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NEW YORK—The Food and Drug Administration (FDA) is facing a dilemma. More and more products of biotechnology are making their way through the regulatory approval process, straining the agency's existing resources. At the same time, the federal government has been looking for ways to narrow its budget gap, both through cutbacks and "revenue enhancements." And now that the Administration has submitted its fiscal-year (FY) 1990 budget to Congress, the issue has become who should pay the difference between what the FDA has, and what almost everyone agrees it needs. In particular, private-industry representatives are objecting to the government's renewed call for user fees.

Of the \$570 million proposed—a \$28-million increase over 1989's estimated budget—\$100 million is slated to come from user fees for reviewing new product applications, putting the actual government contribution below FY 1989 levels. Increases include an added \$14.5 million for "biotechnology initiatives," \$1.6 million for new drug review, and \$1.5 million for medical device review. The requested budget also provides for 7,507 full-time employee equivalent staff (FTEs), an increase of 157 over last year. Yet 183 new FTEs have been designated for work on acquired immunodeficiency syndrome activities, leaving fewer total staff for other projects. The number of FTEs peaked at almost 8,200 in 1979, and declined to under 7,000 in 1987.

Reaction to the budget proposals has been swift. Dick Godown of the Industrial Biotechnology Association (IBA, Washington, DC) believes that the Administration "has not addressed the problem of new people and facilities." Without more space, FDA would be hard-pressed to find room for any new hires. The conditions at the agency are currently so cramped that, according to Congresswoman Barbara Boxer (D-CA), chairperson of the Human Resources Task Force of the House Budget Committee, some "FDA staff are forced to work out of their homes 60 percent of the time because FDA cannot accommodate them in any facilities."

IBA is actively lobbying for more FDA funds. In particular, Godown would like to see an added \$15 million to hire 350 new employees (scientific examiners and support staff) and \$75 million to consolidate the existing 23 buildings into three new, expand-

ed facilities, which would "get the FDA together on a campus, hopefully closer to the National Institutes of Health (Bethesda, MD) and area universities." He notes that the Howard Hughes Institute in Bethesda has land that could be set aside for that purpose, either by grant or at a purchase price below the market.

Other Washington-based trade groups—the Pharmaceutical Manufacturers Association (PMA, Washington, DC), the Health Industry Manufacturers Association (Washington, DC), and the Proprietary Association (Washington, DC)—are joining IBA in opposing the user fee proposal. In a joint statement, the four point out that "User fees on FDA-regulated medical technologies are the worst kind of new taxes because they tax research, innovation and our competitive potential....The benefit is to the American public, not to the individual companies which are regulated by the FDA."

Godown adds that "You don't go to the people you're regulating and ask them to pay for the cost of regulation." He would have more sympathy for the proposal "If the dollars coming in were to go directly to speed up approvals," however, and so "avoid a situation similar to the patent backlog, which serves no one's interest."

A new lobbying group was formed six months ago to examine these issues from an integrated perspective. The FDA Council (Washington, DC) is a coalition of profit, non-profit, and consumer organizations that, according to president Terry Lierman, advocates a new infrastructure for FDA to make the agency more efficient. "If we're ever going to get things to come out the other end as products, we have got to address the infrastructure. That means facilities, staff, training, and equipment."

Lierman sees this as "a triple-win situation. The government will save money through reimbursement, industry will get accelerated product approvals, and consumers will reap the fruits of research faster, and at a lower price."

PMA's Judee Shuler agrees with that strategy. She points out that "PMA has urged President Bush to retain Frank Young as head of FDA. The agency needs consistency in leadership and knowledge of management mechanisms. Commissioner Young has a plan in mind." More to the point, she notes that "The bottom line is that these things require money."

—Mark Ratner

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