

## US r&d spending increases for 1998

Projected US federal government spending in research and development (R&D) suggests an increase in most sectors affecting biotechnology in 1998. Overall modest increases of 2% could take the amount spent on civilian (R&D) programs to \$75.5 billion. The US Food and Drug Administration (FDA, Rockville, MD) is slated to receive an increase of 7%, largely funded by increased fees to industry. There are cutbacks in agriculture, but agricultural biotechnology funding will not be cut back.

The prevailing view of the US Department of Agriculture (USDA, Washington, DC) as a soft target for downsizing could lead to cuts in overall R&D funding within the USDA, of 4% to \$1.48 billion. However, it is the budget for the Cooperative State Research, Education, and Extension Service, which handles information services to farmers which is set to decrease—from \$850 to \$842 million. The Agricultural Research Service, which supports most of the biotechnology research, is earmarked to receive an increase in funding of around 1% to \$741 million.

The US National Institutes of Health (NIH, Bethesda, MD), as the most prominent source of federal spending for biotechnology, is slated to receive a 2.6% budget increase to \$13.1 billion in FY '98. Much of this increase—\$271 million, which is a 3.9% increase in a \$7.4 billion program—is devoted to relatively small-scale research project grants, the bulk of which are held by university scientists. Another NIH program that supports small businesses and the transfer of technology into the private sector could increase by almost 3% to \$253 million.

The NIH budget request calls for an overall \$223 million increase in support for research in several specific scientific areas, including brain disorders (\$36.7 million), disease pathogenesis (\$34.6 million), disease prevention, including vaccine development (\$51.1 million), genetic medicine (\$40.9 million), advanced instrumentation and computers (\$20 million), and new avenues for therapeutics development (\$39.8 million). The NIH budget also includes \$1.5 billion for AIDS research, an increase of 2.6% over the previous year.

Smaller overall than that of NIH, the US National Science Foundation (NSF, Arlington, VA) FY '98 budget for the biological sciences is slated to increase by 3.3% to nearly \$331 million. Priority interests include studies of microbial and other life forms in extreme environments, bioinformatics, and computational neuroscience.

The US Department of Energy (DOE, Germantown, MD) funds several programs

supporting biotechnology-related research. For instance, the agency requests an increase of 3% to almost \$377 million for biological and environmental research; \$85.1 million in that program supports genome analysis research. In the environmental remediation program, funding for bioremediation research increases by 32% to \$28.1 million as efforts move into field research centers to evaluate cost-effective remediation strategies.

The US Department of Commerce (DOC, Washington, DC), which is now on a more solid footing after some queries about its future, is slated for a 22% increase to \$275 million. The DOC makes some small grants to emerging biotechnology companies through its Advanced Technology Program (ATP) at the National Institute of Standards and Technology (NIST, Gaithersburg, MD).

At the FDA, the FY '98 budget requests a 7% increase in funding to \$1.064 billion. However, \$244 million in the agency budget will be derived not from the federal purse, but from industry user fees. These fees, which include application fees and continu-

ing fees for being assessed and regulated by the FDA, were instituted in 1993 and now apply to otherwise untapped areas of regulation involving foods, biologics, medical devices, animal drugs, import inspections, and generic and over-the-counter drugs. The extra user fees would generate an extra \$136 million over fiscal 1997, more than the 7% increase in the budget request. Thus, federal government funding for FDA would, under these proposals, actually be cut by \$61.5 million.

In its "Agenda for Toxics" segment, the Environmental Protection Agency (EPA, Washington, DC), requests a 4.6% increase to \$31.8 million and calls for reviewing more than 2,200 new chemical and biotechnology products for potential human health and safety concerns. The Special Environmental Hazards research program, which focuses on endocrine disruptors, is to increase by 31% to \$15.9 million, whereas the budget for waste management and site remediation research includes \$27.2 million, an increase of 17% over the previous year.

Jeffrey L. Fox

## Plant patents double biotechnology litigation

In 1996, biotechnology in the United States became streetwise. A report issued in February by the Biotechnology Committee of the American Intellectual Property Law Association (AIPLA, Washington, DC) says that the number of new litigations in biotechnology is up 69% over the two previous years. Agricultural biotechnology was largely responsible, according to William S. Feiler (Morgan & Finnegan, New York) who chaired the committee responsible for the report. "A number of major companies were involved in litigation over biotechnology-modified seeds," he said.

DeKalb Genetics (DeKalb, IL), Mycogen (San Diego, CA), and Pioneer Hi-Bred International (Des Moines, IL), Monsanto (St. Louis, MO), Agrigenetics (Madison, WI), Novartis (Basel, Switzerland), Northrup

King (Golden Valley, MN), and AgrEvo (Frankfurt, Germany) were all involved in a circle of legal actions (producing 16 new



cases) concerning ownership of patents for the stable transformation of transgenic seeds. To date, only one suit had been resolved: DeKalb's action against Novartis over methods of transforming monocots was dismissed.

Besides agricultural biotechnology, many