Genetic advancements have presented numerous discrimination predicaments to individuals, the healthcare community, and legislators at state and federal levels. Oncology nurses should be knowledgeable about the Genetic Information Nondiscrimination Act of 2008 (GINA) and its applications to clinical practice. GINA is the first federal law passed to protect U.S. citizens with inherited disorders from being treated unfairly because of their genetic makeup. Understanding the legislation known as GINA, including how it modifies existing federal laws governing health insurance coverage and employment discrimination, can assist oncology nurses in providing important education and advocating for patients and their extended families. Federal agencies that govern and enforce GINA's provisions are identified. Case situations are included to demonstrate how to apply information concerning GINA to patients with cancer and their families who are considering or have already completed genetic testing. Privacy of genetic information is a timely issue but difficult to understand; therefore, provisions of GINA should be addressed and evaluated carefully.

Genetic testing is used to identify inherited propensities to predict risk for future disease, diagnose hereditary conditions with guidance for treatment decisions, provide information for reproductive decisions, and profile individuals or their tumors for selection of medication and personalized dosing for best results (Genetics and Public Policy Center, 2008). More than 1,500 genetic tests are available to date. According to Francis Collins, MD, PhD, past director of the National Human Genome Research Institute and current director of the National Institutes of Health, “Many people are afraid that their genetic information will be used against them and are unwilling to participate in medical research or be tested clinically, even when they are at substantial risk for serious disease” (National Human Genome Research Institute, 2007, para. 2). Because of this fear, many patients who have obtained genetic testing have done so anonymously or under assumed names because of concerns about discrimination from employers and insurance companies. Those patients face additional financial strain if they choose to pay for their genetic tests out of pocket because genetic testing and counseling can cost thousands of dollars.
dollars for a single gene mutation, whether a change in the genetic code is present or not (National Human Genome Research Institute, 2007).

Background

Genetic discrimination can occur in multiple situations. Of special concern is when employers have used genetic information to deny employment, discharge current employees, or deny workers’ compensation benefits. One well-known case of genetic discrimination concerned Lawrence-Berkeley Laboratories, a state and federal research institution. From 1968–1993, Lawrence-Berkeley Laboratories included tests for syphilis, sickle cell genetic markers, and pregnancy in its pre-employment and annual medical examinations without the employees’ knowledge or consent. Employees were told only that they were “having cholesterol testing.” The use of testing without informed consent was revealed and condemned in a major lawsuit decision in 1998, in which the court held that the employer’s actions constituted the “most basic violation possible” of the employees’ rights to privacy guaranteed under the U.S. Constitution (Coalition for Genetic Fairness, 2008).

In a retrospective cohort study conducted by Armstrong et al. (2003), fear of genetic discrimination played an important factor in the decision of whether to undergo genetic testing to determine familial breast cancer. The researchers found that 294 participants (46%) who had undergone genetic counseling described fear of genetic discrimination as a reason for refusing genetic testing. The women who refused testing expressed concerns about life insurance discrimination if their genetic test results were made available to insurance companies (Armstrong et al., 2003).

Fears of genetic discrimination also can cause adverse financial impacts on individuals and the healthcare system, although the potential exists for saving healthcare dollars. Early detection and prevention via genetic testing results could reduce the financial costs related to late diagnosis and chronic illnesses such as cancer. Avoidance of genetic tests because of discrimination fears ultimately may cost thousands of dollars for additional detection and treatment. Individuals treated at a later stage of cancer often face financial crisis in the form of increased cost sharing and out-of-pocket medical bills that create significant medical debt. According to the Genetic Alliance (2008), a not-for-profit organization dedicated to promoting health care for people with genetic disorders, medical debt is a leading source of personal financial bankruptcy in the United States, leading to home foreclosures and possible financial difficulties. Lost income during extended illnesses such as cancer also can become an issue. Therefore, Americans can benefit from personal genetic testing if they know that their health insurance and employment will not be at risk because of positive genetic test results.

Although the Genetic Information Nondiscrimination Act of 2008 (GINA) offers some protection against genetic discrimination, the protection is incomplete. Many people may have to choose between undergoing genetic testing that could lead to early detection and prevention of cancer or forgoing genetic testing to protect their families economically from adverse genetic discrimination (Rothstein, 2008).

