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February 2, 2009

Congressional Research Service

Report RL34584

*The Genetic Information Nondiscrimination Act of 2008*  
(GINA)

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October 2, 2008

**Abstract.** On May 21, 2008, the Genetic Information Nondiscrimination Act of 2008 (GINA), referred to by its sponsors as the first civil rights act of the 21st century, was enacted. GINA, P.L. 110-233, prohibits discrimination based on genetic information by health insurers and employers. The sequencing of the human genome and subsequent advances raise hope for genetic therapies to cure disease, but this scientific accomplishment is not without potential problems. An employer or health insurer could decide to take adverse action based on a genetic predisposition to disease, and situations have arisen where discriminatory action based on genetic information did occur. In addition, there is evidence that the fear of genetic discrimination has an adverse effect on those seeking genetic testing, as well as on participation in genetic research. GINA was enacted to remedy this situation. This report provides background on genetic information, legal implications regarding the use of this information, and relevant laws. It also discusses the statutory provisions of GINA.

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# CRS Report for Congress

## The Genetic Information Nondiscrimination Act of 2008 (GINA)

Updated October 2, 2008

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Prepared for Members and  
Committees of Congress

# The Genetic Information Nondiscrimination Act of 2008 (GINA)

## Summary

On May 21, 2008, the Genetic Information Nondiscrimination Act of 2008 (GINA), referred to by its sponsors as the first civil rights act of the 21<sup>st</sup> century, was enacted. GINA, P.L. 110-233, prohibits discrimination based on genetic information by health insurers and employers. The sequencing of the human genome and subsequent advances raise hope for genetic therapies to cure disease, but this scientific accomplishment is not without potential problems. An employer or health insurer could decide to take adverse action based on a genetic predisposition to disease, and situations have arisen where discriminatory action based on genetic information did occur. In addition, there is evidence that the fear of genetic discrimination has an adverse effect on those seeking genetic testing, as well as on participation in genetic research. GINA was enacted to remedy this situation.

GINA is divided into two main parts: Title I, which prohibits discrimination based on genetic information by health insurers; and Title II, which prohibits discrimination in employment based on genetic information. Title I of GINA amends the Employee Retirement Income Security Act of 1974 (ERISA), the Public Health Services Act (PHSA), and the Internal Revenue Code (IRC), through the Health Insurance Portability and Accountability Act of 1996 (HIPAA), as well as the Social Security Act, to prohibit health insurers from engaging in genetic discrimination. Title II of GINA prohibits discrimination in employment because of genetic information and, with certain exceptions, prohibits an employer from requesting, requiring, or purchasing genetic information. The law prohibits the use of genetic information in employment decisions — including hiring, firing, job assignments, and promotions — by employers, unions, employment agencies, and labor-management training programs.

This report provides background on genetic information, legal implications regarding the use of this information, and relevant laws. It also discusses the statutory provisions of GINA.

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# The Genetic Information Nondiscrimination Act of 2008 (GINA)

## Introduction

On May 21, 2008, the Genetic Information Nondiscrimination Act of 2008 (GINA), referred to by its sponsors as the first civil rights act of the 21<sup>st</sup> century, was enacted. GINA, P.L. 110-233, prohibits discrimination based on genetic information by health insurers and employers.

In April 2003, the sequence of the human genome was deposited into public databases. Scientists involved in the Human Genome Project (HGP)<sup>1</sup> reported that the finished sequence consists of overlapping fragments covering 99% of the coding regions of the human genome, with an accuracy of 99.999%.<sup>2</sup> These rapid advances provide powerful tools for determining the causes of, and potentially the cures for, many common, complex diseases such as diabetes, heart disease, Parkinson's disease, bipolar disorder, and asthma.

Although the sequence information should facilitate the identification of genes underlying disease and create a foundation for the development of genetic therapies, this scientific accomplishment is not without potential problems. For instance, the presence of a specific genetic variation may indicate a predisposition to disease but does not guarantee that the disease will manifest. An employer or health insurer could decide to take adverse action based on a genetic predisposition, and situations have arisen where discriminatory action based on genetic information did occur. GINA was enacted to remedy this potential situation. This report provides background on genetic information, legal implications regarding the use of this information, and relevant laws. It also discusses the statutory provisions of GINA.

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<sup>1</sup> The Human Genome Project, begun in 1990, was a 13-year effort coordinated and funded by the U.S. Department of Energy and the National Institutes of Health to identify all of the protein-coding genes in human DNA; determine the sequence of the 3 billion chemical bases that make up human DNA; store this information in databases; develop tools for data analysis; and address the ethical, legal, and social issues (ELSI) that may arise from the project. For more detailed information see "The National Human Genome Research Institute," [<http://www.genome.gov/>], and "Human Genome Project Information," [[http://www.ornl.gov/sci/techresources/Human\\_Genome/home.shtml](http://www.ornl.gov/sci/techresources/Human_Genome/home.shtml)].

<sup>2</sup> "International Human Genome Sequencing Consortium Describes Finished Human Genome Sequence," Oct., 20, 2004, at [<http://www.genome.gov/12513430>].

## Background

### Human Genome Research

In congressional testimony, Dr. Francis Collins, the Director of the National Human Genome Research Institute, described the potential that the information generated by the HGP holds for medicine and public health.<sup>3</sup> He stated that

the human genome sequence provides foundational information that now will allow development of a comprehensive catalog of all of the genome's components, determination of the function of all human genes, and deciphering of how genes and proteins work together in pathways and networks. Completion of the human genome sequence offers a unique opportunity to understand the role of genetic factors in health and disease, and to apply that understanding rapidly to prevention, diagnosis, and treatment. This opportunity will be realized through such genomics-based approaches as identification of genes and pathways and determining how they interact with environmental factors in health and disease, more precise prediction of disease susceptibility and drug response, early detection of illness, and development of entirely new therapeutic approaches.<sup>4</sup>

As Dr. Collins stated, with completion of the human genome sequence, scientists will now focus on understanding the clinical and public health implications of the sequence information. All disease has a genetic component and, therefore, genomic research has the potential to substantially reduce the collective burden of disease in the general population. Clinical genetic tests are becoming available at a rapid rate, with 1,271 clinical genetic tests currently available.<sup>5</sup> In addition, private insurers are beginning to include some clinical genetic tests in their health insurance benefits packages as evidence of the tests' clinical validity accumulates.<sup>6</sup>

### Concerns About the Use of Genetic Information

These scientific advances in genetics, while promising, are not without potential problems. The ethical, social, and legal implications of genetic research have been the subject of significant scrutiny and a portion of the funds for the Human Genome

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<sup>3</sup> Dr. Collins is expected to be stepping down as director of the National Human Genome Research Institute in August 2008. For more information on NHGRI, please see [<http://www.genome.gov/>].

