



DATE DOWNLOADED: Wed May 6 12:39:05 2020

SOURCE: Content Downloaded from [HeinOnline](https://heinonline.org)

Citations:

Bluebook 20th ed.

Perry W. Jr. Payne, Genetic Information Nondiscrimination Act of 2008: The Federal Answer for Genetic Discrimination, 5 J. Health & Biomedical L. 33 (2009).

ALWD 6th ed.

Perry W. Jr. Payne, Genetic Information Nondiscrimination Act of 2008: The Federal Answer for Genetic Discrimination, 5 J. Health & Biomedical L. 33 (2009).

APA 6th ed.

Payne, P. (2009). Genetic information nondiscrimination act of 2008: The federal answer for genetic discrimination. Journal of Health & Biomedical Law, 5(1), 33-64.

Chicago 7th ed.

Perry W. Jr. Payne, "Genetic Information Nondiscrimination Act of 2008: The Federal Answer for Genetic Discrimination," Journal of Health & Biomedical Law 5, no. 1 (2009): 33-64

McGill Guide 9th ed.

Perry W Jr Payne, "Genetic Information Nondiscrimination Act of 2008: The Federal Answer for Genetic Discrimination" (2009) 5:1 J of Health & Biomedical L 33.

MLA 8th ed.

Payne, Perry W. Jr. "Genetic Information Nondiscrimination Act of 2008: The Federal Answer for Genetic Discrimination." Journal of Health & Biomedical Law, vol. 5, no. 1, 2009, p. 33-64. HeinOnline.

OSCOLA 4th ed.

Perry W Jr Payne, 'Genetic Information Nondiscrimination Act of 2008: The Federal Answer for Genetic Discrimination' (2009) 5 J Health & Biomedical L 33

Provided by:

The Moakley Law Library at Suffolk University Law School

-- Your use of this HeinOnline PDF indicates your acceptance of HeinOnline's Terms and Conditions of the license agreement available at

<https://heinonline.org/HOL/License>

-- The search text of this PDF is generated from uncorrected OCR text.

-- To obtain permission to use this article beyond the scope of your license, please use:

[Copyright Information](#)

Genetic Information Nondiscrimination Act of 2008: The Federal Answer for Genetic Discrimination

Perry W. Payne, Jr., MD/JD/MPP¹

I. Introduction

In the nation's capital sits a man-made inlet to the Potomac River known as the Tidal Basin. On the banks of this small body of water rests the Thomas Jefferson Memorial. Words from the third President adorn the walls of the memorial and seem to emanate from the mind of the large statue of Jefferson situated in the circle of walls. On one of the walls is a quote from Jefferson which captures the challenge of drafting meaningful legislation in the consistently changing, technology driven world of today. Jefferson, in a letter to historian Samuel Kercheval, writes, "I am certainly not an advocate for frequent and untried changes in laws and constitutions. . . I know also that laws and institutions must go hand in hand with the progress of the human mind. As that becomes more developed, more enlightened, as new discoveries are made, new truths disclosed, and manners and opinions change with the change of circumstances, institutions must advance also, and *keep pace with the times*."² This oft cited quote represents the ongoing challenge which consensus based, inherently inefficient and overburdened state and federal governments face as they attempt to prevent the venture capital sponsored and highly efficient genetic technology industry from harming humanity as it seeks to unravel the puzzles of human life.

Today, the concept of DNA is well known to most Americans. Television shows, such as CSI (and all its derivatives), and the movie, GATTACA, popularized the

¹ Assistant Research Professor, The George Washington University School of Public Health and Health Services. Dr. Payne has received research support from National Heart Lung and Blood Institute, National Institutes of Health, Grant No. 1K12HL090020-01.

² Letter from Thomas Jefferson to Samuel Kercheval (July 12, 1816), in PORTABLE JEFFERSON, at 559; Letter available at <http://www.teachingamericanhistory.org/library/index.asp?document=459> (last visited on Nov. 7, 2008) (emphasis added).

idea that a complex substance known as deoxyribonucleic acid serves as the “blueprint” of humans. Indeed, DNA is found in all cells of the human body and serves as the template which leads to the creation of every aspect of our body. The power of this acid lies in its ability to be passed from one human to another in a fairly conserved manner, such that the DNA in parents affects that of the children. As a result, DNA is one factor which can impact a person’s future. If a parent has a particular disease, then the possibility of a child having the disease may increase. In contrast, if a person lives for ninety years, the child may have the potential to live for ninety years. The best and worst aspects of one’s heredity may be passed on to the next generation via DNA. This predictive power of DNA is not absolute since the environment modifies human life in each generation, but DNA can provide some indication of the future of individuals and those related to them.

The predictive power of DNA creates the potential for harmful societal effects. Genetic tests which analyze the presence of certain DNA characteristics (i.e. genetic markers associated with particular diseases) can identify the risk that a person has for a particular disease, whether a person will respond positively or negatively to a drug, or the potential to pass on a trait for a disease to a child. These tests are used to harness the predictive power of DNA and hopefully improve human health. However, because of the predictive power of DNA, the potential to use genetic tests and genetic information for harmful purposes exists. Because of this potential, the need for a government response to genetic technologies which seek to mine the power of DNA exists. Citizens are worried about the misuse of this information in various areas of life including employment and insurance, particularly health insurance.

After thirteen years of proposed bills, lobbying, and debates, the Genetic Information Nondiscrimination Act (GINA) was enacted on May 21, 2008 as an effort to prevent the harmful uses of information that spring from DNA.³ GINA was created to prohibit the discriminatory use of genetic information by health insurance companies and employers. Although this Act appears to be the federal answer to the problem of genetic discrimination, it is only a landmark in what will continue to be a challenging and potentially life altering concern – the inappropriate use of genetic information.

This article provides an overview of GINA’s protections, limitations, and potential future impact. Section II focuses on the definition of genetic information which is essential for defining what GINA protects. Section III explores the case for

³ M. Allison, *Industry Welcomes Genetic Information Nondiscrimination Act*, 26 NATURE BIOTECHNOLOGY 596, 596 (2008).

and against legislation to prohibit discriminatory use of genetic information. Section IV reviews current state legislative approaches to prohibiting the misuse of genetic information with regard to health insurance and employment as well as maintaining the privacy of this information. Section V discusses the development of the federal legislative approach to protecting genetic information and the actual protections that GINA provides and how these protections should be enforced. Section VI covers the limitations of GINA. Section VII focuses on how GINA impacts state laws. Section VIII concludes with an outlook on the future impact of GINA. Section IX concludes the article and discusses the way forward.

II. Defining Genetic Information and its Significance

A. Definition of Genetic Information

Although the genetic technology is rapidly evolving, the concept of genetic information is not an innovation. For decades, physicians have used either written or oral family medical histories of their patients in order to determine what diseases their relatives have died or suffered from. This information was genetic information being conveyed as family medical history. It aided physicians in figuring out which ailments a patient would likely have in the future just as genetic information using more sophisticated means does today. However, genetic information is much more than a family medical history of disease today. Instead, genetic information may determine the risk for diseases of various types – rare and common – which may or may not be present in any family members. Genetic information may also predict other information about the human body – such as the type of cancer an individual has and whether a person is likely to have a severe reaction to a drug. For legislative purposes, the definition of genetic information provides the basis for understanding what a law, such as GINA, that prevents the misuse of genetic information, will protect. If the definition of genetic information is limited to family medical history, then a law would only protect information about a person's family and not about the actual person. If genetic information focused only on genetic information about a person, then the law would miss the fact that genetic tests of one individual can reveal information about his or her relatives. Hence, the definition of genetic information which is most useful for legislation is one which includes protections for a person and his/her family members which is the common definition used by state legislative bodies.⁴

⁴ Mark A. Rothstein, *Keeping Your Genes Private*, SCIENTIFIC AMERICAN, Sept. 2008, at 64, 65.

