231. Other studies have noted that people fear the insurance industry and their employers are the two entities these people trust the least to have access to their genetic information. See GENETICS & PUB. POL’Y CTR., U.S. PUBLIC OPINION ON USES OF GENETIC INFORMATION AND GENETIC DISCRIMINATION 2 (Apr. 24, 2007), available at http://www.dnapolicy.org/resources/GINAPublic_Opinion_Genetic_Information_Discrimination.pdf.


65. Harmon, supra note 1.

66. Id.

67. See id.

68. See supra note 44 and accompanying text.
problem exists. But, this is not the only area where problems arise.

D. HEALTH INSURANCE, EMPLOYMENT, AND GENETIC DISCRIMINATION

Most health insurance coverage in the United States is provided through employment. In 2006, 59.7% of people with health insurance coverage received it from their employers. Most employers will pay reduced rates under a corporate plan and will receive tax deductions for contributions to health care for their employees. However, the rising cost of insurance premiums has led to decreased coverage offered by employers. These higher premiums also decrease the profitability of the company if the employer does provide health care coverage. Despite discounted premiums, these costs have increased dramatically in past years. If an individual employee presents a higher risk of disease and draws claims because of sickness, this can increase the already rising premiums the employer pays for group coverage.

In extreme cases, this can potentially lead to genetic discrimination. For instance, in Norman-Bloodsaw v. Lawrence Berkeley Laboratory, several employees brought suit against their employer who conditioned employment upon medical examinations where genetic information was clandestinely obtained. The United States Court of Appeals for the Ninth Circuit reversed the grant of summary judgment in favor of the employer, and equated the secret extraction of this information to a violation of the


70. See Holmes, supra note 12, at 533. This is true even though insurance is underwritten on an individual basis. Id.


72. See Henry J. Kaiser Family Found. & Health Research & Educ. Trust, Employer Health Benefits: 2007 Annual Survey (2007), available at http://www.kff.org/insurance/7672/upload/76723.pdf. In 2007, health insurance premiums paid by employers increased 6.1%. Id. This doubled the inflation rate, bringing the average annual premium paid for an individual employee to $4,400. Id. Employers with less than 24 employees saw an increase in premiums of 6.8%. Id. Since 2000, health insurance premiums paid by employers have increased 100%. Id.

73. See William O. Cleverly, I Handbook of Health Care Accounting and Finance 982 (Aspen 1982) (stating that premium rates for employers with less than 100 employees are fully pooled and, thus, subject to particularly scrutinizing annual review for premium calculation and increases).

74. 135 F.3d 1260, 1269 (9th Cir. 1998).

75. Id.
plaintiffs’ right to privacy.  

III. THE GENETIC INFORMATION NONDISCRIMINATION ACT OF 2008

Thirteen years of legislative proposals and debates have led to the passage of the Genetic Information Nondiscrimination Act of 2008 ("GINA"). This bill represents a selection and combination of provisions from over twenty earlier proposed bills. GINA combined the foci of earlier legislation in an attempt to address the problems in each specific area where genetic discrimination may occur.

Generally, the protections afforded by this legislation are delivered in two Titles. The first title addresses the use of genetic information in the health insurance sector, while the second applies specifically to genetic information used by employers, employment agencies, and those similarly situated. There are some provisions that are found in both titles. For

76. Norman-Bloodsaw v. Lawrence Berkeley Laboratory, 135 F.3d 1260, 1269 (9th Cir. 1998).
77. See supra note 6.
80. GINA, §§ 101-104.
instance, the definitions of "genetic test" and "genetic information" are the same in Title I and Title II, though each is particularly tailored in the context of each title.\textsuperscript{81} Overall, though similarities exist, because each title is applicable to specific industries, the differences outweigh the similarities.

A. DEFINITIONS

Both the definitions of "genetic information" and "genetic test" are the same in both titles of the Genetic Information Nondiscrimination Act.\textsuperscript{82} These definitions are important because the protections afforded by each respective title hinge on these definitions. For instance, Title I prohibits insurers that provide group and individual health coverage from increasing premiums or contributions based on genetic information.\textsuperscript{83} Additionally, Title I restricts the ability of an insurer in the individual market to deny eligibility based on genetic information.\textsuperscript{84} Similarly, Title II bars many employment entities from discriminating against employees in hiring, firing, promotion, or other "privileges of employment" on the basis of genetic information.\textsuperscript{85} Also, genetic information cannot be used to classify or exclude employees. In both cases, the restrictions are based on what is considered genetic information.


\textsuperscript{83} See GINA § 101(a), 29 U.S.C. § 1182(b)(3) (2008) (amending § 702(b) of ERISA). This amendment states that: "[f]or purposes of this section, a group health plan, and a health insurance issuer offering group health insurance coverage in connection with a group health plan, may not adjust premiums or contribution amounts for the group covered under such plan on the basis of genetic information." \textit{Id.} However, a rule of construction qualifies this amendment in several ways. See \textit{infra} note 123 and accompanying text.

\textsuperscript{84} GINA § 102, 42 U.S.C. § 300gg-53 (2008) (amending the PHSA). GINA amends the PHSA by stating that "[a] health insurance issuer offering health insurance coverage in the individual market may not establish rules for the eligibility (including continued eligibility) of any individual to enroll in individual health insurance coverage based on genetic information." \textit{Id.}


The definition of "genetic information" is based primarily on the definition of "genetic test." In Title I, group health plans or the insurance companies providing the plans cannot request or require an individual to undergo genetic testing or use genetic information for underwriting. Employers can only require an employee to undergo genetic testing if the information relates to genetic monitoring or if certain safeguards are observed by the employer. Otherwise, employers also cannot discriminate on the basis of genetic information. Thus, the actions of insurers and employers are determined by these definitions.

1. GENETIC INFORMATION

Both titles of GINA contain the same definition of "genetic information." This has proved to be the most treacherous area in drafting genetics legislation for several reasons. First, the incorporation of genetics into the more general practice of medicine has made its uses more varied and commonplace than before. Second, the continual and unceasing progress of genetics has made it difficult to graft a definition that will keep up with new developments without requiring perpetual amendment.

87. See, e.g., GINA § 101(d), 29 U.S.C. § 1191b(d)(6)(A) (2008). GINA amends ERISA § 733(d) by defining genetic information, inter alia, as "[an] individual's genetic tests[.]" Id. This interplay between the definitions of genetic information and genetic test is the same throughout Title I and Title II.

88. GINA § 101(b), 29 U.S.C. § 1182(c)(1) (2008). This section states that "[a] group health plan, and a health insurance issuer offering health insurance coverage in connection with a group health plan, shall not request or require an individual or a family member of such individual to undergo a genetic test." Id. Other provisions limit the ability of the group health plan or an insurer providing such coverage from requesting such information prior to enrollment or as a condition of eligibility, or otherwise using such information for underwriting purposes. See 29 U.S.C. § 1182(d)(1)-(2) (2008).

89. GINA § 202(b)(5), 42 U.S.C. § 2000ff-1(b)(5) (2008). There are stringent requirements for an employer to be able to undertake genetic monitoring on its employees. First, the employer must provide written notice of the genetic monitoring to the employee. 42 U.S.C. § 2000ff-1(b)(5)(A) (2008). Second, the employee has to provide prior, knowing, voluntary, and written authorization, unless the monitoring is required by state or federal law. Id. § 2000ff-1(b)(5)(B). Third, the employee has to be informed of the individual results. Id. § 2000ff-1(b)(5)(C). Fourth, the monitoring must be in compliance with federal and state genetic monitoring regulations. Id. § 2000ff-1(b)(5)(D)(i)-(ii). Finally, the results must be presented to the employer only in aggregate form, keeping individual results of the genetic testing confidential. Id. § 2000ff-1(b)(5)(E).


91. Compare GINA § 102, 42 U.S.C. § 300gg-1(b) (2008) (amending the PHSA) (defining genetic information as "... information about (i) [an] individual's genetic tests, (ii) the genetic tests of family members of [an] individual, and (iii) the manifestation of a disease or disorder in family members of such individual.", with GINA § 201, 42 U.S.C. § 2000ff (2008) (providing the same definition of genetic information).

92. See supra notes 33-36 and accompanying text.

93. See infra notes 97-99 and accompanying text.
Third, critics of genetics legislation argue that the definition leads to legislation that is both overbroad and underinclusive.94 Finally, the definition of genetic information within the legislation’s framework defines the scope of information that can be used by insurance companies or employers and what information is prohibited from consideration.95 In light of these factors, legislators had to draft a definition that would be flexible and broad, but narrow enough to accurately exclude information that is not considered genetic. In an attempt to address these concerns, GINA defines genetic information as follows:

(A) IN GENERAL—Except as provided in subparagraph (B), the term ‘genetic information’ means information about—

(i) an individual’s genetic tests;

(ii) the genetic tests of a family member of the individual; or

(iii) subject to [exclusion], the manifestation of a disease or disorder in family members of the individual.

...

(C) EXCLUSIONS—The term ‘genetic information’ shall not include information about the sex or age of the individual.96

This definition of genetic information is a marked change from the initially proposed definitions. For example, the first formal definition of genetic information proposed was “information about genes, gene products or inherited characteristics that may derive from an individual or family member.”97 The problem with this definition was its enormity; it classified readily observable information like hair color, eye color, and sex within the purview of protected genetic information.98 Furthermore, this first definition was broad enough to include diagnostic and post-diagnostic information about the development of certain diseases, which would hinder actual medical treatment.

