

FDA Scientists Resist Cuts in In-House Research Positions

A quiet rebellion is spreading among the roughly 280 scientists who combine research with regulation at the Food and Drug Administration's (FDA's) Center for Biologics Evaluation and Research (CBER). These biologists, biochemists, and physicians have a life that is outwardly very like that of their colleagues at the National Institutes of Health (NIH). Their labs are on the NIH campus in Bethesda, Maryland. They attend many of the same scientific meetings. They even get to park their cars in NIH lots. But there's a big difference in the public support they receive: NIH scientists are in clover after 3 years of substantial budget increases, while CBER researchers face a traumatic downsizing. Under current plans, nearly one-third of CBER's research job slots will disappear over 2 years because the FDA has promised not to draw on pharmaceutical industry "user fees" to fund them.

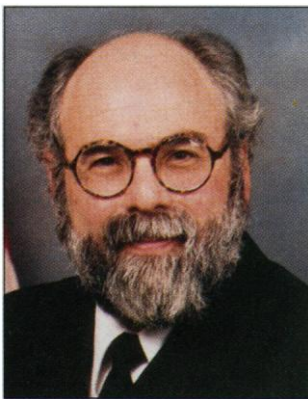
Faced with that dire prospect, some CBER scientists are trying to recruit support in Congress, and others are appealing to outside scientists for help. (See letter in *Science*, 9 January, p. 157.) At stake, the CBER scientists say, is the safe and efficient regulation of products such as vaccines and cell-derived proteins, the biological therapeutics that are at the heart of the biotech revolution.

Last week, they apparently got some powerful new allies. A prestigious panel of non-FDA scientists, chaired by pharmaceutical scientist Leslie Benet of the University of California, San Francisco, reviewed the entire CBER research program and came away impressed. "This is a very important resource for the country, in terms of being able to protect both the population and our world leadership in biotechnology," Benet told *Science*. Emphasizing that he was speaking for himself, Benet said it was important for CBER to retain "a very strong research component."

Some FDA staffers who spoke on condition of anonymity insist that the agency is trimming its independent research capability to please industry, and they speak darkly of a "sellout" by acting FDA Commissioner Michael Friedman. On the contrary, says Friedman, "I believe a vigorous, vital, high-quality corps of scientists is necessary for FDA, and I feel that for the entire agency." But over the past 5 years, he says, budget pressure has forced "very painful" research cuts in other parts of FDA, while CBER has

been "relatively protected."

No matter what drives the staff cutback, "it's coming at exactly the wrong time in the history of biomedical science," says former Stanford University medical school dean David Korn, now an official of the Association of American Medical Colleges in Washington, D.C. Korn chaired a panel last year that recommended a management overhaul to strengthen the FDA's intramural science program. (See Korn's editorial in *Science*,



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—Acting FDA Commissioner Michael Friedman

13 June 1997, p. 1627.) Recently, he received a written appeal from 22 CBER scientists to come to their rescue. "We're on the threshold of all kinds of new biologicals that nobody even knew about 10 years ago," Korn says. "And they're all being developed by new scientific and technological approaches" that demand the active involvement of those who aim to understand and control them.

Researchers at CBER were warned more than a year ago that deep cutbacks were looming, but the threat materialized only last fall when Congress reauthorized the Prescription Drug User Fee Act (PDUFA) of 1992. Under PDUFA, prescription drug manufacturers pay user fees—about \$132 million in fiscal year 1999, more than 10% of the total FDA budget—to expand staff and accelerate new drug applications. In negotiations leading up to PDUFA's reauthorization, FDA officials promised to stop drawing on user fees to support CBER research.

As a result, even though PDUFA fees are rising, CBER now is under orders to shed 40 "full-time equivalent" research positions this year and 39 more by the end of 1999. It plans to do this by transferring personnel or redefining jobs.