B. Significance of Genetic Information

Although the predictive power of genetic information is recognized, whether genetic information is significant or unique as compared to other forms of health information is a point of contention for scholars.⁵ Indeed, genetic information seems unique in that it links people to one another unlike most medical tests – such as measuring a person's blood pressure or the level of iron in a person's blood. However, some scholars argue that other medical tests, such as tests that measure cholesterol, also provide predictive information about disease and potentially information about a person's family. These scholars argue that genetic information should be treated the same as other forms of private health information and protected appropriately. They see no reason for special protections for genetic information. This debate appears moot among the public as they continue to be concerned about the use of their genetic information and not as concerned about information that comes from other medical tests. Hence, the key opinion in this area appears to be the public who are likely to use genetic tests and find the information unique and deserving of unique protections. Indeed, with the growing possibility of genetic technologies that are likely to reveal all of a person's genetic traits (genome) for an affordable price, the significance of this information becomes greater each day.

C. A Caveat Regarding Genetic Conditions

Genetic condition is also a difficult term to define. As more genetic discoveries occur, the growing consensus among researchers is that genetic factors exist for most diseases.⁶ In fact, most diseases have genetic and non-genetic factors which contribute to how severe the diseases are. So, the idea that genetic information alone is predictive of a genetic disorder is not true today. Genetic information is predictive of disease generally. Hence any protections for genetic information are likely to protect people who have any type of disease, as long as a genetic test is developed for the disease. For this reason, the definition of genetic information cannot be limited to genetic diseases alone.

⁵ See generally Deborah Hellman, *What Makes Genetic Discrimination Exceptional?*, 29 AM. J.L. & MED. 77 (2003); Jennifer S. Geetter, *Coding for Change: The Power of the Human Genome to Transform the American Health Insurance System*, 28 AM. J.L. & MED. 1 (2002); Sonia M. Suter, *The Allure and Peril of Genetics Exceptionalism: Do We Need Special Genetics Legislation?*, 79 WASH. U. L.Q. 669 (2001).

⁶ Rothstein, *supra* note 4, at 64-65.

III. The Case For and Against Laws to Prohibit the Discriminatory Use of Genetic Information

The decision to develop legislation to prohibit inappropriate use of genetic information has not been a unanimous one. State and federal policymakers have debated for years about whether such legislation is necessary. This debate is important because inappropriately designed legislation could lead to more problems than benefits for citizens. This section will review the existing arguments for and against legislation in this area.

A. Everyone is at Risk for Genetic Discrimination

One line of rationale used to support genetic information nondiscrimination legislation is that all humans are at risk of being discriminated against because they all possess genes that predispose them to some medical problem which could increase their health related expenditures. Louise Slaughter, the member of Congress who has promoted this legislation longer than any other member of Congress, indicated in a recent article that “all humans are genetically predisposed to between 5 and 50 serious disorders.”⁷ Further, she states, this means that “every person is at risk for genetic discrimination.”⁸ Francis Collins, the former director of the National Institutes of Health National Human Genome Research Institute reiterates this point by remarking that each person has dozens of genetic variations which put him or her at risk and “we all would have had a reason to be concerned about the possible misuse of genetic information.”⁹ No studies are used to back up this argument, only probabilistic statements regarding how much genetic risk for disease exists in society. One counterargument to this rationale for legislation is that, while everyone has some level of risk, the level of risk may vary. Some individuals have risk for diseases that are more costly to society than others. This differential risk information is at the heart of how insurance companies do businesses and should be preserved in order for them to prosper. Another counterargument is that environmental factors modify genetic risk, so that one who has a risk for heart disease, may be able to engage in dietary changes that lower risk. Hence, having information that the person is at risk is not a guarantee that

⁷ Louise M. Slaughter, *The Genetic Information Nondiscrimination Act: Why Your Personal Genetics are Still Vulnerable to Discrimination*, 88(4) SURGICAL CLINICS OF NORTH AMERICA Aug. 2008, at 723, 725.

⁸ *Id.*

⁹ Hank Greely & Francis S. Collins, *Genetic Information Gains Federal Bias Protection* (2008), http://insurancenewsnet.com/article.asp?n=1&neID=200806013000.1_a58c0036a6ee057a (last visited Jan. 26, 2009).

he or she will have a disease. For anyone to use this information with the idea that it is an absolute determinant of the future would be incorrect. Perhaps instead of legislation, one could argue that there is a need for educating insurance companies, employers, and other key targets of such legislation about what genetic risk actually means.

B. Fear of Discrimination Prevents the Use of Genetic Testing

Another argument used to support genetic information nondiscrimination legislation is that scientific progress is being slowed because research participants are fearful of what will happen with their genetic test results. In addition, patients not involved in research are also less likely to have genetic tests performed because of fears that the information will be misused. As a result, the genetic research enterprise is being slowed down and patients are not reaping the benefits that genetic testing can offer. Thus, legislation should be created to quell these fears. While this may sound like a strange reason to legislate, the power of fear can not be underestimated. Legislation often takes place in order to deal with fears that people may lose their jobs, the economy may worsen, or that the threat of diseases, such as pandemic flu, may impact our lives. Thus, fear may be a good reason to legislate. However, the fear should not be irrational. In the case of genetic discrimination, evidence is actually used to support the existence of the fear and its impact. A study of hereditary non-polyposis colon cancer in the late 1990's demonstrated that when people from families known to have genetic risk factors for this deadly disease were asked to undergo genetic testing, 39% of them declined and cited fears about the misuse of the genetic information by insurance companies as the reason.¹⁰ Authors of the study argued that these fears prevented people from receiving the benefits of the tests and that legal protection was needed to address these fears.¹¹ Another study demonstrated that 108 of 159 genetic counselors who sought genetic testing did not submit claims to their insurance company because of fears that the information would be used to discriminate against them.¹² Twenty-five percent indicated that they would use a fake name when seeking the test in order to decrease the chances of breaches of confidentiality.¹³ A poll of Americans by Cogent Research also revealed that 65% of people were concerned about inappropriate use of this information by insurance companies and 54% were concerned about their employers accessing this information in an unauthorized manner.¹⁴ In addition, the poll revealed support for

¹⁰ Slaughter, *supra* note 7, at 725. See also Donald W. Hadley et al., *Genetic Counseling and Testing in Families with Hereditary Nonpolyposis Colorectal Cancer*, 163 ARCH INTERN MED 573, 573 (2003).

¹¹ Slaughter, *supra* note 7, at 725; Hadley et al., *supra* note 10, at 573.

¹² Slaughter, *supra* note 7, at 727.

¹³ Slaughter, *supra* note 7, at 727.

¹⁴ Slaughter, *supra* note 7, at 727; see also COGENT RESEARCH, AMERICANS' ATTITUDES TOWARDS

legislation in this area with 72% of people agreeing that federal legislation should be created to protect the privacy of genetic information and 85% believing that employers would likely discriminate against people without this legislation.¹⁵ These fears are supported by a survey by the American Management Association which indicated that a small number of employers use genetic information for employment purposes – such as “hiring, reassigning, retaining, or dismissing employees.”¹⁶ Among the employers using the information for these purposes, 1% of them use sickle cell anemia information, 0.8% used Huntington’s disease information, and 5.5% used family history information which as stated above can be considered genetic information.¹⁷

Numerous anecdotes exist regarding the fears patients have. One article refers to a law firm partner whose mother died from ovarian cancer and, as a result, he knew that his risk for cancer might be higher. However, he was awaiting for the passing of legislation in this area before getting a genetic test because of fears that the information could be misused by a health insurance company.¹⁸ A woman from North Carolina was terminated from her job after having a genetic test indicating she was at risk for a lung disorder, although she was healthy at the time.¹⁹ During Congressional hearings on this issue, researchers also cited numerous anecdotes about patients from various backgrounds who indicate that they have been discriminated against or that they are fearful of testing because of the possibility of discrimination. Individuals also provide their own stories of genetic discrimination.²⁰

One counterargument to this data is that people may have various reasons for not seeking genetic tests or worrying about their privacy – such as psychological concern or concern about family members’ responses. They may simply indicate discrimination on surveys because it is an easy response to give.²¹ For research participants to say that the genetic test might result in a divorce would likely be a tougher answer for them to

GENETIC DISCRIMINATION, 3–4 (2006).