Another definition was proposed in 1997.99 It defined genetic information as “information from a human DNA sample about molecular genotype, information from mutation analysis, or information about

95. See supra note 87.
96. GINA § 101(d), 29 U.S.C. § 1191b(d)(6)(A) (2008). Although this definition is taken from a GINA provision that amends § 733(d) of ERISA, the definition is consistent throughout the Act.
98. See Suter, supra note 31, at 702.
nucleotide sequence [sic] of a gene."\textsuperscript{100} While this definition was more specific in identifying the methodology that produced the genetic information, it did not narrow the focus. For example, this definition would still include information about the sex of an individual. Notwithstanding, the definition did do something noteworthy—it shifted the focus from the nature of the genetic information to linking the definition of genetic information with the definition of a genetic test. This approach was retained and found its way into the current definition.

The first working form of the current definition was drafted in 1999, not as "genetic information," but as "predictive genetic information."\textsuperscript{101} Yet, the current legislation adds some restrictions that make the 1999 definition less inclusive.\textsuperscript{102} The limitation contained in both titles excludes "information about the sex or age of the individual."\textsuperscript{103} Insurers can thus consider physical examinations for general wellness or sex determinations of fetuses in prenatal testing to make underwriting and actuarial decisions.

2. GENETIC TEST

Though the definition of genetic information is considered a point of contention, it is the definition of "genetic test" that truly defines the protections and allowances of the legislation.\textsuperscript{104} Looking at the definition of genetic information, it is clear that the limits on what information can be considered are set by what is disclosed in a genetic test.\textsuperscript{105} Both titles of GINA define a genetic test as:

"An analysis of human DNA, RNA, chromosomes, proteins, or metabolites, [sic] that detects genotypes, mutations, or chromosomal changes."\textsuperscript{106}

\textsuperscript{100} See S. 422, 105th Cong. § 3(10) (1997).
\textsuperscript{101} See Genetic Nondiscrimination in Health Insurance and Employment Act of 1999, H.R. 2457, 106th Cong. § 101(a)(2)(A) (1999). The definition was framed as "predictive genetic information." Unless otherwise noted, citations refer to this definition.
\textsuperscript{104} See, e.g., GINA § 101(d), 29 U.S.C. § 11916(d)(6)(C) (2008) (highlighting the interplay between the definitions of genetic information and genetic test). For further discussions, see supra Part III.A.1.
\textsuperscript{105} See supra note 87. What qualifies as genetic information depends on the definition of a "genetic test." The broader the definition of a genetic test, the more that will be classified as genetic information.
\textsuperscript{106} GINA § 101(d), 29 U.S.C. § 1191b(d)(7)(A) (2008). Again, although the definition of
The legislative changes from earlier forms of this definition show that legislators tried to properly narrow the definition of genetic testing. For instance, the first proposed definition of a genetic test encompassed all tests “determining the presence or absence of genetic characteristics” and included all tests of nucleic acids that use DNA and RNA.\textsuperscript{107} This definition included almost every medical test, with certain exceptions.\textsuperscript{108} Eventually, the definition became even broader because the number of exceptions decreased.\textsuperscript{109} Though some proposed legislation began placing more emphasis on specificity, the definition eventually incorporated into GINA was a hybrid of earlier definitions.\textsuperscript{110} The first appearance of the basic definition of genetic test was in 1999.\textsuperscript{111} It stated that a genetic test was the “analysis of human DNA, RNA, chromosomes, proteins and certain metabolites in order to detect genotypes, mutations, or chromosomal changes.”\textsuperscript{112}

Both titles of GINA include an exception to what constitutes a genetic test.\textsuperscript{113} This exception states that an analysis of proteins or metabolites that does not include “genotypes, mutations, or chromosomal changes” is not considered a genetic test.\textsuperscript{114} Title I inserts an additional exception to genetic test is taken from the section that specifically amends § 733(d) of ERISA, the definition is consistent throughout the numerous sections of GINA.

107. See H.R. 2690, 104th Cong. § 3(a) (1995). The definition was actually broader than the excerpted portion, because the definition also included tests using mitochondrial DNA. Id. Notwithstanding the definition in H.R. 2690, this was not the broadest definition that was proposed. See H.R. 328, 106th Cong. § 2(C)(15) (1997) (defining genetic test as a “test for determining the presence or absence of genetic characteristics in an individual”).


109. Compare H.R. 2690, 104th Cong. § 4(a)(2)(A)-(E) (1995) (providing five exceptions), with GINA § 101(d), 29 U.S.C. § 1191b(d)(7)(B)(i)-(ii) (2008) (providing two exceptions). GINA, as enacted, excepts from inclusion as a genetic test: “(i) an analysis of proteins or metabolites that does not detect genotypes, mutations, or chromosomal changes” and “(ii) an analysis of proteins or metabolites that is directly related to a manifested disease, disorder, or pathological condition that could reasonably be detected by a health care professional with appropriate training and expertise in the field of medicine involved.” Id.


112. Id. The only change from the definition proposed in this bill was the striking of “in order to detect” and replacing it with “that detects.” See GINA § 101(d), 29 U.S.C. § 1191b(d)(7)(A) (2008). This is important because it shifts the focus of the genetic test from a subjective realm—i.e. whether the use is for a particular purpose—to objectively focus on whether the test, regardless of what it is used for, actually detects genetic information.


genetic testing. This exception states that "an analysis of proteins or metabolites that is directly related to a manifested disease, disorder, or pathological condition" is not a genetic test if it could be reasonably detected by a health care professional with appropriate knowledge of the disorder.\textsuperscript{115}

B. TITLE I

A. GENERAL PROVISIONS

In Title I, there are four sections that each amend a currently enacted portion of the United States Code. Each amending section of Title I contains several provisions that frame the restrictions the title places on insurers. Most of these provisions, with some exceptions, are consistent throughout. These restrictions apply to group health plans, insurers that provide group health insurance, and to health insurers providing coverage in the individual market.\textsuperscript{116}

The first provision in all amending sections limits insurers from using genetic information in determining premiums or contribution amounts.\textsuperscript{117} As a result, the individual is not singled out by being charged higher premiums because of certain genetic information, nor can the group be charged a higher premium overall because of the predisposed individual. The second provision states that group plans and insurers who provide coverage to group plans cannot use genetic information for underwriting purposes.\textsuperscript{118} These plans and insurers cannot consider genetic information

\begin{itemize}
\item \textsuperscript{115} GINA § 101(d), 29 U.S.C. § 1191b(d)(7)(B)(ii) (2008). The exception implies that a protein or metabolic analysis is associated with a manifested disease if the condition can be identified by a reasonable health care professional, referencing the rule of construction that qualifies the definition of genetic information. \textit{Id.}

\item \textsuperscript{116} See GINA § 101(a), 29 U.S.C. § 1182(b)(3)(A) (2008). This provision limits the ability of group health plans from considering genetic information for increasing premiums. \textit{Id.} The provision that places restrictions on health insurance issuers providing coverage in the individual market can be found in section 102. \textit{See} GINA § 102(a)(1)(B), 42 U.S.C. § 300gg-1(b)(3) (2008). It is important to note that although individual premiums cannot be raised, insurers still have the right to increase employer premiums if a disease manifests itself. GINA § 101(a), 29 U.S.C. § 1182(b)(3)(A) (2008).


\item \textsuperscript{118} GINA § 101(b), 29 U.S.C. § 1182(d)(1) (2008); GINA § 102(a)(1)(B), 42 U.S.C. § 300gg-1(d)(1) (2008) (these sections prohibit insurers in the group and individual markets respectively from requesting, requiring, or purchasing genetic information for underwriting purposes). Underwriting, for purposes of Title I, is defined as:

rules for, or determination of, eligibility (including enrollment and continued eligibility) for benefits under the plan or coverage;
the computation of premium or contribution amounts under the plan or coverage;
\end{itemize}
to deny coverage of an individual who is joining the group health plan.\textsuperscript{119} Also, insurers cannot "request, require, or purchase genetic information with respect to any individual prior to such individual's enrollment under the plan or coverage in connection with such enrollment."\textsuperscript{120} Thus, if an individual applies for group coverage as part of a particular plan, the group plan or its insurer cannot acquire genetic information about the individual in order to make underwriting decisions before accepting the application. However, because of the voluminous amount of data insurers collect, incidental collection of pre-enrollment information is excused.\textsuperscript{121}

The second provision that is part of all amending sections in Title I deals with genetic testing. This section states that a group plan or insurers providing group coverage "shall not request or require an individual or a family member of such individual to undergo a genetic test."\textsuperscript{122} This restriction makes it impossible for an insurer to condition health coverage on genetic testing. However, a rule of legislative intent is placed immediately after this provision to guide its interpretation.\textsuperscript{123} This rule of construction states that the limitation on requesting or requiring genetic tests "shall not be construed to limit the authority of a health care professional who is providing health care services to an individual to request that such individual undergo a genetic test," but the physician still cannot require genetic testing.\textsuperscript{124} Also, group plans or insurers providing group plans can request that an individual undergo certain research-related genetic tests if specific conditions are met by the insurer.\textsuperscript{125} Despite these

