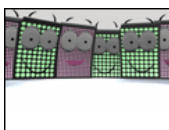




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Senate Unanimously Passes GINA, Though With 'Compromises'; Now Faces Sympathetic House

[April 30, 2008]

By [Turna Ray](#)

After installing compromises and "minor" changes, including a "firewall" separating the potential liabilities insurers and employers could face, the US Senate last week unanimously passed the Genetic Information Nondiscrimination Act.

The bill, which seeks to protect individuals' genetic information from being misused by insurers and employers, now moves to the House, where it is also expected to pass, and then to the White House, where President Bush is expected to sign it into law.

According to American Society of Human Genetics Executive VP Joann Boughman, the Senate version of the bill adopts language appearing in the House bill (HR 493) designed to "limit, but not completely prevent," employees from suing their employer for being denied insurance based on genetic information obtained by a payor.

The bill exempts employers from liabilities if the employer "inadvertently" garners genetic information through a company-sponsored wellness program, or must request such information in order to monitor biological effects of toxic substances in the workplace. The bill's language also specifies that "an employer, employment agency, labor organization, or joint labor-management committee shall not be considered to be in violation ... [for the] use, acquisition, or disclosure of medical information that is not genetic information about a manifested disease, disorder, or pathological condition of an employee or member, including a manifested disease, disorder, or pathological condition that has or may have a genetic basis."

Industry observers have long said that the lack of legal protections for people's genetic information deters them from participating in clinical trials for gene-based therapies and tests, which in turn hampers advances in the genetics field.

In an NIH-funded study of families newly -diagnosed with a hereditary cancer syndrome named hereditary non-polyposis colorectal cancer, researchers found that participants consistently asked how their involvement in the study would impact their and their families' insurance. During the study, "it was clear that there was an overwhelming concern, and in some cases, a palpable anxiety about the impact of genetic testing on health insurance," Donald Hadley, an associate investigator and a genetic counselor with the National Human Genome Research Institute, said in a 2004 testimony to the HHS Secretary's Advisory Committee on Genetics, Health, and Society.

"These concerns dominate our informed consent process and recur session after session with an intensity that opened our eyes to the level of concern that the public feels about genetic discrimination," Hadley said in his testimony.

With the expected passage of GINA, academic genetic researchers, diagnostics firms, and pharmacogenomics companies can better assure clinical trial participants that their genetic data will not be used to make insurance or employment decisions, and that they have recourse under the law if their genetic information is abused in such a manner.

GINA is expected to go back to the House of Representatives where it will be aligned with the Senate version of the bill and voted on again. Because GINA has already passed in the House twice with "considerable support," it is not expected to encounter any problems when the lower chamber votes on it, which can happen as early as this week.

Once it clears the House, GINA is expected to be signed into law "in short order," Kurt Bardella, press secretary for GINA sponsor Sen. Snowe, told *Pharmacogenomics Reporter* sister publication *GenomeWeb Daily News* last week.

In a recent address to the National Institutes of Health, President George Bush said he is willing to sign the bill into law if it passes Congress.

GINA's Long Haul

Since last summer, after GINA cleared the House the first time by a vote of 420 to 3, the bill has had many detractors. The bill's main opponent was Senator Coburn, who placed a hold on GINA, citing concern that the bill could potentially increase lawsuits against employers.

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Mainly, Coburn wanted the bill to include a “firewall” that would prohibit employees from being able to sue their employers if an insurer denied coverage based on genetic information.

“Although nearly 40 states have had individual forms of the legislation in place, with the federal passage of GINA, the message would be unambiguous: the misuse of genetic information resulting in discrimination in employment or health insurance is against the law in all U.S. states.”

Then in March, in a surprising move, the House passed GINA by a vote of 264 – 148 as part of the Paul Wellstone Mental Health and Addiction Equity Act of 2007 (H.R. 1424), which would require health insurers to cover mental health and substance abuse-related disorders under group health plans.

Attaching GINA to that bill appeared to invite more detractors to the expanded legislation. When the Wellstone bill passed in the House, 11 senators, including Coburn, sent a letter to Democratic leaders in Congress raising concerns about GINA’s ability to “maintain current law distinctions between employee benefit disputes ... and disputes about civil rights in the employment context.”

Some of GINA’s other detractors, including the US Chamber of Commerce, the National Association of Manufacturers, and the National Retail Federation, shared the Senators’ concerns. These groups, which formed the Genetic Information Non-Discrimination in Employment Coalition, remained optimistic that the group may be appeased with “minor technical fixes” to

GINA, according to Michael Eastman, executive director of labor policy at the US Chamber of Commerce.

With GINA’s passage in the Senate, it seems those “minor fixes” are now in place.

Senator Coburn’s office did not return requests for comment on GINA’s passage prior to deadline.

Employer Exemptions

Although the bill would make it unlawful for an employer to obtain genetic information from an employee or a family member in order to make employment decisions, the employer is not held liable for a number of scenarios.

For example, an employer would not be breaking the law if he “inadvertently requests or requires family medical history of the employee or family member of the employee” through a employee-provided wellness program; if the employee provides prior, knowing, voluntary, and written authorization; if the employee and the doctor receive individually identifiable information concerning the results of such services; and if the employer receives genetic information regarding these services in “aggregate terms that do not disclose the identity of specific employees.”

The employer is also exempt if genetic information is requested to comply with medical leave laws; if an employer purchases documents that are commercially and publicly available that include family medical history; or where the information involved is to be used for genetic monitoring of the biological effects of toxic substances in the workplace. In the last instance, the employer is required to provide written notice of the genetic monitoring on an employee.

Genetic Alliance President Sharon Terry described the compromise as a product of a “great conversation” between all parties involved and the engagement of the genetics community. She also suggested that the sudden advancement in consumer genetic testing businesses over the past year, and greater discussion in the media about the uses and ethics of such tests, could have helped push the bipartisan effort to pass GINA.

Grassroots Instruction

Expecting GINA to be signed into law, its supporters are now focused on educating physicians and patients regarding their rights.

“Our challenge now is to make sure that doctors and patients are aware of these new protections so that fear of discrimination never again stands in the way of a decision to take a genetic test that could save a life,” Kathy Hudson, director of the Genetics and Public Policy Center at Johns Hopkins University.

The pending passage of the bill also was lauded by the Personalized Medicine Coalition, a collection of industry, academic, payor, and other partners. The PMC lauded two of its members, IBM and Eli Lilly, for adding genetic nondiscrimination to their employment policies in advance of GINA’s passage.

“GINA closes important gaps in the current patchwork of federal and state protections against the misuse of genetic information,” the PMC said in a statement. “Current federal statutes for protecting medical information, including the Health Insurance Portability and Accountability Act, do not prohibit insurers from requiring genetic testing or from denying coverage based on genetic information; and while the Americans with Disabilities Act protects individuals with symptomatic genetic disabilities, it is not clear if it explicitly covers discrimination based on unexpressed genetic susceptibility to disease.”

In the ASHG’s view, the promulgation of a national genetic anti-discrimination law will help clear up the confusing patchwork of state laws that have emerged.

“Although nearly 40 states have had individual forms of the legislation in place, with the federal passage of GINA the message would be unambiguous: the misuse of genetic information resulting in discrimination in employment or health insurance is against the law in all US states,” the ASHG said in a statement.

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