

Legal update: living with the Genetic Information Nondiscrimination Act

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The Genetic Information Nondiscrimination Act of 2008 promises to make genetic discrimination illegal in the contexts of employment and health insurance. The promises of the law may be difficult to fully deliver. This article will examine some of the more important provisions that offer protection against genetic discrimination and the major shortcomings of the legislation. It concludes that the Genetic Information Nondiscrimination Act is an important piece of civil rights legislation, but it is not fully protective of individuals who are worried about genetic discrimination in employment or insurance. **Genet Med 2008;10(12):869–873.**

Key Words: *genetic discrimination, employment discrimination, insurance discrimination, Genetic Information Nondiscrimination Act*

The Genetic Information Nondiscrimination Act (GINA) was signed into law by President G.W. Bush on May 21, 2008.¹ The bill's passage is the result of over 13 years of work that started in 1995, when there were only a few hundred genetic tests available. Yet the concerns were in place even before the first genetic tests were formulated, and many forward-thinking individuals worked to make sure the rapid scientific progress in genetics would not be encumbered by backward-looking legislation that failed to take into account new technological realities. This article is not intended to be an in-depth analysis of the text of GINA. It will take a preliminary look at life after GINA takes effect in November of 2009. It will anticipate areas of interest to physicians and patients who may be struggling with concerns about genetic discrimination on one hand and the desire to use genetic medicine to its fullest benefit on the other hand.

Genetic discrimination has been a concern of policy makers, scholars, and patients at risk for genetic disorders since the beginning of the Human Genome Project.² Genetic discrimination is the differential and adverse treatment of asymptomatic individuals based solely on their or their relative's actual or presumed genetic characteristics.^{3,4} Reports of genetic discrimination have been mostly anecdotal, although recent scholarship suggests it may be more widespread than previously suspected.⁵ There is reason to believe the concerns of individuals who are at risk for carrying a disease gene may keep them from taking full advantage that the revolution in

genetic science has brought to health care and may have other burdensome effects in employment, insurance, and other aspects of life.

Advances in genetic science have the potential to help individuals plan effectively for their future, including planning for appropriate education, health care and lifestyle adjustments, reproductive choices, and medical treatments including personalized medical decision making. These same advances can be used as the basis for decisions by third parties to limit access to opportunities such as health insurance or employment. As more genetic tests become available, a potential for good as well as ill is more apparent. The passage of GINA may mean an end to genetic discrimination and the misuse of genetic information in employment and health insurance, but it may also mean a more subtle use of genetic information by third parties beyond the health insurance and employment domains.

WHAT IS GENETIC INFORMATION USED FOR?

Genetic information can be gleaned from family history, such as family members who are symptomatic for Huntington disease (HD) or a family history of breast cancer. The definition of genetic information in GINA specifically includes family history, including the manifestation of disease in family members. The information about one's family may provide significant insight into the likely propensities of an insured or employee, including the likelihood of alcoholism, depression, risk-taking behavior, mental health, and other health experiences. Although useful in predicting behaviors, the age and sex of individuals is specifically excluded in the definition of genetic information and are protected by separate antidiscrimination laws.

Individuals' genetic information may also be discovered through a genetic test to determine the presence of a genetic predisposition to disease, whether a family history indicates such a genetic component. This testing may be done for personal reasons or for medical indications. One of the promises

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of personalized medicine is that pharmaceuticals may be individualized based on the existence of a genetic target that is known to respond favorably to a specific drug or compound.⁶ By knowing the genetic makeup of an individual, drugs that may cause serious adverse drug reactions can be avoided through targeting the most effective drug to the patient's genotype.^{7,8} These medical uses of genetic information provide an impetus to enable individuals to have genetic testing conducted without fear of misuse of their genotype information.

Other uses of genetic information, either family history or genetic test information, may be of interest to third parties beyond the context of employment or insurance. The known presence of a predisposition to a neurologic condition such as HD may be attractive information for opposing litigants in cases where the mental capacity of a person could mitigate damages. For example, should an individual be struck from behind in an automobile accident, the defendant driver of the car causing the accident could claim the plaintiff's potential manifestation of HD was a possible mitigating cause. It will continue to rest with the courts to determine how to handle such incidents and wrestle with claims of genetic causation of behaviors with legal implications. Thus, all worries about genetic discrimination will not be resolved by the passage of GINA.