\textsuperscript{125} GINA § 101(b), 29 U.S.C. § 1182(c)(3)(A) (2008); GINA § 102(a)(2), 42 U.S.C. 300gg-1(c)(3)(A) (2008). An insurer, either in the individual or group market can request, but not require, an insured to undergo certain research-related genetic tests when:

\( (A) \) The request is made, in writing, pursuant to research that complies with part 46 of title 45, Code of Federal Regulations, or equivalent Federal regulations, and any applicable State or local law or regulations for the protection of human subjects in research.
restrictions, insurers are not precluded from accessing and using the results of genetic tests in order to make appropriate payments for the services, as long as only the minimum amount of information is used for that purpose.\(^{126}\) The last provision that is common to all sections deals with fetuses and embryos. It states that genetic information, when referencing a woman who is pregnant, includes the genetic information of the fetus.\(^ {127}\) Additionally, if there is assisted reproduction, then the genetic information contained in the embryo is also protected.\(^ {128}\)


2. AMENDMENTS TO THE EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974

The first section of Title I amends the Employee Retirement Income Security Act of 1974 ("ERISA"). ERISA is a federal statute that was enacted, inter alia, to establish minimum standards for private group health plans. ERISA also provides standards of conduct that group plans must meet. Section 101 of GINA begins by amending section 702 of ERISA, which prohibits discrimination against individuals who are part of a group plan based on "health status-related factors." GINA amends section 702(b) to prohibit an increase in premiums or contribution amounts based on genetic information. Taken literally, this prohibits insurers from considering the genetic information of an individual or the group as a whole and increasing premiums based on genetic information. GINA also inserts prohibitions on regarding genetic testing. An insurer cannot

---


130. See Employee Benefits Sec. Admin., U.S. Dep't of Labor, Compliance Assistance, http://www.dol.gov/ebsa/compliance_assistance.html (last visited Feb. 17, 2009). ERISA requires group health plans to provide the individual participants with information about the group plan. Also, it holds the people who manage group health plans to fiduciary standards in some cases. ERISA further extends health insurance coverage to employees when they leave current employment under the Congressional Omnibus Budget Reconciliation Act.

131. See ERISA § 702(b), 29 U.S.C. § 1182(b) (2008). Section 702(b) of ERISA places numerous restrictions on group health plans and the insurance issuers for such plans. This section states:

A group health plan, and a health insurance issuer offering insurance coverage in connection with a group health plan, may not require any individual (as a condition of enrollment or continued enrollment under the plan) to pay a premium or contribution which is greater than such premium or contribution for a similarly situated individual enrolled in the plan on the basis of any health status-related factor in relation to the individual or to an individual enrolled under the plan as a dependent of the individual.

132. GINA § 101(a), 29 U.S.C. § 1182(b) (2008). Section 702 of ERISA prohibits a group health plan from discriminating against an individual for enrollment eligibility based on "health status-related factors." ERISA § 702, 29 U.S.C. § 1182 (2008). These factors include health status, medical condition (including both physical and mental illnesses), claims experience, receipt of health care, medical history, evidence of insurability (including conditions arising out of acts of domestic violence), disability, and genetic information. Section 702(b) prohibits group health plans from discriminating on the basis of these same factors in determining premium or contribution amounts from individuals. See supra note 131.


134. However, this does not limit the ability of a group health plan or insurer offering group coverage from increasing the premiums of the employer. See GINA § 101(a)(2), 29 U.S.C. § 1182(b)(3)(B) (2008).

135. GINA § 101(b), 29 U.S.C. § 1182(c) (2008). The restriction highlights the crux of the fears behind genetic discrimination. See Jungreis, supra note 2, at 231 (arguing that individual's fears of genetic discrimination should be the basis for genetics legislation).
"request or require" an individual in a group health plan to undergo genetic testing, but a health care provider providing services to an individual may request—but not require—the person undergo genetic testing.\(^{136}\) An insurer is allowed access to the results of this testing to determine whether payment for the treatment is appropriate, limited specifically to the information necessary to make this decision.\(^{137}\) Furthermore, an insurer providing group coverage or the group plan itself cannot "request, require, or purchase genetic information" about an individual before their enrollment in the plan; however, incidental collection is excused.\(^{138}\) Additionally, GINA states that "the provisions of [earlier amended subsections] shall apply to group health plans and health insurance issuers without regard to section 732(a) [of ERISA]."\(^{139}\) Section 732(a) establishes special exemptions to ERISA.\(^{140}\) However, the requirements and prohibitions of GINA apply to these exceptions, even if ERISA does not.\(^{141}\)

3. AMENDMENTS TO PUBLIC HEALTH SERVICE ACT AND INTERNAL REVENUE CODE

a. Public Health Service Act

Title I also amends the Public Health Service Act ("PHSA").\(^{142}\) The PHSA was passed in 1946 to consolidate and amend the then-existing regulations for public health and welfare.\(^{143}\) Since its inception, the PHSA has been amended by several legislative enactments, including the Health Insurance Portability and Accountability Act of 1996\(^{144}\) and the Congressional Omnibus Budget and Reconciliation Act of 1985.\(^{145}\)


\(^{140}\) See ERISA § 732, 29 U.S.C. § 1191a (2007). Section 732 exempts ERISA applications from entities offering group plans that contain less than two participants who are current employees. ERISA § 732, 29 U.S.C. § 1191a(a) (2007). The section also excludes ERISA applications if health benefits are incidentally afforded under a separate policy or certificate or are not considered an integral part of the group plan. ERISA § 732, 29 U.S.C. § 1191a(c)(1) (2007).


\(^{142}\) GINA § 102, 42 U.S.C. § 300gg-1(b) (2008). This section of Title I amends five sections of the PHSA. See id. (amending 42 U.S.C. §§ 300gg, 300gg-1, 300gg-1(a)(1)(F), 300gg-22(b), 300gg-91(d) (2008)).


\(^{145}\) Consolidated Omnibus Budget Reconciliation Act of 1985, Pub. L. No. 99-272, 100 Stat. 82 (1986). Although COBRA, as the Act is generally called, is best known for extending some form of health insurance coverage after leaving employment, its most important provisions deny
With one important exception, the provisions amending the PHSA are equivalent to the ERISA amendments.\textsuperscript{146} Under section 101 of GINA, insurers cannot increase premiums of contribution amounts in group health plans based on genetic information, nor can insurers request or require genetic testing.\textsuperscript{147} But unlike section 101, the amendments to the PHSA extend protection against genetic discrimination into the individual market.\textsuperscript{148} ERISA only applies to group health plans.\textsuperscript{149} As a result, the protections of section 101 only apply to those individuals whose health insurance comes from a group health plan; it does not cover those individuals who acquire individual health insurance policies who could possibly be subject to increased premiums or denied coverage because of genetic information.

Section 102 of GINA addresses this problem. This section states that insurers offering individualized health insurance “may not establish rules for the eligibility (or continued eligibility) of any individual to enroll . . . based on genetic information.”\textsuperscript{150} This provision is coupled with another restriction which limits an insurer from considering genetic information of the person or his or her family members in adjusting the premiums the person pays.\textsuperscript{151} These provisions taken together bar insurers from using genetic information to deny initial eligibility, rescind coverage, or increasing premiums because of genetic susceptibility to disease. Like the ERISA provisions, insurers in the individual market cannot “request, require or purchase” genetic information for underwriting purposes.\textsuperscript{152} This restriction correlates closely with the provision limiting the use of genetic information for determining eligibility, so genetic information cannot be required as a condition for coverage or be used to deny coverage.

\textsuperscript{146} Compare GINA § 101(a)-(e), 29 U.S.C. §§ 1182(b)-(f), 1191b(d), 1132(a)(6), 1132(b)(3), 1132(c)(9)(A)-(E) (2008) (amending ERISA by adding restrictions regarding group health insurance coverage and consideration of genetic information), with GINA § 102(a)(1)-(5), (b)(1), 42 U.S.C. §§ 300gg-1(b), 300gg-1, 300gg-91(d), 300gg-22(b), 300gg-53 (2008) (placing similar restrictions on both group plans and individual market health insurance).

\textsuperscript{147} See supra notes 133-36 and accompanying text.


\textsuperscript{150} GINA § 102(b)(1), 42 U.S.C. § 300gg-53(a)(1) (2008). Section 102(b) of GINA creates an addition to the PHSA to specifically address the possibility of genetic discrimination in the individual insurance market. \textit{Id}.