¹⁵ Slaughter, *supra* note 7 at 727; see also COGENT RESEARCH, AMERICANS’ ATTITUDES TOWARDS GENETIC DISCRIMINATION, 3–4 (2006).

¹⁶ Slaughter, *supra* note 7 at 725. See also ERIN D. WILLIAMS ET AL., CONGRESSIONAL RESEARCH SERVICE REPORT, *Genetic Discrimination: Overview of the Issue and Proposed Legislation* 10 (updated March 7, 2007).

¹⁷ Slaughter, *supra* note 7 at 725. See also ERIN D. WILLIAMS ET AL., CONGRESSIONAL RESEARCH SERVICE REPORT, *Genetic Discrimination: Overview of the Issue and Proposed Legislation* 10 (updated March 7, 2007).

¹⁸ Allison, *supra* note 3, at 597.

¹⁹ Slaughter, *supra* note 7, at 725.

²⁰ WILLIAMS ET AL., *supra* note 16.

²¹ Greely & Collins, *supra* note 9.

give. Alternatively, they may not be asked questions of this nature in existing surveys. Another counterargument is that such fears should not drive the creation of legislation that could have great implications for how the insurance industry assesses risk and whether employers are able to hire the best employees for their companies. This concern seems more of an issue in the age where larger insurers, like AIG, are struggling to survive and unemployment is skyrocketing. Perhaps such legislation provides an extra strain on these businesses that may push them away from the United States into countries with less stringent regulation.

Another counterargument is that these fears are unwarranted because of the “ambiguous meaning of most genetic tests.”²² Because these tests simply provide some probability that a person may have a disease, they are usually not deterministic or reliable for predicting illness, and as such the fear of them being misused is irrational. Insurance companies cannot misuse them if they are not consistent and reliable sources of information which can actually help determine whether or not a person will have a disease, and thereby raise the costs of their health care. For this reason, legislation in this area has been deemed as being ahead of its time or being created before a real problem exists.²³

C. Past Cases of Genetic Discrimination Support New Laws

Another source of support for genetic information nondiscrimination legislation is the existence of documented cases of genetic discrimination. In many ways, genetic discrimination is an old problem with roots in the discrimination individuals with sickle cell disease faced in the 1970s.²⁴ These individuals faced discrimination in various areas of life, including education, employment and health insurance. Beyond this historical genetic discrimination, there are more recent cases. In 1998, Lawrence Berkeley National Laboratory performed sickle cell, syphilis, and pregnancy tests on primarily African American and Latino workers without their consent.²⁵ The genetic testing issue in this case was sickle cell disease, mimicking the discrimination of the past. In 2000, Burlington Northern Santa Fe Railroad also performed genetic tests on employees without their consent. One employee who refused to undergo the testing was threatened with termination of his employment. This case of genetic discrimination was

²² George J. Annas, Patricia Roche, Robert C. Green, *GINA, Genism, and Civil Rights*, 22 (7) *BIOETHICS* ii, ii (Sep. 2008).

²³ *Id.*

²⁴ Greely & Collins, *supra* note 9.

²⁵ Slaughter, *supra* note 7, at 725.

settled in April 2001, for \$2.2 million.²⁶ An Australian study also supports the notion that genetic discrimination exists. A study conducted from 1998 to 2003 regarding genetic testing before individuals had symptoms of disease indicated that 10% of 951 individuals who had genetic testing performed receive negative treatment. Of these individuals, the negative treatment came from different sources with the most from life insurance (42% of the people) and health related sources (20%). Five percent experienced negative treatment from employers. In addition, only 15% of the individuals knew to whom they should complain when treated negatively because of genetic information.²⁷

Despite these actual cases of discrimination and in some cases genetic discrimination litigation, opponents argue that the legislation is misplaced. One argues that there is “virtually no evidence of genetic discrimination in the insurance market” even though most of the legislation in this area focuses on health insurance or entities that pay for health insurance – namely employers.²⁸ This scholar indicates that the lack of discrimination by insurance companies is due to the fact that the majority of Americans have health insurance not subject to “traditional underwriting practices” or assessment of risk at the individual level.²⁹ Most Americans have group health insurance where rates are set based upon a larger group of people, decreasing the chance of an individual being discriminated against. However, even with these critiques of legislation, one opponent notes that legislation could lay any unrealistic fears to rest that people have and make them more comfortable with the idea of seeking genetic testing.³⁰

D. Industry Supports Legislation

Whether the existing evidence supports the need for legislation or not, companies developing genetic technologies are interested in this legislation. Companies, similar to genetic researchers, see genetic information nondiscrimination legislation as critical to their business model. One article in a reputable scientific journal is entitled, “Industry Welcome Genetic Information Nondiscrimination Act” which signals the

²⁶ *Id.*

²⁷ S. Taylor et al., *Investigating Genetic Discrimination in Australia: A Large-Scale Survey of Clinical Genetics Clients*, 74 CLINICAL GENETICS 20, 20 (July 2008).

²⁸ Louis P. Garrison et al., *A Review of Public Policy Issues in Promoting the Development and Commercialization of Pharmacogenomic Applications: Challenges and Implications*, 40(2) DRUG METABOLISM REVIEWS 377, 395 (May 2008).

²⁹ *Id.*

³⁰ Greely, *supra* note 9.

clear support of the private biotechnology sector.³¹ Indeed, if legislation in this area can comfort those who seek the testing, then these individuals are more likely to purchase tests which will enhance the profits of these companies. Also, as commercial genetic testing continues to grow, alleviating the possibility of discrimination is important for stimulating the growth of this industry.

IV. State Protection Against Genetic Information Discrimination

The arguments for genetic information nondiscrimination laws have led states to take on this issue by developing their own standards in the midst of no federal standards. As a result, multiple states have protections against the inappropriate use of genetic information. These various state protections are best captured by data collected by the National Conference of States Legislatures. **Chart 1** is a modification of information collected by NCSL for each state. The degree of protection varies among states but their similar focus on use of this information by employers and health insurers as well as maintaining the privacy of this information points to similar concerns among citizens throughout the country.

³¹ Allison, *supra* note 3, at 596.

CHART 1 – State Genetic Nondiscrimination Protections³²

Protection	Number of States
HEALTH INSURANCE	
Prohibits discrimination in the individual health insurance market	43
Prohibits discrimination in the group health insurance market	45
May not establish rules for insurance eligibility based on genetic information	44
Insurer may not require genetic testing	26
Insurer may not use genetic information for risk selection or risk classification	42
Insurer may not disclose information without informed consent of insured	26
Insurers license can be revoked or suspended for genetic discrimination	21
A private right of action exists for the person being discriminated against	8
Regulatory penalties are authorized	22
Civil liability, criminal penalties, or administrative fines	38

³² National Conference of State Legislatures, Health Insurance Information, *available at* <http://www.ncsl.org/programs/health/genetics/ndishlth.htm> (last visited Jan. 27, 2009); National Conference of State Legislatures, Health Insurance Enforcement Information, *available at* <http://www.ncsl.org/programs/health/genetics/healthinsenforce.htm> (last visited Jan. 27, 2009).

