

# Law Limits Third-Party Use of Genetic Info

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Patients will soon be able to undergo genetic testing without fear of discrimination from either their health insurers or their employers, thanks to a new law signed by President Bush.

The Genetic Information Nondiscrimination Act (H.R. 493), which passed both houses of Congress by wide margins, prohibits health insurers from using genetic information in determining eligibility or setting premiums and forbids employers from using that information for decisions about hiring, firing, job assignments, or promotions. The law also prohibits health insurers and employers from requesting or requiring that individuals take a genetic test. The health insurance provisions in the law will go into effect in 12 months, and the employment provisions will take effect in 18 months.

“Genetic testing holds great promise for improving public health, and patients must be able to trust that their genetic information will be protected from inappropriate and discriminatory uses,” Dr. Edward Langston, board chair of the American Medical Association, said in a statement. “This new law will allow patients to take advantage of scientific advances in genetics, such as screenings and therapies, without worrying that their personal health information could be used against them by insurers or employers.”

Supporters of the law are hailing it as the first civil rights legislation of the new millennium. In practice, experts say that patients who might have been hesitant to undergo testing for fear of discrimination may be more willing. Some patients who would be good candidates for genetic testing have been refusing or taking tests under assumed names, said Sharon Terry, president of the Coalition for Genetic Fairness and CEO of the Genetic Alliance.

The frequency of genetic discrimination has been difficult to document, but it's clear that fear of discrimination has been a barrier to genetic services for some, said Dr. Matthew Taylor, director of adult clinical genetics at the University of Colorado in Denver. Last year, the Genetics and Public Policy Center at Johns Hopkins University, Baltimore, conducted a survey of 1,199 U.S. adults on genetic testing and discrimination and found that 92% of respondents expressed concern that the results of a genetic test for disease risk could be used against them in some way.

One of the biggest impacts of the law may be its potential to alleviate concerns about genetic discrimination among both patients and physicians, Dr. Taylor said.

Another area where the law is likely to have a significant impact is in research. Many informed consent forms for clinical trials include statements warning partici-

pants that they could be discriminated against on the basis of their genetic information, according to Ms. Terry. The Coalition for Genetic Fairness plans to mount an educational campaign to make patients and physicians aware of the new protections in the law in the hopes of increasing participation in research, she said.

The law was a long time coming, according to supporters. Legislation on genetic nondiscrimination was first introduced in 1995. The bill has had broad



President Bush signs the bill into law. Experts say it might ease patients' concerns about discrimination.

support in Congress for many years but couldn't get to the House floor under the Republican leadership, according to Susannah Baruch, associate director of the Genetics and Public Policy Center at Johns Hopkins University. The other change that propelled the legislation forward was the explosion in the number of genetic tests available, she said.

About 1,200 genetic tests can be used to identify thousands of health conditions, according to the Coalition for Genetic Fairness. Only about 100 genetic tests were available a decade ago.

Over time, the legislation has garnered support from a broad coalition of groups, including the health insurance industry. “With this landmark bipartisan legislation, Congress and the President have taken strong action to prohibit discrimination based on a person's genetic makeup and to protect patients' privacy as they pursue genetic evaluations,” Karen Ignagni, president and CEO of America's Health Insurance Plans, said in a statement. “This legislation also ensures that patients can continue to benefit from health plans' innovative early detection and care coordination programs that improve the safety and quality of care.”

But more work needs to be done, Ms. Terry said. The Coalition for Genetic Fairness has been working with Sen. Edward Kennedy (D.-Mass.) and Sen. Barack Obama (D.-Ill.) on better oversight for genetic testing in general. And the Agency for Healthcare Research and Quality recently issued a report calling for improvements to public health surveillance databases and health information technology used to monitor genetic tests.