WHAT LEGAL PROTECTIONS WILL GINA PROVIDE?

The GINA was designed to provide individuals with limited legal protection against genetic discrimination. This article is not intended to provide a comprehensive examination of the provisions of GINA but will outline the major provisions of the law and discuss some likely implications on patient groups and others. Some legal protections existed before GINA, although they were widely criticized as being inadequate. The Health Insurance Portability and Accountability Act of 1996, for example, provides that health insurance plans cannot establish rules for eligibility for a plan based on an individual's presymptomatic genetic status but permits employers to not offer health insurance at all.⁹ Similarly, the Americans with Disabilities Act (ADA) has been found in employment contexts to not cover presymptomatic individuals who suffer genetic discrimination.¹⁰ The goal of GINA is admittedly not perfect and was not designed to provide protection for individuals with a diagnosed genetic condition, or to provide privacy or discrimination protection for all persons suffering from medical conditions.¹¹ Lawmakers opted to protect family health information and genetic information that could predict future disease.¹²

GINA is not the first major civil rights legislation to add a corrective to insidious discrimination. The Civil Rights Act of 1964 provides that "no person in the United States shall; on the ground of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be otherwise subjected to discrimination."¹³ Employment discrimination based on gender is also prohibited under the Act, yet claims of both continue to increase.¹⁴ Recent studies have validated the existence of such continuing discrimination.¹⁵ It may be a number

of years before we know what effect GINA will have on lowering the incidence of reported genetic discrimination.

HEALTH INSURANCE PROTECTIONS

Title I, sections 101–106 of the law prohibits a number of important sources of discriminatory behavior. In the area of health insurance, group health plans,¹⁶ individual health insurance,¹⁷ and any Medicare insurer:¹⁸

- Cannot establish rules for eligibility or adjust premiums based on genetic information.

- Cannot request or require a genetic test from an individual or family member, except to make a written request for a genetic test if it is in conjunction with voluntary participation in federally approved research. In such a case, protections against retaliation for noncompliance are in place.

- Cannot request, require, or purchase genetic information before or after enrollment.

- May obtain the results of a genetic test only for payment purposes and can only request the minimum necessary information.

- May obtain genetic information incidentally without penalty.

- Cannot exercise any preexisting condition clause unless and until the disease condition is manifest.

- Cannot determine the rules for the creation, renewal, or replacement of a health insurance contract.¹

The provisions covering health insurance in group markets or Medicare take effect for plan or policy years beginning after May 21, 2009. The effective date is May 21, 2009 for individual health insurance sold or renewed on or after that date.¹

The penalties for noncompliance with GINA range from \$300,000 per incident when noncompliance is intentional and a minimum of \$2500 to a maximum of \$500,000, where noncompliance with the law is unintentional.¹ The law also extends the protections of confidentiality in Health Insurance Portability and Accountability Act to genetic information used or disclosed by a health insurer or Medicare supplemental policy.⁹ Genetic information will be protected under HIPAA beginning no later than 60 days after May 21, 2009.¹

EMPLOYMENT PROVISIONS

Title II, sections 201–213 of the law provides that employers, employment agencies, and labor organizations must not discriminate based on an individual's genetic information. Specifically these entities:

- Cannot fail or refuse to hire, discharge, or otherwise discriminate against any employee with respect to compensation, terms, conditions, or privileges.

- Cannot limit, segregate, or classify employees or in any way deprive any employee of employment opportunities.

Cannot cause or attempt to cause (for employment agencies and labor organizations) an employer to discriminate against an employee.

Cannot discriminate with respect to an individual's admission to or employment in any apprenticeship, training or retraining program, and cannot segregate or classify participants in such programs.