\textsuperscript{152} \textit{Id} § 300gg-53(e)(1).
Furthermore, the collection of genetic information about an individual prior to enrollment in an individual health insurance plan is also prohibited.\footnote{153} Even with all these protections, insurers could still classify a genetic predisposition as a preexisting condition. However, the drafters of GINA anticipated this, and restricted the ability of insurers to create preexisting condition exclusions based on genetic information.\footnote{154}

Finally, mirroring the ERISA restriction, insurers offering individual health insurance coverage cannot require an individual to undergo genetic testing; however, the same exceptions for physicians providing coverage and requests for payment purposes and research-related testing are included in this section.\footnote{155} Also, plans that were typically exempt from compliance with the PHSA regulations are not exempt from the restrictions enacted by section 102 of GINA.\footnote{156}

b. Internal Revenue Code of 1986

One crucially important amendment that Title I makes is to the Internal Revenue Code.\footnote{157} In order to appreciate the gravity of this amendment, some background discussion is needed. Historically, an employer who provided group health insurance coverage for employees was able to deduct the contributions it made towards paying its employees’ premiums.\footnote{158} In 1996, Congress passed the Health Insurance Portability and Accountability Act ("HIPAA").\footnote{159} Specifically, HIPAA added Section 9802 to the Internal Revenue Code, which prohibited a group health plan, whether subject to ERISA or not, from discriminating against its

\begin{footnotesize}
\footnote{153} \citelaw{42 U.S.C. \$ 300gg-53(c)(2) (2008).} \\
\footnote{154} \citelaw{Id. \$ 300gg-53(c)(1) (referencing the definition of \"preexisting condition\" found in PHSA \$ 2701(b)(1)(A), 42 U.S.C. 300gg(a)(1) (2008)). This section defines a preexisting condition, \"with respect to coverage, [as] a limitation or exclusion of benefits relating to a condition based on the fact that the condition was present before the date of enrollment for such coverage, whether or not any medical advice, diagnosis, care, or treatment was recommended or received before such date.\" \citelaw{Id. \$ 300gg(b)(1)(A)}. The section goes on to state that genetic information cannot be classified as a \"condition\" in the absence of manifested diagnosis. \citelaw{Id. \$ 300gg(b)(1)(B)}.} \\
\footnote{155} \citelaw{See GINA \$ 102(b), 42 U.S.C. \$ 300gg-53(d)(1)-(3) (2008). The same research exception provided throughout GINA is also provided in section 102. See \textit{supra} note 125.} \\
\footnote{156} \citelaw{See GINA \$ 102(c), 42 U.S.C. \$ 300gg-21(b)(2) (2008). Previously, HIPAA regulations regarding genetic information did not apply to non-federal governmental group plans or group plans with two or less members. See \citelaw{42 U.S.C. \$ 300gg-21 (2008)}.} \\
\footnote{157} \citelaw{See GINA \$ 103, I.R.C. \$ 9802(b) (2008).} \\
\footnote{158} \citelaw{See I.R.C. \$ 162(a)(1) (1989). This section allows deductions for ordinary and necessary business expenses, of which such contributions are a part. \citelaw{Id. Additionally, employees receive the benefit of employer contributions for group health coverage, because such contributions are not included in the employee’s gross income. See I.R.C. \$ 106 (1989).}} \\
participants on the basis of health status.\textsuperscript{160} If discrimination occurs, then a tax is levied, generally against the employer, and contributions cannot be deducted.\textsuperscript{161} GINA extends the protections granted by HIPAA to genetic information. Besides this one amendment, the amendments in section 103 are almost identical to the provisions in section 101.\textsuperscript{162}

4. AMENDMENTS TO THE SOCIAL SECURITY ACT

a. Title XVIII—Medigap

In addition to amending ERISA and the PHSA, Title I amends two sections of the Social Security Act.\textsuperscript{163} First, GINA amends the Title of the Social Security Act that specifically applies to Medigap.\textsuperscript{164} Medigap refers to private supplemental health insurance policies that literally fill the gap between medical costs and the amount provided under Medicare benefits.\textsuperscript{165} Specifically, GINA amends section 1882 of the Social Security Act.\textsuperscript{166} Under section 1882, supplemental health insurance used in conjunction with Medicare is required to have a six-month eligibility window where the individual applying for the insurance does not have to undergo a physical examination.\textsuperscript{167} After this six month period expires, medical examination is

\begin{footnotesize}
\begin{enumerate}
  \item See I.R.C. § 9802 (1989).
  \item See I.R.C. § 4980D (1989). This section imposes a penalty of $100 a day per person for violations. Id. § 4980D(b). Such a penalty is similar to the enforcement remedies added by section 101 and 102 of GINA. However, section 4980D has a more technical and expansive breakdown of potential liability, depending on the classification of the group plan. Id.
  \item See supra note 156.
  \item 42 U.S.C. § 1395ss(s)(2) (2008). This section states: If a medicare supplemental policy replaces another medicare supplemental policy, the issuer of the replacing policy shall waive any time periods applicable to preexisting conditions, waiting period, elimination periods and probationary periods in the new medicare
\end{enumerate}
\end{footnotesize}
required. GINA amends this section to bar consideration of genetic information to deny or condition supplemental policies, even outside of this six-month window. Also, genetic information cannot be used in order to apply preexisting condition exclusions in the policy. Furthermore, supplemental insurance providers cannot require individuals to undergo genetic testing, although there is a research exception. GINA restricts the request, receipt, or purchase of genetic information prior to enrollment in a supplemental insurance plan. In order to effectively integrate these changes, GINA requires modification of the National Association of Insurance Commissioners’s Model Regulations to implement the changes to the Medigap provisions.

b. Title XI –Application of HIPAA Regulations

GINA also amends title XI of the Social Security Act. Title XI deals with disclosure of health information and sets standards for administrative simplification of disclosure procedures. GINA adds a section that extends the privacy protections established by the Health Insurance Portability and Accountability Act (“HIPAA”) to genetic information. First, this section requires the Secretary of Health and Human Services to amend the current HIPAA protections to bar insurers providing group, individual, or supplemental health insurance from using supplemental policy for similar benefits to the extent such time was spent under the original policy.

Id. The GINA amendments ensure that genetic information is another prohibited method of denying coverage.

172. GINA § 104(b)(1), 42 U.S.C. § 1395ss(x)(2)(A) (2008). These amendments also include the exception for the incidental collection of information and the rule of construction regarding payment. See supra notes 121, 126.
173. GINA, Pub. L. No. 110-233, § 104(d)(2), 122 Stat. 881 (2008). This provision states that the National Association of Insurance Commissioners has to modify its Model Regulations relating to Medigap. Id. However, if these actions are not taken, then the Secretary of Health and Human Services will undertake modifying the NAIC’s Model Regulations. See GINA, Pub. L. No. 110-233, § 104(d)(3), 122 Stat. 881 (2008).
genetic information in the underwriting process. It states that this is not a permitted use or disclosure of genetic information. This section specifically defines underwriting in the same manner as other sections, and references the definitions of group plan, health insurance coverage, and others as defined in the PHSA and the SSA.

C. TITLE II

The restrictions and prohibitions in Title II of the Genetic Information Nondiscrimination Act ("GINA") apply to employers, employment agencies, and labor organizations, including municipal, state, and federal governments. Most definitions in Title II, with the exception of genetic test and genetic information, are the same as those in the Civil Rights Act. Only one general provision of Title II applies to employers, labor

178. Id.

Additionally, an employment agency is defined as "... any person regularly undertaking with or without compensation to procure employees for an employer or to procure for employees opportunities to work for an employer and includes an agent of such a person." 42 U.S.C. § 2000e(c) (2008). In the same vein, an employer is defined as:

[A] person engaged in an industry affecting commerce who has fifteen or more employees for each working day in each of twenty or more calendar weeks in the current or preceding calendar year, and any agent of such a person, but such term does not include (1) the United States, a corporation wholly owned by the Government of the United States, an Indian tribe, or any department or agency of the District of Columbia subject by statute to procedures of the competitive service (as defined in section 2102 of Title 5), or (2) a bona fide private membership club (other than a labor organization) which is exempt from taxation under section 501(c) of Title 26[.] 42 U.S.C. § 2000e(b) (2008).

A labor organization under the Civil Rights Act is defined as:

[A] labor organization engaged in an industry affecting commerce, and any agent of such an organization, and includes any organization of any kind, any agency, or employee representation committee, group, association, or plan so engaged in which employees participate and which exists for the purpose, in whole or in part, of dealing with employers concerning grievances, labor disputes, wages, rates of pay, hours, or other terms or conditions of employment, and any conference, general committee, joint or system board, or joint council so engaged which is subordinate to a national or international labor organization.

Id. § 2000e(d). However, some definitions are established in Title II. For instance, the term
organizations, employment agencies, and training programs. None of these entities can "request, require, or purchase" genetic information.

There are five notable exceptions to the prohibition on the entities regulated in Title II against requesting genetic information. The first exception is aptly referred to as the "water cooler problem." Under a formalistic interpretation of GINA, if an employer inquires about a genetic disease of an employee or a family member of the employee, then this is a request of genetic information. Title II excludes such requests from violating these prohibitions. Second, Title II allows employers to request genetic information when the employer offers certain genetic services, including those "services offered as part of a bona fide wellness program" as long as certain conditions are met. The third exception is where an employer requests family medical history in order to comply with the Family and Medical Leave Act of 1993 or similar state law provision. Fourth, there is the obituary exception, where an employer acquires publicly or commercially available information and it contains references to the genetic information of an employee or family member of the employee. However, this exception does not cover medical databases or public health databases.


