committee cut NIH's parent agency, the Department of Health and Human Services, by $1.1 billion (3.6%), the Department of Labor by 11.3%, and the Department of Education by a whopping 15.9%.

Already, say key congressional aides, House Democrats are planning to offer alternative proposals when the bill comes to a vote on the floor of the House, tentatively scheduled for 25 July, to achieve a "better balance" between support for NIH and other domestic programs. And White House Chief of Staff Leon Panetta has warned that the president will veto this legislation if it retains cuts in jobs and education reform programs.

But it's not just Democrats who are expressing concern. Republican Senate leaders such as Mark Hatfield (R–OR) and Arlen Specter (R–PA) have indicated they won't support everything approved by the Porter subcommittee. Specter has promised to protect energy subsidies to the poor—the Low Income Home Energy Assistance Program (LIHEAP)—a $1 billion item that Porter's subcommittee zeroed out. Porter himself acknowledges that "Senator Specter is a very strong supporter of LIHEAP, and I'm sure he'll have a different bill." Hatfield is also known to favor the curriculum reform effort known as "Goals 2000," which Porter's plan would kill. The subcommittee handling this legislation in the Senate, which Specter chairs, is expected to begin work on its version just after Labor Day, according to an aide.

Finally, there's a wild card in the deck that could throw everyone's calculations off balance: the 1995 rescission bill. As *Science* went to press, this legislation (H.R. 1944), which aims to cut $16 billion from current spending, was stalled in the Senate, and some observers feared it might die. If it fails, Congress would need to cut 1996 spending more severely to meet established deficit reduction targets. This would mean, for example, that Porter's subcommittee would have to cut another $1.4 billion from programs in its jurisdiction. As Porter's aide David Kohn says, this would turn "a difficult situation into a nightmare."

For now, Porter and the biomedical community are assuming the rescission bill will pass, and they're savoring their midsummer victory. Porter told *Science* of his long-term support for biomedical research and his efforts to get the House leadership to see things his way. Preparations for the vote began last May, Porter said, when he "set up a meeting" that brought together House Speaker Newt Gingrich (R–GA), leaders of the Federation of American Societies for Experimental Biology, and several biotech executives. The visitors "presented their case extremely well," Porter said. "The Speaker listened intently and said, 'Let me see what I can do to help biomedical research and all scientific research.' "

After that initial meeting, Gingrich conferred with Republican committee chairs and spoke about the importance of federal science funding (*Science*, 9 June, p. 1428). Then, said Porter, "just before we broke for the Fourth of July ... I sat down with the Speaker, the chairman of the appropriation committee, and the House Majority Leader and told them that my intention was to ask for a substantial increase in biomedical funding." According to Porter, Gingrich responded enthusiastically, endorsing the plan.

While they breathe a sigh of relief after this first skirmish of the appropriations season, biomedical leaders are not yet breaking out the champagne. Says NIH Director Varmus: "We're taking this one step at a time."

–Eliot Marshall

BIOMEDICAL REGULATION

FDA Panel OKs Baboon Marrow Transplant

A panel of scientific experts recommended last week that the U.S. Food and Drug Administration (FDA) allow San Francisco AIDS patient Jeff Getty to receive a transplant of bone marrow from a baboon. The panel acknowledged that the procedure may carry public health risks, but decided that this long-shot treatment should be attempted anyway. The Biological Response Modifiers Advisory Committee also proposed guidelines for future transplants of animal organs and tissues into humans.

If the FDA accepts the recommendation on the marrow transplant, as expected, it could take place "immediately," says transplant developer Suzanne Ildstad of the University of Pittsburgh. She doesn't know exactly how long it will take to provide the additional data the agency wants, however. The hope is that the transplant will restore Getty's immune function, as the AIDS virus does not infect baboon immune cells.

