

GENETIC CONFLICT

Advocates, legislators gear up for battle in the fight to keep genetic information, testing secure from employers, insurers

Carolina Hinestrosa was 35 when she beat breast cancer. She was 40 when she beat it a second time. Her younger sister also battled breast cancer twice, and over the past few years, two of her cousins and an aunt were diagnosed with the disease.

Of course, Hinestrosa, an executive vice president with the National Breast Cancer Coalition, strongly suspects that a genetic mutation for breast cancer runs in her family. Knowing for sure could help her and her relatives take steps to possibly avoid or better manage the disease. But she said she has chosen not to seek confirmation through a genetic test for fear of the potential consequences it may have on her 15-year-old daughter.

Hinestrosa worries that if she tests positive for the “breast cancer gene,” her daughter might be obligated to disclose having a hereditary predisposition to the disease—personal information that could be misused to deny her health insurance or even employment in the future.

“As a mother, my highest priority is protecting my next generation, my daughter,” Hinestrosa said. “I went to genetic counseling and determined there weren’t enough protections to make me feel confident that this information wouldn’t be used against me or my daughter.”

But that could soon change.

Congress is on the brink of breaking a 12-year impasse over federal legislation designed to prohibit so-called genetic discrimination, in which otherwise healthy individuals based solely on their potential for developing an illness down the road (Feb. 13, 2006, p. 6).

The legislation has reappeared in every Congress since 1995, when it was first introduced by Rep. Louise Slaughter (D-N.Y.). Versions of the bill passed the Senate by unanimous votes in both 2003 and 2005, only to be squelched by Republican House committee leaders before the legislation could reach the House floor. But with both houses

That’s welcome news for many scientists, clinicians and patient advocates who say federal legislation would go a long way toward allaying the fears that have prevented many Americans from participating in important genetic research studies or undergoing genetic tests that could help them prevent or better cope with hereditary illnesses. “I’m very excited. If Congress passes this bill, a huge sigh of relief would settle on the research community,” said Francis Collins, a physician and director of the National Human Genome Research Institute at the National Institutes of Health.

Still, after waiting more than a dozen years to get to this point, Collins said he’s “still concerned about any kind of glitch that might prevent this bill from crossing the finish line.”

Indeed, employer groups continue to oppose the bill, calling it a premature effort that would result in higher costs, new administrative hassles and a slew of frivolous lawsuits. “It’s a remedy in search of a cause,” said Burton Fishman, a Washington-based attorney with the law firm Fortney & Scott who represents a coalition of business interests, including the U.S. Chamber of Commerce. “We think it’s really based on the politics of fear and anecdote and not on reality.”

Insurers have also raised concerns that a poorly worded genetic-privacy law, if enacted, could impede important advances in disease management and personalized medicine, in which doctors use genetic insights to tailor individual treatments. “We completely support the intent of the bill,” said Mohit Ghose, spokesman for the trade group America’s Health Insurance Plans. “With that said, what

“There weren’t enough protections to make me feel confident that this information wouldn’t be used against me or my daughter.”

—Carolina Hinestrosa



GOODMAN/VAN RIPER PHOTOGRAPHY

of Congress now under Democratic control for the first time since 1994, quick passage is all but guaranteed.

Reintroduced by Slaughter on Jan. 16, the bill has already sailed through all three House committees with a say on the issue, and is expected to go before the full House after Congress returns April 9 from a week-long spring recess. A companion bill, sponsored by Sen. Olympia Snowe (R-Maine), passed out of Senate committee Jan. 31 and is awaiting reconciliation with the House version. President Bush has said he would sign the bill into law.

we don't want is to create a system where genetic testing and genetic information cannot be used in any way to improve the quality of care being provided to our members."

Genetic revolution

The bill, formally known as the Genetic Information Nondiscrimination Act of 2007, would amend a number of federal laws, including the Employee Retirement Income Security Act of 1974, to prohibit employers from using genetic information in hiring, firing and other job-placement decisions, and to prevent insurers from denying coverage or charging higher premiums based on someone's predisposition to a genetic condition.

The legislation also would bar insurers and employers from "requesting or requiring" individuals to undergo genetic tests, enforce strict limitations on the use and disclosure of genetic information and impose financial penalties on companies that violate these provisions.

Rapid advances in genetic research during the past few years have made these broad protections more important than ever, the bill's supporters say.

Since the sequencing of the entire human genome was completed in April 2003 under Collins' leadership, researchers have identified genetic markers for hundreds of hereditary conditions, and genetic tests have been developed for everything from the rarest illnesses to some of the most common conditions, such as colon cancer and heart disease. According to the University of Washington's GeneTests Laboratory Directory, the number of diseases for which there are genetic tests has climbed more than 700% to 1,359 from just 169 in 1997 (See chart). Some 1,151 clinics and 615 laboratories now offer such tests.

