(For some work involving major public facilities, the government holds the rights.) And few professors are eager to claim their rights: Only 129 patent applications were filed in 1994 by faculty members at the country's 98 national universities, a minuscule 0.04% of the nation's total, despite the fact that 35% of the country's researchers work in academia. By contrast, U.S. academic researchers, who make up less than 15% of the total R&D workforce, were awarded 1871 patents in 1995, a 3% slice of the overall patent pie. As a result, says Tsuruzono, Japan has few examples of academic research spurring industrial advances.

To help bring academic research to market, the new law paves the way for TLOs that meet yet-to-be-defined criteria to handle patenting, marketing, and licensing on behalf of university researchers. In return, they will receive public subsidies and an exemption from all patent application fees, as well as the right to a share of any royalties. The law also directs existing industrial development programs to give preferential treatment to venture businesses and small and midsize companies trying to commercialize university discoveries.

Funding for the TLO program is a pittance—about $500,000 in the current fiscal year. But Katsuya Tamai, an intellectual property law professor at the University of Tokyo, says the real benefit is that it signals a shift in attitude toward how to do technology transfer successfully. Tamai is working with a group of University of Tokyo professors setting up a TLO they hope will represent researchers at national universities throughout Japan.

Tamai's group is one of a dozen or so TLOs at different stages of development. Some plan to work with a single university, while others are focusing on a particular specialty. Each will set its own policies. In Tamai's group, for example, 50% of any royalties will go to the research lab that generated the patent, with the other half split between the liaison office and the university. The university's share is not required, he says, but the group wanted to foster "a sense of accountability to the taxpayers."

One challenge for the fledgling centers is finding staff who understand both market needs and high-technology developments. "It's our biggest worry," says a Monbusho official involved in university-industry cooperation. An even bigger obstacle, however, may be the attitudes of researchers. Yoshizaki says that even faculty members in the applied sciences tend to focus on papers, not patents. "What we need is a success story," says Yoshizaki. "If a successful venture business springs from university research results, for example, that would really provide an incentive for university researchers to pay attention to patents."

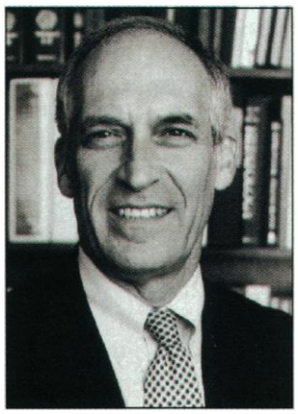
–Dennis Normile

FOOD AND DRUG ADMINISTRATION

Panel Issues Plea to Boost FDA Research

Last October, after academic researchers learned that a retrovirus found in pigs could infect human cells, the U.S. Food and Drug Administration (FDA) ordered a temporary halt to clinical trials involving transplantation of pig tissues into patients. Experts were concerned that the pig virus might thrive in humans, become infectious, and threaten public health. Within weeks, however, the concern abated when an FDA staffer doing independent research—Carolyn Wilson—developed an assay for the pig virus. By January, FDA officials were confident enough of the assay's reliability that they began to lift the research moratorium, asking each company to maintain virus-free materials (*Science*, 30 January, p. 648).

The agency's measured response to the pig virus alarm, some scientists say, shows why it is important to fund independent research at FDA. Only if FDA staffers are directly involved in the science they regulate, the argument goes, will they understand the risks well enough to make good public health decisions. This is the theme of a strongly worded report delivered to FDA on 19 May by a panel of outside experts headed by Leslie Benet, a pharmaceutical scientist at the University of California, San Francisco.



Going to bat for CBER. Panel chair Leslie Benet.

Benet's 27-member group—which included representatives from government, academia, and industry—was asked to conduct a detailed review of science at one of the five centers that make up the FDA, the Center for Biologics Evaluation and Research (CBER). This is the first comprehensive, outside look at any aspect of FDA science "in memory," says acting FDA Commissioner Michael Friedman, who adds that he "pushed for this." He says the report will be followed by similar assessments of FDA's four other centers, all intended to help revitalize science at the agency. Friedman, meanwhile, has named a search committee under physician David Kipnis of Washington University in St. Louis to recruit a chief scientist to oversee research at the agency.

The Benet panel began playing its own role in this process with a bang: It rewrote its orders. The group decided, as its report says, to "go beyond its specific charge and address the committee's unanimous concern that inadequate funding ... for laboratory research within CBER would risk potential damage not only to the health of the population of the United States but also the health of our economy." The panel was driven to this dire prognosis by a recent decision that is taking a heavy toll on FDA's research—especially at CBER, which spends more than any other FDA center on in-house science (*Science*, 13 February, p. 976).

Last year, the pharmaceutical industry, whose licensing fees help finance FDA's budget, asked for and got a directive from Congress that those fees would not be used to finance research. As a result, CBER's research budget has declined from $18.4 million in 1994 to $6.9 million in 1998. And CBER official Neil Goldman says it is planning to lose 154 half-time research positions in 3 years.

Benet says he didn't begin this review expecting to issue a broadside about the inadequacy of research funds, but he became convinced that it was critical to do so after talking to staffers and "interacting with my colleagues." In impassioned phrases, the panel says it "is of utmost importance that the scientists in CBER have research capabilities at the cutting edge," including $1 million worth of new analytical equipment. The report also offers some traditional review comments, urging better use of statistics, the establishment of a new measurement science group headed by a protein chemist, and consolidation of less productive divisions.

When Benet presented his panel's report last week to FDA's Science Advisory Board—which is chaired by Kipnis—most members seemed to agree with the recommendations for changes within CBER. But Kipnis said in a phone interview that the board did not agree with the Benet panel's argument that CBER had a greater need than other FDA centers for research support. At last week's meeting, science board member Pedro Cuatrecasas, retired president of the Parke-Davis pharmaceutical company, strongly objected to singling out CBER for special funding, as did FDA staffer James MacGregor, research chief at the Center for Drug Evaluation and Research.

Friedman says an equally strong case can be made for boosting intramural research in other parts of FDA, and he welcomes any "nonparochial" efforts to improve the quality of research. The Benet report must now be revised and endorsed by the full science board.

–Eliot Marshall