
EDITORIAL

Before Ordering a Genetic Test Get to Know GINA

Urologists, other health care providers and even consumers who order their own genetic testing should really get to know GINA. Who or what is GINA? Is it some new virtual voice activated personal assistant? Is she a new Italian super star? Neither choice is correct. GINA stands for the Genetic Information Nondiscrimination Act, a US federal law that was put in place to protect consumers from discrimination based on their genetic testing. GINA celebrated its 10th anniversary in 2018.

There has been a rapid expansion of genetic testing in health care from risk assessment through determining treatment options. Once only in the domain of health care providers, anyone can now go on line to order a variety of disease specific genetic tests on their own. It is imperative that the consequences of ordering what appears to be a routine test must be clearly understood by both providers and consumers. This is why we all need to get to know GINA.

GINA was signed into law by President George W. Bush in 2008. However, the first legislative attempts to pass such a bill actually date back to 1995. As the Human Genome Project took shape in the early 1990's, the implications of this historic advance in medicine began to be considered. Scientific researchers, patient advocacy groups and lawmakers began to address the perceived fears and the need for fundamental protections against discrimination that could result from the clinical application of this new research. Over the next 13 years there were many attempts to pass a federal law protecting individuals from discrimination based on their unique genetic information. With the 2008 passage of GINA, the director of the National Human Genome Research Institute Dr. Francis Collins stated "It will make it safe for Americans to benefit from the medical results of the Human Genome Project. . . . It will make it safe to have their genes examined without fear that they may be discriminated against in employment or health insurance".

Multiple federal agencies have jurisdiction over GINA which has two main components, Title I and Title II. Title I of the law regulates the implementation of GINA in matters of health insurance with administration and the enforcement of Title I overseen by the Department of Labor, the IRS, and the Centers for Medicare & Medicaid Services. The Equal Employment Opportunity Commission takes responsibility for administering and enforcing the GINA Title II nondiscrimination provisions in the workplace.

What are the protections provided by GINA? Title I covering health care insurance prohibits the use of genetic information to determine premiums and forbids insurance companies from requiring an individual undergo genetic testing. It also addresses issues concerning eligibility determinations, premium computations, and the use of pre-existing condition exclusions. Title II of GINA prohibits the use of genetic information in employment decisions, including hiring, firing or job assignments. GINA strengthened the safeguards implemented by Health Insurance Portability and Accountability Act (HIPAA) in further restricting the use of genetic information.

However, the protections afforded by GINA are not all encompassing. It has been suggested by groups such as the American Society of Human Genetics that there is a lack of understanding of GINA's protections by both the public and health care providers. There are some important areas not covered by GINA. It does not provide coverage for life, disability or long term care insurance. It does not apply to companies with less than 15 employees or members of the US military and other government entities such as the Indian Health Service and TRICARE. In defined areas of medicine such as the potential for the treatment of advanced prostate cancer based on genetic germ line testing, the opportunities are clear. However, the implication of testing men with early stage prostate cancer it is less clear on how it may impact their insurance options in the future.

In the age of personalized medicine and with the increasing use of genetic testing the "genetic information" obtained will continue to evolve as a powerful tool in improving health care. Patients must be informed that while GINA is a strong law it is not perfect and may limit some insurance options for patients who have been identified with a disease specific genetic predisposition. It is essential that a proper informed consent be obtained before the genetic test is ordered by a health care provider and that the provider understands what protections GINA does and does not afford the patient. For the individual who independently orders an on-line test that provides more genetic information than just their Neanderthal ancestry, "Caveat emptor" (let the buyer beware).

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