Some tests are used to clarify diagnoses in patients already showing symptoms while others are predictive, helping to identify people at future risk for conditions that may be preventable or could benefit from early treatment. Scientists are also hard at work on a new wave of tests that can detect genetic variations that affect the way patients respond to certain medications. These so-called pharmacogenomic tests can help doctors determine which drugs and dosages to prescribe to get the best results while preventing potentially life-threatening adverse reactions in specific patients.

Last month, HHS Secretary Mike Leavitt announced his department would spend up to \$352 million next year to support personalized medicine and create standards for including genetic information in electronic medical records. "Personalized healthcare will combine the basic scientific breakthroughs of the human genome with computer-age ability to

exchange and manage data," Leavitt said at a March 23 meeting of the Personalized Medicine Coalition. "Increasingly it will give us the ability to deliver the right treatment to the right patient at the right time—every time."

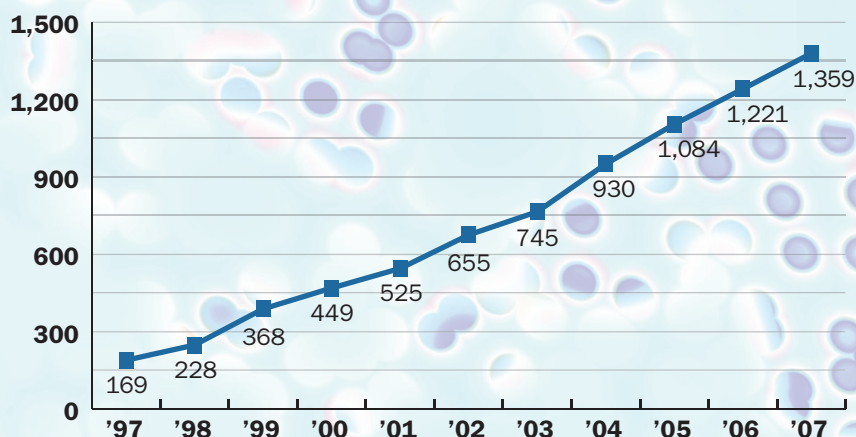
Consumers are generally optimistic about the benefits of such advances. According to a survey released last month by the Genetics and Public Policy Center at Johns Hopkins University, 90% of Americans support the use of genetic testing by doctors to identify a patient's

This fear of reprisal has had a chilling effect on genetic research, industry observers said. Not only are patients forgoing tests that could help improve their lives but a growing number of people are also refusing to take part in research studies or clinical trials for fear their genetic information will be misused, said Catherine Schaefer, director of Kaiser Permanente's Research Program on Genes, Environment and Health.

Schaefer is heading up a new project to

GENETIC TESTING EXPLOSION

Number of diseases for which genetic testing is available



Note: Numbers are as of Jan. 31 of each year

Source: GeneTests Laboratory Directory

risk for future disease.

Yet the same survey found that patients remain highly wary of payers' financial motives: Seventy-five percent of respondents said they don't trust their insurers to have access to their genetic test results, while 83% said they don't trust their genetic information in the hands of their employers. A full 90% of respondents said they were concerned that their genetic information could be used to harm them.

'Tipping point'

"We're at a very interesting tipping point in terms of the future of genetic testing. People are overwhelmingly enthusiastic about the benefits of genetic testing, but overwhelmingly pessimistic about their privacy being protected," said Kathy Hudson, director of the Genetics and Public Policy Center. "Genetic testing has the potential to revolutionize the delivery of healthcare and create safer and more effective medicine. But that won't happen as long as people are afraid their genetic information could be exploited in improper ways."

create an enormous "biobank" of genetic information that would serve as a worldwide resource for clinicians studying the links between genes, environmental factors and disease. In the first step to building the database, Kaiser's research division in February began asking the HMO's 1.9 million adult members in Northern California to participate by completing a health survey. Within a few years, Schaefer said, she hopes to recruit 100,000 to 500,000 of those members to voluntarily provide blood and saliva samples for genetic analysis.

The program has taken pains to ensure potential participants that their survey responses and genetic information will be kept confidential and will not be shared with Kaiser's insurance arm. Still, Schaefer said, some members have expressed reluctance.

"The most common concern we hear among people is that their genetic information will be used to discriminate against them in terms of health insurance or employment or all the possible ways that this kind of infor-

See **GENETIC** on p. 12