

The new genetic privacy law

How GINA will affect patients seeking counseling and testing for inherited cancer risk

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With passage of the Genetic Information Nondiscrimination Act (GINA), patients will be able to pursue predictive genetic testing without fearing the loss of their health insurance or job. But the bill, just signed into law, does not address the life insurance, disability insurance, or long-term care insurance markets. This article explores the application of GINA protections to a hereditary cancer counseling setting.

Signed into law by President George W. Bush on May 21, 2008, the Genetic Information Nondiscrimination Act (GINA) is the most comprehensive legislation available to protect individuals from the inappropriate use of their genetic information by health insurers and employers.

Fear of losing one's job or health insurance has been a driving force in deciding whether or not to undergo genetic testing. The literature,^{1,2} media,³ and policy makers^{4,5} have all documented the pervasiveness of this fear. In a 2007 survey of 1,199 Americans, 93% of respondents said that employers should not have access to their genetic test results; the same percentage also opposed health insurers having access to their results.⁴ In addition, health professionals can attest to the consequences of allowing this fear to deter patients from learning about their risk of developing cancer.

Over the past decade, more than 40 states have passed legislation addressing genetic discrimination in health insurance. Approximately 30 states have enacted employment protections.⁶ Some laws are comprehensive while others define genetic information more narrowly. But these laws vary widely, with inconsistent and sometimes inadequate definitions of genetic information. Many fail to include meaningful remedies for those who have experienced discrimination. This patchwork quilt of protections is inadequate to protect all Americans and cemented the need for a Federal standard.

Federal laws, including the Health Insurance Portability and Accountability Act (HIPAA), Americans with Disabilities Act (ADA), Title

VII of the Civil Rights Act of 1964, and Executive Order 13145 currently do offer some protections against genetic discrimination, but significant gaps remain: They don't fully define genetic information, protect predictive information, or apply to individual health plans and non-Federal employees (Table 1).

After more than a decade of consideration, Congress overwhelmingly passed GINA in May 2008. When enacted next year, this new law will ban the use of predictive genetic information in underwrit-

KEY POINTS

Once enacted in 2009, GINA will offer new Federal-wide protections against discrimination based on genetic information.

Genetic information is defined as predictive genetic tests, family members' genetic tests, and family history information.

GINA's protections apply to group and individual health insurance as well as to employment practices. It does not cover life, disability, long-term care, and other forms of insurance.

The authors explore how GINA applies to a hereditary cancer counseling setting.

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ing, enrollment, and coverage decisions by group and individual health insurers and in employment-related decisions. By setting the minimum protections that must be offered to most Americans, this Federal floor will supersede weaker state laws, although states may choose to enact protections stronger than GINA.

By the end of next year, all patients will be able to pursue predictive genetic testing without fearing the loss of their health insurance or job. Protections in health insurance will take effect in May 2009; the employment protections will be implemented in November 2009. However, GINA does not address the life insurance, disability insurance, or long-term care insurance markets. It also does not apply to active-duty military personnel.

Applying GINA

Thanks to the passage of GINA, individuals who test positive for a mutation that places them at increased risk for developing cancer (or any other genetically related disease) may no longer feel it is necessary to pursue anonymous testing, pay out of pocket for the test, keep results out of their medical record, or worry that an employer will require a genetic test

as a condition of employment. In the pre-GINA era, all of these were real concerns. Families may now feel more comfortable speaking openly about their hereditary risks. If someone does experience genetic discrimination, he or she can seek remedies and not worry about the consequences of revealing family members' at-risk status.

GINA protects genetic information, which includes information from genetic tests, family members' genetic tests, and the manifestation of disease in family members (ie, family history). As legislated, family members include dependents and relatives who are first degree (children, siblings, parents), second degree (grandparents, aunts, uncles, nieces, nephews, grandchildren), third degree (first cousins, great grandparents, great aunts and uncles), and fourth degree (first cousins once removed). GINA also protects the genetic information of a fetus or embryo.

The bill defines a genetic test as "an analysis of human DNA, RNA, chromosomes, proteins, or metabolites that detects genotypes, mutations, or chromosomal changes (Source: Public Law No: 11-233)."⁷

There is a significant exception to this definition: GINA does not protect information from a genetic test that is directly related to a manifest-

ed disease that could be reasonably detected by a healthcare professional. Thus, GINA only protects *predictive* genetic information.

In the boxed case example, the woman's genetic test result and her family history are information protected under GINA. Her health insurer could not use her mutation status or family history in underwriting, coverage, and enrollment decisions related to her group or individual health insurance plan. Also, her employers could not use this information in employment decisions such as whether to hire, fire, or promote her. This patient can confidently include this information in her health record and take preventive health measures without risking discrimination in health insurance coverage and the workplace.

However, this information could potentially be used against her if she applies for life, disability, or long-term care insurance. Like the laws that came before it, GINA does not address this area.

If she were to develop breast cancer, GINA would not apply to her diagnosis of her manifested disease. Despite not falling within the scope of GINA, breast cancer survivors would still be protected by HIPAA, ADA, and other civil rights legislation (Table 1).⁸⁻¹² Moreover, any genetic testing performed on the tumor for classification purposes or to inform treatment decisions would be information not protected by GINA, as it is related to the manifestation of disease. Consequently, health insurers could use this information to make underwriting, enrollment, and coverage decisions.