CBER is vulnerable because, alone among the five FDA centers, it combines the roles of researcher and reviewer. Some pharmaceutical

industry officials consider the amount of CBER staffers' time that goes to research—roughly half—a waste of PDUFA money. But CBER scientists say that their research enables them to do reviews better and faster. "If you're doing research in a field, you'll have built-in expertise," says Bascom Anthony, who retired last month as director of CBER's Division of Bacterial Products. "When an application comes along, you can review it quickly ... without having to get up to speed on it."

Biotech industry scientists—whose companies are more directly affected by CBER actions—tend to agree with the agency staff. Alan Goldhammer, director of technical affairs for the Biotechnology Industry Association in Washington, D.C., says that industry scientists recounted numerous occasions when CBER "reviewers were particularly knowledgeable," enabling the agency "to make a rather quick decision."

That perception apparently got strong support from Benet's 27-member panel, which reviewed CBER's research program in an intense 4-day session on 3 to 6 February. Its main purpose was to help CBER director Kathryn Zoon decide how to reduce research slots. But when the panel presents its final report to the FDA Science Board on 19 May, it may instead urge the FDA to try to find the money to keep CBER science going. "To do good [license application] reviews in this rapidly expanding, cutting-edge field, you've got to understand the science," Benet says. "And you can only understand the science by having the experience. That's why I personally believe it's important to combine research and review." In fact, CBER scientists say that this is the heart of the issue: whether the model of the CBER researcher-reviewer will survive.

Korn says his study panel agreed that reviewers "who knew what the science really was" were in the best position to judge "wholly new kinds of materials and drugs." Moreover, Korn suggests, such reviewers will probably make quicker decisions: "The less you understand, the more timid you generally become in putting your neck on the line." However, Korn also acknowledges that the researcher-reviewer model "may turn out to be too costly."

Stung by the charge that he doesn't care about research, Friedman insists that he hopes for "a scientific renaissance" within FDA. Friedman, who has been running the agency since FDA Commissioner David Kessler left early last year, says he already is putting into effect some recommendations of the Korn report. He has begun recruiting a chief scientist, for example. Whether this person will actually have the broad authority

recommended by Korn will be a decision for the next FDA commissioner, Friedman acknowledges. And no one is likely to accept the job before a new commissioner is named. But Friedman notes that a major job search can take 6 months to a year, and says that starting the process now will avoid "needless delay." As for intramural research, Friedman says, "I personally am not going to see our laboratory infrastructure neglected."

Does that mean he will seek additional funding for research during this year's congressional appropriations hearings? Friedman gives a good-soldier response: "We have

a budget agreement with [the Department of Health and Human Services] and the Administration that identifies certain priorities ... and we're committed to participating loyally and actively in that overall framework." In other words, no.

CBER scientists hope to persuade Congress that maintaining their independent research function is worth the money. One of their goals is to get FDA intramural research included in the National Research Investment Act, the legislation introduced last year by Senators Phil Gramm (R-TX), Joseph Lieberman (D-CT), Pete Domenici

(R-NM), and Jeff Bingaman (D-NM), calling for a doubling of federal basic research funding over 10 years. The FDA, they say, was the only research funding agency that was left out of the bill.

At the very least, repairing that oversight would help legitimize CBER scientists' bid for more support from the agency and congressional appropriators. It might also get them a little respect.

—Bruce Agnew

Bruce Agnew is a writer and editor in Bethesda, Maryland.

NASA BUDGET

Red Ink Will Not Wash Out Space Science

While most U.S. R&D agencies are savoring the prospect of big budget increases if Congress approves the Clinton Administration's 1999 request, NASA is contemplating a less palatable fate: a smaller budget than it received this year. That possibility brought congressional advocates of the space program rushing to NASA's defense last week. They charged that a declining budget coupled with ballooning space station overruns could cripple science, aeronautics, and technology programs. Says Representative James Sensenbrenner (R-WI), who chairs the House Science Committee, "NASA's budget is a mess."