EMPLOYMENT³³

Genetic information cannot be used in hiring, firing, and/or terms, conditions, or privileges of employment	35
Employer cannot <i>request</i> that employee have genetic test performed	18
Employer cannot <i>require</i> that employee have genetic test performed	25
Employer cannot perform genetic test	16
Employer cannot obtain genetic information or genetic test result	11
Penalties for genetic discrimination in employment	14

PRIVACY³⁴

Personal access to genetic information required	4
Person must consent to genetic test being performed or required	12
Person's consent required to obtain or access their genetic information	7
Person's consent required to retain genetic information	8
Person's consent required to disclose genetic information	27
Genetic information defined as personal property	5
DNA samples defined as personal property	1
Specific penalties existing for genetic privacy violations	19

³³ National Conference of State Legislatures, Employment information, *available at* <http://www.ncsl.org/programs/health/genetics/ndiscrim.htm> (last visited Jan. 27, 2009).

³⁴ National Conference of State Legislatures, Privacy information, *available at* <http://www.ncsl.org/programs/health/genetics/prt.htm> (last visited Jan. 21, 2009).

V. Towards Federal Protection Against Genetic Information Discrimination by Health Insurers and Employers

A. The History of Federal Genetic Information Nondiscrimination Protection

The evidence for legislation in this area bolstered state approaches to prevent misuse of genetic information. In addition, there have been efforts at the federal level to prevent such discrimination prior to GINA. In 1995, the Equal Employment Opportunity Commission (EEOC) provided guidance regarding whether genetic information can be used as an indication of disability under the Americans with Disabilities Act of 1990.³⁵ According to the EEOC, an employer that discriminates on the basis of genetic information is treating an individual as having an impairment, so the person would be covered by the ADA. However, whether this interpretation is supported by courts is not clear, because there is no case law in this area yet. The Health Insurance Portability and Accountability Act of 1996 (HIPAA) also provides protections against genetic discrimination. HIPAA addresses genetic discrimination directly. It prohibits group health plans from using genetic information to adjust premiums, limit someone's eligibility for insurance, or deny a person insurance coverage. HIPAA does not apply to the individual insurance market. HIPAA also clearly indicates that genetic information cannot be used to designate someone as having a preexisting condition and thereby excluding them from receiving coverage for a certain period of time.³⁶ Even with the HIPAA protections, employers are not forced to offer health coverage to employees, so an employer could stop offering coverage as a result of genetic information about workers. HIPAA also makes health information confidential and genetic information appears to be protected under the relevant provisions. Protection from genetic discrimination also exists for federal employees. An executive order by President Clinton prohibits the use of genetic information for federal employment decisions (hiring, firing, promotion, etc.).³⁷

³⁵ The U.S. Equal Employment Opportunity Commission, §902, *available at* <http://www.eeoc.gov/policy/docs/902cm.html> (last visited Jan. 21, 2009) (defining term disability).

³⁶ U.S. DEPT. HEALTH & HUMAN SERVICES, HEALTH INFORMATION PRIVACY, *available at* <http://www.hhs.gov/ocr/privacy/index.html> (last visited Feb. 20, 2009).

³⁷ Exec. Order No. 13,145, (Feb. 8, 2000), *available at* http://www.opm.gov/pressrel/2000/genetic_eo.htm (last visited Feb. 20, 2009).

B. Terminology – Genetic Information and Genetic Testing

As stated above, the definition of genetic information is fundamental for determining the kind of protections that are created by genetic nondiscrimination legislation. GINA provides a comprehensive view of genetic information. Genetic information is defined, with respect to an individual, as information about the individual's genetic tests, genetic tests of family members of the individual, and manifestation of a disease or disorder in family members of the individual.³⁸ Also, any request for, or receipt of genetic services and participation in clinical research by an individual or family member is included in the definition of genetic information. Sex and age are not considered genetic information. Genetic services are defined as genetic testing, genetic counseling, and genetic education. Genetic testing is defined broadly as "analysis of human DNA, Ribonucleic Acid (RNA), chromosomes, proteins, or metabolites, that detect genotypes, mutations, or chromosomal changes."³⁹ GINA also excludes certain types of tests analyzing proteins or metabolites that "do not detect genotypes, mutations, or chromosomal changes" or analysis that "is directly related to a manifested disease" that could be reasonably detected by a health care professional.⁴⁰ These definitions form the core of GINA and determine the breadth of its protections.

C. GINA's Protections

The passage of GINA on May 21, 2008 signaled a new era in genetic information nondiscrimination legislation. This era was well supported by Congress with the Senate passing GINA unanimously (95-0) and the House passing it with overwhelming support (414-1). The bill creates a federal minimum standard for health insurance companies and employers to follow. Although the standard was supported as a way to decrease confusion with regard to the various state laws, GINA does not preempt state laws that offer more protections. Hence the protections are only a starting point for those who must comply with them. Health insurers and employers must still review state laws and comply with them.

The purpose of GINA is simply "to prohibit discrimination on the basis of genetic information with respect to health insurance and employment."⁴¹ GINA

³⁸ Genetic Information Nondiscrimination Act of 2008 (GINA), Pub. L. No. 110-233, §101(d), 122 Stat 881, 884-85 (2007).

³⁹ *Id.*

⁴⁰ *Id.*

⁴¹ Genetic Information Nondiscrimination Act of 2008 (GINA), Pub. L. No. 110-233, 122 Stat 881, 881 (2007).

modifies a number of existing laws that relate to health insurance and coverage under employee health benefit plans and employment laws, including the Employee Retirement Income Security Act of 1974, the Public Health Service Act, the Internal Revenue Code of 1986, Title XVIII of the Social Security Act, and the Health Insurance Portability and Accountability Act of 1996. GINA is administered by the U.S. Departments of Health and Human Services, Treasury, and Labor. Title I of GINA focuses on health insurance and Title II of GINA deals with employers.

1. Health Insurance

a. Protections and Enforcement

GINA offers protection against genetic discrimination in the group and individual health insurance markets. Also, genetic discrimination is prohibited for Medicare supplemental policies. GINA clearly states that HIPAA privacy laws for health information include genetic information.

i. Group Insurance Market Protections.

Section 101 of GINA has provisions that focus on group health plans and health insurance issuers offering group health insurance in connection with a group health plan. These entities will be collectively referred to as “group health insurers” for the rest of the article. GINA prohibits group health insurers from adjusting premiums or contribution amounts for the *group* covered under their plans on the basis of genetic information.⁴² Prior to GINA, there was a ban on adjusting premiums and contribution amounts for *individuals* based on genetic information. GINA expands this protection. This protection does not limit the ability of a group health insurer to increase premiums for an employer based on the manifestation of a disease or disorder of an individual enrolled in a health plan.⁴³ However, the manifestation of a disease in an individual cannot be used as genetic information about other group members and thereby increase the premium of the employer.⁴⁴ For example, a group health insurer cannot use the manifestation of Alzheimer’s disease in an employee as genetic information about the employee’s family member who does not visibly have the illness, and increase the employer’s premium as a result of the potential future costs of the disease. GINA prohibits this.

⁴² Genetic Information Nondiscrimination Act of 2008 (GINA), Pub. L. No. 110-233, §101(a)(2), 122 Stat 881, 883 (2007).

⁴³ *Id.*

⁴⁴ *Id.*

With regard to genetic testing, group health insurers are prohibited from requesting or requiring an individual or his or her family member to undergo a genetic test.⁴⁵ There are exceptions to this rule. The first exception is that a health professional providing health care services to an individual can request the person to undergo a test.⁴⁶ This exception encourages physicians to offer genetic testing as part of their regular practice without the fear of violating GINA. Of course, an individual can still refuse to be tested under this circumstance. Another exception is for group health insurers. They can obtain and use the results of a genetic test to make a determination regarding payment.⁴⁷ This allows group health insurers to make sure testing is done prior to paying for the testing or charging an individual a certain amount for the testing without the fear of violating GINA. For this exception, there is a standard for the amount of information that the group health insurers may collect. The standard is defined as the “minimum amount of information necessary to accomplish the intended purpose.”⁴⁸ A third exception to the genetic testing rule is that group health insurers may request, but not require, that a participant undergo a genetic test for the purposes of research.⁴⁹ There are five criteria for the research project which must be satisfied in order for this exception to apply. They are: 1) the request complies with state and federal laws for the protection of human subjects in research; 2) the group health insurer clearly indicates to the participant that: a) compliance with the request is voluntary; and b) if the participant does not comply there will be no effect on his or her enrollment status or premium/contribution amounts; 3) no genetic information collected or acquired during the research will be used for underwriting purposes; 4) the group health insurer must notify the Secretary of Labor in writing that this research exception is being used and describe the research project to the Secretary; and 5) comply with any other rules created by the Secretary regarding this exception.⁵⁰ This exception allows group health insurers to conduct research without the fear of violating GINA. However, this exception may offer a backdoor way for group health insurers to develop a database of information about someone and potentially use this information to look for diseases to manifest in the future. Yet, the restrictions on the exception are likely to make it an infrequently used one and also one which will not result in activity likely to harm insured individuals.