<sup>4</sup> Testimony of Francis S. Collins, director, National Human Genome Research Institute, National Institutes of Health, Before the Subcommittee on Health of the House Committee on Energy and Commerce (May 22, 2003).

<sup>5</sup> Gene Tests, available at [<http://www.genetests.org/>]. Accessed May 29, 2008.

<sup>6</sup> For more information on the status of genetic tests and further discussion of what constitutes "genetic information," see CRS Report RL33832, *Genetic Testing: Scientific Background for Policymakers*, by Amanda K. Sarata.

Project were set aside to support the analysis and research of these issues.<sup>7</sup> As scientific knowledge about genetics becomes increasingly widespread, numerous researchers and commentators, including Dr. Francis Collins, have expressed concerns about how this information will be used.<sup>8</sup> In congressional testimony, Dr. Collins stated,

while genetic information and genetic technology hold great promise for improving human health, they can also be used in ways that are fundamentally unjust. Genetic information can be used as the basis for insidious discrimination....The misuse of genetic information has the potential to be a very serious problem, both in terms of people's access to employment and health insurance and the continued ability to undertake important genetic research.<sup>9</sup>

Legal cases of genetic discrimination have been few.<sup>10</sup> However, studies have shown that public fear of discrimination is substantial and negatively influences the uptake of genetic testing and the use of genetic information by consumers and health professionals. The Secretary's Advisory Committee on Genetics, Health and Society (SACGHS) learned that 68% of Americans are concerned about who would have access to their personal genetic information; 31% state this concern would prevent them from having a genetic test; and 68% agree that insurers would do everything possible to use genetic information to deny health coverage.<sup>11</sup> A 2004 survey

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<sup>7</sup> The group working on these issues is referred to as the Ethical, Legal and Social Implications (ELSI) program. See [<http://www.genome.gov/page.cfm?pageID=10001618>].

<sup>8</sup> Testimony by Dr. Francis Collins, director, National Center for Human Genome Research, before the Senate Committee on Labor and Human Resources (Mar. 6, 1996). See also, Hudson, Rothenberg, Andrews, Kahn, and Collins, "Genetic Discrimination and Health Insurance: An Urgent Need for Reform," 270 *Science* 391 (Oct. 20, 1995); Annas, Glantz, and Roche, "Drafting the Genetic Privacy Act: Science, Policy and Practical Considerations," 23 *J. of Law, Medicine and Ethics* 360 (1995); Gostin, "Genetic Discrimination: The Use of Genetically Based Diagnostic and Prognostic Tests by Employers and Insurers," 17 *Am. J. of Law & Med.* 109 (1991); Rothstein, Mark, *Genetic Secrets: Protecting Privacy and Confidentiality in the Genetic Era* (1997).

<sup>9</sup> Testimony of Francis S. Collins, director, National Human Genome Research Institute, National Institutes of Health, before the Senate Health, Education, Labor and Pensions Committee (July 20, 2000).

<sup>10</sup> But see *Norman-Bloodsaw v. Lawrence Berkeley Laboratory*, 135 F.3d 1260 (9<sup>th</sup> Cir. 1998), where blood tests for sickle cell trait were found to give rise to a Title VII claim. See also the discussion of the Americans with Disabilities Act, *supra*, and Geller, Alper, Billings, Barash, Beckwith, and Natowicz, "Individual, Family, and Societal Dimensions of Genetic Discrimination: A Case Study Analysis," 2 *Science and Engineering Ethics* 71 (1996), which found that a number of institutions, including health and life insurance companies, health care providers, blood banks, adoption agencies, the military, and schools, were reported to have engaged in genetic discrimination against asymptomatic individuals. This study has been criticized by the insurance industry as relying on anecdotal information. See American Council of Life Insurance, "Statement Regarding the Council for Responsible Genetics 'Study' on Genetic Discrimination" (Apr. 11, 1996).

<sup>11</sup> Meeting of the Secretary's Advisory Committee on Genetics, Health, and Society, October 2005. Accessed at [<http://www4.od.nih.gov/oba/SACGHS/meetings/>]  
(continued...)

conducted by the Genetics and Public Policy Center found that 92% of Americans oppose employer access to personal genetic information and 80% oppose access to this information by health insurers.<sup>12</sup>

In addition, SACGHS as well as its predecessor committee, the Secretary's Advisory Committee on Genetic Testing (SACGT), sponsored two public forums in 2000 and 2004 to gather perspectives on genetic discrimination. Many comments were received from patients, consumers, health professionals, scientists, genetic test developers, educators, industry representatives, policymakers, lawyers, students, and others representing a wide range of diverse ethnic and racial groups.<sup>13</sup> The comments and testimony revealed several anecdotal cases of discrimination. SACGT sent the first of two letters to the Secretary of HHS urging support for nondiscrimination protections after the 2000 forum:

During consultations with the public SACGT heard from many Americans who are concerned about the misuse of genetic information by third parties, such as health insurers and employers, and the potential for discrimination based on that information. Many stated that fear of genetic discrimination would dissuade them from undergoing a genetic test or participating in genetic research studies. Others stated that they would pay out of pocket for a genetic test to prevent the results from being placed in their medical record. Such concerns are a deterrent to advances in the field of genetic testing and may limit the realization of the benefits of genetic testing.<sup>14</sup>

A joint report by the Department of Labor, the Department of Health and Human Services, the Equal Employment Opportunity Commission (EEOC), and the Department of Justice summarized the various studies on discrimination based on genetic information and argued for the enactment of federal legislation. The report stated that “genetic predisposition or conditions can lead to workplace discrimination, even in cases where workers are healthy and unlikely to develop disease or where the genetic condition has no effect on the ability to perform work” and that “because an individual’s genetic information has implications for his or her family members and future generations, misuse of genetic information could have intergenerational effects that are far broader than any individual incident of

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<sup>11</sup> (...continued)

October2005/10-20%20Public%20Attitudes%20toward%20Advances%20in%20Genetics-White.pdf].