Need for Legislation

Many Americans, while optimistic that their genetic information could improve their health, also express concern that the same information could be used to discriminate against them. They fear that health insurers would either refuse to insure them or cancel existing health insurance if they are found to be predisposed to future onset of a genetic disease. Similarly, Americans fear that employers only would retain or hire individuals who are not predisposed to genetic disease to ensure having healthy, productive employees. As a result of those fears, most Americans, in addition to scientists and health advocacy groups, expressed a need for federal legislation to protect all Americans from genetic discrimination (U.S. Department of Health and Human Services [HHS], 2009).

Federal nondiscrimination legislation was proposed as a solution to prevent cases of previously documented genetic discrimination and fears of future genetic discrimination by employers and insurance companies. Individuals realized the privacy protections of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) did not prohibit health insurers from requiring genetic testing or from denying coverage based on genotypic information (Coalition for Genetic Fairness, 2008). A majority of state legislatures responded to concerns of individual genetic discrimination by health insurers, employers, or both, but states’ laws did not provide uniform protection to American families at the national level. Unfortunately, the patchwork of state laws left some individuals vulnerable to genetic discrimination. One provision of GINA is that it would not preempt more protective state laws so that an individual would receive the maximum protection allowed by federal and state laws in any situation (Rothstein, 2008).

To date, 18 states have no genetic privacy laws. Seventeen states require signed informed consent from an individual before insurers or employers can request a genetic test or genetic information can be obtained. Genetic information is considered personal property in Alaska, Colorado, Florida, Georgia, and Louisiana. Nineteen states have civil or criminal penalties for violation of genetic privacy laws, whereas Washington is the only state that treats genetic information the same as other health information. For a complete table of each state’s discrimination laws regarding genetics and health insurance as well as genetic employment, visit the National Conference of State Legislatures (2008) Web site at www.ncsl.org/default.aspx?tabid=14280.

Who Is Affected?

Determining how many Americans are affected by genetic discrimination is impossible. A literature search using CINAHL®, Academic Search Premier, MEDLINE®, ERIC, PsycINFO, Health Source: Nursing/Academic Edition, and the Cochrane Database of Systematic Reviews for this data located no statistics. However, the literature stated that Americans who fight discriminatory practices and win often have to invest significant time, money, and effort to assert their rights (National Partnership for Women and Families, 2008). Unfortunately, not every afflicted individual will have the knowledge of discriminatory
practices and resources available to assert those rights. Some will find themselves uninsured or unemployed because of their genetically induced risk for disease and associated healthcare-related costs (National Partnership for Women and Families, 2008).

**Legislative History**

Representative Louise Slaughter (D-NY), a microbiologist, first introduced legislation to address genetic discrimination in 1995 during the 104th Congress (HHS, 2009). In 1996, Senator Olympia Snowe (R-ME) introduced similar legislation in the Senate. Both bills addressed health insurance discrimination; however, neither passed. Similar legislation was introduced in both chambers in the next four successive Congresses. In the 109th Congress, Representative Judy Biggert (R-IL) introduced the bill in the House of Representatives; although it again passed in the Senate under Snowe’s efforts, GINA still did not pass in the House. GINA finally passed after the Democratic Party gained control of the House in 2006 and the concern of possible increased healthcare costs for employers and insurance companies was addressed (Couzin, 2008). After passing through the three jurisdiction committees of Education and Labor, Energy and Commerce, and Ways and Means, GINA passed through the Senate on April 24, 2008, and the House on May 1, 2008, during the 110th Congress. With the perseverance of Representatives Slaughter and Biggert, Senator Snowe, a bipartisan congressional effort, and a strong coalition of interested organizations, GINA was “born” after a gestation period of 13 years in the U.S. Congress (Coalition for Genetic Fairness, 2008; Couzin, 2008) (see Figure 1). Although GINA is not a perfect nondiscrimination law, it exemplifies how legislative advocacy and a coalition of organizations effectively fought for a common cause. The result was a more comprehensive genetic nondiscrimination law on a federal level, rather than having 50 different individual state nondiscrimination laws.