With regard to underwriting, group health insurers may not request, require, or

⁴⁵ GINA, Pub. L. No. 110-233, §101(b), 122 Stat 881, 883-85 (2007).

⁴⁶ *Id.*

⁴⁷ *Id.*

⁴⁸ *Id.*

⁴⁹ GINA, Pub. L. No. 110-233, §101(b), 122 Stat 881, 883-85 (2007).

⁵⁰ *Id.*

purchase genetic information for underwriting purposes.⁵¹ Underwriting purposes is defined broadly as: “1) rules for, or determination of, eligibility (including enrollment and continued eligibility) for benefits under the plan or coverage; 2) computation of premium or contribution amounts under the plan or coverage; 3) application of any pre-existing condition exclusion under the plan or coverage; 4) other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits.”⁵² In addition, group health insurers cannot request, require, or purchase genetic information prior to an individual’s enrollment in a plan or prior to coverage of a particular health service that the individual will receive (such as treatment of an illness that has a genetic test associated with it).⁵³ There is an incidental collection exception to this rule. If a group health insurer obtains genetic information incidental to requesting, requiring, or purchasing of some other information concerning an individual, the request, requirement, or purchase is not considered a violation of the prior enrollment provision.⁵⁴ The incidental collection exception does not apply if the information is used for underwriting purposes after the group health insurer obtains it.

For the purposes of all of these provisions, genetic information in reference to an individual or family member who is pregnant includes the fetus being carried by the pregnant woman.⁵⁵ Also, when genetic information is used in reference to an individual or family member using assisted reproductive technology, the scope of genetic information will also include any embryo legally held by the individual or family member.⁵⁶ This expanded notion of who is protected appears to provide equal protection to a fetus and embryo “post-birth humans.” This is a unique feature of GINA and may be a source of dispute in the future. This expansion of who is protected may also be quite useful in the future given such technologies as pre-implantation genetic diagnosis which allows individuals to have their embryos undergo genetic testing prior to implanting the embryos. Also, for the purposes of section 101 of GINA, the term family member includes dependents of an individual, relatives up to the fourth-degree in relationship to an individual, and relatives who are up to the fourth-degree of relationship with a dependent.⁵⁷ This definition is quite broad and could include people who are unknown to an individual. The broad protection is a clear signal to group health insurers that the protections of GINA are meant to cover any individual that may

⁵¹ *Id.*

⁵² GINA, Pub. L. No. 10-28, § 101(d).

⁵³ GINA, Pub. L. No. 10-28, §101(b).

⁵⁴ *Id.*

⁵⁵ GINA, Pub. L. No. 10-28, §101(c).

⁵⁶ *Id.*

⁵⁷ GINA, Pub. L. No. 10-28, §101(d).

be related in some way to the insured person and is likely to serve as a strong preventive measure for insurers who seek to get around GINA's protections by using family history information as genetic information. For these provisions, sex and age are not considered genetic information.⁵⁸

ii. Enforcement of Group Health Insurer Protections and Effective Date

The Secretary of Labor enforces these provisions. For group health insurers that violate GINA, a penalty of \$100 per day is imposed.⁵⁹ They receive the penalty for each insured person who is subject to the violation of GINA. The penalty is imposed during a noncompliance period which begins the date that the failure to follow GINA occurred and ends on the date that the failure is corrected. There are provisions for minimum penalties. For one or more failures with respect to an insured person, if the penalty occurs and is not corrected prior to a notice from the Secretary being sent to the group health insurer, the minimum penalty will be \$2,500.⁶⁰ If the violations are more than *de minimis* (i.e. involving multiple violations or multiple people), the minimum penalty is raised to \$15,000.⁶¹ There are limits on the penalty. There is no penalty if the group health insurer did not know and if exercising "reasonable diligence" would not have known, the failure existed.⁶² Although such a limit on the penalty does not help a person who is discriminated against, this limitation is necessary to prevent group health insurers from fearing that they will be penalized for violating GINA in situations where they were unaware that the law was being disobeyed. Essentially, a violation of GINA requires some level of knowledge. There is also no penalty if the failure to follow GINA was due to reasonable cause and not willful neglect and the failure is corrected during a thirty day period which starts the first day a group health insurer knew or would have known (if exercising reasonable diligence) that a failure existed.⁶³ If a penalty is due to reasonable cause and not willful neglect, but it is not corrected in this thirty day period, then a group health insurer will be penalized. However, the penalty is limited. The penalty will not exceed the lesser of \$500,000 or ten percent of the "aggregate amount paid or incurred by the plan sponsor during the preceding taxable year for group health plans."⁶⁴ Additionally, when the failure is due to reasonable cause and not willful neglect, the Secretary may waive part or the entire penalty if the Secretary finds that the

⁵⁸ *Id.*

⁵⁹ GINA Pub. L. No. 10-28, §101(e).

⁶⁰ *Id.*

⁶¹ *Id.*

⁶² *Id.*

⁶³ *Id.*

⁶⁴ *Id.*

payment of the penalty would be excessive relative to the failure involved.⁶⁵

The amendments become effective on January 1, 2010, which is referred to in GINA as “plan years beginning after the date that is 1 year after the date of enactment.”⁶⁶ Also, final regulations will be issued by the Secretary of Labor twelve months after the enactment of GINA (May 21, 2008).

iii. GINA Section 102(a), Section 103 and Group Health Insurers

Section 102(a) mimics section 101 except it amends the Public Health Service Act (PHSA) and section 101 amends ERISA. The same prohibitions are created in the PHSA for group health insurers. The same exceptions and definitions apply. However, in this case, the Secretary of Health and Human Services must develop regulations and enforce the provisions instead of the Secretary of Labor as in section 101. In section 103, amendments were made to the Internal Revenue Code for group health insurers which mirror those made to ERISA. However, there is a different enforcement mechanism. A tax penalty is created for group health insurers violating the Internal Revenue Code. This tax penalty mirrors the penalty existing for the other Secretaries, but it is assessed as a tax instead of a monetary penalty. This mechanism allows the money to be recuperated from group health insurers when they are not willing to pay, but have violated GINA.

iv. Individual Insurance Market Protections

Section 101(b) of GINA focuses on the individual insurance market. Health insurance issuers offering health insurance coverage in the individual market (hereinafter “individual health insurers”) are prohibited from establishing rules of eligibility for enrollment based on genetic information.⁶⁷ The rule does not prevent individual health insurers from establishing rules for eligibility or enrollment on the basis of the manifestation of a disease in an individual or covered family member.⁶⁸ Individual health insurers cannot adjust premiums or contribution amounts for an individual on the basis of genetic information regarding the individual or a covered family member. Again, this rule does not prevent the individual health insurer from adjusting premium or contribution amounts on the basis of a manifestation of a disease in the individual or a covered family member. However, in this case, the manifestation of the disease in one

⁶⁵ *Id.*

⁶⁶ GINA, Pub. L. No. 10-28, §101(f).

