

The GINA Law: Consumer Protection in a New Era of Genetic Testing

The mapping of the human genome in 2003 has resulted in both challenges and promises. A new federal law addresses the problem of potential health insurer discrimination based on genetic information, and the promise of personalized medicine gives clinicians refined options for diagnosis and treatment. Meanwhile, consumers must sort through the implications of more easily available genetic information, and also the allure of direct-marketed at-home testing.

Genomics—research into the human genome, or the cells that represent our genetic “makeup”—plays a role in learning more about the 10 leading causes of death. In 2008-2009, new genetic markers were identified for high blood pressure, diabetes, heart disease and stroke, Crohn’s disease, and cancer. This research can enhance the potential for targeted drug development, for screening and diagnostic tests, and for understanding the etiology of chronic diseases.

Before the mapping of the human genome in 2003, clinicians relied primarily on patients’ and family members’ memory about personal disease risk. Now, genomic discoveries are revolutionizing science, allowing consumers to acknowledge disease risk factors more accurately, pursue treatment options, and maintain their health. Some older adults may claim that such discoveries cannot benefit them directly, but others embrace their potential for their children and future generations.

In May 2008, the Genetic Information Nondiscrimination Act (P.L. 110-233), or GINA, was enacted, nearly 15 years after Congress began examining the issue. Its passage is a major step toward effectively managing and appropriately integrating into our health care system the power of genomics and genetic testing.

Unfortunately, such progress comes with a double-edged sword, perhaps best described by GINA co-sponsor Senator Edward Kennedy (D-MA). He observed, “Discrimination in health insurance and the fear of potential discrimination threaten both society’s ability to use new genetic technologies to improve human health and the ability to conduct the very research we need to understand, treat, and prevent genetic disease.”¹

GINA under the Microscope: What the Law Does and Does Not Do²

GINA is heralded for strengthening safeguards of the 1996 Health Insurance Portability and Accountability Act by limiting insurers’ ability to use genetic information to raise rates for an entire group.³ Also, without preempting existing state laws, GINA sets a national level of protection.

What GINA Does

- Prohibits group and individual health insurers from using a person’s genetic information in determining eligibility or premiums
- Prohibits an insurer from requesting or requiring that a person have a genetic test
- Prohibits employers from using a person’s genetic information in

- making decisions regarding hiring, firing, job assignments, and the like
- Prohibits employers from requesting, requiring, or purchasing genetic information about persons or their family members

Enforcement of the law resides with the Department of Health and Human Services, Department of Labor, and Department of Treasury, as well as the Equal Opportunity Employment Commission.

Examples of Protected Tests:

- Tests for BRCA1/BRCA2 (breast cancer) or HNPCC (colon cancer) mutations
- Classifications of genetic properties of an existing tumor to help determine therapy
- Tests for Huntington’s disease mutations
- Carrier screening for disorders such as cystic fibrosis, sickle cell anemia, and spinal muscular atrophy

GINA crusaders were quick to acknowledge that “the law is not perfect.”⁴ Critics have cited the “arbitrary nature of the categories” it creates (such as the protected tests listed above) and have predicted that insurers might overlook “clearly relevant information such as family history in their risk assessment,” instead relying even more “on current health status when setting rates, even when it has only slight value in predicting future illness.”⁵

What GINA Does Not Do:

- Does not prohibit medical underwriting based on current health status
- Does not cover life, disability, or long-term care insurance
- Does not mandate coverage for any particular test or treatment

- Does not prevent health care providers from recommending genetic tests to patients
- Does not apply to members of the military

The Promise of Personalized Medicine

Since the mapping of the human genome was completed six years ago, there has been a flurry of related clinical and consumer developments. Thanks to advances in genomics and genetic testing, before a medicine is prescribed, a patient might undergo a test to predict how a drug will work given the patient’s genetic makeup. The test might also help predict one’s possible response in terms of the drug’s side effects. Having this precise, personalized information before initiating drug therapy can help clinicians select the most appropriate pharmaceutical intervention or “personalized medicine.”

Studying the linkage of how drugs work (pharmacology) with genomics is called pharmacogenomics. It can help predict the probability of a drug response based on one’s genetic makeup.⁶ For example, several such federal studies involving the common blood-thinner drug warfarin (brand name: Coumadin®) are underway. A National Institutes of Health–sponsored clinical trial involving 1,200 patients taking warfarin began in February 2009. The trial compares a gene-based prescribing strategy with traditional (non-genetic) methods.