GINA, also known as Public Law 110-233, was signed by President George W. Bush on May 21, 2008. The late Senator Ted Kennedy (D-MA) applauded GINA as “the first civil rights bill of the new century of the life sciences” (Coalition for Genetic Fairness, 2011, para. 2). This law makes it illegal for health insurers or employers to discriminate against individuals based on their genetic information. The health insurance provisions of the bill, Title I, took effect 12 months after the signing date on May 21, 2009. The protections in employment, Title II, took

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**Figure 1. Genetic Information Nondiscrimination Act (GINA) Legislative History**

*Note. Based on information from Coalition for Genetic Fairness, 2008; U.S. Department of Energy Genome Program, 2009.*
effect 18 months after the signing date on November 21, 2009 (Coalition for Genetic Fairness, 2008). Title II applies to private employers as well as local and state governments with 15 or more employees. It also applies to labor unions, employment agencies, labor-management programs, Congress, and federal executive agencies (U.S. Equal Employment Opportunity Commission, 2009). GINA has shortcomings as a genetic discrimination bill. The goal of comprehensive genetic nondiscrimination is difficult with a health finance system where individual health insurance is medically underwritten. Current employment laws do not protect the complete privacy of employees’ health information, and GINA’s provisions do not apply to life, long-term care, and disability insurance.

Proponents and Opponents

GINA had many official actors in the federal legislature and thousands of unofficial actors who were personally concerned about their own future or realized that genetic discrimination could occur. In 1997, when genetic discrimination bills did not pass the 106th Congress, the largest organized unofficial actor, the Coalition for Genetic Fairness, was formed. The Coalition for Genetic Fairness includes a number of diverse organizations, including Alpha-1 Association, Genetic Alliance, Hadassah, National Partnership for Women and Families, National Society of Genetic Counselors, and the National Work Rights Institute. The Coalition for Genetic Fairness’s objective is to educate the public and Congress about genetic discrimination so that introduced genetic nondiscrimination legislation can be seriously considered. Since its founding, the Coalition for Genetic Fairness (2008) has united hundreds of organizations and thousands of individuals as one voice against genetic discrimination. These organizations recognize that their mutual goal among diverse groups is to accomplish passing genetic nondiscrimination legislation, a goal out of reach for any single organization (Coalition for Genetic Fairness, 2008).

In 2005, the Coalition for Genetic Fairness expanded to include industry and employers. Once those groups were educated about GINA, they supported its proposed legislation. GINA was supported by a majority of legislators, the Coalition for Genetic Fairness, and more than 500 organizations, medical groups, individuals, and companies including the American Medical Association, American Nurses Association, National Education Association, and March of Dimes (Lengell, 2008).

GINA legislation was opposed by insurance companies and the Genetic Information Nondiscrimination in Employment Coalition, composed of the National Association of Manufacturers, the National Retail Association, and others. This coalition included the U.S. Chamber of Commerce, which argued that the bill’s language was too broad, did not support many state laws, and provided for severe punitive damages. Opponents also claimed worried plaintiffs would turn common ordinary disputes over insurance coverage into full-blown civil rights cases (U.S. Chamber of Commerce, 2007). The U.S. Chamber of Commerce’s executive director for labor policy stated disappointment with current provisions of GINA, noting that other concerns of the U.S. Chamber of Commerce were not addressed before the bill was passed (McGowan, 2008).

Provisions

Genetic information includes an individual or family member’s genetic tests, the occurrence of disease in family members, or the individual or family member’s participation in research that includes genetic testing, counseling, or education (Genetics and Public Policy Center, 2008; Rothstein, 2008). Genetic information does not include information about the gender or age of an individual. A genetic test assesses genotypes, mutations, polymorphisms, or any chromosomal changes in an individual (Genetics and Public Policy Center, 2008). Four main concerns regarding the use of genetic information in employment and health insurance drove efforts to obtain genetic nondiscrimination legislation. The four concerns include privacy of health records, required pre-employment genetic testing, disqualification of insurance coverage and employment based on misinterpretation of genetic information, and the exclusion of insurance coverage for untested family members. These concerns could be applied to future campaigns regarding use of genetic information in life, disability, and long-term care insurance (Rothstein, 2008).