Cannot request, require, or purchase genetic information with respect to an employee or any family member. *However, the exceptions to this provide ample opportunity to disclose genetic information. Genetic information may be legally obtained when the employee is enrolled in a wellness program, when the individual provides written authorization, when the employer conducts genetic monitoring of employees, or where the employee provides family history under the Family Medical Leave Act.*

May possess genetic information without penalty if the employee gives this information voluntarily. The employer must maintain this information as a confidential medical record subject to ADA confidentiality and disclosure standards.

May conduct genetic monitoring of individuals to determine the effect of workplace conditions upon the health of employees including acquired modifications to their genetic material.¹

The effective date of the provisions covering employment takes effect on November 21, 2009.¹

LIMITATIONS OF GINA

The protections offered by GINA are important steps forward and provide necessary protections against genetic discrimination. Yet there are several areas, where the law may not provide the protection individuals and policy makers would hope for.¹² Legal scholars have long pointed out one of the most problematic limitations of laws that attempt to protect against genetic discrimination. Mark Rothstein has pointedly observed that the "inability to solve a fundamentally flawed system through incremental approaches raises important issues of politics and advocacy. One wonders whether it is efficacious, tactically sound, or ethical for genetic advocacy groups to promote legislation prohibiting genetic discrimination Indeed, such legislation may even result in further stigmatizing genetic conditions and fragmenting support for meaningful health care reform."¹⁹ It remains to be seen if support for broad-based health care reform becomes more fragmented or more solidified, but the current legislation represents a strategic decision to recognize different types of law governing different types of insurance.¹² The law itself may be more an artifact of a fundamentally flawed health care delivery system than a one-size-fits-all solution to the problem of genetic discrimination, but it does afford some much needed protection against genetic discrimination.

Insurance

The most obvious limitation of the insurance provisions of GINA is what the law does not cover. It does not extend to coverage of life insurance, disability insurance, long-term care insurance, or other forms of protection commonly desired by individuals at risk for a genetic disorder. The law does not mandate coverage for any particular tests or treatments. Also, the protections that the law offers for health insurance do not extend to other medical conditions or manifest conditions of genetic origin. This was a political compromise. It would seriously disrupt the private insurance market to afford protection from discriminatory coverage decisions based on any medical condition. Such a provision would draw us so close to universal health coverage that it would necessarily become a part of the larger debate now occurring at a societal level.

A second concern about the potential effectiveness of the insurance provisions in GINA relates to the limitation on monetary sanctions imposed for violation of the law. The law provides for a minimum of \$2,500 per violation and a maximum of \$500,000 per violation.¹ In an era where annual health care costs can rise into seven figures very quickly, one insured person with a devastatingly expensive genetic condition may cost the company much more than a half-million dollars over the course of the illness. It may in fact be more cost effective for the insurer to violate the law and pay the statutory fine than to comply with the law and pay for an insured's health care costs. This is another area where we should take a wait and see attitude before trusting our insurance carrier will not ever use genetic information in an illegal manner.

Employment

The employment provisions also fail to address important issues raised by legal scholars and policy makers. First, the law provides a number of legal ways for employers to access employee's genetic information. These methods include where the employee is enrolled in a wellness program, or the individual provides information voluntarily, or for genetic monitoring, or where the employee provides family history under the Family Medical Leave Act. These cover a very large number of opportunities to access genetic information. Second, the law does not address the coercive effects that potential employers may exert on applicants to provide preemployment consent for a release of all medical records, which may contain genetic information. Under the section 102(d)³ of the ADA an employer may, during the preemployment period, require a conditional offeree sign a consent form giving access to her medical records for review by the employer.²⁰ The problem is that when such an authorization is signed, all medical records are sent to the employer. GINA will not change the way such preemployment information is protected and it needs to be considered in conjunction with the ADA provisions.¹¹ Moreover, although GINA specifically prohibits the use of incidentally gained information such as the examples listed earlier, we have to assume that some employers would illegally use that infor-

mation, simply because employers continue to discriminate based on race and gender, with even less cost-effective results in the latter cases.

