

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.

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.”



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