⁶⁷ GINA, Pub. L. No. 10-28, §102(b)(1).

⁶⁸ *Id.*

individual cannot be used as genetic information about other individuals covered under the policy. An individual health insurer may not impose a pre-existing condition exclusion on an individual on the basis of genetic information.⁶⁹ Such exclusions are often used to prevent individuals from receiving health insurance, forcing them to pay higher premiums/contribution amounts, and other actions which either increase the costs for or decrease the health care coverage available to an individual. An individual health insurer cannot request or required an individual or a family member to undergo a genetic test. There are exceptions to this rule just as there were exceptions for the group health insurers. The exceptions are the same: 1) health professional exception; 2) exception regarding determination of payment; and 3) research exception. Individual health insurers cannot request, require, or purchase genetic information, with respect to an individual, for underwriting purposes or prior to an individual's enrollment in the plan. The incidental collection which exists for group health insurers also exist for individual health insurers. Also, the concept of genetic information includes a fetus or embryo.

v. Individual Insurance Market Enforcement and Effective Date

The Secretary of Health and Human Services is given the authority to regulate companies offering individual health insurance in states through GINA in the same manner that the Secretary does in the Public Health Service Act.⁷⁰ The maximum amount of penalty imposed under the PHSA for violations of GINA is \$100 for each day for each individual that was subject to the violation.⁷¹ The previous record of compliance of the individual health insurer is taken into account by the Secretary when assessing the penalty.⁷² The penalty does not apply if the individual health insurer, exercising reasonable diligence would not have known or did not know that the failure took place. The penalty does not apply for failures corrected in thirty days which were due to reasonable cause and not willful neglect. The individual health insurer receiving the penalty has an opportunity for hearing by request after receiving notice of the failure from the Secretary. The decision resulting from the hearing is subject to judicial review and future appeal. If penalties are not paid, they are recovered by the Attorney General. Additionally, individual health insurers are also subject to the same penalties existing for group health insurers (discussed above) for violating GINA.

⁶⁹ *Id.*

⁷⁰ GINA, Pub. L. No. 10-28, §102(b)(2).

⁷¹ 42 U.S.C. §300gg-22(b)(2)(C)(i) (detailing maximum penalty imposed for violating healthcare coverage requirements).

⁷² 42 USCS §300gg-22(b)(2) (outlining the scope of enforcement procedures for healthcare coverage requirement mandated by the Act).

The effective date for these provisions are the same as the other health insurance provisions, January 1, 2010, the plan year beginning after the date which is one year after the enactment of the act.⁷³ The Secretary will issue final regulations by May 21, 2009, one year after the enactment of GINA.⁷⁴

vi. Medicare Supplemental Policy Protections

Section 104 of GINA prohibits genetic discrimination with regard to Medicare Supplemental or Medigap policies. An issuer of a Medigap policy cannot deny or condition the issuing or effectiveness of a policy on the basis of genetic information.⁷⁵ Also, an issuer of a Medigap policy cannot discriminate in the pricing of the policy based on genetic information about an individual.⁷⁶ This rule does not prevent the issuer from denying or conditioning the issuance or effectiveness of the policy or increasing the premium for an employer based on the manifestation of a disease in an individual who is covered under the policy. In addition, the rule does not prevent an issuer of a policy from increasing the premium for an individual who receives a Medigap policy on the basis of the manifestation of a disease. The manifestation of the disease cannot be used as genetic information about other group members and to further increase the premium of the employer. An issuer of a Medigap policy cannot request or required an individual or family member to undergo a genetic test.⁷⁷ The exceptions to this rule are the same as those for group health insurers. Also, an issuer of a Medigap policy cannot request, require, or purchase genetic information for underwriting purposes or prior to an individual's enrollment under the policy. For this provision, there is no mention of Medigap coverage, hence an issuer may request, require, or purchase genetic information prior to covering health services. The exception which is mentioned is the incidental collection exception which is the same as discussed above for group health insurers. These rules expand genetic information to include a fetus or embryo.⁷⁸ This rule provides consistency with the other similar provisions, but is unlikely to be used because most Medicare beneficiaries are beyond childbearing years. The effective date of the provisions is the policy year which is one year after the enactment date of GINA or

⁷³ GINA, Pub. L. No. 10-28, §102(d)(2) (codified as amended at 42 U.S.C. §2000ff-1 – 42 U.S.C. §2000ff-11) (2008) (prohibiting genetic information based discrimination in employment practices and healthcare coverage).

⁷⁴ 42 U.S.C. § 300gg-1 (2008).

⁷⁵ 42 U.S.C. §1395ss (prohibiting healthcare coverage pricing discrimination based on genetic information).

⁷⁶ *Id.*

⁷⁷ *Id.*

⁷⁸ *Id.*

January 1, 2010. Section 104 does not have a specific enforcement mechanism but instead modifies the Social Security Act to indicate that issuers of Medicare supplemental policies must comply with these provisions.⁷⁹ Section 104 also has provisions which help relevant state regulatory bodies adjust to these new rules for issuers Medigap policies. The National Association of Insurance Commissioners is tasked with created a model regulation that adjusts section 1882 of the Social Security Act to conform with the new provisions. States will not be viewed as being out of compliance with section 1882 of the Social Security Act if they do comply with these GINA provisions, until after July 1, 2009, or soon thereafter, depending on the meeting schedule of the state legislature.⁸⁰

vii. Privacy and Confidentiality Protections and Enforcement

Section 105 revises the HIPAA privacy regulation. Genetic information is treated as health information by HIPAA. The use or disclosure of protected health information that is genetic information about an individual for underwriting purposes is not permitted by a group health insurer or issuer of a Medigap policy. GINA requires these revisions to be made by notice in the Federal Register sixty days after the enactment of GINA, and the revisions become effective upon publication without opportunity for any prior public comment. The provisions related to HIPAA are enforced using HIPAA penalties.⁸¹ Final regulations for these provisions should be issued 12 months after the enactment. The amendments are effective one year after the enactment of GINA, earlier than the other provisions of Title I of GINA. The final section of Title I assures that the various Secretaries who must issue regulations for Title I work in a coordinated fashion.

2. Employment

The employment protections provided by GINA focus on every aspect of employment – hiring, firing, job assignments, promotions, and more.⁸² The protections apply to employers, unions, employment agencies, and labor-management training programs or apprenticeships. This section will review the key aspects of the statute with regard to employment.

⁷⁹ 42 U.S.C. §1395ss.

⁸⁰ *Id.*

⁸¹ 42 U.S.C. §1320d-9 (extending HIPAA protection to genetic information).

⁸² Slaughter, *supra* note 7, at 725.

a. Preventing Discriminatory Employment Practices

Section 202 details the employment practices that employers cannot conduct once GINA is effective. Employers are defined in different ways by GINA including: 1) an employer as defined by the Civil Rights Act of 1964; 2) entity employing a state employee; 3) employing office defined by the Congressional Accountability Act of 1995; 4) an employee office defined in section 411(c) of title 3, United States Code; and 5) an entity to which section 7171(a) of the Civil Rights Act of 1964 applies. Most employers, public and private, are covered by this description.⁸³ One unlawful employment practice created by GINA is failing or refusing to hire or discharging any employee or discriminating with regarding to compensation, terms, conditions, or privileges of employment on the basis of genetic information.⁸⁴ Another prohibited employment practice is using genetic information to limit, segregate, or classify employees in any way that would deprive or tend to deprive them of employment opportunities or otherwise adversely affect their employment status. Employers cannot request, require, or purchase genetic information regarding an employee or a family member of the employee. There are six exceptions to this rule.⁸⁵ The first exception is when the employer inadvertently requests or requires the family medical history of an employee or family member. The second exception applies when: 1) health or genetic services are offered by the employer including wellness programs; 2) the employee provides prior, knowing, voluntary and written authorization; 3) only the employee and a licensed health care professional received individually identifiable information; and 4) the individually identifiable information is not disclosed to the employer except as aggregate information about numerous employees devoid of the employee's identification. The third exception is when an employer requires a family medical history in order to comply with the Family and Medical Leave Act of 1993. Another exception occurs when an employer purchases documents which are commercially and publicly available and include family medical history. Another exception is when the genetic information is used for monitoring the effects of toxic substances in the workplace. This exception only applies if five criteria are met. The last exception is when employers conduct DNA analysis for law enforcement purposes as a forensic laboratory or to identify human remains and requests or requires the genetic information of an employee for quality control to detect contamination of samples. For any genetic information acquired under these exceptions, the genetic information cannot be used in a way that would violate the first two employment practice prohibitions. Employment agencies have similar prohibitions

⁸³ 42 U.S.C. 2000ff (defining the areas that the protections provided for in GINA will cover).