<sup>12</sup> Testimony of Kathy Hudson, director, Genetics and Public Policy Center, before the Secretary's Advisory Committee on Genetics, Health, and Society. Accessed at [http://www4.od.nih.gov/oba/SACGHS/meetings/October2004/transcript/Hudson\_trans.pdf].

<sup>13</sup> Highlights and transcripts of Jan. 27, 2000, testimony can be found on the SACGT website at [http://www4.od.nih.gov/oba/sacgt/sacgtmtg.htm]. Transcripts of the Oct. 18, 2004, testimony can be found on the SACGHS website at [http://www4.od.nih.gov/oba/SACGHS/meetings/October2004/SACGHSOct2004postmeeting.htm].

<sup>14</sup> From a letter from SACGT to Secretary Tommy Thompson, May 3, 2001, at [http://www4.od.nih.gov/oba/sacgt/ltr\_to\_secDHHS5-3-01.pdf].



misuse.”<sup>15</sup> Concluding that existing protections are minimal, the report went on to call for the enactment of legislation.

The National Council on Disability (NCD), an independent federal agency that advises the President and Congress on issues affecting individuals with disabilities, published a position paper on March 4, 2002, arguing for the enactment of federal legislation prohibiting genetic discrimination. The NCD argued that recent advances in genetic research have brought an increasing potential for genetic discrimination, that genetic discrimination is a historical and current reality, that genetic discrimination undermines the purposes of genetic research and testing, that genetic test information has little value for purposes of making employment decisions and insurance decisions, and that existing laws are insufficient to protect individuals from genetic discrimination.<sup>16</sup>

## Federal Law Relating to Genetic Discrimination Prior to GINA

### Health Insurance Portability and Accountability Act of 1996 (HIPAA).

Title I of GINA extends the current HIPAA protections against discrimination by group health plans and issuers of health insurance in both the group and individual markets. HIPAA prohibits a group health plan or issuer of a group health plan from using genetic information to establish rules for eligibility or continued eligibility and provides that genetic information shall not be treated as a preexisting condition in the absence of the diagnosis of the condition related to such information. It also prohibits a group health plan or issuer of a group health plan from using genetic information in setting a premium contribution. These protections apply to individuals within the group plans; however, they do not apply to the acceptance of the whole group or to the premiums set for the group. Thus, HIPAA prohibits group health plans or issuers of group health plans from charging an individual a higher premium than a similarly situated individual; however, the law does not prevent an entire group from being charged more. The HIPAA nondiscrimination provisions do not apply to individual health insurance policies, and genetic information may be used to set premiums for individual policies (although HIPAA establishes both guaranteed issue for individuals who lose group coverage and guaranteed renewal for those with existing individual coverage).

HIPAA would not prohibit group health plans or issuers of plans (i.e., insurers) from requiring or requesting genetic information or testing and does not prevent them from excluding coverage for a particular condition or imposing lifetime caps on all benefits, or on specific benefits. Finally, HIPAA does not address the use of genetic information in contexts other than health insurance, such as employment.

Under the HIPAA Privacy Rule, health plans and insurers may use or disclose health information for payment and other health care operations, including

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<sup>15</sup> Department of Labor, Department of Health and Human Services, Equal Employment Opportunity Commission, Department of Justice, “Genetic Information and the Workplace,” Jan. 20, 1998, [<http://www.dol.gov/oasam/programs/history/herman/reports/genetics.htm>].

<sup>16</sup> National Council on Disability, “Position Paper on Genetic Discrimination Legislation” [[http://www.ncd.gov/newsroom/publications/2002/geneticdiscrimination\\_principles.htm](http://www.ncd.gov/newsroom/publications/2002/geneticdiscrimination_principles.htm)].

underwriting, premium rating, and other activities related to the creation, renewal, or replacement of an insurance contract.

**Americans with Disabilities Act.** The Americans with Disabilities Act (ADA)<sup>17</sup> prohibits discrimination against an individual with a disability in employment, public services, public accommodations, and communications. The threshold issue in any ADA case is whether the individual alleging discrimination is an individual with a disability. The act defines the term disability with respect to an individual as having “(A) a physical or mental impairment that substantially limits one or more of the major life activities of such individual; (B) a record of such an impairment; or (C) being regarded as having such an impairment.”<sup>18</sup> Although the statutory language of the ADA does not reference genetic traits, there was a discussion of the issue during congressional debate.<sup>19</sup> So far there have been no judicial decisions specifically dealing with genetic predisposition to disease and the ADA, but one case was brought by the EEOC and settled.<sup>20</sup> In addition, Terri Seargent filed with the EEOC alleging genetic discrimination and received a determination on November 21, 2000, that the EEOC’s investigation supported her allegation of discrimination under the ADA.<sup>21</sup>

The ADA has been interpreted by the EEOC as including genetic information relating to illness, disease, or other disorders.<sup>22</sup> The legislative history was cited by

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<sup>17</sup> 42 U.S.C. § 12101 et seq. For a detailed discussion of the ADA see CRS Report 98-921, *The Americans with Disabilities Act (ADA): Statutory Language and Recent Issues*, by Nancy Lee Jones.

<sup>18</sup> 42 U.S.C. § 12102. Legislation, H.R. 3195, 110<sup>th</sup> Cong., and S. 1881, 110<sup>th</sup> Cong., is currently pending that would amend the ADA to change the definition of disability. For a discussion of this legislation see CRS Report RS22901, *The Americans with Disabilities Amendments Act*, by Nancy Lee Jones.