The first concern focused on individuals who worry about having pieces of their health records combed through by insurance companies probing for any evidence of genetic information (Rothstein, 2008). For example, Ms. X had family members in multiple generations with breast and ovarian cancer. Ms. X was concerned about having this information identified when her insurance company requested documentation of medical necessity for a gall bladder “attack.” Rather than supply only the necessary pieces of medical chart information, the busy staff at the physician’s office faxed Ms. X’s entire patient chart to the insurance company, thus revealing her genetic information.

The second fear was that genetic testing could be required as a provision of employment. Once the results are received, the patients may discover information about personal health risks that they did not want to know.

Third was the concern that a future employer or health insurer underwriter may misinterpret a person’s genetic information, using it to disqualify him or her from a job or insurance coverage (Rothstein, 2008). Oncology professionals know a genetic mutation in a gene does not mean individuals will develop cancer, nor does the possibility of developing cancer prevent individuals from performing a job for which they are qualified. Therefore, genetic information should not disqualify individuals from insurance.

Fourth was the fear that inquiring about and having a genetic test would exclude individuals from insurance benefits available to those who have never had any genetic testing. Individuals were concerned that even negative results would prevent them from obtaining adequate insurance (Rothstein, 2008).

GINA addresses the four concerns by prohibiting use of an individual’s genetic information to set eligibility on premiums or contribution amounts for group and individual health insurers. Health insurers are prohibited by GINA from requesting or requiring an individual to take any genetic test. However, a health insurer or group health plan involved in research may request, but not require, a genetic test in conjunction with specific research activities. The research must comply with federal regulations regarding protection of human subjects,
and insurers must notify the federal government in writing that they are conducting research. Of note, patients with cancer (beneficiaries or legal guardians) participating in clinical trials should receive requests for voluntary genetic testing in writing with the clear statement that research genetic testing would have no effect on eligibility for benefits and would not affect premiums (U.S. Department of Labor, 2009).

Employers also are prohibited in the use of an individual’s genetic information (e.g., family history, genetic testing, counseling, education, participation in any clinical research) in any employment decision such as hiring, firing, job assignments, or promotions. Finally, GINA prohibits employers from requesting, requiring, or purchasing genetic information about an individual’s family members (up to and including fourth-degree relatives), as well as genetic tests of any fetus of a pregnant family member or legally held embryo from assisted reproductive technology of an individual (Rothstein, 2008).

GINA does not prohibit medical underwriting based on an individual’s current health status; those diagnosed with breast cancer after genetic testing has identified a BRCA mutation may still have their insurance cancelled because of the disease, but not the genetic testing. GINA also does not mandate insurance coverage for any specific medical test or treatment. GINA does not interfere with a healthcare professional requesting that an individual or family member undergo a genetic test. It does not limit a healthcare professional who may be employed by a health plan or insurance company from notifying an individual about diagnostic or predictive genetic tests or providing information to an individual about a genetic test as part of a wellness program. GINA does not subject employers to rules and regulations that are different from other civil rights laws. Workplace collection of genetic information for toxic-monitoring programs, employer-sponsored wellness programs, administration of federal and state family and medical leave laws, and certain cases of unintended acquisition of genetic information is not prohibited. However, the employer may not use or disclose the genetic information for any purpose (Genetics and Public Policy Center, 2008). GINA does not include protection from genetic discrimination in life insurance, disability insurance, or long-term care insurance. GINA’s provisions do not apply to members of the U.S. military, veterans obtaining health services through the Veteran’s Administration, or care through the Indian Health Service (Genetics and Public Policy Center, 2008) (see Table 1).

Changes to Existing Federal Laws

An existing law impacted by GINA is the Employee Retirement Income Security Act (ERISA). Amendments to ERISA include provisions that prohibit group health insurance issuers from denying coverage or discriminating in premium pricing or policy because of an individual’s genetic information. GINA also prohibits those issuers from requesting or requiring a pre- or postenrollment individual to have genetic testing. This means individuals with a family history of inherited cancers (e.g., breast, ovarian) cannot be required by their insurance companies to have genetic testing. In addition, GINA prohibits insurance companies from requesting, requiring, or purchasing the results of genetic tests.

