David Resnick, a partner at the Boston-based law firm Nixon Peabody, confirms that with his own story. After his mother died of ovarian cancer, Resnick learned that combined with his ethnic background, that fact meant he had about a 16% chance of having inherited a cancer-related mutation. In part for his young daughter's sake, he wants to eventually be tested. "But I was waiting for GINA, because I was concerned [the mutation] could be considered a preexisting condition."

Insurers often cover the test for women who have a family history of breast or ovarian cancer, have had one of these cancers or are of Ashkenazi Jewish descent. But women may prefer to pay for testing themselves to keep the information private.

The test has become increasingly popular as the company has begun direct-to-consumer advertising. For the third quarter of 2008, Myriad's ad campaign fueled a 55% jump in sales, to $59 million for the quarter. The direct-to-consumer radio and television spots have so far run only in the Northeast, but Myriad reportedly plans to expand their distribution later this year.

Consumer-directed advertising of such tests in the US is controversial. Some experts fear that it means more patients will not get adequate genetic counseling when they are tested. Navigenics is one firm that offers genetic counseling as part of its service; it has links to top-flight medical centers, including the Mayo Clinic. But the question is, Will the supply of qualified genetic counselors be able to keep pace with the demand for genetic information from consumers? And in many physician's offices or testing laboratories, there is no genetic counseling available for patients at all.

Beyond privacy concerns and the interpretation of testing results, there are also reservations about the accuracy of some of the information being provided by personal genomics companies. The commercial services say they offer consumers more control of their health and empower consumers with knowledge.

But some experts worry that consumers are receiving information about gene risks that are still being worked out. "These companies are popping up like spring flowers to make money on genetics," Tanzi says. "They should be helping to fill in all the blanks instead."

The growth of genetic testing has naturally garnered some attention from regulators as well. The bulk of such tests do not require Food and Drug Administration (FDA) review because they are carried out in independent clinical labs and are thus exempt from oversight. But a report just released from the Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS) recommended that the FDA should oversee all laboratory tests. The report also advised strengthening monitoring and enforcement of claims about tests, including direct-to-consumer advertisements.

It is also hoped that GINA will boost enrollment in clinical trials that include genetic testing. "If people hear a trial uses an electronic medical record, they are afraid the information will get to their insurance company and they could be discriminated against," says Raju Kucherlapati, a professor at Harvard Medical School and director of the Boston-based Harvard-Partners Center for Genetics and Genomics.

> The bill is timely, as "the industry is pursuing more and more targeted therapies, based on genetic tests."

Quintiles' Cohen concurs. "This will impact the clinical trials arena," he says. The bill is timely, as "the industry is pursuing more and more targeted therapies, based on genetic tests," he adds. "That's the future of personalized medicine."

This particular effect of GINA should be felt across many fields, because "there is increasing recognition that genetics plays an important role in all aspects of human health and disease," according to Kucherlapati.

Even after 13 years of fine-tuning, GINA doesn't please everyone. It does not cover long-term insurance or life insurance. Tanzi points out that many tests will determine risk for conditions, such as heart or central nervous system disease, that typically means the patient will require years of long-term care.

Tanzi would next like to see progress on that long-term care issue as well as an increase in the number of genetic and psychological counselors available to patients who take these tests. He and many other experts agree that better validation of tests and more options for patients who test positive are also needed. Milos, meanwhile, points to another potential landmark for genetics. "I think it's time to reinvigorate the energy around a US National [Genomic] Biobank," she says. "That would be great fuel for new studies."

Malorye Allison, *Acton, Massachusetts*

IN brief

Patent reform stalls

A US District Court has put to rest a battle between the biotech and pharma industries and the US Patent and Trademark Office (USPTO) over patent reform. The USPTO's proposed changes would have radically altered the way the US patent system works and were fiercely opposed by the biotech and pharma industries. In October, GlaxoSmithKline filed suit, arguing that the USPTO lacks the decision-making authority needed to implement such sweeping changes. On April 1, the US District Court for the Eastern District of Virginia ruled in favor of the London-based company, agreeing that the rule changes fall outside the USPTO's authority. The proposed rules would limit the number of amendments inventors can make to existing filings and restrict the number of claims in 'continuation' applications, for example, for new indications. The USPTO maintains changes in patent practice are necessary to cut down on the 760,000 backlogged applications and to help curtail abuses—companies have been known to push forward with rejected patents for decades while an infant technology develops. But biotech companies argue that, given the uncertainties of the discovery process, it is necessary to design broad patents and resubmit applications. "The rules may be resurrected in some form, but most likely after Congress passes some new law and more likely after the new administration takes office in 2009," says Shantanu Basu, a patent attorney at the San Francisco–based law firm Morrison & Foerster. The USPTO has not decided whether to appeal. —*Amy Coombs*

In silico vaccine

The first vaccine designed solely from genomic information has breezed through phase 2 trials in infants. The vaccine—aimed at bacterial meningitis and developed by Novartis Vaccines in Siena, Italy—is the first produced using 'reverse vaccinology', in which genomic information rather than the organism itself is the starting point for vaccine development. The serogroup B *Neisseria meningitidis* bacterium causes sepsis and meningitis in children and young adults and remains a significant threat across the world. For the vaccine, five surface antigens were selected from hundreds of candidates from the serogroup B meningococcus (MenB) genome. These appear to protect against 85 strains of MenB. "This is one of the most important vaccine candidates so far identified," says Muhamed-Khier Taha, of the Pasteur Institute in Paris. The trial, which took place in the UK, demonstrated the safety and tolerability of the recombinant vaccine in babies receiving their first dose at two months, reported researchers at the European Society for Pediatric Infectious Diseases annual meeting held in May in Graz, Austria. Phase 3 trials are due to start in 2008. "If this example reaches the market, it will open a big window on the development of other vaccines taking advantage of the genomic era," says Taha. —*Henry Nicholls*