The last major preliminary concern about the employment provisions of GINA relates to the enforcement of damages to which an employee may be entitled. The law provides the same remedies contained in Title VII of the Civil Rights Act of 1964. Title VII prohibits race and gender discrimination in federally funded programs and places the full burden and expense on the employee to prove that the information was used for an illegal purpose, prove damages were incurred, and bring suit to recover. The expense, time commitment, and psychological ill effects of bringing a Title VII complaint is significant and well documented.²¹ Although GINA specifically provides a prohibition against retaliation for bringing a complaint or for assisting others in their complaint, the threat of retaliation can be emotionally and physically exhausting and may deter individuals from enforcing their rights. Employees who make claims of discrimination or who support others in making such claims, even though the illegal behavior complained of is odious and disruptive within the workplace, are seen as overreaching their position and transgressing the social order.²² These social constraints on behavior as well as the significant time and financial costs of making a discrimination complaint make the remedies afforded under GINA problematic in the same way the original Title VII remedies remain inadequate to fully eliminate the existence of discrimination based on race, color, religion, gender, or national origin.

WHAT DIFFERENCE WILL GINA MAKE?

Given the limitations of the law, the flawed health care system in which it operates, and the likely political infeasibility of fundamental health care reform, GINA will likely have a positive but incomplete impact on banning genetic discrimination. One thing that GINA will not do is to change the manner in which we view privacy rights in this country. Outside of constitutional interpretation, privacy rights in this country are viewed as something conferred upon the individual much like the rights one has in property and may be bargained for or contracted away.²³ For most of the world, the right to privacy is viewed as a central part of the notion of human dignity and means “being treated in a way that allows or enables one to live a becoming existence.”²⁴ In GINA, the US view of privacy rights as conferred upon individuals by legislative mandate is apparent. This view implies that individuals will only have so much protection of their genetic information as they are willing to bargain for, protect through withholding consent to access the information, and litigate to fend off the illegal use of the information. GINA does not make the privacy of genetic information a fundamental right or an aspect of human dignity, but continues the American tradition of viewing privacy rights as conferred upon individuals through legislation and legal precedent.

The GINA will lower the barriers of genetic discrimination perceived by individuals who may benefit from genetic testing. This should expand the willingness of both patients and providers to use genetic testing in the provision of med-

ical care.²⁵ The passage of GINA should calm the fears of genetic discrimination and prove to be a decidedly beneficial effect of the law, whether actual genetic discrimination is occurring or not.

GINA may also provide potential substantive vindication for the fears of organized groups that represent patients and their families who live with a knowledge that the revelation of their genetic secrets can be harmful. Pilot studies of individuals at risk for carrying the HD gene have previously demonstrated widespread experience of genetic discrimination based on genetic test results.²⁶ These individuals who are facing the risks of a devastating neurologic condition often express a desire to know their genetic traits to make important life choices, but likewise express a fear of discrimination, a feeling of “differentness,” or a sense that social perceptions of illness where none is manifest will prevent others from treating them equal to similarly situated others. Although GINA is imperfect, cumbersome to enforce, and not yet in effect, it is a welcome acknowledgment that the sense of discriminatory treatment some have perceived for years is worthy of respect.

The final impact of the law will depend on the one who asks for an appraisal of what GINA means. Legal scholars will very pragmatically point out the shortcomings of the law. Patient groups may take quiet solace in knowing they have been heard, but they are aware that the law is not perfect. History will be the final judge. Much will depend on how the administrative agencies and courts charged with interpreting the law will act. Much will depend on how well we educate clinicians, patients, and attorneys about the law and its potential to protect that part of our population who are at risk for genetic disease. Much will depend on our political will to extend the protections of GINA to other areas of society where genetic discrimination occurs, including life, disability, and other forms of insurance.

GINA is an important recognition of the power of genetic medicine, the injustice of discrimination based on genetic factors beyond individual control, and the importance of health care and employment to each individual. GINA represents a success of law and policy over human tendencies to discriminate, but it does not represent the conclusion of our need to examine our health care policies, make adjustments, and recognize the worth of each human life. It reminds us that we are all in this together, with our own unique genetic strengths, and genetic risks. It represents the first small step toward a much needed new health policy for the 21st century.

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