

UNIPHOTO

Fast track? House plan would let drug firms use private reviewers.

Alternative Route for FDA Drug Reviews?

The House has unveiled a long-awaited plan to reform drug approvals by the Food and Drug Administration (FDA) that, among other changes, would offer companies the option of sending initial applications to outside, private organizations.

In some respects, the proposal is similar to the Senate's version of FDA reform (*Science*, 1 March, p. 1228), which was approved by a committee last month. Like the Senate bill, the House measure, introduced on 29 March by Representative James Greenwood (R-PA), would encourage collaboration between FDA and companies on clinical trial design and establish a fast track for drugs to treat life-threatening conditions.

But the bills differ in how they would streamline the process. The Senate would give FDA 2 years to meet its own 6-month standard for completing reviews before it would have to farm some out to external reviewers. The Greenwood plan, however, would have FDA soon offer the option of an external review by an FDA-accredited group. FDA would give final approval. That falls short of a rumored proposal to abolish internal FDA reviews, but it's "an improvement" over the Senate version, says a spokesperson for the Pharmaceutical Research Manufacturers of America. The House plan would also restrict FDA scientific research to sup-

porting regulatory functions.

House Commerce Committee members say that, despite the short time left on the legislative calendar, they're determined to push their plan through. The committee may send the bill to the full House by May, they say. The Senate is to debate Nancy Kassebaum's (R-KS) bill in May. If both chambers approve their bills, they would then need to work out a compromise. Meanwhile, FDA already seems to be moving toward third-party reviews. It announced a pilot plan for external review of medical devices last week, and a House staffer says the agency may be formulating a similar plan for drug reviews.

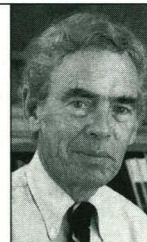
Leaders Changing at Scripps, UC Schools

When physicist Robert Dynes takes over as chancellor of the University of California, San Diego (UCSD), in July, one of the first things on his plate will be to select a replacement for his colleague Edward Frieman, who has run the school's pre-eminent Scripps Institution of Oceanography for the past decade.

Frieman, 70, announced on 3 April that he plans to retire "late

this summer." He says he had been planning to retire in a year or two, but he timed his move in part with the naming of Dynes as chancellor on 9 April. Frieman didn't want his departure to be "misinterpreted" as a case of him not getting along with the new chief, he explains. Also on 9 April, M.R.C. Greenwood, formerly of the White House Office of Science and Technology Policy, was appointed head of UC Santa Cruz.

A theoretical plasma physicist, Frieman helped Scripps boost its federal contract and grant intake by 85%, acquire a new research ship, and start projects to study climate forecasting and the ocean's role in climate. "The institution is in extremely good shape," says Frieman, who now plans to focus on influencing policy. "What it needs is somebody to carry it into the next century." As new chancellor, Dynes, a National Academy of Sciences member noted for his work on semiconductors, will head an international search for Frieman's successor.



Edward Frieman

Pasteur Implicated in Blood Scandal?

The latest charges in France's contaminated blood case threaten to involve the prestigious Pasteur Institute in Paris. Last week, Jean Weber, a former chief executive of Pasteur Diagnostics (PD)—in which Pasteur's foundation holds shares—was charged by an examining judge with "complicity in poisoning" for his alleged role in the scandal.

The case centers on a 3-month period in 1985 when the French government allegedly tried to keep an HIV antibody test made by the U.S. firm Abbott off the market while waiting for PD to get its own version ready. During this time, several hundred people may have received HIV-tainted blood transfusions. Previously, attention has focused on the actions of government ministers and their scientific advisers. But now the Pasteur name has been directly implicated. The French firm Sanofi owns 71.2% of PD, but 26.2% of the shares are held by the Pasteur Institute Foundation, and PD exclusively markets the discoveries of Pasteur scientists.

According to documents leaked to the French press, Weber urged the government to delay Abbott's application. For example, on 26 April 1985, Weber allegedly wrote to government adviser François Gros that "a rapid approval of the two Abbott and Pasteur tests in France would be particularly dangerous for the national interest."

PD declined to comment on the charges, and Weber—now a bank president—was unavailable for comment. However, last week Weber told the French daily *Le Monde* that he was simply doing his job and that all final decisions about the tests were in government hands. Meanwhile, Pasteur scientist Luc Montagnier, whose group did early work on the French test, told *Science* he didn't know "of any pressure from this institute on the government," adding that by 1985 the research had been transferred to PD.

NAE Launches Plan to Depose President

The campaign to unseat Harold Liebowitz, president of the National Academy of Engineering (NAE), is heating up. Last week the NAE Council sent ballots to the organization's 1800 members for a change in bylaws that would allow the membership to remove elected officers and council members. The move followed a 29 March council vote of no confidence in Liebowitz, who has drawn fire since winning an upset victory in 1995 (*Science*, 22 December 1995, p. 1915).

In a 4 April statement, the council cites Liebowitz's "unacceptable performance," his "unresponsiveness to the directions of the NAE Council," and "his failure to abide by the long-established policies" set by the NAE and its sister group, the National Academy of Sciences (NAS). The NAS Council had criticized Liebowitz in February in a public statement. And last week, NAS President Bruce Alberts said he supports the NAE Council's decision and that action is "essential" to protect the work of the National Research Council, which is run by the NAE and NAS.

Liebowitz defends his actions in a 3 April letter sent to NAE members, and he accuses his foes of conducting "a behind-the-scenes campaign to preserve the status quo. ... The interests of engineering take a back seat to those of the entrenched NRC staff," he says, adding that the proposed bylaw amendment is "not sound" and would deter future candidates. If NAE members approve the ballot measure, NAE sources say, the council intends to seek a vote in May on removing Liebowitz from the presidency.