<sup>19</sup> Rep. Owens stated that “[t]hese protections of the ADA will also benefit individuals who are identified through genetic tests as being carriers of a disease-associated gene. There is a record of genetic discrimination against such individuals, most recently during sickle cell screening programs in the 1970s. With the advent of new forms of genetic testing, it is even more critical that the protections of the ADA be in place.” 136 Cong. Rec. H 4623 (daily ed. July 12, 1990) (remarks of Rep. Owens). Similarly, Rep. Edwards and Rep. Waxman also stated that individuals who are carriers of a disease-associated gene may not be discriminated against under the ADA. 136 Cong. Rec. H 4625 (daily ed. July 12, 1990) (Statement of Rep. Edwards); *Id.* at H 4627 (Statement of Rep. Waxman).

<sup>20</sup> The EEOC alleged that Burlington Northern Sante Fe (BNSF) Railroad tested its employees for a genetic marker linked to carpal tunnel syndrome in an attempt to address a high number of repetitive stress injuries leading to employee compensation. The EEOC and BNSF reached a settlement agreement rejecting the testing of employees for the genetic marker. See Paul Miller, EEOC commissioner, “Analyzing Genetic Discrimination in the Workplace,” 12 Human Genome News (Feb. 2002) at [[http://www.ornl.gov/sci/techresources/Human\\_Genome/publicat/hgn/v12n1/09workplace.shtml](http://www.ornl.gov/sci/techresources/Human_Genome/publicat/hgn/v12n1/09workplace.shtml)].

<sup>21</sup> Testimony of Janiori Goldman before the House Committee on Energy and Commerce, Subcommittee on Health, 107<sup>th</sup> Cong., 1<sup>st</sup> sess. (Mar. 22, 2001).

<sup>22</sup> Equal Employment Opportunity Commission, Compliance Manual, vol. 2, section 902, (continued...)

the EEOC in its guidance to the definition of disability for its compliance manual. In this guidance, the EEOC examined the definition of disability under the ADA, noting that the definition was composed of three prongs: disability means (1) a physical or mental impairment that substantially limits one or more of the major life activities of an individual, (2) a record of such an impairment, or (3) being regarded as having such an impairment.<sup>23</sup> It was under the third prong that the EEOC determined that discrimination based on genetic information relating to illness, disease, or other disorders was prohibited.

Although this EEOC interpretation was widely heralded as a significant step for the protection of rights for individuals whose genes indicate an increased susceptibility to illness, disease, or other disorders, it is limited in its application and may be even more limited after the recent Supreme Court decisions on the definition of disability.<sup>24</sup> However, the EEOC has not withdrawn this guidance, and at Senate hearings EEOC Commissioner Paul Miller stated that the ADA “can be interpreted to prohibit employment discrimination based on genetic information. However, the ADA does not explicitly address the issue and its protections are limited and uncertain.” In addition, Commissioner Miller observed that even if the ADA were found to cover genetic discrimination, the requirements of the ADA may not protect workers from all types of genetic discrimination. He stated, “for example, the ADA does not protect workers from requirements or requests to provide genetic information to their employers.... In addition, once the applicant is hired, the employer may request that the employee take a medical exam, such as a genetic test, if the employer can demonstrate that the information from that test is job related and consistent with business necessity.”<sup>25</sup>

Although the combination of the ADA’s legislative history and the EEOC’s guidance has led some commentators to argue that the ADA would cover genetic discrimination, the merit of these arguments has been uncertain since there have been no reported cases holding that the ADA prohibits genetic discrimination. This uncertainty has increased in light of Supreme Court decisions on the definition of

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<sup>22</sup> (...continued)

order 915.002,902-45 (1995). It is also possible that Title VII of the Civil Rights Act of 1964, 42 U.S.C. § 2000e et seq., may provide some protection against certain kinds of genetic discrimination since an argument could be made that discrimination based on genetic disorders that are more common in certain racial or ethnic groups, such as sickle cell disease, is prohibited under Title VII. There are relatively few genetic conditions that have a strong connection with a racial or ethnic group, thus limiting the scope of potential coverage. However, in *Norman-Bloodsaw v. Lawrence Berkeley Laboratory*, 135 F.3d 1260 (9<sup>th</sup> Cir. 1998), blood tests for sickle cell trait were found to give rise to a Title VII claim.

<sup>23</sup> 42 U.S.C. § 12102(2).

<sup>24</sup> See *Sutton v. United Airlines*, 527 U.S. 471 (1999); *Murphy v. United Parcel Service, Inc.*, 527 U.S. 516 (1999).

<sup>25</sup> Statement of Commissioner Paul Steven Miller, U.S. Equal Employment Opportunity Commission, before the Senate Committee on Health, Education, Labor and Pensions, July 20, 2000.

disability under the ADA.<sup>26</sup> The Supreme Court's decisions do not directly address ADA coverage of genetic discrimination. They emphasize an individualized approach to the determination of whether an individual has a disability under the ADA. Although an argument could be made that the ADA would cover individuals with genetic defects in certain cases, the Court's decisions, particularly *Sutton* and *Murphy*, use reasoning that would make it unlikely that most ADA claims based on genetic discrimination would be successful.<sup>27</sup>

In addition, even assuming the ADA was found to apply, it may not protect employees from having their employers have access to their genetic information. Although the ADA prohibits an employer from making medical inquiries prior to a job offer, the employer may obtain medical information in certain cases after the offer of employment has been made. Assuming that the prohibitions against discrimination in the ADA would apply, it is difficult to prove that genetic information was the reason for discrimination.

**Executive Order.** On February 8, 2000, President Clinton issued an executive order prohibiting discrimination against federal employees based on protected genetic information. The executive order defines "protected genetic information" as "(A) information about an individual's genetic tests; (B) information about the genetic tests of an individual's family members; or (C) information about the occurrence of a disease; or medical condition or disorder in family members of the individual." Current health status information would not be protected under this executive order unless it was derived from the information described above. The EEOC has issued guidance on the executive order.<sup>28</sup>

## State Statutes Relating to Genetic Nondiscrimination

Many states have enacted statutes dealing with various aspects of genetic discrimination. Early state statutes focused on particular genetic conditions. The first statute to prohibit discrimination based on a genetic trait was enacted in North Carolina and prohibited employment discrimination based on the sickle cell trait. In 1991 Wisconsin became the first state to enact a comprehensive law to prohibit

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<sup>26</sup> For a discussion of the Supreme Court's ADA decisions see CRS Report RL31401, *The Americans with Disabilities Act: Supreme Court Decisions*, by Nancy Lee Jones.