Amendments to the Public Health Service Act include prohibiting health insurance companies from offering coverage to individuals based on their genetic information. GINA prevents insurance companies from excluding coverage of preexisting

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<th>Table 1. Provisions of the Genetic Information Nondiscrimination Act</th>
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<td><strong>PROVISION</strong></td>
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<tr>
<td>Prohibits use of an individual’s genetic information in setting eligibility or premium amounts by group and individual health insurers</td>
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<tr>
<td>Prohibits health insurers from requesting or requiring an individual to take a genetic test</td>
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<tr>
<td>Prohibits use of an individual’s genetic information by employers in decisions such as hiring, firing, job assignments, and promotions</td>
</tr>
<tr>
<td>Prohibits employers from requesting, requiring, or purchasing genetic information about an individual employee or family member</td>
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<tr>
<td>Does not prohibit workplace collection of genetic information for toxic-monitoring programs, employer-sponsored wellness programs, and administration of federal and state family and medical leave laws</td>
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<td>The law went into effect for health insurers on May 21, 2009. The law in regard to employment genetic discrimination went into effect in November 2009.</td>
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conditions based on genetic information. GINA states that genetic information should be treated the same as an individual’s private health information under HIPAA (U.S. Department of Labor, 2008, 2009). This means genetic test results or a pedigree indicating an inherited cancer syndrome or family history of cancer cannot be the only reason for denying insurance coverage. In addition, patients cannot be denied coverage for a preexisting condition based on genetic test results showing positive for a mutation (Genetics and Public Policy Center, 2008). GINA also prohibits using genetic information for Medicare purposes and to issuers of Medigap policies, amending both the Internal Revenue Code and Social Security Act (Laurent, Klamut, & Sullivan, 2008; U.S. Department of Labor, 2009) (see Table 2).

GINA’s health insurance provision does not apply to three groups of Americans. Prior to genetic testing, oncology nurses should carefully determine whether patients or their families are planning to receive or are receiving health care through the U.S. military, Veteran’s Administration, or Indian Health Service (Genetics and Public Policy Center, 2008). The U.S. military and the Veteran’s Administration have their own internal policies that prevent discrimination because of genetic information. The Indian Health Service also has nondiscriminatory policies in place; however, limited funding is available to this organization for genetic testing (National Coalition for Health Professional Education in Genetics, 2011).

### Enforcement

GINA’s health provisions are enforced through agencies whose laws were amended, thus affected, by GINA. The U.S. Departments of Labor, Treasury, and HHS enforce Title I of GINA, and the Equal Employment Opportunity Commission is responsible for the enforcement of Title II (HHS, 2009). The privacy provisions in Title II of GINA, enforced through HIPAA, include civil fines of $100 per violation incidence and criminal fines up to $250,000 with 10 years in prison for violations of a commercial and malicious nature (Laurent et al., 2008). Title II also includes the provision that individuals have the right to pursue private litigation (HHS, 2009). ERISA and the Public Health Service Act enforce discrimination provisions with fines of $100 per day per person, ranging from $2,500–$15,000, with a maximum of $500,000 for unintentional discrimination violations. Penalties for violations of discrimination because of reasonable cause or neglect are authorized by the Secretary of Labor (Laurent et al., 2008).

Examples of protected genetic tests under GINA are the mutations associated with hereditary breast and ovarian cancer and hereditary nonpolyposis colorectal cancer, genetic properties of an existing tumor that could help determine therapy, Huntington disease mutation, and carrier screening for disorders such as cystic fibrosis, sickle cell anemia, spinal muscular atrophy, and fragile X syndrome. Routine tests (e.g., complete blood counts, cholesterol, liver function) are not protected under GINA. In addition, DNA analysis of infectious agents (e.g., bacteria, viruses, fungi) is not protected under GINA. Following this reasoning, an HIV test is not covered under GINA because HIV is a retrovirus that inserts itself into humans, not human DNA (Genetics and Public Policy Center, 2008). Under GINA, a genetic test also is not an analysis of proteins or metabolites that relate directly to a disease or pathology that could be detected by a healthcare professional on an annual examination or follow-up appointment (HHS, 2009) (see Figure 2).