⁸⁴ 42 U.S.C. 2000ff-1 (outlawing genetic information employment discrimination).

⁸⁵ *Id.*

as employers which are detailed in Section 203.⁸⁶ There are two differences. There is an additional practice that is prohibited: to cause or attempt to cause an employer to discriminate against an individual. Also, the sixth exception to acquisition of genetic information (DNA analysis for law enforcement) which exists for employers does not apply to employment agencies.

Section 204 covers labor organization practices.⁸⁷ A labor organization cannot exclude or expel a person from the membership or otherwise discriminate against a member on the basis of genetic information. Labor organizations cannot limit, segregate, or classify their members or fail or refuse to refer for employment any member in any way that would deprive the person because of genetic information. The organization also cannot cause or attempt to cause an employer to discriminate against a member of the organization because of genetic information. With regard to the acquisition of genetic information, there are five exceptions to the rule that a labor organization cannot request, require or purchase genetic information with respect to a member or his or her family member. These exceptions are the same as those for employers minus the exception that focuses on DNA analysis for law enforcement. Section 205 contains prohibitions for training programs, which are the same as those for employers.

b. Confidentiality of Genetic Information

According to Section 206, if any of the employment entities above possesses genetic information about employees, the information must be maintained on separate forms in separate medical files and treated as a confidential medical record. The standard for the confidential medical records is based on the Americans With Disabilities Act.⁸⁸ These employment entities should not disclose the genetic information. There are six exceptions for when the information can be disclosed. The information can be disclosed to: 1) the employee or member of a labor organization after his or her written request; 2) to an occupational or other health researcher conducting research in compliance with federal laws governing the protection of human subjects in research; 3) courts in response to a court order as long as the information is limited to what is asked for in the court order and with notice to the employee or member of the labor organization; 4) government officials investigating GINA

⁸⁶ 42 U.S.C. §2000ff-2 (outlawing genetic information based discriminatory practices in employment agencies).

⁸⁷ 42 U.S.C. §2000ff-3 (outlawing genetic information based discriminatory practices in labor organizations).

⁸⁸ 42 U.S.C. §2000ff-5 (making genetic information confidential).

compliance; 5) comply with certification provisions of the Family and Medical Leave Act of 1993; and 6) to a public health agencies which need to survey the spread of contagious diseases as long as the person's whose information is disclosed is notified. These confidentiality rules do not affect HIPAA rules regarding disclosure of health information.

c. Enforcement and Remedies

Section 207 covers the enforcement and remedies provisions for the employment section of GINA.⁸⁹ The power, procedures, and remedies of the Civil Rights Act of 1964 are applicable to the employment provisions of GINA. The Equal Employment Opportunity Commission enforces these provisions. Similarly, the costs, fees, and damages are similarly covered by existing civil rights statutes. Special enforcement provisions are available for state employees.

d. Disparate Impact

Section 208 indicates that the disparate impact cause of action is not created by GINA. Six years after the enactment of GINA (May 21, 2014), a Commission will be established known as the Genetic Nondiscrimination Study Commission to review the science of genetics and assess whether to provide a disparate impact cause of action under GINA. Section 208 provides details on the unpaid membership of this Commission. All of the members are appointed by members of Congress. A report will be submitted to Congress by the Commission within one year after the members are appointed.

e. Construction of Title II of GINA and Regulations

Section 209 focuses on key issues regarding the scope of Title II of GINA. Section 209(a) indicates that Title II does not preempt and federal or state statutes offering equal or greater protection than GINA. GINA also does not limit the right of an individual to bring an action against one of the employment entities described above. This section also states that Title II does not apply to Armed Forces Repository of Specimen Samples for Identification of Remains. The law does not limit or expand protections that come from workers' compensation laws. Title II does not require any specific benefit for an employee or family member under any group health insurer. In

⁸⁹ 42 U.S.C. § 2000ff-6 (detailing remedies available for those who have been discriminated against based on their genetic information).

addition, Title II, like Title I, expands genetic information to include fetus and embryo for pregnant individuals or those using assisted reproductive technology respectively. Regulations will be developed one year after the enactment date of Title II of GINA. The effective date for Title II is eighteen months after the enactment of the Act, or November 30, 2009.

VI. Limitations of GINA

GINA, as with any law, has gaps in its protections. The most notable gaps are for the types of insurance which are not affected by GINA. Long term care insurance, often used for health reasons, is not covered by GINA. Disability insurance, which is clearly linked to health, is also not affected by GINA. Genetic information can still be used to raise premiums and determine eligibility for these types of insurance. Life insurance is also not covered by GINA. The core of the life insurance business model requires assessments of future risks. Therefore, legislators learned in the early years of drafting GINA that they could not prohibit the use of genetic information in this arena without disrupting the life insurance industry substantially. These important limitations may leave individuals without essential anti-discrimination protections. Thus, even in GINA's wake, insurers will be able to use genetic testing information related to chronic diseases such as Alzheimer's disease to determine eligibility for life, long term care, or disability insurance.⁹⁰ This may be an area of future federal and state legislation since some states already offer protections for long term care, disability, and life insurance. The director of the Genetics and Aging Unit at Massachusetts General Hospital in Boston notes that GINA is a first step, but "[g]uaranteed long term care, more treatments for genetically rooted diseases, and more clinically useful tests are still needed to reach the full promise of genetics."⁹¹ Another apparent limitation of GINA is that it does not apply to Medicare or Medicaid. However, these programs have eligibility standards which are inherently non-discriminatory. Eligibility for these programs is based on age, disability, income, and years working in the United States.

VII. Impact of GINA on State Laws

The health insurance provisions of GINA do not preempt state laws, but establish a federal minimum standard for states. The employment provisions of GINA preempt weaker state laws but do not modify stronger laws. The floor created by GINA

⁹⁰ Cathleen D. Zick et al. *Genetic Testing For Alzheimer's Disease And Its Impact On Insurance Purchasing Behavior*, 24 HEALTH AFFAIRS 483 (2005).

⁹¹ Allison, *supra* note 3, at 596.

does not address the industry's objection to the lack of national standards for genetic discrimination.⁹² As a result, health insurers and employers operating in multiple states will need to continue complying with state laws that place different requirements on them. Some states will clearly need to expand their protections. At least one state has already made changes to its laws as a result of GINA.⁹³ Approximately three months after the passage of GINA, Illinois revised its decade old genetic nondiscrimination laws to modernize them based on the new GINA standards. In certain areas the Illinois law appears to be more stringent by covering all employers regardless of their size and covering some civil servants not covered under GINA.⁹⁴ The Illinois law became effective January 1, 2009.⁹⁵

Given the variance in definitions of genetic information that likely exists among states, reconciling the federal law will be no small feat. In a similar effort, a recent study examined over 500 HIPAA "preemption" cases which involved the meaning of more stringent state health information privacy laws. The study found that litigation and confusion arose over how such a standard should be applied.⁹⁶ Similarly, the extent to which a state law offers safeguards that are greater or less than GINA may not be known for sure unless there is a judicial challenge.