187. GINA § 202(b)(2), 42 U.S.C. § 2000ff-1(b)(2) (2008). This section is similar to the rule of construction found in Title I that expresses legislative intent for interpretation. See supra note 129 and accompanying text. There are certain requirements in order for an employer to offer these services. First, the employee has to give informed consent in writing prior to engaging in the offered services. GINA § 202(b)(2)(A), 42 U.S.C. § 2000ff-1(b)(2)(A) (2008). Second, only the employee undergoing the testing and either "a licensed health care professional or board certified genetic counselor" are to receive information which discloses the specific results of such testing. GINA § 202(b)(2)(B), 42 U.S.C. § 2000ff-1(b)(2)(B) (2008). Finally, the information that results of such testing shall only be disclosed to the employer "in aggregate terms that do not disclose the identity of specific employees[.]" GINA § 202(b)(2)(C), 42 U.S.C. § 2000ff-1(b)(2)(C) (2008).


the disclosure of information as required by courts and thus contained in court records.\textsuperscript{190} The final exception deals with genetic monitoring.\textsuperscript{191} Genetic information can be requested or required where it is used to evaluate the biological effects of toxic substances in the workplace.\textsuperscript{192} As with insurer-provided genetic testing, certain qualifications and safeguards must be observed before the information can be used.\textsuperscript{193}

Title II begins by regulating employers.\textsuperscript{194} Section 202 adopts the definition of “employer” established in the Civil Rights Act of 1964, and therefore, the regulations and prohibitions of Title II are limited to employers who have more than 15 employees.\textsuperscript{195} Title II bars employers from discriminating for hiring, firing, promotion, or other “privileges of employment” on the basis of genetic information of the individual or family member.\textsuperscript{196} Also, employers are barred from classifying or dividing employees on the basis of genetic information if such classification would deprive the employee of “employment opportunities or otherwise adversely affect the status of the employee[.]”\textsuperscript{197}

\begin{itemize}
  \item \textsuperscript{193} \textit{Id.} To fall within the genetic monitoring exception, the employer has to provide notice to the employee of the potential request or requirement of and disclosure of this information. GINA § 202(b)(5)(A), 42 U.S.C. § 2000ff-1(b)(5) (2008). Also, the employee must either provide prior written and “voluntary” notice or the genetic monitoring is required by state or federal law. GINA § 202(b)(5)(B)(i)-(ii), 42 U.S.C. § 2000ff-1(b)(5) (2008). The results of this information must be disclosed to the employee. GINA § 202(b)(5)(C), 42 U.S.C. § 2000ff-1(b)(5) (2008). Furthermore, the monitoring has to be in compliance with federal or state regulatory limitations, specifically those provided for or created in response to the Occupational Safety and Health Act, the Atomic Energy Act, and the Federal Mine Safety and Health Act. Also, like the earlier exception of information for services provided by an employer, the information received by the employer cannot specifically identify the genetic information of particular employees, but must be disclosed in the aggregate. \textit{Id.}
  \item \textsuperscript{195} \textit{See supra note 181.}
  \item \textsuperscript{196} GINA § 202(a)(1), 42 U.S.C. § 2000ff-1(a)(1) (2008). The full text of these sections provide that it is unlawful for an employer:
    \begin{itemize}
      \item to fail or refuse to hire, or to discharge, any employee, or otherwise to discriminate against any employee with respect to the compensation, terms, conditions, or privileges of employment of the employee, because of genetic information with respect to the employee;
      \item or to limit, segregate, or classify the employees of the employer in any way that would deprive or tend to deprive any employee of employment opportunities or otherwise adversely affect the status of the employee as an employee, because of genetic information with respect to the employee.
    \end{itemize}
\end{itemize}
Title II applies to employment agencies and labor organizations. In terms of employment agencies, restrictions are placed on the use of this information as a basis for deciding whether to refer an individual for employment. As it applies to labor organizations, the labor organization cannot use genetic information "to exclude or to expel [an individual] from the membership" of the organization. Additionally, neither employment agencies nor labor organizations can use genetic information to limit, classify, or fail to refer potential employees by using the information in any way that would "deprive or tend to deprive an individual of employment opportunities, or otherwise adversely affect the status of the individual[]."

Also, these entities are banned from attempting to influence an employee to discriminate based on genetic information.

Finally, training programs are regulated. The term "training program" is broad enough to apply to apprenticeships and joint-management training; even training provided by employers, employment agencies, and labor organizations are regulated. Any training program, whether provided by employers, employment agencies, labor organizations, or even independent training programs in connection with employment, are prohibited from using genetic information to deny "admission to, or employment in, any program established to provide apprenticeship or other training or retraining."

Title II also establishes standards for the storage and disclosure of genetic information. Section 206 requires that any employer, employment agency, or labor organization that has genetic information about an individual to create and maintain separate records for the information. However, these separately maintained records are subject to the same confidentiality as other medical information. As a result of

204. Id. Title II uses the term training program in reference to training or retraining programs that are offered by employers, employment agencies, and labor organizations. See supra note 180.
207. GINA § 206(a), 42 U.S.C. § 2000ff-5(a) (2008). While these records must be kept separately, they are considered as part of the employee's confidential medical record. Id.
208. Id.
these confidentiality requirements, disclosure of this information by employers and others is prohibited save for several specific circumstances.\footnote{209}

Finally, Title II contains miscellaneous provisions that attempt to effectively implement this legislation.\footnote{210} First, Section 209 states that Title II does not override or limit any rights that may be available to individuals under the Americans with Disabilities Act ("ADA").\footnote{211} This is important because the protections afforded to genetic information are still unclear under the ADA.\footnote{212} Also, this section states that the provisions contained in


212. Id. The Americans with Disabilities Act of 1990 is federal legislation that prohibits, under certain circumstances, discrimination based on disability. See 42 U.S.C. §§ 12101-12122 (2008). A disability is defined as “a physical or mental impairment that substantially limits a major life activity.” Id. § 12102(2)(A)-(C). Protection for genetic information under this standard is unclear. Although the EEOC brought suit on behalf of aggrieved employees against Burlington Northern and Santa Fe Railroad under the ADA for employment discrimination based on genetic information, the lawsuit was settled and so interpretation of the ADA standard in the genetic context was rendered. See EEOC v. Burlington N. Santa Fe Ry. Co., No. C 01-4013-MWB (N.D. Iowa 2001); see also Stephen Fink, EEOC v. BNSF: The Risks and Rewards of Genetic Exceptionalism, 42 WASHBURN L.J. 525, 525 (Spring 2003) (discussing the background of the case in light of genetic exceptionalism); Samantha French, Genetic Testing in the Workplace: The Employer’s Coin Toss, 2002 DUKE L. & TECH. REV. 0015, 0018 (discussing the decision and

[Vol. 55]
Title II will not be construed to counterbalance or negate the protections in Title I.\textsuperscript{213} Section 209 explains that this legislation provides only floor protection, and that state and federal laws that offer greater protections will not be limited as a result of GINA.\textsuperscript{214}

Probably the most important section in Title II is section 208. This section makes clear that Title II does not recognize disparate impact as a cause of action under Title II.\textsuperscript{215} Disparate impact occurs when "a facially neutral employment practice...has an unjustified adverse impact on members of a protected class."\textsuperscript{216} This form of discrimination does not require a claimant to prove the intent to discriminate.\textsuperscript{217} Thus, to prove a violation of GINA in the employment context, you have to show that genetic information was purposefully used to discriminate against an employee.

The absence of disparate impact is not unqualified. Title II establishes the Genetic Nondiscrimination Study Commission "to review the developing science of genetics and make recommendations to Congress" as to whether this particular section should be repealed in the future.\textsuperscript{218} The commission will be bipartisan, consisting of members of the House of Representatives and the Senate who will undertake such research six years after GINA becomes effective.\textsuperscript{219}

The last important section in Title II makes an explicit distinction arguing that no valid ADA claim existed in the suit brought against BNSF). However, Title II will ensure that if there is concurrent protection then GINA will not hinder those remedies available under the ADA.


\textsuperscript{214} GINA § 209(a)(1), 42 U.S.C. § 2000ff-8(a)(1) (2008). One additional and important provision contained within section 209 is that it does not require "any specific benefit for an employee or member or a family member of an employee or member under any group health plan or health insurance issuer offering group health insurance coverage in connection with a group health plan." GINA § 209(a)(7), 42 U.S.C. § 2000ff-8(a)(7) (2008).


[Title VII of the Civil Rights Act] proscribes only overt discrimination but also practices that are fair in form, but discriminatory in operation. The touchstone is business necessity...[G]ood intent or absence of discriminatory intent does not redeem employment procedures or testing mechanisms that operate as 'built-in headwinds' for minority groups and are unrelated to measuring job capability.

401 U.S. 424, 431-32 (1971). In order for a business practice that has a discriminatory impact to stand, it has to have a demonstrable factual relationship to increasing profitability. \textit{Id}.


\textsuperscript{218} GINA § 208(b), (e), 42 U.S.C. § 2000ff-7(b), (e) (2008).

\textsuperscript{219} \textit{Id}.
between the protections afforded genetic information and other health information. Section 210 states that no provision in Title II applies to medical information. The language of this section states that entities restricted under Title II can acquire or disclose medical information that is not genetic information or genetic information dealing with a manifested disease or disorder. This is similar to the exception to the definition of genetic testing found in Title I, but absent in Title II. Under Section 210, an employer or other entity similarly situated will not violate Title II for using, acquiring, or disclosing this type of information.

D. Remedies

1. Title I

The prohibitions against genetic discrimination in Title I are enforced through section 502 of the Employee Retirement Income Security Act and sections 2722(b) and 2761(b) of the Public Health Service Act. These sections are amended to include a remedies section that is specific to GINA. Despite these similar amendments, both section 502 of ERISA and 2761(b) of the PHSA have different limitations regarding who can actually enforce these regulations.