<sup>27</sup> In testimony before the Senate Committee on Health, Education, Labor and Pensions, Andrew J. Imparato, the President and CEO of the American Association of People with Disabilities, testified that "the ADA as drafted does provide some protections against genetic discrimination in employment, but the law has been interpreted by the Supreme Court and lower federal courts in a manner which weakens its protections. Whereas the ADA can be and has been used to stop genetic discrimination in some instances, the protections it affords offer little security to people with genetic markers and health conditions that have not yet developed into full-blown debilitating conditions." Testimony of Andrew J. Imparato, "Protecting Against Genetic Discrimination: The Limits of Existing Laws," before the Senate Committee on Health, Education, Labor and Pensions, 107<sup>th</sup> Cong., 2<sup>nd</sup> sess. (Feb. 13, 2002), reprinted at [[http://help.senate.gov/Hearings/2002\\_02\\_13/Imparato.pdf](http://help.senate.gov/Hearings/2002_02_13/Imparato.pdf)].

<sup>28</sup> [<http://www.eeoc.gov/policy/docs/guidance-genetic.html>]

discrimination based on genetic test results. Currently, the states vary in their provisions with some prohibiting discrimination in employment while others deal solely with discrimination in insurance. A recent survey of state law found that 34 states and the District of Columbia have enacted genetic nondiscrimination in employment laws.<sup>29</sup> These laws vary and the National Conference of State Legislatures noted the following:

All laws prohibit discrimination based on the results of genetic tests; many extend the protections to inherited characteristics, and some include test results of family members, family history and information about genetic testing, such as the receipt of genetic services. Most states also restrict employer access to genetic information, with some prohibiting employers from requesting, requiring and obtaining genetic information or genetic test results, or directly or indirectly performing or administering genetic tests. Some states may also make exceptions to statutory requirements if, for example, genetic information may identify individuals who may be a safety risk in the workplace.<sup>30</sup>

A related survey found that 47 states and the District of Columbia have passed laws pertaining to the use of genetic information in health insurance.<sup>31</sup> Many state genetic laws also include specific provisions relating to genetic privacy.<sup>32</sup> In a recent survey, 27 states were found to require consent to disclose genetic information while 17 states require informed consent for a third party to perform or require a genetic test or obtain genetic information. Nineteen states were found that establish specific penalties for violating genetic privacy laws.<sup>33</sup>

Although these state statutes do provide some measure of protection against discrimination, they do not cover employer self-funded plans providing private health insurance for employees and their dependents. These plans are exempt from state insurance laws due to the preemption provision in the federal Employee Retirement Income Security Act (ERISA).<sup>34</sup> Since 55% of covered workers obtain their coverage through self-funded plans, the ERISA exemption limits the application of state laws significantly.<sup>35</sup>

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<sup>29</sup> National Conference of State Legislatures, Genetics Tables, State Genetics Employment Laws, [<http://www.ncsl.org/programs/health/genetics/ndiscrim.htm>].

<sup>30</sup> *Id.*

<sup>31</sup> National Conference of State Legislatures Genetics Tables, State Genetic Nondiscrimination in Health Insurance, [<http://www.ncsl.org/programs/health/genetics/ndishlth.htm>].

<sup>32</sup> National Conference of State Legislatures Genetics Tables, State Genetic Privacy Laws, [<http://www.ncsl.org/programs/health/genetics/prt.htm>].

<sup>33</sup> *Id.*

<sup>34</sup> 29 U.S.C. §§ 1001-1145.

<sup>35</sup> Kaiser Family Foundation, "Employer Health Benefits, Annual Survey 2007," accessed at [<http://www.kff.org/insurance/7672/upload/76723.pdf>].

## Genetic Information Nondiscrimination Act of 2007 (GINA)

### Background

On May 21, 2008, GINA was signed into law. The path to enactment of P.L. 110-233 was lengthy and tortuous. H.R. 493, the Genetic Information Nondiscrimination Act of 2007, was introduced by Representative Slaughter with 143 cosponsors on January 16, 2007. After being reported out of the House Education and Labor Committee, the House Energy and Commerce Committee, and the House Ways and Means Committee, the bill passed the House on April 25, 2007, by a vote of 420 to 3. On April 24, 2008, the Senate took up H.R. 493, replaced the existing language with an amendment in the nature of a substitute, added new language strengthening the “firewall” between Title I (discrimination by health insurers) and Title II (discrimination in employment), and passed the measure, as amended, by a vote of 95-0. The House passed H.R. 493 (as amended) on May 1, 2008. On May 2, 2008, both the House and Senate passed H.Con.Res. 340 to make corrections in the enrollment of H.R. 493. These changes would

- revise deadlines for implementation of requirements related to Medicare supplemental policies;
- exempt an employer that conducts DNA analysis for purposes of human remains identification from the prohibition against an employer, labor organization, or joint labor-management committee requesting, requiring, or purchasing an employee’s genetic information; and
- remove the requirement that DNA analysis conducted by an employer for law enforcement purposes as a forensics laboratory be included in the Combined DNA Index System.

The first legislation relating to genetic discrimination was introduced in 1995 by Representative Slaughter (H.R. 2748, 104<sup>th</sup> Cong.) and Representative Stearns (H.R. 2690, 104<sup>th</sup> Cong.). In each subsequent Congress legislation was introduced, and twice legislation passed the Senate. In the 108<sup>th</sup> Congress, the Senate passed the Genetic Information Nondiscrimination Act of 2003 (S. 1053).<sup>36</sup> This bill would have prohibited health insurance plans from denying enrollment or charging higher premiums to individuals based on the individual’s or family members’ genetic information. In addition, the bill banned the collection, use, and disclosure of genetic information for insurance underwriting purposes. In the employment context, this bill would have prohibited the use of genetic information in employment decisions, such as hiring, firing, job assignments, and promotions. The bill also would have prevented the acquisition and disclosure of genetic information as well as applied the procedures and remedies authorized under the Civil Rights Act of 1964 to cases of genetic discrimination. Although President Bush supported genetic discrimination

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<sup>36</sup> 149 Cong. Rec S12394-12508 (daily ed. Oct. 4, 2003).

legislation and the House held a hearing in July 2004,<sup>37</sup> the House did not pass a bill in the 108<sup>th</sup> Congress.

