IN brief

Agency on hiring spree

The US Food and Drug Administration (FDA) in April announced an ambitious plan to hire by the end of September more than 1,300 staff—nearly three times the number of people hired from 2005 to 2007. The agency hopes to achieve this goal with a temporary authority from the federal government allowing it to skip certain rating and ranking steps in the hiring process. The expedited system could put people on the job within three weeks of receiving an offer. "Normally, once you're offered a job [at the FDA], it can take nine months to start working," says Ray Woosley, president of the Critical Path Institute, an independent Tucson, Arizona–based nonprofit organization created to help the FDA safely bring new products to market. The FDA in the past has lost good candidates who weren't able to wait that long for a job, he says. The agency intends to create 770 new jobs and fill 547 vacant positions, and it will hold at least 18 recruiting fairs this summer. Biologists, epidemiologists, pharmacologists and medical officers are needed. Most of the positions will be in the Center for Drug Evaluation and Research, the department that reviews new drugs. About 500 of them will be funded with user fees: money paid by drug and device makers when filing applications to market new products. Legislation passed in September 2007 will increase user fee collections by nearly $139 million in 2008 over the previous year, according to Chris Kelly, an FDA spokesperson. —*Emily Waltz*

University patents probed

After enjoying nearly a decade of protection, states' immunity to intellectual property lawsuits is being challenged in the federal courts. The petitioner in the case, Biomedical Patent Management Corporation, claims that sovereign immunity laws (*Nat. Biotechnol.* **18**, 101, 2000) unfairly shield states—including state universities and research institutions—from patent infringement while allowing them to enforce their own patent rights. The petition argues that, by regularly using the court system to pursue alleged violations from the private sector, universities waive that immunity. In April, the Supreme Court asked the government to comment on the petition before making a decision—a sign that the Court will seriously consider taking the case, say experts. The outcome could have broad implications for biotech companies whose efforts to enforce their own patent rights are often thwarted by courts upholding states' immunity laws. For example, since 1990, six patent actions have been brought against California, and in each case the state raised its patent shield. In the same period, the University of California filed with the courts at least 14 patent infringement suits, according to Biomedical Patent Management Corporation. "You can say it's unfair," says Stephen Albainy-Jenei, a patent attorney with Frost Brown Todd in Cincinnati. "But the university people involved will say it's the law and that they are just making use of it." —*Emily Waltz*

Industry welcomes Genetic Information Nondiscrimination Act

After innumerable iterations, more than 12 years of development and 224 cosponsors, the Genetic Information Nondiscrimination Act (GINA) was signed into law on May 21. GINA passed both the House and the Senate with an overwhelming majority last month (just one vote against). The bill, which targets insurers and employers, prohibits the use of genetic information to set health insurance premiums, deny coverage or affect employment. It also requires that genetic test results be kept private. Passage of the Act has been widely welcomed by commercial genetic testing services that seek a clearer framework for regulating the industry.

Personal genomics companies are likely to benefit by the bill's passage, as people feel more confident about taking genetic tests.

Many companies selling genetic tests, tools for testing or information services reacted with enthusiasm to the news of GINA's passage. "Having federal protection sends a message that the future is now for technology related to genetic information," says Amy DuRoss, head of Policy and Business Affairs at Redwood Shores, California–based Navigenics. Boston-based Helicos's CSO Patrice Milos agrees: "I am confident the public will take this as a positive signal," adding, "This shows we have an informed Congress now. They are knowledgeable about what the future of genomics holds."

Others were more circumspect. "GINA is huge," says Rudi Tanzi, professor of neurology at Harvard Medical School and director of the Genetics and Aging Unit at Massachusetts General Hospital in Boston, Massachusetts. "But we need to remember that this is just one step." Guaranteed long-term care, more treatments for genetically rooted diseases, and more clinically useful tests are still needed to reach the full promise of genetics, he argues.

Many believe that the protections outlined in GINA will now provide the necessary safety net to encourage more patients to take advantage of the new wave of genetic tests currently flowing onto the market. People often cite fear of employment discrimination or health insurance loss as a reason to avoid genetic testing, even if a doctor recommends such tests.

Critics of the bill, meanwhile, contend that it is unnecessary and burdensome, particularly to employers. Companies now need to guard against even unwittingly divulging genetic information; they could face large fines as penalties for breaking the law. "Some people say there hasn't been any discrimination, so why bother having a law?" comments DuRoss. "But the perception of risk is just as real a problem as actual discrimination. People did not feel safe."

By raising confidence in safeguards to protect the confidentiality of personal genetic information, GINA's passage should propel demand for consumer-directed tests. It is certainly fortuitous timing that as GINA passed through Congress, personal genomics companies such as Navigenics and 23andMe, headquartered in Mountain View, California, were busy making high-profile launches of services that scan an individual's genome and then can help them assess and address their own risk, with or without their doctor's or insurance plan's involvement. Testing services such as DNADirect of San Francisco, which offer access to a range of established tests, are also likely to benefit from the bill.

Myriad Genetics, a company based in Salt Lake City, Utah, that markets the *BRCA1* and *BRCA2* tests for hereditary breast and ovarian cancer risk assessment, could be a big winner from the new legislation. "The BRCA test is one I'd expect to become much more sought-after now," says Oren Cohen, senior vice president of clinical research strategies at CRO Quintiles Transnational. "There's pent-up demand for that test, because there was widespread fear of discrimination."

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*