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).

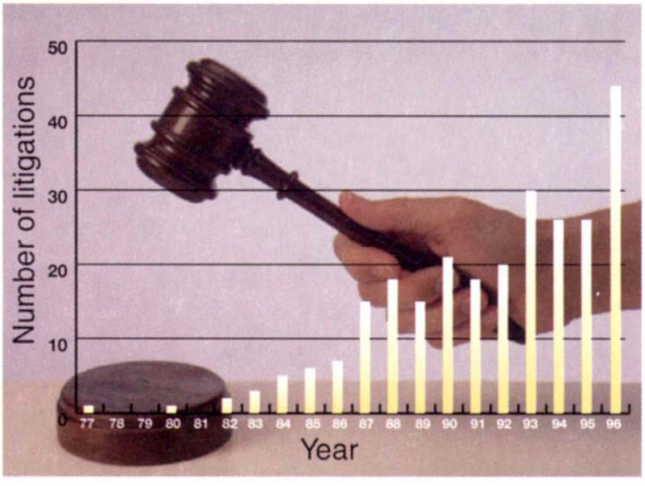
At the FDA, the FY '98 budget requests a 7% increase in funding to $1.064 billion. However, $244 million in the agency budget will be derived not from the federal purse, but from industry user fees. These fees, which include application fees and continuing fees for being assessed and regulated by the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

of the other suits predictably concerned biotechnology's valuable therapeutic products: β-interferon for the treatment of multiple sclerosis (*Berlex v. FDA*; *Berlex v Biogen*; *Biogen v. Berlex*), human tissue plasminogen activator (*Genentech v. Boehringer Mannheim*), antiviral 3TC (*Emory University v. BioChem Pharma*), human growth hormone (*Genentech v. Novo Nordisk*), granulocyte colony stimulating factor (*Genentech v. Amgen*), and interferon-like peptides (*Schering v. Amgen*). There were also fights over technical methods: PCR (*Promega v. Invitrogen*); and functional drug screening (*Sibia v. Cadus*).

Perhaps the most unusual was Jeremy Rifkin's (Foundation on Economic Trends, FET, Washington, DC) attempt to bar the US Patent and Trademark Office (Washington, DC) from granting patents on genes. Forming a coalition with politicians and public health groups, Rifkin took aim at Myriad Genetics' (Salt Lake City, UT) patent for *BRCA1*—the so-called breast cancer gene. Rifkin, along with feminists Gloria Steinem and Betty Friedan and former congresswoman Bella Abzug, brought the suit in an effort to halt the patenting of human genes for profit because, they say, it will discourage other researchers in the area.

The report also highlights the history of biotechnology litigation since the 1977 *Diamond v. Chakrabarty* case, a suit over the patentability of a genetically modified organism. The most litigious biotechnology companies have been Genentech (S. San Francisco, CA), with 24 lawsuits completed or ongoing, and both Amgen (Thousand Oaks, CA) and Chiron (including Cetus, Emeryville, CA), each with 16 suits. That doesn't necessarily make these three companies the bad boys of biotechnology: they were involved in many cases simply because they were the first into their business stride.

The report also highlights the history of biotechnology litigation since the 1977 *Diamond v. Chakrabarty* case, a suit over the patentability of a genetically modified organism.

While some cases, such as *Amgen v. Chugai Pharmaceutical Co.*, define the industry through precedent-setting legal battles, others reflect simple stupidity. Take the 1988 case involving John Stephens Wilson, a former Amgen employee who tried to solicit money from rival Genetics Institute (GI, Cambridge, MA) for trade secrets concerning Amgen's blockbuster drug erythropoietin (EPO). When his initial inquiry letter received no response, he mailed another one. GI notified Amgen. Amgen called in the FBI. And—within one year of his apprehension—Wilson found his "entrepreneurial" ambitions tempered by a 15-month prison term.

So how much are biotechnology companies spending on legal battles? An AIPLA survey for 1995 indicates that for patent battles in which markets worth more than $100 million are at risk—and that would be the case for most biotechnology products—each litigation costs at least $3 million.

Stephen M. Edgington