However, in May 2009, the Centers for Medicare and Medicaid Services (CMS) said that “available evidence” of such pharmacogenomic testing for Medicare patients on warfarin does not show improved health outcomes,⁷ so Medicare will likely exclude coverage of the tests that can cost up to \$500.⁸ CMS proposed reserving coverage for patients in certain clinical trials who are prescribed warfarin.

CMS is also looking at pharmacogenomic testing to predict adverse reactions to anticancer agent irinotecan (Camptosar®), along with other “gene expression” profiling tests to help inform cancer therapy decisions.⁹

The Food and Drug Administration (FDA) began a research partnership in 2008 with pharmacy benefit manager Medco to identify marketed or premarketed drugs “for which pharmacogenomics may improve the dosing, effectiveness, or safety,” said Larry Lesko, Ph.D., director of FDA’s Office of Clinical Pharmacology.¹⁰ Medco and FDA researchers report that about 10 percent of drugs on the market include pharmacogenomic labeling information.¹¹ Blood pressure reducer Toprol XL® and acid reducer Nexium® are the most commonly prescribed drugs with such labeling. According to some genetics policy experts, pharmacogenomics has resulted in only a “modest pay-off” thus far, but the field is ripe with potential.¹²

A Genetic Test for Everyone?

When prescient scientists, policy-makers, and advocates began working on GINA, about 300 genetic tests were available, most of which were for rare diseases. By 2008, testing was available for more than 1,300 conditions. Most tests are offered in clinical settings, and some can be ordered via direct-to-consumer (DTC) test kits.

More than 30 companies offer DTC genetic testing, some with discounts for older adults.¹³ In 2008, the Google-backed startup “23andMe” reduced its personal DNA test price from \$999 to \$399.¹⁴ The company hopes that consumers will see genetic testing as “accessible technology” like that of the iPod and iPhone.

A Memorial Sloan-Kettering Cancer Center (NY) geneticist cautioned that the “implicit marketing strategy of these companies is to involve the consumer in a

‘voyage of genetic self-discovery,’ even if some of the initial paths charted lead nowhere. In the worst-case scenario, the paths may lead to unnecessary medical interventions or false reassurances and missed diagnoses.”¹⁵

This appears to be a common refrain, with the clinical value of most DTC genome tests remaining unproven.¹⁶ “Research is needed to evaluate the predictive value of genomic tests and their potential to improve the use of clinically effective interventions.”¹⁷

Given this relative research void to date, the American College of Medical Genetics, a society for physicians and other clinicians who specialize in genetics, advocates the following minimum requirements for DTC testing:¹⁸

- A knowledgeable professional should be involved in ordering and interpreting a genetic test.
- The consumer should be fully informed as to what the genetic test can and cannot say about his or her health.
- The scientific evidence on which the test is based should be clearly stated.
- The clinical testing laboratory should be accredited by the federal Clinical Laboratory Improvement Amendments, or applicable state law.
- Privacy concerns must be addressed.

States have addressed some DTC concerns: in 2008, over half (26 states plus the District of Columbia) permitted DTC testing without restriction. Thirteen states required a physician or other approved health professional to order tests.

Implementing GINA will help guide the market in terms of fair decision-making when considering health insurance eligibility. Meanwhile, it will take clinicians, geneticists, ethicists, consumers, patients, and caregivers

working together to appropriately harness the power of genomics and genetic testing.

Family Health History: Moving Beyond “Ask Grandma!”

Long before the mapping of the human genome, questioners of a family member’s health history were directed to “Ask Grandma!” Grandmothers are likely to have the best information regarding family members’ medical conditions. Complemented by scientific advancements in genomics, and by sophisticated technology in genetic testing, older adults continue to play a key role in sharing, and verifying, their family’s health history.

Indeed, 96 percent of Americans believe that knowing their family health history is important, yet only one-third have recorded it. To help close this gap, the Department of Health and Human Services offers a new tool, the **Surgeon General’s My Family Health Portrait**, at: <https://familyhistory.hhs.gov>.

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³ Ibid.

⁴ Ibid.

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⁸ Pollack A., “Gene Test for Dosage of Warfarin is Rebuffed,” *The New York Times*, May 5, 2009

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