Such heartfelt concern from Capitol Hill might seem a godsend to NASA brass, but agency officials insist it is misplaced. Testifying on 5 February before the Science Committee's space and aeronautics panel, NASA Administrator Dan Goldin staunchly defended the proposed 1.3% decline in the agency's current \$13.6 billion budget. Most science would get a boost, he pointed out, and that would hold true even if NASA transfers \$100 million from the science budget this year to pay for half of the \$200 million in station overruns, as Goldin has proposed. NASA-funded researchers, at least, seem convinced. "Last year I was so disheartened; now I can't tell you how happy I am," says Anneila Sargent, associate director of Owens Valley Radio Observatory in California and chair of the NASA space science advisory panel.

The reason for such optimism is simple: After threatening for months to slash the agency's science accounts, the Administration has proposed instead to infuse them with more money. The budget request released on 2 February would boost life and microgravity research by 13%, to \$242 million. And while earth science spending would stay roughly flat at \$1.37 billion, officials say it's enough to keep ongoing work on track. Space scientists, in particular, say they are delighted with a requested

\$2 billion in 1999—nearly a 4% raise—and a proposed 2003 budget of \$2.6 billion. The additional funding would help continue the U.S. portion of the international solar terrestrial program—which faced an early shutdown before the solar maximum early in the next century. Researchers are eager to gather data on the maximum—which some fear could devastate certain satellite communication systems—to better understand the sun's cycle. The request also includes funds to study a next-generation space telescope; for the 2002 start of the Gamma-Ray Large Area Space Telescope, which would probe black holes, dark matter, and star formation; and to start a Europa orbiter mission. NASA also wants to spend \$41 million on prep work for the Constellation X-ray mission late next decade to examine galaxy evolution.

"It's really remarkable," says Sargent. Just a few months ago, the White House Office of Management and Budget had been considering radical cuts to the space science account that could have wiped out a host of proposed programs, including robotic missions to Mars, Administration sources say. But they say that congressional support for space science combined with the possibility of using money from the government's proposed tobacco settlement—although that funding may never materialize (see p. 974)—ultimately protected the program. According to NASA space science chief Wes Huntress, the program survived "a very dire, dire situation."

The favorable long-term outlook makes Goldin's plan to transfer \$50 million in 1998 funds from space science to the station more palatable, Huntress says. The bulk of that

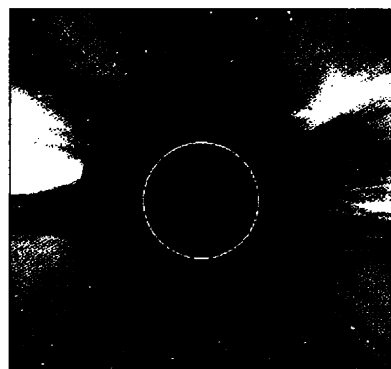
money, he says, would come from delaying by a few months the renewal of grants for outside researchers who analyze NASA data. "I don't think individual researchers will feel it," says Sargent. NASA also wants to take \$50 million from the earth science program in 1998 for station overruns. Ghassem Asrar, the new earth science chief, told *Science* that this cut would have little impact on NASA's Earth Observing System—launch of the first massive probe is slated for July—or on research, primarily because of the program's slow spending rate.

Despite the good vibes coming from NASA and the scientific community, Sensenbrenner and other lawmakers say they fear further space station raids on science. At last week's hearing, Goldin sought to reassure Congress by pledging that NASA would not ask for similar transfers in 1999—barring a Russian pull-out from the coalition. He added that the

station's cost overruns, nearly \$1 billion now, appear under control. Goldin also promised that \$600 million NASA had borrowed from funds set aside to build life and microgravity facilities for the station will be returned in time to get them in orbit. "We'll deliver every single science facility we agreed to," he said.

With only themselves carping—and given the importance the White House assigns to the space station—Sensenbrenner and other lawmakers may have a hard time denying Goldin's request to transfer funds to pay for the overruns, say Administration officials. Still, a lean NASA budget is likely to continue to draw catcalls from the Hill. Says Representative Dana Rohrabacher (R-CA), "I hardly think we should be happy the space program is bleeding to death more slowly."

—Andrew Lawler



Solar windfall. Studies such as coronal imaging fare well in NASA request.

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