In the 109<sup>th</sup> Congress, S. 306, the Genetic Information Nondiscrimination Act of 2005, was introduced by Senator Snowe on February 7, 2005. The Senate Health, Education, Labor and Pensions Committee reported S. 306 out with an amendment in the nature of a substitute by a voice vote. The bill was passed, with an amendment, on February 17, 2005, by a vote of 98-0. The amendment would have deleted former Section 103 which would have added a prohibition of discrimination based on genetic information or services in church health insurance plans to the Internal Revenue Code because this provision had to originate in the House. A companion bill, H.R. 1227, was introduced in the House on March 10, 2005, by Representative Biggert but did not pass.

## Overview of Statutory Provisions

GINA contains a statement of findings which discusses the significance of the sequencing of the human genome, the history of discrimination based on genetics, and the inadequacy of current federal and state laws. The statute is then divided into three titles: Title I, which prohibits genetic discrimination in health insurance, Title II, which prohibits genetic discrimination in employment, and Title III, which contains miscellaneous provisions on severability and child labor protections.

## Definition of Genetic Information

One of the most discussed provisions of GINA was the definition of genetic information. Both Title I and Title II contain a definition of genetic information which states the following:

GENETIC INFORMATION-(A) IN GENERAL- The term ‘genetic information’ means, with respect to any individual, information about — (i) such individual’s genetic tests,(ii) the genetic tests of family members of such individual, and (iii) the manifestation of a disease or disorder in family members of such individual.(B) INCLUSION OF GENETIC SERVICES AND PARTICIPATION IN GENETIC RESEARCH- Such term includes, with respect to any individual, any request for, or receipt of, genetic services, or participation in clinical research which includes genetic services, by such individual or any family member of such individual. (C) EXCLUSIONS- The term ‘genetic information’ shall not include information about the sex or age of any individual.

## Definition of Genetic Test

The definition of genetic test is of pivotal importance to defining the scope, and ultimately determining the impact, of the law. Importantly, this definition is different in Title I and Title II of the act. The Title I definition exempts genetic tests that are “an analysis of proteins or metabolites that [are] *directly related to a manifested*

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<sup>37</sup> “Genetic Non-Discrimination: Examining the Implications for Workers and Employers” Subcommittee on Employer-Employee Relations, House Committee on Education and Workforce (July 22, 2004).

*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.” While Title II does not include this exception, it does contain Section 210, which states,

An employer, employment agency, labor organization, or joint labor-management committee shall not be considered to be in violation of this title based on the use, acquisition, or disclosure of medical information that is not genetic information about a manifested disease, disorder, or pathological condition of an employee or member, including a manifested disease, disorder, or pathological condition that has or may have a genetic basis.

This difference in the definition of genetic test implies that employers who use genetic information about a manifested disease to discriminate may be in violation of this act, while health insurers who use genetic information about a manifested disease to discriminate will not be in violation of this act.

## Genetic Nondiscrimination and Health Insurance

**Overview of Health Insurance Provisions.** Title I of GINA strengthens and clarifies existing HIPAA nondiscrimination and portability provisions through amendments to the Employee Retirement Income Security Act of 1974 (ERISA), the Public Health Services Act (PHSA), and the Internal Revenue Code (IRC), as well as to the Social Security Act (SSA). In this way, group plans under ERISA, group and individual plans under the PHSA, Church Plans under the IRC, and Medigap plans under the SSA are all brought under the jurisdiction of the law. The complexity of the health care financing system required this multi-faceted approach in order to ensure protection for all individuals, regardless of their insurance situation.

**Prohibited Health Insurer Practices.** Broadly, GINA prohibits health insurers from engaging in three practices: (1) using genetic information about an individual to adjust a group plan’s premiums, or, in the case of individual plans, to deny coverage, adjust premiums, or impose a preexisting condition exclusion; (2) requiring or requesting genetic testing; and (3) requesting, requiring, or purchasing genetic information for underwriting purposes. Each of these provisions is discussed below in more detail.

**Discrimination in Premium Setting and Eligibility Prohibited.** GINA prohibits health plans, group and individual health insurers and issuers, and issuers of Medicare supplemental policies from adjusting a group or individual’s premium based on genetic information about an individual in the group, an individual seeking individual coverage, or an individual’s family members. It also prohibits individual insurers from conditioning eligibility or continuing eligibility on genetic information, and prohibits individual insurers from treating genetic information as a preexisting condition. Issuers of supplemental Medicare policies may not deny or condition the issuance of a policy based on genetic information (and may not impose a preexisting condition exclusion based on genetic information).



**Genetic Testing Requirements Prohibited.** GINA prohibits health plans, group and individual health insurers and issuers, and issuers of Medicare supplemental policies from requesting or requiring that individuals or their family members undergo a genetic test. This prohibition does not limit the authority of a health care professional to request that an individual undergo genetic testing as part of his or her course of health care. The act provides for a research exception to this provision, by allowing a group or individual insurance issuer to request, but not require, an individual to undergo genetic testing if specific conditions are met.

**Collection and Use of Genetic Information Restricted.** GINA prohibits health plans, group and individual health insurers and issuers, and issuers of Medicare supplemental policies from requesting, requiring, or purchasing genetic information for the purposes of underwriting prior to an individual's enrollment or in connection with enrollment. "Incidental collection" of genetic information would not be considered a violation.

**Application to Genetic Information of a Fetus or Embryo.** Title I of the act clarifies that genetic discrimination based on the genetic information of either the fetus of a pregnant woman or an embryo legally held by an individual or family member is prohibited.

**Rule of Construction.** GINA provides clearly that nothing in the act should be construed to preclude the use of information about a manifested disease or disorder in an individual (or an individual's family member) by health plans, group and individual health insurers and issuers, and issuers of Medicare supplemental policies to establish premiums or conditions of eligibility. In addition, nothing in the act should be construed to prohibit health plans, group and individual health insurers and issuers, and issuers of Medicare supplemental policies from obtaining or using the results of genetic tests to determine payment. However, only the minimum amount of information required to achieve this purpose may be requested.

