

GINA Finally Becomes a Reality

The law's passage means new freedom for patients and researchers.

By Joann Boughman

July 14, 2008 | After more than a decade of discussions about establishing a federal standard barring discrimination in employment and health insurance on the basis of personal genetic information, the Genetic Information Nondiscrimination Act (GINA) has been signed into law. The insurance sections of the bill will become effective in twelve months, and the employment provisions in eighteen months.

The purpose of GINA is to prevent potential genetic discrimination in decisions about employment and health insurance coverage on the basis of an individual's genetic testing or screening results. The GINA statute will:

- Prohibit insurance companies that offer group or individual health plans from making decisions about eligibility or adjusting premiums based on an individual's genetic information;
- Prohibit insurance companies from requesting that applicants for group or individual health care coverage plans be subjected to genetic testing or screening, and prohibit them from discriminating against applicants based on their personal genetic information;
- Prohibit employers from using genetic information to refuse employment or collecting employees' personal genetic information without their explicit consent.

While GINA accomplishes the most basic goals intended, exuberance over this legislation must be tempered with the realities of the U.S. health care system—patient access, reimbursement, and privacy issues surrounding the collection and storage of genetic data in scientific research and medical records.

Three Perspectives

1. For clinicians and counselors: Fear of discrimination has deterred many Americans from having medically indicated genetic testing and screening procedures performed. Once GINA takes effect, genetic counselors will not need to spend as much time explaining to their patients the possible adverse insurance or employment consequences that they could experience as a result of misuse of their genetic information. At-risk individuals may now take advantage of predictive genetic testing that will inform early screening, diagnosis, and intervention for diseases with a genetic component (such as cancers, heart disease, diabetes, and depression). Furthermore, clinicians can now order genetic tests for patients and their families in a manner that ensures the full realization of the advantages of personalized medicine models, while easing concerns about genetic discrimination.

However, clinicians' discussions with patients about insurance reimbursement for these tests will remain a challenge, as many patients will not have adequate health care coverage to pay for them. In addition, it will still be difficult for clinicians to gain access to specific genetic tests in some situations because of the patenting process and exclusive licensing practices.

2. For researchers: Fear of discrimination has also kept families and individuals from volunteering to participate in genetic research studies and clinical trials. Now that these concerns have (mostly) been alleviated, Americans can

feel more confident that their personal genetic information cannot be used against them, and encouraged to participate in scientific research studies that require the collection and storage of genetic data. However, GINA will not diminish challenges in the informed consent process surrounding genetic studies.

3. For all individuals: American health care consumers and employees will no longer have to fear potential adverse effects of having themselves or family members tested to assess their genetic disease risk.

The American Society of Human Genetics is pleased that the U.S. government has finally made a commitment to establish a national standard that aims to protect the American people from genetic discrimination. Although many states already had legislation in place, the passage of GINA means the misuse of genetic information resulting in discrimination in employment or health insurance is against the law.

It has taken 13 years of very hard work to get GINA passed. A much larger and more challenging problem is now the integration of genetics into health care practice. A new perspective and much learning must be applied to successfully implement the promise of personalized medicine—enabling clinicians to tailor the testing, intervention, and treatment for each individual patient. However, it is important to note that access to and use of genetic testing, preventative therapies, and tailored treatments must be incorporated fully into the health care system in order to successfully apply genetic knowledge in medical practice, and reap the benefits of preemptive medicine and the resulting cost savings.

Looking back on efforts over the past decade to get GINA passed, Capitol Hill has seemed more like a mountain at times—and we have only just started to climb it!

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