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Protecting your genome

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by Jeffrey Bouley

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WASHINGTON—In what the [Coalition for Genetic Fairness](#) is calling the first civil rights legislation of the new millennium, the Genetic Information Nondiscrimination Act (GINA) was signed into law by President George W. Bush on May 21 after a 95-0 vote in favor by the Senate in late April and a 414-1 vote in favor in the House a week later. The measure bans employers and health insurance plans from discriminating against people based on genetic tests that show they may be predisposed to various conditions.

The question is, what effect, if any, will this have on the drug development community? That answer depends on whom you ask, though the buzz seems pretty upbeat at the moment.

“With the long-awaited federal passage of GINA, researchers and clinicians can now actively encourage Americans to participate in clinical trials without the fear of genetic discrimination,” Joann Boughman, executive vice president of the [American Society of Human Genetics](#), said in a statement after the House passed the bill. “Furthermore, under the federal protection provided by GINA, health care practitioners will be able to recommend appropriate genetic testing and screening procedures unencumbered by the fear of discrimination based upon the results.”

Sharon Terry, president of the Coalition for Genetic Fairness and CEO of the [Genetic Alliance](#) also sees the arrival of GINA as having enormous impact on drug development, noting the frustration that she says exists over many some people’s reluctance to enroll in clinical trials. That reluctance, she maintains, often arises from fears that their genetic information will leak out to their employers or insurers.

“The consent forms tell you clearly that you may be discriminated against in employment or insurance as a result of participating in trials, and who would want to do that?” Terry asks. “That’s a phrase that can start being taken out in the next year to year-and-a-half as the employment provision of GINA goes into effect in 12 months and the insurance provision goes into effect in 18 months.”

As a side benefit, Terry notes that the members of the U.S. Congress have shown a vastly increased literacy about bioresearch and genetic issues than ever before during the debates and discussions about GINA.

“With so many pharmas relying on venture money and people who will back risky projects, I think they will be heartened to know that Congress has shown an interest in becoming so much more knowledgeable about these issues now,” Terry says.

But some analysts don’t see much impact, and one of them is Dr. Kenneth G. Krul, a senior analyst and contributing editor with [Kalorama Information](#), a market research firm focused on pharmaceuticals, medical devices, diagnostics, biotechnology and healthcare. He cannot recall any circumstances in which genetic information from a trial was ever attached to a specific person and resulted in discrimination.

“GINA certainly isn’t going to make the pharma world jump out of any windows to put new processes in place, as companies have already tightened up on privacy and nondisclosure policies over the years and have gotten pretty good at it,” Krul says. “They already have a great system in place. Also, many patients don’t really read the consent forms with a highly critical eye, so they often aren’t even aware how their genetic information is being handled or where it might be going anyway, so I don’t think this has held many people back from trial participation.”

Also, Krul is concerned about the fact that while GINA addresses the issue of health insurance discrimination, it ignored the issue of life insurance discrimination. Given that plenty of companies offer both life and health insurance, Krul finds it unlikely that genetic information in the hands of those companies won't cross over that invisible line, no matter what GINA says.

Terry herself has concerns about the life insurance issue and says that her organizations and other advocacy groups will be working to correct that oversight in future legislation. She adds that long-term disability coverage was also excluded from the GINA umbrella and that, too, is a loophole she plans to see closed.

As for the one voice of dissent in the House regarding GINA—recent Republican Party candidate for president Ron Paul—the Texas representative said in part on the House floor in late April that given the federal government's poor record in protecting privacy, "I do not believe the best way to address concerns about the misuse of genetic information is through intrusive federal legislation." DDN

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