**Privacy and Confidentiality.** GINA directs the Secretary of Health and Human Services to revise the HIPAA Privacy Rule<sup>38</sup> to reflect that genetic information shall be treated as health information and the use or disclosure by a covered entity of protected health information (i.e., genetic information) for the purposes of underwriting shall not be a permitted use or disclosure. The Secretary, in consultation with the Secretaries of Labor and the Treasury, has 12 months after enactment of the act to issue final regulations to carry out these revisions.

**Remedies and Enforcement.** GINA permits the Secretary to impose a penalty of \$100 per day per beneficiary or participant to whom the failure relates during a period of noncompliance with the provisions in Title I. Where willful neglect was found, there is established a minimum penalty of \$2,500, or \$15,000 for more severe or prolonged violations. There are three limitations to the penalties that may be imposed by the Secretary. First, the penalty does not apply if the person otherwise liable for the penalty did not know that the noncompliance occurred. Second, the penalty does not apply to failures corrected within 30 days (in cases not

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<sup>38</sup> 45 C.F.R, Part 46.

due to willful neglect). Finally, a limit to the total penalty for unintentional failures is set at \$500,000 or 10% of the aggregate amount paid or incurred by the plan sponsor during the preceding year for group health plans.

## Genetic Nondiscrimination and Employment

**Overview of Employment Provisions.** GINA prohibits discrimination in employment because of genetic information and, with certain exceptions, prohibits an employer from requesting, requiring, or purchasing genetic information. The law prohibits the use of genetic information in employment decisions, including hiring; firing; job assignments; and promotions by employers, unions, employment agencies, and labor-management training programs.

**Definition of Employee and Employer.** GINA defines employees and employers as those defined in Section 701(b) and (f) of Title VII of the Civil Rights Act of 1964,<sup>39</sup> a state employee or employer as defined in Section 304(a) of the Government Employee Rights Act of 1991,<sup>40</sup> and a covered employee or employing office as defined in Section 101 of the Congressional Accountability Act.<sup>41</sup> Generally, this includes employees and applicants working in the private sector for an employer who employs 15 or more employees, federal and state governments, as well as congressional employees. The corresponding employers of these individuals, as well as employment agencies, labor organizations, and training programs, also are covered by the law.

**Prohibited Employment Practices.** As noted previously, GINA prohibits the use of genetic information in employment decisions, including hiring; firing; job assignments; and promotions by employers, unions, employment agencies, and labor-management training programs. In addition, an employer, employment agency, labor union, or training program may not “request, require or purchase genetic information” with respect to the employee, individual, union member, or family member.

There are exceptions to this prohibition on employers, employment agencies, labor unions, and training programs. The first exception applies when one of these entities inadvertently requests or requires family medical history of the employee, individual, union member, or a family member. The House Education and Labor Report noted that this exception “addresses the so-called ‘water cooler’ problem, in which an employer unwittingly receives otherwise protected genetic information in the form of family medical history through casual conversations with a worker.”<sup>42</sup> The second exception is for health or genetic services offered by the entity as part of a wellness program. To qualify for the exemption

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<sup>39</sup> 42 U.S.C. §§ 2000e(f)(employees), 2000e(b)(employers).

<sup>40</sup> 42 U.S.C. § 2000e-16c(a).

<sup>41</sup> 2 U.S.C. § 1301.

<sup>42</sup> H.Rept. 110-28, Part 1 at 37 (March 5, 2007).

- the employee, individual or union member must provide prior, knowing, voluntary, and written authorization;
- only the employee, individual, union member, or family member and the licensed health care profession or board certified genetic counselor involved in providing such services can receive individually identifiable information concerning the results of the services; and
- any individually identifiable genetic information is only available for such services and shall not be disclosed to the employer except in aggregate terms that do not identify individuals.

The third exception is for information necessary for certification procedures under federal and state family and medical leave laws. This exception was described as “eliminat[ing] the potential for conflict with existing laws.”<sup>43</sup> The fourth exception, like the first, concerns the inadvertent acquisition of genetic information by the purchase of documents, such as newspapers, that are commercially and publicly available and that include family medical history. This exception was intended to address the concern that GINA could be violated by such actions as the purchase of a newspaper “containing the obituary of an employee’s parent who died of breast cancer.”<sup>44</sup>

The fifth exception applies when the information involved is to be used for genetic monitoring of the biological effects of toxic substances in the workplace. However, in order for this exception to apply,

- the employer, employment agency, labor union, or training program must provide written notice of the genetic monitoring to the employee;
- the employee, individual, or union member must provide prior, knowing, voluntary, and written authorization; or the genetic monitoring is required by federal or state law;
- the employee, individual, or union member must be informed of individual monitoring results;
- the monitoring must be in compliance with federal genetic monitoring regulations, or state genetic monitoring regulations; and
- the employer, employment agency, labor union, or training program, excluding any licensed health care professional or board certified genetic counselor, must receive the results only in aggregate terms that do not disclose the identity of specific employees.

There is a sixth exception for employers and training programs but not for employment agencies or labor unions. This exception, which was changed by H.Con.Res. 340, would allow employers and training programs that conduct DNA analysis for law enforcement purposes as a forensic laboratory or for purposes of human remains identification to request or require genetic information from their

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<sup>43</sup> *Id.* at 38.

<sup>44</sup> *Id.*

employees, but only when it is used for analysis of DNA identification markers for quality control to detect sample contamination.

GINA also provides that, even if an exception applies, genetic information may not be used in a manner that violates nondiscrimination or confidentiality requirements.