VIII. Outlook for the Future

The passing of GINA signals the beginning of more comprehensive federal genetic information nondiscrimination protection. However, the impact of this law has yet to be felt. There are numerous implications that arise from GINA, known and unknown. This section reviews the potential ways that GINA is likely to impact society in the future and offers recommendations for dealing with these problems when relevant.

⁹² 42 U.S.C. § 2000ff-2; BUREAU OF NATIONAL AFFAIRS, *Bush Signs Measure Banning Genetic Bias in Workplace*, 59(22) BNA CATALOG, available at <http://subscript.bna.com/pic2/hr2pic.nsf/id/BNAP-7F3P5P> (last visited Feb. 22, 2009).

⁹³ CBS 2 Chicago, *State's Genetic Nondiscrimination Law Strengthened*, available at <http://cbs2chicago.com/local/genetic.nondiscrimination.law.2.805750.html> (last visited Feb. 22, 2009).

⁹⁴ *Id.*

⁹⁵ *Id.*

⁹⁶ Rosenbaum S., et al. *Does HIPAA Preemption Pose a Legal Barrier to Health Information Transparency and Interoperability?*, 16(11) BNA Health Policy Reports (Mar. 19, 2007) available at http://www.gwumc.edu/sphhs/departments/healthpolicy/chsrp/downloads/BNH_HIPAA_Privacy_Preemption_031907.pdf (last visited Feb. 22, 2009).

A. Promoting GINA

GINA creates specific challenges for the public health community, the first of which is simply informing the public of its existence and protections. GINA was passed at a time when Americans were focused on other major historic issues – namely, the war in Iraq, Presidential elections, and a declining economy. In addition, the protections offered by GINA may not be easy for citizens to understand quickly. The law concerns a genetic testing market that remains quite limited other than perhaps cancer screening and genetic testing for newborns. However, as the use of genetic testing grows, the importance of GINA will grow. In addition, the need to translate GINA for the public will grow. Public health workers, health professionals and patient advocates will need to work collaboratively to ensure that the communities they serve are clear about what protections GINA offers and does not offer. An unfortunate result of GINA could be the perception that the law prohibits discrimination by all insurers. Hence, patients and those who interact with them need to be fully informed. Employment entities also need to be made fully aware of these protections to understand how to adjust their policies appropriately. Patients participating in genetic testing for work need to be aware of what kinds of discrimination are allowed and not allowed.

B. Evaluating the Effectiveness of GINA

After the development of regulations, a key challenge will be determining how to judge the success of GINA. Successful outcomes may include an increase in the use of genetic tests deemed important for the health care of patients and research participants. The fears that led to the creation of GINA will hopefully decline as a result of this Act. Although fears are quite subjective and hard to measure, increased testing will provide some indicators of whether fears are increasing or decreasing. A decrease in the number of people who decline these tests in research studies will also be an indicator of GINA's effectiveness. In addition, there should be an increase in the number of people who participate in genetic testing clinical trials. One author indicates that GINA should help increase demand for consumer-directed genetic tests.⁹⁷ The growth of these tests will likely be an indicator of GINA's success. Whether these companies are subject to GINA's rules may be a future concern legislators will have to address as more people are drawn to having genetic tests conducted using these services.

There is some doubt as to whether GINA will actually allay fears. A survey conducted after GINA passed demonstrated that privacy is still a barrier for those

⁹⁷ Allison, *supra* note 3, at 596.

considering genetic tests.⁹⁸ Of the people surveyed most of them would share genetic test results with family and friends, but only 22% were interested in sharing this information with a research institution, 3% with a health insurer, 2% with their employer, and 1% with their prospective employer.⁹⁹

C. Opening the Door for Future Litigation

Numerous opponents of GINA stated prior to the passing of the Act that it would open a Pandora's Box of litigation. In particular the US Chamber of Commerce feared that employees would try to use any genetic test results in the possession of an employer as leverage for claims regarding negative action taken against employees. Whether this occurs remains to be seen. However, given the low level of litigation in the past, GINA is unlikely to lead to a large level of litigation unless there is an increase in the number of violations of GINA. In addition, if employees maintain a fear that employers might misuse this information, then employers may not have the opportunity to discriminate. Also, GINA protects employers from being sued for inadvertent acquisition of genetic information and requires claimants to exhaust their administrative remedies before seeking damages through lawsuits. There is also a cap on the amount of damages one can receive.¹⁰⁰ These factors make the chance of increase litigation unlikely.

D. GINA May Incentivize People to Get Genetic Testing to Avoid Health Insurance Discrimination

Ongoing discoveries are revealing genetic association with most diseases, common and rare. This makes sense given that people who have similar genetic backgrounds may have similar susceptibilities. GINA's protections "reward" people who have genetic tests performed whereas those who have a disease without any prior genetic testing are not rewarded in the same way. In the future, if most illnesses have a genetic component, the key to preventing health insurance discrimination in the group or individual market will be to get a genetic test prior to being diagnosed. Practitioners might seek to help patients by ordering genetic testing just in case. Although these statements are speculative, they demonstrate the potential changes that such a law may cause in medical practice as genetic technology grows in popularity.

⁹⁸ Annas et al., *supra* note 22, at ii.

⁹⁹ *Id.*

¹⁰⁰ Slaughter, *supra* note 7, at 725.

E. Harm to Others With Pre-existing Conditions

Because of GINA, insurance companies may no longer make use of clearly relevant information such as family history in their risk assessment. As a result, two scholars indicate that companies may rely more heavily on current health status when setting rates, even when it has only slight value in predicting future illness. In a post-GINA world, not only will the very sick have even more trouble obtaining affordable insurance, but so may individuals who are well.¹⁰¹

F. Impact of Obama-Biden Health Plan on Genetic Discrimination

The Obama-Biden health plan is focused on providing universal coverage for all Americans.¹⁰² In addition, the plan seeks to eliminate pre-existing condition limitations which are commonly imposed on people seeking insurance in the individual market. If successful, this plan is likely to remove one of the which GINA seeks to address. Hence, the Obama-Biden plan may reiterate a portion of GINA's protections.

G. Considering Stronger Protections in the Future

A number of scholars are calling for stronger protections than those provided by GINA. States provide models for these protections. In particular, protection for individuals seeking long term care insurance may need to be created in the future. As baby-boomers age, the need for long-term care insurance increases. What was once considered a luxury is now more of a necessity for an increasing number of Americans. Medicaid currently pays for most long-term care. However, with a growing baby boomer population and state budgetary challenges, other sources of support need to have a greater role. Limiting individuals' access to long term care insurance simply based on genetic tests alone seems to contradict the social need for people to have these insurance policies.

IX. Conclusion

GINA represents a definitive federal step towards prohibiting the misuse of genetic information. The law is a reflection of Congress listening to the public's fears and responding to them, even though numerous scholars and interest groups viewed

¹⁰¹ Russell Korobkin & Rahul Rajkumar, *The Genetic Information Nondiscrimination Act — A Half-Step toward Risk Sharing*, 359 NEW ENG. J. MED. 335, 336 (2008).

¹⁰² Health Care, available at <http://www.barackobama.com/issues/healthcare/> (last visited Jan. 14, 2009).

this response as too heavy handed. The impact of GINA on state laws is already beginning, yet the full impact remains to be seen. Future challenges to state laws may reveal the clear similarities and differences between GINA and the state protections. Whether GINA's enforcement mechanisms are strong enough also remains to be seen in the future. Appropriate monitoring of these concerns will be necessary going forward. Researchers and genetic technology companies will welcome GINA's protections and will likely see a financial boost as a result of this law.

GINA is not without flaws. Educating the public about GINA's limitations and the limitations of state laws will be critical for those seeking to prevent genetic discrimination. Overall, the law provides the current federal answer to genetic information nondiscrimination and opens the door for a world in which patients can lower their anxieties and fears with regard to treatments requiring genetic testing and human genetic research.