Potential discrimination in life insurance and long-term disability insurance also needs to be addressed, Ms. Terry said. “This is a first-step bill for sure.” ■

## POLICY & PRACTICE

### Grassley Seeks Paxil Inquiry

Sen. Chuck Grassley (R-Iowa) is asking the Food and Drug Administration to investigate data it has from Glaxo-SmithKline on paroxetine (Paxil), alleging that the company may have withheld knowledge of a risk of suicide and suicidal ideation. In a letter to FDA Commissioner Andrew von Eschenbach, Sen. Grassley cited a report by Harvard University psychiatry professor Dr. Joseph Glenmullen contending that GSK knew of Paxil's heightened suicide risk when it first sought FDA approval in 1989, but obscured the findings. Dr. Glenmullen's report was prepared for a plaintiffs' lawyer in August 2007 and was recently unsealed. Sen. Grassley also cited a recent report by the U.K. Medicines and Health Regulatory Authority, which determined in February that GSK knew of the risks in 1988. The company's responses to the senator so far “have been less than candid,” the senator said. In a lengthy statement, the company said it had requested a meeting with Sen. Grassley “to clarify some misunderstandings,” and also attacked Dr. Glenmullen, saying that his methodology is “scientifically flawed and unreliable.” “We remain firm in our belief that we acted properly and responsibly in the conduct of our clinical trials program for Paxil, documentation and submission of results from studies to regulators, and communication of important safety information to regulatory agencies, the scientific community, and the public,” the company said.

### THC Levels Highest Ever

The federal government says that levels of tetrahydrocannabinol (THC) in marijuana are at the highest-ever recorded amounts, and that the potency may be contributing to increasing numbers of teenagers seeking treatment for dependence. The University of Mississippi's Potency Monitoring Project tests marijuana primarily taken during law enforcement seizures. The project is funded by the National Institute on Drug Abuse. A normal THC level is 1%-5%, but the average potency from the latest quarterly report was 9.6% for marijuana and 24% for hashish. The report is based on 1,248 marijuana samples and 33 hash samples. The highest recorded potency was 37% for marijuana and 66% for hashish. “The increases in marijuana potency are of concern since they increase the likelihood of acute toxicity, including mental impairment,” said Dr. Nora Volkow, NIDA director, in a statement. The federal Office of National Drug Control Policy said increasing potency might be linked to the increase in treatment admissions for marijuana abuse from 6% in 1992 to 16% in 2006.

### DOD Improves on Mental Health

The Department of Defense is making some progress on screening troops for traumatic brain injury (TBI) and on screening for mental health issues before deployment, but there are still

many gaps in the system, according to a report released last month by the Government Accountability Office. The GAO reviewed predeployment mental health screening, tracking of postdeployment mental health referrals, and implementation of screening for mild TBI. The agency determined that clinicians have received inconsistent instructions on predeployment screening. During visits to three sites, for instance, investigators found that physicians did not know they were supposed to review medical records as part of the predeployment screen. Tracking of referrals is often hampered by a lack of electronic record keeping, and the fact that National Guard and Reserve troops receive civilian care, said the agency. The military is doing better on TBI screening, said the GAO. Screening questions were added in January to postdeployment assessments, and, starting in July 2008, all troops will be assessed for mild TBI before they go overseas.

### Drug Lobby Spending Is Up 32%

The pharmaceutical and medical device industries had yet another banner year for spending on lobbying in 2007, according to a new report by the Washington-based Center for Public Integrity. Last year, the pharmaceutical industry alone spent at least \$168 million on lobbying members of Congress, a 32% increase from 2006, according to the report. Forty companies and three trade organizations—the Pharmaceutical Research and Manufacturers of America, the Biotechnology Industry Organization, and the Advanced Medical Technology Association—accounted for 90% of the spending. PhRMA led the way, spending \$23 million in 2007. Amgen Inc. and Pfizer Inc. were the two biggest individual spenders, at \$16 million and \$13 million, respectively. Most efforts went into blocking drug reimportation, protecting patents, and on free-trade agreements. The industry also went to bat for reauthorization of the State Children's Health Insurance Program, and extensions of the Prescription Drug User Fee and Best Pharmaceuticals for Children acts, according to the center's analysis of lobbying records submitted to the Senate Office of Public Records.

### Consumer Reports Rates Hospitals

Consumer Reports has begun grading hospitals and plans to eventually add ratings for other health care providers. The ratings, which include nearly 3,000 hospitals, are available at [www.consumerreportshealth.org](http://www.consumerreportshealth.org). The online tool allows consumers to compare hospitals based on their treatment approaches for nine chronic conditions. The comparison includes the time spent in the hospital and average out-of-pocket costs for each condition. The effort is the first project of the newly launched Consumer Reports Health Ratings Center.

—Alicia Ault