**Confidentiality of Genetic Information.** Generally, GINA requires that genetic information shall be maintained on separate forms and in separate medical files and be treated as a confidential medical record, and prohibits employers, employment agencies, labor unions, and joint labor-management committees from disclosing genetic information. These entities are considered to be in compliance with the maintenance of information requirements if the genetic information is treated as a confidential record under § 102(d)(3)(B) of the Americans with Disabilities Act.<sup>45</sup> However, the general prohibition on disclosure is subject to six exceptions. Genetic information may be disclosed

- to the employee or member of a labor union (or family member receiving genetic services) at the written request of the employee or member;
- to an occupational or other health researcher if the research is conducted in compliance with 45 C.F.R. Part 46, which provides for protection of human research subjects;
- in response to a court order except that only the genetic information expressly authorized by the order shall be disclosed; if the court order was obtained without the knowledge of the employee or member to whom the information refers, the employee or member shall be informed of the court order and the information may be disclosed;
- to government officials who are investigating compliance with Title II of GINA, if the information is relevant;
- where such disclosure is made in connection with the certification provisions of the Family and Medical Leave Act or state family and medical leave laws; or
- to a federal, state, or local public health agency regarding a contagious disease that presents an imminent hazard of death or life-threatening illness, and there is notification.

GINA also contains a provision concerning the relationship of the confidentiality provisions with the HIPAA Privacy Rule. GINA does not prohibit an entity covered under HIPAA “from any use or disclosure of health information that is authorized for the covered entity under such regulations.”

**Remedies and Enforcement.** Generally, GINA uses the remedies and enforcement mechanisms available in Title VII of the Civil Rights Act of 1964,<sup>46</sup> although for employees covered by the Government Employee Rights Act of 1991,

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<sup>45</sup> 42 U.S.C. § 12112(d)(3)(B).

<sup>46</sup> 42 U.S.C. § 2000e-4 et seq.

the Congressional Accountability Act of 1995, chapter 5 of Title 3 of the U.S. Code, or Section 717 of the Civil Rights Act of 1964, the remedies and procedures track those acts and statutory provisions. Under Title VII, complaints of discrimination are filed with the Equal Employment Opportunity Commission (EEOC) and may result in the award of back pay, hiring, promotion, reinstatement, front pay, or other equitable relief that will make an individual “whole.” Remedies also may include payment of attorneys’ fees, expert witness fees, and court costs.

**Disparate Impact.** Section 703(k) of Title VII of the Civil Rights Act of 1964 provides for a cause of action based on the disparate impact of a particular employment practice on employment based on race, color, religion, sex, or national origin.<sup>47</sup> GINA specifically provides that such disparate impact does not create a cause of action under its provisions. However, GINA requires that a commission be established six years after the date of enactment to review the science of genetics and make recommendations to Congress regarding whether to provide a disparate impact cause of action under GINA.

**Construction.** Section 209 of GINA contains several rules of construction, including a provision concerning the relationship between Title I and Title II of the act. GINA provides that nothing in Title II is to be construed to limit the rights or protections of an individual under any federal or state statute that provides equal or greater protection. In addition, nothing in Title II is to limit the rights or protections of an individual to bring an action, or provide for enforcement of, or penalties for, any violation under Title I of GINA, certain sections of ERISA, the Public Health Services Act, and the Internal Revenue Code. This provision has been referred to as a “firewall” between Titles I and II, and has been described as clarifying “that employers are not liable for health insurance violations under civil rights laws unless the employer has separately violated a provision of Title II governing employers.”<sup>48</sup>

GINA also states that it does not

- apply to the Armed Forces repository of specimen samples for the identification of remains;
- limit or expand the protections, rights, or obligations of employees or employers under applicable workers’ compensation laws;
- limit the authority of a federal department or agency to conduct or sponsor health research conducted in compliance with rules for research on human subjects;
- limit the statutory or regulatory authority of the Occupational Safety and Health Administration or the Mine Safety and Health Administration regarding workplace safety and health laws and regulations; or
- require any specific benefit for an employee or member or a family member under any group health plan.

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<sup>47</sup> 42 U.S.C. §2000e-2(k).

<sup>48</sup> 154 Cong. Rec. H2972 (daily ed. May 1, 2008)(statement of Rep. Dingell).

Section 209 also specifies that any reference in Title II to genetic information concerning an individual or family member also includes the genetic information of any fetus carried by a pregnant woman. In addition, genetic information on any embryo legally held by the individual or family member would also be included in the reference to genetic information.

Finally, Section 209 provides that Title II does not prohibit the activity of a group health plan or health insurance issuer offering group health insurance coverage that is authorized by Title I, and certain sections of ERISA, the Public Health Services Act, and the Internal Revenue Code.

**Manifested Diseases.** Section 210 of GINA clarifies that the act does not cover medical information that is not genetic information about a manifested disease, disorder, or pathological condition, including a manifested disease, disorder, or pathological condition that has or may have a genetic basis.

**Regulations.** Regulations are to be issued by the EEOC within a year of enactment.

**Authorization of Appropriations and Effective Date.** Such sums as may be necessary are authorized to be appropriated. The effective date of GINA is eighteen months after the date of enactment.

## Title III — Miscellaneous Provisions

GINA includes a severability provision. If any provision of the act is declared unconstitutional, the remainder of the act is not to be affected.

Section 16(e) of the Fair Labor Standards Act<sup>49</sup> regarding child labor protections is amended.

## Issues for Consideration

The enactment of GINA raises some issues for consideration. Educating the public and health care providers about the scope and application of GINA will be an important part of the implementation phase. This is particularly the case because there are very relevant limitations to the law of which the public and practitioners should be made aware in order to avoid confusion or misunderstanding. First, the scope of the law is limited to the settings of health insurance and employment. It does not cover the following: long term care insurance; life insurance; short-term disability insurance; or long-term disability insurance. Moving forward, this distinction may need to be presented clearly to the public, so there is not an expectation of blanket protection from genetic discrimination in all settings where genetic information may be disclosed, requested, required or used.

Second, GINA does not extend protections against discrimination in health insurance and employment to individuals with manifested diseases or disorders,

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<sup>49</sup> 29 U.S.C. §216(e).

genetic or otherwise. Specific provisions in Titles I and II clarify that health insurers and employers will not be in violation of GINA if they utilize other medical information about, or knowledge of, a manifested disease or disorder to establish premiums, set enrollment eligibility or preexisting exclusion requirements, or make employment decisions. Again, educational efforts may be useful in ensuring that the public is aware of the scope of the law.