

Bipartisan Genetic Research Privacy Protection Act Introduced

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ON APRIL 5, 2016, United States Senators Elizabeth Warren (D-MA) and Mike Enzi (R-WY) introduced the bipartisan Genetic Research Privacy Protection Act. This Act aims to enhance and expand privacy protections for those involved in biomedical research.

At the present time, there is a great deal of interest in sharing genetic information in the course of research and that interest will only increase. The Genetic Information Nondiscrimination Act of 2008 (GINA) was forward looking in offering protections that have been important to the development of genomic science and precision medicine. When GINA was passed in 2008, those of us who had worked on it for more than 12 years remarked that we would have to do a great deal of education about the Act, since for many Americans the word “genetic” was not in their general lexicon. Now TV and Facebook regularly have ads for Ancestry.com and 23andMe. It is not unusual to hear a radio commercial for the local hospital claiming to use personalized or precision medicine as a part of everyday care, including “examining your genotype.” Americans know the word “genetic” and even the word “genomic” now. GINA was limited to prohibiting genetic discrimination in health insurance and employment.

This familiarity does not mean Americans understand the implications of genetics and genomics in our lives. This is still an area of intense research and the need for increasing discoveries. It does mean that we are more concerned about the ubiquitous nature of what once seemed relegated to rare conditions. When employers are talking about using genetic information to make decisions about wellness programs, we know we are in a very different era than when GINA was passed. In another dramatic indication of more widespread use of genomic information, the Precision Medicine Initiative will build a database of more than 1 million people, and eventually store the genomic information from these individuals. Thus a large increase in research that includes genomic information is quite possible.

In introducing the Genetic Research Privacy Protection Act, Warren said, “To help to bring forward the next generation of precision medicine, researchers are collecting more and more genetic information. When that genetic information is stored at our nation’s research institutions, families should have complete confidence that it will remain private.”

The Genetic Research Privacy Protection Act offers these provisions (Genetic Research Privacy Protection Act, 2016):

- Adds a specific Freedom of Information Act exemption for all identifiable information, including genetic information, in the Public Health Service Act.
- Requires the NIH to issue Certificates of Confidentiality to all federally funded researchers who collect identifiable information and strengthens Certificates of Confidentiality so that identifiable information must be kept private. Important exceptions to CoCs allow for research data sharing, protection of health and safety, and research participants to access their own data.
- Protects any information that is identifiable from FOIA requests and, through enhanced Certificates of Confidentiality, ensures that research participants are protected currently and into the future.

In April when this new Act was introduced, Enzi said, “I was proud to work on the Genetic Information Nondiscrimination Act in 2008 and have championed this issue. There is almost nothing more personal than an individual’s genetic information and by strengthening the privacy protections, we not only provide security for those participating in the research, but help secure the future of advanced medical research.” Senator Enzi was a key supporter of GINA in the years just before it was passed. Rep. Louise Slaughter (D-NY) introduced GINA and relentlessly pursued it in Congress after Congress. Other major supporters included the late Senator Edward Kennedy (D-MA) and Rep. Judy Biggert (R-IL).

The year before GINA was passed, at a hearing in the House of Representatives, Francis Collins, then director of the National Human Genome Research Institute, quoted Thomas Jefferson’s words on the Jefferson Memorial and this is still a poignant remark. Jefferson said, “Our laws and institutions should keep pace with the progress of the human mind.” Certainly science is accelerating drastically, and policy seems to have a difficult time keeping pace.

The Genetic Research Privacy Protection Act has been introduced almost 20 years after GINA was introduced. The world is a much different place since that time. Although that bill was forward looking, it is time to provide important protections so that personal genetic information in the

possession of federal agencies would not be made public, and to guarantee confidentiality by federally funded researchers.

A fact sheet (Fact Sheet on the Genetic Research Privacy Protection Act, 2016) about the Genetic Research Privacy Protection Act and a copy of the bill text (Text of the Bill, 2016) are both available on Senator Warren's website.

Author Disclosure Statement

No competing financial interests exist.

References

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Text of the Bill. www.warren.senate.gov/files/documents/Genetic_Research_Privacy_Protection_Act.pdf (Accessed April 20, 2016).

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