For instance, the remedial amendments to ERISA give rights of enforcement to several people. Section 502 allows a civil action to be brought by “a participant or beneficiary” of a group health plan, or by

221. Id.
222. GINA § 210, 42 U.S.C. § 2000ff-9 (2008). This is referencing the exception to the definition of a genetic test that is found in Title I of GINA.
223. See supra notes 113-15 and accompanying text.
227. See 29 U.S.C. § 1132(a) (2008) (allowing ERISA enforcement by any participant or beneficiary of the group plan or the Secretary of Labor).
fiduciary of the plan. Additionally, the Secretary of Labor can initiate civil proceedings against a group health plan or insurers providing group coverage that violates Title I. Section 502(a) allows for equitable remedies such as permanent injunctions, mandamus, or even declaratory judgments. On the other hand, the amendments to section 2722(b) the PHSA, dealing with group and individual health plans, are enforced by the Secretary of Labor.

The amendments to ERISA and the PHSA that are contained in Title I have identical penalties for violating GINA. If the discrimination takes place in a group health plan or in the individual market, then non-compliance is penalized at $100 per day. However, if the violation occurs in a group health plan with violations against multiple people, the penalty is $100 per day per person for length of the non-compliance period. There is a minimum penalty of $2,500 which applies if the violations are not rectified before formal notice of the violation is received. However, if violations by a particular defendant for any one-year period are more than de minimus, the threshold penalty is increased to $15,000.

Notwithstanding, these penalties will not apply when reasonable diligence was used or where reasonable diligence would not have discovered the violation. There is also no penalty if there was a reasonable cause for the violation, or it was not the product of willful neglect, and in both cases is corrected within 30 days of discovery. Also,

229. Id. § 1132(b).
231. Id.
the legislation caps damages for "unintentional failures," stating that when failures are not due to willful neglect, the penalty will not be more than 10% of the amount paid by the employer in the preceding year for health plans or $500,000, whichever is less.\(^{239}\)

2. TITLE II

The remedies provided for violations of Title II differ significantly from those in Title I. Unlike Title I, the enforcement of Title II takes place through several provisions of the Civil Rights Act of 1964.\(^{240}\) In order to enforce Title II, an employee who has been the victim of genetic discrimination has to file a complaint with the Equal Employment Opportunity Commission (EEOC).\(^{241}\) After an investigation takes place, the EEOC either refers the claim to the Department of Justice or grants the individual the right to sue.\(^{242}\) In Title II, all the remedies afforded to the EEOC under the Civil Rights Act are available.\(^{243}\) This title makes filing actions based on genetic discrimination accessible. Section 207(a)(2) of GINA makes the provisions of 42 U.S.C. § 1988(b) and (c) applicable to violations identified and litigated under Title II where the claimant prevails.\(^{244}\) This allows for the recovery of both attorney's fees and expert fees as part of costs.\(^{245}\) These remedies extend to actions against employers who are limited under other sections, such as the Government Employee Rights Act of 1991, the Congressional Accountability Act of 1995, and Title V of the United States Code.\(^{246}\)

IV. ANALYSIS

Despite the long incubation of genetics legislation and the careful approach of lawmakers in shaping the Genetic Information Nondiscrimination Act of 2008, problems remain. There are unintended consequences that result from GINA's attempt to correct the possibility of genetic discrimination. The bill as a whole adopts a genetics exceptionalist approach but delineates an amorphous line between medical and genetic information without solving the adverse impact to the insurance industry.


\(^{241}\) See 29 C.F.R. §§ 1601.6-1601.7 (2008).


In fact, the legislation actually deprives the underwriting process of information they were previously allowed to use. In Title II, employers are left to draw the same distinction between medical and genetic information that this legislation attempts to draw. This legislation attempts to quell fears of genetic discrimination in order to facilitate wider genetic testing, but there is no indication that this legislation will solve the problem. Additionally, the difficulty in implementing the goals GINA seeks to achieve, in addition to the added strain on the EEOC and employers generally, will have a harsher impact before progress is made.

GINA is a quintessential example of what has been deemed genetics exceptionalism. Many proponents of genetics legislation highlight that genetic testing and its resultant genetic information is able to suggest the possible manifestation of disease, making it more significant than diagnostic or symptomatic observations and qualifying it for special protections. In response, Title I specifically creates a new approach to the use (or alleged misuse), storage, and privacy of genetic information. Despite the attempt to treat genetic information differently from what is considered general medical information, the protections remain relatively the same. Many genetic diseases already receive protection under provisions of ERISA and the ADA. But by creating new protections specifically for genetic information, class inequalities will arise because environmental factors that can aggravate genetic traits are typically

247. See GINA § 101(d), 29 U.S.C. § 1191b(d)(6)(A)(iii) (2008) (including the manifestation of a disease or disorder in family members of such individual as genetic information). The inclusion of this as genetic information restricts the ability of insurers providing group or individual coverage from requesting or requiring this information as a condition of enrollment or for use in increasing premiums. See GINA § 101(a), 29 U.S.C. § 1182(b)(3)(A)-(B) (2008).


249. See Jungreis, supra note 2, at 215 (noting the significance of information that can show predispositions but not fully guarantee their development or lack thereof).

250. See supra Part III.B.1.


252. ERISA protects against discrimination against “health status-related factors.” See supra notes 131-32. However, even before GINA, ERISA included genetic information as part of these factors; GINA merely focused it. See 29 U.S.C. § 1182(a)(1)(F) (2006). Additionally, the EEOC has brought suit against an employer where it framed information relating to the development of carpal tunnel syndrome as a “disability” under the ADA. See EEOC v. Burlington N. Santa Fe Ry. Co., No. C 01-4013-MWB (N.D. Iowa 2001). The overall disposition of this case, however, is unclear because the defendant settled the claim.
associated with the socioeconomic factors of an individual.  

When focused more narrowly, the area of concern is where genetic information does not lend enough accuracy or background information to determine whether a genetically marked condition will develop. Even so, this kind of information is no different than a symptomatic diagnosis that shows the possible development of a more severe physical problem. For instance, someone who undergoes a colonoscopy that shows a predisposition to the development of colon cancer is in the same position as someone who is genetically predisposed to a particular illness; both have the potential for the development of further disease and both will theoretically be subject to higher insurance premiums or a denial of coverage. But regardless of these distinct similarities, GINA treats these two medical observations differently: the person who is genetically predisposed is covered, while the colonoscopy patient is not. This legislation draws a line at disease manifestation; precursors for disease identified in regular screening are not protected, even though genetic information—which is essentially the same thing—is.

In making the nebulous distinction between genetic and medical information, GINA deprives the underwriting process of a tool previously incorporated into its calculations. Historically, insurance underwriters were allowed to consider an applicant’s family history to determine the risk the particular applicant posed. However, GINA restricts the ability of insurers—both those providing individual and group coverage—from considering this previously allowed information. The argument behind this restriction is that family history can identify familial genetic predispositions for certain diseases that could be used to unfairly discriminate. But, diseases that manifested in family members could have developed without explicit reference to genetic information; e.g.

254. See supra note 39 and accompanying text.
256. Id.
258. See supra notes 94, 118.

The [HELP] committee realizes that a family medical history could be a surrogate for a genetic trait by a health plan or health insurance issuer. A consistent history of a heritable disease in a patient’s family may be viewed to indicate that the patient himself or herself is at increased risk for that disease. For this reason, the committee believes it is important to include family medical history in the definition of ‘genetic information.’

Id.
environmental factors may have caused the development of some diseases. On the other hand, the use of family history may not show a propensity or risk of disease development, because a genetic condition or carrier that has passed down may not have developed. However, GINA does not distinguish between family history that foreshadows the development of genetic diseases or information that may have arisen as a result of environmental factors; there is a blanket prohibition on all family history consideration. This overbroad approach has adverse consequences to the underwriting and actuarial process. By removing the ability of insurers to consider family history in their actuarial analysis, GINA does not only change the future use of certain information—it actually disadvantages underwriting in a manner previously allowed.

Where genetic information was not an integral factor of underwriting decisions, family history was.

This new restriction will make the actuarial process less accurate than before, without considering that the actuarial process generally does not consider uncertain information. Even if such information is taken into account, then it is only done so in relation to its predictability. For example, suppose A applies for health insurance and produces a family history where one out of four members identified suffered a stroke. Although relevant, the information would be actuarially discounted because

260. See Suter, supra note 31, at 715-16. Professor Suter gives an example that illustrates the difficulty in taking a blanket approach to excluding relevant medical information. She posits that two women who have high likelihood of developing breast cancer, where one has genetic susceptibility and the other environmental, will be differently classified where their risk is still the same. Id. In that situation, different protections will result even though there was no genetic predisposition, only environmental disposition. Id. at 716-17.

261. See Dennis Karjala, A Legal Research Agenda for the Human Genome Initiative, 32 JURIMETRICS J. 12, 147 (Winter 1992); see also Jungreis, supra note 2, at 230-32.

262. See supra note 94.

263. Because actuarial analysis is only as good as the information used to predict and classify potential risk, depriving this process of the ability to use information that was previously available will inevitably make the process less accurate. For instance, if one’s family history showed the potential for the development of breast cancer, then this risk would be factored in accordingly. However, without this information, premiums and coverage would be calculated at a lower rate, making it less likely that accurate financial payments would be made to prevent others from subsidizing this cost.