There is nothing in GINA that would interfere with the practice of medicine. As has previously been the case, an insurance company can request genetic tests related to manifest disease, such as an HER2 test, so that it can assess the utility of trastuzumab (Herceptin) treatment before cover-

Case example

This is a scenario of a patient who should seek genetic counseling and testing:

A healthy 32-year-old woman presents with a family history of early-onset breast cancer. Her mother received her first diagnosis of breast cancer at age 40 and a second primary diagnosis of breast cancer at age 54. Her maternal aunt was diagnosed with breast cancer at age 48 and her maternal grandmother died of breast cancer at age 38. This family history suggests a hereditary predisposition to breast cancer. Genetic

testing for a mutation in the *BRCA1* and *BRCA2* genes is offered. The woman's family pursues genetic testing after a thorough pretest genetic counseling session and after weighing the emotional and physical risks and benefits of testing. She and several other family members test positive for a mutation that suggests they are at increased risk for breast and ovarian cancers. Based on this information, she begins early surveillance and makes lifestyle choices to prevent and/or reduce her risk of developing cancer.

TABLE 1

Comparison of legislation addressing genetic privacy

Law	Coverage	Addresses predictive genetic information	Limitations	Penalties	Applies to all Americans
Civil Rights Act of 1964	<ul style="list-style-type: none"> • Applies to employment only • Only applicable to discrimination based on genetic information if associated with a racial or ethnic group 	No	<ul style="list-style-type: none"> • Does not address health insurance • Only a few diseases have a strong association with racial or ethnic groups 	Yes	Yes
Americans with Disabilities Act of 1990	Addresses disabilities associated with manifesting genetic information	No	Does not address health insurance	Yes	Yes
Health Insurance Portability and Accountability Act (HIPAA)	<ul style="list-style-type: none"> • Protects genetic information • Forbids excluding an individual in a group plan due to genetic information • Prohibits charging higher premiums to different members of a group plan • Predictive genetic information is not a preexisting condition 	Yes	<ul style="list-style-type: none"> • Does not ban insurers from requiring genetic tests • Does not define genetic information • Allows use of genetic information in underwriting plans • Does not limit disclosure of genetic information • Does not apply to individual health plans, unless covered by the portability provision • Does not address employment 	Yes	Yes
Executive Order 13145	Prohibits genetic discrimination in the workplace for Federal employees.	Yes	Does not address health insurance.	Yes	No
State genetic non-discrimination laws	Where enacted, prohibit genetic discrimination in the workplace and in health insurance	Some	<ul style="list-style-type: none"> • Some states only address employment • Some states only address health insurance • Inconsistent definitions of genetic information • Inconsistent remedies for discrimination • Patchwork of state laws leaves people unprotected if they live in one state and receive healthcare or work in a neighboring state 	Some	No
Genetic Information Nondiscrimination Act of 2008 (GINA)	<ul style="list-style-type: none"> • Prohibits genetic discrimination in the workplace and in health insurance • Defines genetic information clearly and broadly • Applies to both group and individual insurance markets • Prohibits use of genetic information in underwriting • Bans employers and insurers from requiring genetic testing 	Yes	<ul style="list-style-type: none"> • No private right of action (file civil suit) unless all administrative remedies have been exhausted • Does not cover life, disability, and long-term care insurance 	Yes	No*

* GINA does not apply to military personnel on active duty.

Source: National Human Genome Research Institute^{8,10}; Library of Congress⁹; The White House¹¹; Williams et al¹²

ing the cost of the treatment.

Seeking redress

After GINA takes effect, health-care professionals can more confident-

ly reassure patients such as the woman in the case example that their family history, having a *BRCA* (or other predictive genetic) test, and learning their mutation status does not put them

at risk of losing group or individual health insurance. And if patients do experience genetic discrimination, GINA outlines the action they can take to seek remedies. If a health insur-

ance company acts inappropriately, the penalties include a minimum of \$100 a day during the noncompliance period. This minimum amount can reach as high as \$15,000 for severe violations. The severity of the penalty for health insurers not in compliance with GINA will be determined by the Secretary of the Department of Health and Human Services.

Although individuals cannot initially file a civil law suit against their employer if they feel they have been discriminated against, they can file claims through the appropriate government offices, such as the US Equal Employment Opportunity Commission (EEOC), which have their own penalties in place. Once patients exhaust all administrative remedies, they can then file a suit in Federal court. However, once offices such as the EEOC make a determination that a case lacks merit, it's difficult to proceed through the court system and prevail.

GINA also prohibits health insurers or employers from requiring a person to take a predictive genetic test such as for *BRCA1* or *BRCA2* mutation status. And employers cannot purchase publicly available information that would include employees' mutation status. If information about a genetic test result is inadvertently obtained, (say, during "water cooler" conversations at the office), the employer is not considered to be in non-compliance with GINA. They must treat this information as part of a confidential medical record and keep it in a file separate from employment files.

New rights, better health

On the day the Senate voted, Senator Edward M. Kennedy (D-MA) called GINA "the first new civil rights bill of the 21st century."¹³ This law will enable patients to protect their health by availing themselves of cutting-edge technology and genetic counseling services without having to take extraordinary measures to protect the confi-

dentiality and privacy of their genetic information. GINA should help people feel more confident about sharing important genetic information with their relatives to help decrease cancer burden in the family.

Given the fears and concerns expressed by Americans over the past decade, which led to the public outcry for GINA, it may take some time before patients let go of the fears that have discouraged them from accessing genetic testing. As healthcare providers, we can reassure our patients that this legislation is designed to ease their concerns.

Banning genetic discrimination in the workplace and in health insurance will also encourage patients to participate in clinical research that involves genetic information. Genetic and genomic research is rapidly expanding our understanding of both rare and common diseases, ushering in an era of personalized medicine where healthcare is tailored based on one's DNA. Indeed, protecting the privacy and inappropriate use of genetic information is a significant advancement for healthcare.

Now that Congress has tackled this challenge, policy makers should address such issues as the oversight of genetic tests, reimbursement for diagnostic services and genetic counseling, and genetic literacy among health providers and the public.

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