AIDS activists and Ildstad were pleasantly surprised by the decision. "We didn't expect them to come to a conclusion that rapidly," Ildstad said afterward. After the FDA put a hold on the experiment earlier this spring (*Science*, 5 May, p. 630), proponents of the transplant had worried that Getty's treatment would be delayed for months, if not years, just as the first gene-therapy trials were delayed almost a decade ago because of the potential risks involved.

So far, the concerns about gene therapy have not been borne out, but infectious-disease experts argue that there's compelling evidence that xenotransplants may not prove so innocuous. "If you don't want to risk the public health, then don't do it," said panel member Jonathan S. Allan, a virologist at the Southwest Foundation for Biomedical Research in San Antonio. He and others worry that viruses from the primate donor might infect human populations. They note that the AIDS virus itself likely originated in a nonhuman primate host. The hantavirus cases in the United States and Ebola virus outbreaks in Africa are also evidence of the deadly nature of some trans-species infections, warned officials from the Centers for Disease Control and Prevention in Atlanta. Particularly worrisome, testified virologist Stephen Morse of Rockefeller University, is the possibility that new infectious agents can go undetected until after they have spread from person to person.

Even though the committee members agreed that xenotransplants present a public health risk, particularly when the donors are primates, they were swayed in part by the pleas of Getty's supporters. The committee voted unanimously (with Allan abstaining) to permit the transplant. "From the public health point of view, this is probably the safest xenotransplant protocol," said panel member Hugh Auchincloss Jr., a transplant surgeon at Massachusetts General Hospital in Boston. He and others cautioned that the chances of the transplant prolonging Getty's life are slim. But if he does recover, the risk that he will spread an unknown pathogen to others will be minimized by the precautions taken to protect bone marrow recipients from infection, combined with measures, including practicing safe sex, Getty and others take to prevent the spread of HIV. As long as Getty understands the risks, then he and his doctors should decide whether to proceed, the committee concluded.

SAM KITTNER

Awaiting a decision. Transplant developer Suzanne Ildstad confers with Steven Deeks of the University of California, San Francisco, who will perform the procedure.

The committee did not require any further safeguards to protect health workers and others coming in contact with Getty from potential infections. But they did recommend that tissues from him, the donor baboon, and those who care for him be col-

lected and stored for testing should a problem develop.

These experts considered only Ildstad's proposal, but several other baboon marrow transplants are waiting in the wings. And researchers want to try using other types of xenotransplants to get around shortages of human hearts, livers, and other organs (*Science*, 18 November 1994, p. 1148).

Although the FDA currently has authority to regulate only the transplant of cells and not of solid organs, it is developing guidelines to address concerns about all xenotransplant experiments. The agency will continue to evaluate cellular xenotransplant proposals, but will rely on local research oversight committees to use these guidelines for judging the merits and risks of solid organ xenotransplants.

Based on the committee's recommendations, these guidelines, a draft of which will be available this summer, will require that donor animals be as free as possible of specific pathogens, specify care and quarantine standards for suppliers of donor animals and transplant centers, and urge that blood samples from the donor and recipient—and perhaps those who care for the transplant recipients—be screened for the appearance of unusual pathogens and archived. These data should become part of an international registry. The scientists at this meeting thought these guidelines should preclude the need for a national oversight group similar to the Recombinant DNA Advisory Committee or for new regulations.

–Elizabeth Pennisi

Elizabeth Pennisi is a free-lance science writer in Takoma Park, Maryland.

CONFLICT OF INTEREST

Final Rules Put Universities in Charge

Researchers funded by the National Institutes of Health (NIH) or the National Science Foundation (NSF) will soon have to follow new rules intended to make sure that their financial interests don't influence their research. But it will be up to the researchers and the universities, not the federal government, to decide what constitutes a conflict of interest and what to do about it. As a result, the new policies, announced last week by the Public Health Service (PHS), NIH's parent agency, are drawing a round of applause from universities, which have been fighting a 6-year battle for that authority.

"I think that we got most of what we wanted," says Julie Norris, director of sponsored programs at the Massachusetts Institute of Technology. "It puts the burden where it belongs—on the institution."