Despite comprehensively prohibiting employer acquisition of genetic information, employers likely would continue to obtain genetic information through conversations (e.g., water-cooler talk) and inadvertently through serendipitous discovery when searching for results to common laboratory tests. In accordance with section 102(d)(3) of the Americans With Disabilities Act, after a conditional offer of employment, employers are permitted to require that individuals submit to a medical examination and sign an authorization for the release of their health records. According to Rothstein (2008), potential employees sign an estimated 10.2 million authorizations for release of their health records each year in the United States. Because of the increased networking of electronic medical records, the disclosure of health records is becoming extensive. Even if employers requested only nongenetic records, compliance could not be ensured. Searching for, identifying, and extracting chart specific information to send in response to requests is time consuming; therefore, sending the whole record is easier. In addition, the people sending the complete medical records may not be aware or appreciative of GINA’s provisions. A current concern for individuals is that employers may have inadvertent access to genetic test results. This remains a major issue for many individuals when GINA is enacted. Complete protection of genetic information requires banning employer requests for comprehensive records at preemployment and

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### Table 2. Genetic Information Nondiscrimination Act’s Effect on Existing Federal Laws

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<th>LAW</th>
<th>CHANGE</th>
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<tr>
<td>Employee Retirement Income Security Act</td>
<td>Prohibits group health insurers from denying coverage or discrimination in price policy or premium change because of an individual’s genetic information</td>
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<tr>
<td>Health Information Portability and Accountability Act</td>
<td>Genetic information should be treated as health information.</td>
</tr>
<tr>
<td>Internal Revenue Code of 1986 and Social Security Act of 1965</td>
<td>Prohibits use of genetic information in regard to Medicare and Medigap coverage</td>
</tr>
<tr>
<td>Public Health Service Act</td>
<td>Prohibits health insurers from offering individual coverage based on genetic information</td>
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Note. Based on information from Laurent et al., 2008.
Protected Tests
- Includes analysis of human DNA, RNA, chromosomes, proteins, or metabolites that detect mutations, changes to chromosomes, and genotypes
- Cancer screening tests
  - Hereditary breast and ovarian cancer
  - Hereditary nonpolyposis colorectal
  - Familial cutaneous malignant melanoma
- Genetic tests
  - Huntington disease
  - Cystic fibrosis
  - Sickle cell anemia
  - Spinal muscular atrophy
  - Fragile X syndrome

Nonprotected Tests
- Routine tests
  - Complete blood counts
  - Blood chemistries
  - Cholesterol and liver function tests
  - Analysis of proteins or metabolites relating directly to a disorder or disease
- Infectious agent tests
  - Bacteria
  - Virus (including HIV)
  - Fungi

Figure 2. Laboratory Tests Protected and Not Protected Under the Genetic Information Nondiscrimination Act
Note. Based on information from U.S. Department of Health and Human Services, 2009.

Future of the Genetic Information Nondiscrimination Act

Since GINA was signed by President Bush in 2008, federal bureaucratic agencies began implementing the law under a new administration in 2009. Will GINA change along with the “players” or “official actors” in the federal government? The proposed Obama healthcare plan addresses the problem of genetic discrimination in two ways. First, it prohibits private insurance companies from excluding individuals from coverage based on preexisting health conditions, which GINA currently does not provide. Second, if insurance companies cannot exclude individuals based on preexisting conditions, then claims cannot be denied payment based on those conditions (Obama for America, 2009).

Enactment of GINA declared a national policy against discrimination in health insurance and employment based on genetic information. However, GINA still has many risks. First, GINA could increase the stigma associated with genetic conditions by treating the genetic information separately and differently from other health information. Second, individuals convinced of GINA's value may undergo predictive genetic testing and inadvertently have their test results leaked to current or future employers. Only time will tell if GINA's protections adequately address the issues of genetic discrimination in employment and health insurance.

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References


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3. Is the literature review comprehensive, and are major concepts identified and defined?
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5. Were you aware of the Genetic Information Nondiscrimination Act of 2008 (GINA)? How has this article affected your awareness?
6. Does your practice assist patients who have concerns about genetic testing? If not, how will this article help you integrate assistance for concerned patients into your practice?
7. What are the limitations of GINA and its coverage for patients undergoing genetic testing?
8. What practice changes will you recommend based on the evidence presented in this article?

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