266. Id.
of the uncertainty that a similar condition would develop. However, in a situation where 3 out of 4 of A’s family members suffered a stroke, this information weighs more heavily because it shows a higher likelihood of A suffering a stroke. The weight in the actuarial analysis would be greater because it proves to be a more realistic consideration. But, as previously noted, the concern about genetic information being used discriminatorily is grounded in the fact that such information is uncertain about the subsequent manifestation of disease.\(^{267}\) However, this is not always the case. Some genetic conditions are almost certain to develop.\(^{268}\) Again, the concern is about genetic information that falls in the middle.\(^{269}\) In these cases, less certain areas of genetic information will have less of an impact on the overall individual or group cost of insurance because of its uncertainty, but will allow proper coverage for individuals in the same risk pool.\(^{270}\) Premiums may increase, but only in relation to the probability of the development of the risk, or in these cases, the manifestation of the disease.\(^{271}\) This keeps the insurance assessment accurate and proves to be nothing more than fair discrimination.\(^{272}\)

\(^{267}\). See Jungreis, \textit{supra} note 2, at 216.

\(^{268}\). See Green & Botkin, \textit{supra} note 40, at 572. The authors provide that:

First, although [genetic and nongenetic tests] both can identify risk factors for future illness, detection of highly penetrant genetic mutations may indicate a substantially higher risk than abnormalities discovered by nongenetic tests. For instance, persons with genetic mutations for Huntington disease or familial adenomatous polyposis are nearly certain to develop Huntington disease or colon cancer. So, while the type of information delivered by both genetic and nongenetic tests may be similar, for some positive genetic test results the risks detected are greater and disease is inevitable.

\textit{Id.}

\(^{269}\). See Holmes, \textit{supra} note 12, at 529-30. Professor Holmes pointed out that:

Although the presence of specific genes is all that is required to bring on a disorder, the degree of severity, timing of onset, or whether the disease will ever manifest itself at all, remain a matter of statistical probability. For these reasons, most genetic test information is largely a matter of probability theory and less conclusive than might be assumed from popular perception. This distinction of statistical probability from absolute conclusiveness is important when one explores the issues of economic and social policy in health insurance underwriting, which may, in turn, depend upon the accuracy of genetic testing.

\textit{Id.} While the Human Genome Project has shed light on the development of diseases that relate to single genomic factors, the emphasis has shifted to multifactoral disease development. One commentator has noted that:

Not surprisingly, as we learn more about genetics, we are discovering not only the importance of the role of the environment, but also the role of multigene interactions. In other words, the story has become infinitely more complex than single genes being fully deterministic. Instead, we must now account for the complex interaction between environment and multiple genes.

Suter, \textit{supra} note 31, at 690.

\(^{270}\). Generally, people who pose higher risks pay higher premiums. \textit{See supra} Part II.


\(^{272}\). See Holmes, \textit{supra} note 12, at 531-32. Professor Holmes points out that:

[T]he principle underlying insurance underwriting is ‘fair discrimination’ predicated on
GINA reflects the position that until a certain level of accuracy can be reached, there should be a ban on the use of all genetic information. This position assumes, however, that the actuarial process will take inaccurate information into account in classifying risk, without giving it the probabilistic discount the information deserves. This assumption was proven erroneous in a study conducted by the Health Policy Institute at Georgetown University. In this study, researchers found that in 7 out of 92 decisions, genetic information was a factor in the increase in premiums or in a denial of coverage. However, the study itself used a different array of diseases in its hypothetical questioning of underwriters. The disparity between the diseases used show that each has different actuarial values, which likely contributed to 7 decisions to increase premiums or deny coverage. This shows that it was only a question of predictability of disease development, not of outright discrimination.

Even if GINA protects against potential genetic discrimination, this does not necessarily mean that the number of individuals who will participate in genetic testing will increase. One scholar noted that the purpose behind federal genetics legislation, as GINA itself acknowledges, is to subdue fears about the possibility of genetic discrimination and promote the accelerated development of genetic testing and treatment. Some studies show that people are afraid of undergoing genetic testing because of possibly losing health care coverage or being unable to receive such coverage. These fears, in light of other federal and extensive state protections, are somewhat attenuated. Even if this alleged barrier is removed, it does not mean those people that are fearful of such treatment would undergo genetic testing if this consideration was a non-issue. There efficient, actuarial analysis in establishing risk transference and risk distribution (also called redistribution). In underwriting risks, insurance companies seek 'to measure as accurately as is practicable the burden shifted to the insurance fund by the policyholder and to charge exactly for it, no more and no less. To do so is 'fair' discrimination... Not to do so is unfair discrimination.'

Id. (quoting Spencer L. Kimbal, Reverse Sex Discrimination: Manhart, 1979 AM. B. FOUND. RES. J. 83, 105 (1979)).

273. See supra Part III.A. GINA restricts the use of all genetic information in insurance and employment, save some specific exceptions.


275. Id.

276. Id.

277. See Jungreis, supra note 2, at 216.


are other serious social, emotional, and medical consequences that result from undergoing genetic testing. First, people might refrain from such testing because of the stress and anxiety that could result from discovering potential susceptibility to disease or from the possibility of impairing future generations with this potential susceptibility. Second, these concerns become more acute when there is still the possibility that the disease might not develop. Third, due to the current disparity between genetic testing and the treatments available to monitor of these conditions, people may refrain from genetic testing to avoid learning of susceptibility to a genetic condition that lacks preventive treatment. Thus, although GINA will help soften the possibility that genetic discrimination will occur, it is still unclear if it will fully resolve other issues that come with genetic testing.

The final concern with Title I is the driving force behind the legislation. Genetics research and its combination with the practice of medicine are driving towards the development of a system of personalized health care. This involves the use of genetic testing to determine possible susceptibilities and to create treatment plans that are specifically tailored to that individual. Personalized medicine goes so far as to be able to genetically evaluate patients and prescribe drugs, both in form and quantity, in a way that prevents unnecessary side effects and produces positive results. Although meritorious and eventually potentially cheaper, the concept of personalized medicine runs against the grain of current medical treatment; a personalized approach will complicate the current industry infrastructure.

Take, for example, the concept of pharmacogenomics. This is the

280. See Green & Botkin, supra note 40, at 575.
281. These issues become particularly serious when genetic testing is undertaken by children. See Am. Acad. of Pediatrics Comm. on Bioethics, Ethical Issues with Genetic Testing in Pediatrics, 107 PEDIATRICS 1451, 1451-55 (June 2001); see also Suzanne Bennett Johnson et al., Maternal Anxiety Associated With Newborn Genetic Screening for Type I Diabetes, 27 DIABETES CARE 392, 392-97 (2004) (researching anxiety levels in mothers whose children underwent genetic testing).
282. See supra note 269. Because genetic testing is not fully predictive, even if you have a propensity for the development of certain diseases, there is no failsafe indicator that the disease will develop.
286. Id.
use of genetic testing and protein analysis to determine how certain pharmaceutical chemicals will impact particular genetic differences in individuals. This integration of individual genetic patterns into the production of pharmaceutical drugs has great potential. Drugs can be individually tailored to account for particular genetic predispositions and, thus, prevent dangerous side effects. However, such an approach will require a complete overhaul of the current business model established for the pharmaceutical industry. Generally, the current approach, called the blockbuster model, "assumes that a single compound could effectively treat most or all patients who have a particular condition." The drug approval process generally takes the same approach. Thus, pharmaceutical companies conduct general testing and research trials to determine the effectiveness of the drugs they produce. The cost of developing a new drug, from inception to production, is approximately $802 million. Furthermore, the number of produced drugs that reach the point of profitability is very slim; sales of 7 out of 10 approved drugs did not provide enough gross profit to recoup the research and design investment.

With this fact in mind, pharmacogenomics is ushering more research and development on a wider array of drugs based on individualized genetic predispositions. This requires more research into narrower areas and to produce drugs which are tailored to smaller groups. This mandates abandoning the current pharmaceutical infrastructure in exchange for a process that is more narrowly-focused and requires more investment cost for smaller potential returns. Increased development costs will drive up the cost of pharmaceutical drugs. Generally, these costs are subsidized by insurance companies. Without the ability of health insurance to be able to determine if its policyholders are subject to such risks, then there is no way for them to financially account for these increased costs.

In order to fully usher in a treatment approach where medicine is more

288. PRICEWATERHOUSECOOPER, PERSONALIZED MEDICINE: THE EMERGING PHARMACOGENOMICS REVOLUTION I (Feb. 2005), available at http://www.pwc.com/techforecast/pdfs/pharmaco-wb-x.pdf. This report was published to evaluate the impact of pharmacogenomics on the current pharmaceutical industry. Id. The Global Technology Centre and the Health Research Institute provided contributions for publishing the report. Id.
289. Id. at 5.
290. Id. at 7.
291. PRICEWATERHOUSECOOPER, supra note 288, at 7.
292. Id.
293. Id. at 8.
personalized, research and development will also have to be retooled to approach production individually and genetically. These changes to primary care, even with the specific example of the pharmaceutical industry, will make implementation of such a process slow and exceedingly cost-prohibitive. Change on such a large scale will cause the general cost of health care—and thus insurance—to increase markedly before there are any signs of abatement.  

Finally, such a monumental change in the way health care is approached cannot occur overnight; such a transition could take several decades to implement.