The rules require researchers to inform their institutions if they, their spouses, or their dependent children have financial interests—exceeding $10,000 or 5% ownership—in companies that might be affected by their research. It is then up to the institution to decide whether those holdings constitute a conflict of interest, take the appropriate steps to eliminate the conflict, and tell the government that the problem has been resolved. That's how it should be, says George Galasso, NIH's associate director for extramural research and a veteran of past battles. "[University officials] said they didn't want us to call the shots, but we still reserve the right to step in and look at what they have done if we suspect there's a problem," says Galasso.

PHS's effort to develop these rules dates to 1988, after several researchers involved in a clinical trial of tissue plasminogen activator, a genetically engineered anti-clotting agent developed by Genentech, were found to have financial ties to the company. Congress urged PHS to come up with regulations governing such situations. Its first attempt spelled out what constitutes a conflict of interest and put the government in charge of enforcing the rules (*Science*, 29 September 1989, p. 1440). A wave of complaints from the biomedical community led to the withdrawal of that draft, but PHS came up with a more acceptable one a year ago (*Science*, 8 July 1994, p. 179). Last week it issued the final version with a few minor changes. On the same day, NSF announced technical changes to its policy—adopted last year—that bring it in line with the PHS rules. The rules go into effect on 1 October.

Under the new rules, researchers are free to decide which holdings over the threshold "would reasonably appear to be affected by the research," although PHS suggests a broad interpretation, including, for example, holdings in competing companies as well as interests in specific products or processes under study. The next step is up to the institution. Earlier drafts would have required university officials to decide whether a financial conflict existed before a grant proposal was submitted to a funding agency. But the new rules require universities to review conflict of interest materials only if the government decides to fund a proposal.

If the university determines that there is a conflict, it has several options, including public disclosure of the relationship, outside monitoring of the research to ensure its impartiality, modifying the research to avoid any conflict, removing the scientist from the research, or requiring divestiture. "Our preference would be that they get rid of the financial interest," says Galasso. "But that's not always necessary or fair. The important thing is that [the institution] tells us it's taking care of the problem."

PHS estimates that 20,000 researchers each year—about half of those receiving PHS awards—will have financial interests to disclose, but that institutions will only find about 200 cases where a conflict exists. NSF guesses only 23% of the 10,000 investigators it funds will have to file disclosures, and that there will be "significantly fewer" cases of conflict to resolve because the research it funds "is less likely to affect the financial interests" of the individual scientist.

The rules contain some loopholes, federal officials admit. NSF's policy, for example, allows institutions to waive any conflict if they decide that the researcher is uniquely qualified to perform critically important work, and neither set of rules addresses a situation in which the school itself has a financial interest in the outcome of federally funded research on campus. Both sets also assume a good-faith effort by the grant recipients. "It's really an awareness regulation," says Christopher Ashley of NSF's general counsel office. "We expect schools to take their responsibility seriously."

–Jeffrey Mervis

CONFLICT OF INTEREST AT A GLANCE

What's covered:

A significant financial interest means anything of monetary value, including but not limited to salary or other payments for services (*e.g.*, consulting fees or honoraria); equity interests; and intellectual property rights (*e.g.*, patents, copyrights, and royalties from such rights).

What's at stake:

A conflict of interest exists when the designated official(s) reasonably determines that a significant financial interest could directly and significantly affect the design, conduct, or reporting of Public Health Service (PHS)–funded research.

What can be done:

Examples of conditions or restrictions that might be imposed to manage conflicts of interest include: public disclosure of significant financial interests; monitoring of research by independent reviewers; modification of the research plan; disqualification from participation in all or a portion of the research funded by the PHS; divestiture of significant financial interests; or severance of relationships that create actual or potential conflicts.

SOURCE: FROM THE PHS REGULATION ON OBJECTIVITY IN RESEARCH, *FEDERAL REGISTER*, 11 JULY 1995.