MICROGENESYS

Peer Review Triumphs Over Lobbying

One of Washington's longest-running scientific and political soap operas is broadcasting its final episode. After more than a year of outrage from AIDS researchers, arm wrestling among federal agencies, and pressure from the White House, the fate of a controversial $20 million congressional appropriation to test one company's therapeutic AIDS vaccine has been sealed. In letters to Congress on 4 January, officials of the Department of Defense (DOD), the National Institutes of Health (NIH), and the Food and Drug Administration (FDA) "certified" that the legislated large-scale trial of the gp160 vaccine, a therapeutic AIDS vaccine made by MicroGeneSys of Meriden, Connecticut, should not proceed.

Instead of a large-scale trial of a single product, which Congress ordered after an intense lobbying campaign by MicroGeneSys, the $20 million will be rolled into a fund for general research on HIV vaccine therapy. Unlike the aborted test of the MicroGeneSys vaccine, this research will all be subject to peer review. Edward Martin, acting assistant secretary of defense, explained in his letter that, "based on available data, it is premature" to start a large-scale efficacy trial with MicroGeneSys's gp160. Martin noted, however, that DOD "continues to believe" that vaccine therapy—which uses vaccine technology to treat, rather than prevent, HIV infection—"merits intense exploration." Hence the Army's new vaccine therapy development program.

This solution resolves the central scientific complaint about the $20 million appropriation: that by hiring a team of high-powered lobbyists—including former Senator Russell Long and former Reagan Administration officials—to convince Congress of gp160's merit, MicroGeneSys had done an end-run around peer review. That perception brought outraged responses from Bernadine Healy, then director of NIH, FDA head David Kessler, and many AIDS scientists who believed there was no scientific basis for singling out one company's therapeutic AIDS vaccine for a large-scale trial from at least a half-dozen competitors (*Science*, 23 October 1992, p. 536).

Lobbying will not draw much water in DOD's new vaccine therapy pool. Proposals for that pool, wrote Martin, "will be judged by peer review, and selections will be based on scientific excellence and potential for clinical impact." Martin also made it clear that scientists from both FDA and NIH will be brought into the peer-review process.

But DOD does not have the power to end the gp160 trial on its own. By law, the heads of NIH and FDA also had to notify Congress that they, too, objected to the test. Just such an objection was registered in a 4 January letter co-signed by NIH Director Harold Varmus and FDA commissioner David Kessler. "We feel that the funds in question could more appropriately be used to answer basic questions about the immune response and host defense mechanisms related to vaccines prior to initiating large-scale human trials of a therapeutic vaccine," wrote Varmus and Kessler.

Anthony Fauci, director of the National Institute of Allergy and Infectious Diseases, says he's thrilled by DOD's decision to spend the money on peer-reviewed research. "That sounds like an excellent solution. It serves the best interests of science," enthuses Fauci, who chaired a blue-ribbon panel that evaluated the $20 million appropriation. Col. Donald Burke, head of AIDS research for the military, says he is more than pleased: "I'm delighted that we're at the point where we should have been a year-and-a-half ago."

MicroGeneSys did not return repeated phone calls to discuss the impact that the decision will have on its plans. But the company's corporate partner in developing and marketing the vaccine, the American Home Products division of Wyeth-Ayerst Laboratories, has already weighed in with a verdict of sorts. On 14 January, Wyeth-Ayerst announced it will "terminate its involvement" in the development of the MicroGeneSys vaccine. A Wyeth-Ayerst spokeswoman would not comment on why they are ending their 3-year-old agreement.

DOD has not decided when it will begin soliciting researchers' proposals for what they would like to do with the $20 million, but Burke says that by September, the military will have decided which vaccine researchers will receive the windfall originally intended for MicroGeneSys.

–Jon Cohen

FRANCE

Researchers Nervous About Bioethics Bill

PARIS—The French Senate last week threatened a fragile consensus between legislators and medical researchers over the regulation of practices such as in vitro fertilization (IVF), genetic screening, and organ transplantation. On 21 January, the Senate, the upper house of France's parliament, approved by a large majority amendments to a sweeping bioethics bill that had been crafted to satisfy the concerns of both scientists and ethicists. The Senate's amendments would make some areas of research impossible to continue.

Many French medical researchers are horrified. The amendments "could stop all fundamental research, and halt all progress in medically assisted procreation," says Michelle Plachot, a researcher in the in vitro fertilization and reproductive biology laboratory at Paris's Necker Hospital. There may, however, be an opportunity to modify some of the worst aspects of the Senate's handiwork: The bill will now go back to the National Assembly, the parliament's lower house, for a second reading during the spring, and will probably not become law until May or June.

The ambitious law was originally drawn up by France's previous, socialist government with support from researchers. It passed its first reading by the National Assembly in November 1992. But since then, the political mood has changed in France and conservatives are now in power. If the Senate's amendments are retained, the donation and transplantation of organs, cells, and tissues would be strictly regulated, and menopausal women, single women, and widows would be barred from giving birth to "test-tube babies"—only couples married or living together for at least 2 years would be eligible (see box, p. 464).

From the point of view of France's research community, the thorniest features of the proposed law are two amendments, sponsored by the conservative government, that would severely limit what can be done with human embryos in the laboratory. The first forbids "experimentation" on human embryos, and prohibits their in vitro conception solely for research purposes. Yet "studies" of such embryos would be allowed in exceptional cases, with the permission of the couple and the approval of a special commission, as long as the "integrity" of the embryo is maintained and the research has a "medical end." The second amendment, a ban on preimplantation diagnosis—examination of embryos for genetic defects before they are transferred to the uterus—allows no exceptions.

These restrictions are bad news for many French scientists working in the field of human reproduction. "I respect those who say that the human embryo is too precious to destroy just to gain knowledge," says Plachot, but she argues that the bill would sharply curtail the development of improved culture media and other conservation techniques, particularly if the embryos studied were not intended for ultimate implantation. And most research into why some embryos are viable and others are not—which often requires dissection of the embryo into individual cells—would be proscribed.

Geneticist Axel Kahn, at the Cochin Institute of Molecular Genetics in Paris, says he accepts that human embryos should not be