Because of the grand scale and potential timetable for such implementation, it would be a wiser approach to let insurers help bear the costs of such a transition. Insurance providers should be allowed to properly use genetic information to have those who stand to benefit most from particular advancements to contribute to the progress of such advancements. This is the essence of the insurance industry. Instead, there is a blanket prohibition that forces everyone, even those who pose no such risks, to subsidize these changes. Though the underpinnings of GINA are commendable, the short-term effects of totally barring insurers from considering genetic information will effectively make the goal of personalized medicine cost more and take longer to implement.

Although not as extensive as the potential problems with Title I, Title II of GINA also poses problems for employers. The lack of documented discrimination weighs against implementing unnecessary legislation. Additionally, the creation of unfounded litigation due to overburdened oversight and soft standards of proof will exacerbate already expensive litigation costs for employers.

As it stands, there have only been two documented cases where employers have improperly used genetic information to determine the rights of employees. Although significant, these two examples show that the problem may not be as large as originally thought.  

Furthermore,

294. Cf. McDonald, supra note 264, at 217-31 (acknowledging that depriving use of family history will increase premiums). If deprivation of only one element of the underwriting process will contribute to an increase in premiums, external factors such as the doubled cost of pharmaceutical drugs will unquestionably raise the costs of health insurance.

295. Pollock, supra note 284. Dr. Gregory Downing, who drives the efforts in this transition at the Department of Health and Human Services, acknowledged that such a transition could take this long. Id.

296. As of now, there have only been two cases brought regarding genetic discrimination by an employer. See Norman-Bloodshaw v. Lawrence Berkeley Lab., 135 F.2d 1260, 1269 (9th Cir. 1998); EEOC v. Burlington N. Santa Fe Ry. Co., No. C 01-4013-MWB (N.D. Iowa 2001).

297. See, e.g., Norman-Bloodshaw, 135 F.2d at 1269; Burlington, No. C 01-4013-MWB.

298. See Suter, supra note 31, at 680-81. Professor Suter states that the documented cases of
specifically tailored protections, in light of the current dearth of employment-based genetic discrimination and the already existent state protections, frame GINA as legislative overkill. One argument attempting to explain the practical absence of decisions regarding employment discrimination based on genetic information may be the absence of a cause of action for such conduct. On the contrary, such claims could be brought under wrongful termination theories or better yet, under state anti-discrimination laws that protect genetic information from being used as a discriminatory tool. Plus, other possible avenues of federal protection may be available. In fact, one of the cases involving genetic discrimination was actually brought based on federal law outside of GINA.

In addition to potentially superfluous regulation, enforcing Title II will further press the thin protections afforded to employers against frivolous claims. Title II enforcement will be supervised by the Equal Employment Opportunity Commission. The EEOC serves as the bulwark between disgruntled employees and their employers. The workforce of the EEOC has shrunk over the last several years. However, the amount of litigation—and the backlog it is creating—is increasing. Taken together, these facts show an overburdening of the EEOC. Assuming that genetic discrimination is prevalent enough to require creation of a new cause of action and that state law protection is not adequate, it will place yet another strain on the EEOC.

This encumbrance on the EEOC has implications for employers. Overburdening the EEOC may lead to the issuance of right-to-sue letters simply before the 180-day waiting period expires. If so, unmeritorious claims slip through to arrive in the courts, subjecting employers to

---

299. See generally French, supra note 212.

300. See EEOC v. Burlington N. Santa Fe Ry. Co., No. C 01-4013-MWB (N.D. Iowa 2001). In this case, the EEOC based its initial claim on violations of the Americans with Disabilities Act. Id.


302. See Christopher Lee, EEOC is Hobbled, Groups Contend, WASH. POST, June 14, 2006, at A21, available at http://www.washingtonpost.com/wp-dyn/content/article/2006/06/13/AR2006061301418.html. According to this article, since 2001 the full-time work force of the EEOC has decreased from 2,899 to 2,343. Id. This is a decrease of approximately 19%.

303. Id. Since 2005, the backlog has grown from 33,562 to 47,516 cases.

otherwise frivolous litigation.\textsuperscript{305} The impact of such litigation is real; employer costs for legal fees for preparing, settling, and defending such possible claims have steadily increased.\textsuperscript{306} Additionally, attorney screening of possible claims might not prove to be an effective deterrent of claims because of soft standards of proof established in Title II that can cast otherwise extraordinary claims in a colorable light.\textsuperscript{307} For instance, in the prohibitions stated in Title II, employers are banned from “otherwise . . . discriminat[ing] against any employee with respect to the compensation, terms, conditions, or privileges of employment of the employee, because of genetic information[.]”\textsuperscript{308} Taken to its extreme, this prohibition can open employers up to liability even when genetic information was not the basis of the employer’s action; if the employee has a genetic predisposition, then it may still be a viable claim. Such impact could be enormous without proper limitation. These problems and concerns highlight the difficulties in enacting genetics legislation. Furthermore, with only two documented examples of genetic discrimination—both attributable to the employment sector—having been identified, such sweeping limitations are unnecessary.

There are several possibilities to help mitigate the problems found in the Genetic Information Nondiscrimination Act. First, the regulations the EEOC is required to promulgate could help to clarify some of the requirements found in Title II. Second, Title I could allow for the establishment of reinsurance pools for potential high-risk policyholders. Finally, a sunset provision over both titles could be added so that the Act does not remain in force absent justification.

Under Section 211, the EEOC is required to issue regulations regarding the application and enforcement of Title II.\textsuperscript{309} EEOC regulations attempt to clarify existing law and establish the EEOC’s position on issues relating to enforcement and compliance.\textsuperscript{310} Through these regulations, some of the standards established in Title II could be clarified. For instance, regulations could delineate what is considered an adverse affect on

\textsuperscript{305} There is currently disagreement regarding the ability of a plaintiff to file suit in federal court when a right-to-sue letter is issued before the expiration of the of the 180-day waiting period. \textit{Compare} Walker v. United Parcel Serv., 240 F.3d 1268, 1274 (10th Cir. 2001) (finding that early right-to-sue letters do not preclude the filing of a lawsuit), \textit{and} Brown v. Puget Sound Elec. Apprenticeship & Training Trust, 732 F.2d 726, 729 (9th Cir. 1984) (suit before expiration of the 180-period is valid), with Martini v. Fed. Nat’l Mortgage Ass’n, 178 F.3d 1336, 1347 (D.C. Cir. 1999) (holding that suits filed based on an early right-to-sue letters are untimely).


\textsuperscript{308} \textit{Id.}


the status of an employee in light of genetic information. Illustrations of potential conflicts and hypothetical cases of discrimination with adverse impacts could help employers structure their actions to utilize genetic testing in certain situations without risking GINA violations. Additionally, these regulations should outline proper collection and separation procedures for employers and for those who handle this information. Individual training for discerning between medical and genetic information—especially because of the difficulty in elucidating a distinction—would be an expensive additional cost; regulations that establish what standards render effective compliance with Title II would help employers accurately implement these new guidelines.

Although a more drastic solution, Title I could be amended to allow insurers to establish reinsurance pools to help cover the costs of insuring high-risk policyholders. If this is allowed, risk assessment and allocation could take genetic testing into account. This would allow actuarial analysis to incorporate genetic testing for accuracy. By the formation of reinsurance pools, health insurance premiums for those with higher risks would only increase in proportion to the division of the insurer's reinsurance premium among the members of the pool. Although this would help to assist in the transition that is occurring in the health care industry with the rise of genetics, it would also require a practical repeal of Title I.

Probably the most realistic consideration would be the addition of a sunset provision to the GINA. A sunset provision requires the reenactment of the laws to which it attaches after a certain period of time has passed. Particularly, because of the lack of extensive evidence regarding genetic discrimination in the employment sector and the mainly anecdotal evidence of genetic discrimination by health insurers, such a provision would make sense. In fact, section 208 already contains the inverse workings of such a provision by creating a commission to assess the potential need of allowing a cause of action for genetic discrimination based on disparate impact. By adding a sunset provision, legislators would be required to reevaluate the law to see if genetic discrimination is actually occurring in the insurance sector or whether employers are using genetic information to discriminate against employees. Furthermore, as the field of genetics progresses, coming back and looking at the definitions of genetic information and genetic testing that are now in force will give legislators an opportunity to revise these definitions to align with newer developments.

311. A sunset law is defined as "[a] statute under which a governmental agency or program automatically terminates at the end of a fixed period unless it is formally renewed." Black's Law Dictionary 1478 (8th ed. 1999).
V. CONCLUSION

GINA, while not without rough edges, provides for the use of genetic information in a way that will hopefully help establish a new and more individualized approach to diagnosis and treatment of disease. But because of its recent enactment, the consequences of its application have yet to be tested. Before its use, clarification of standards and an analysis of its potential adverse impact should be assessed to determine if refinement or qualification is needed. These regulations can address some of the concerns of employers by creating breathing room and could help to prevent frivolous litigation. Additionally, extensive research regarding the impact of restrictions on genetic information and the popular response to GINA should be reevaluated after this legislation has been in place for ample time to allow protections where needed. There need to be restrictions against the use of genetic information in a way that will unfairly deprive people of the ability to receive appropriate care if genetic conditions manifest. We should continue, however, to remain vigilant and ensure that such restrictions actually protect individuals where protection is needed and do not merely hamper the systems that attempt to help.

Michael S. Blackwell