

any "clinically significant benefit to patients over standard hematopoietic transplantation techniques," the memo says. It also notes that FDA approved CellPro's device for a narrow use—reducing the toxic side effects of bone marrow transplants.

"To date," the NIH memo continues, "neither party has presented ... any studies documenting that cell separation devices improve stem cell engraftment, disease-free survival, or overall survival." It is "premature," NIH says, "for either Baxter or CellPro to claim patient benefits (other than a decrease in infusional toxicities)."

In reality, clinicians say, the CellPro machine is rarely used for bone marrow transplants; it is used mainly to separate stem cells

from peripheral blood, an "off-label" use. Baxter has asked FDA to approve its own CD34 machine for use on peripheral blood. FDA has not acted as yet, and until it does, Baxter's machine may be used only in experimental studies.

Saying that it wants to involve itself as little as possible in the commercial battle, NIH deferred to Judge McKelvie on most points. In his 24 July opinion, McKelvie castigated CellPro for its "contempt" for Hopkins and Curt Civin—the Hopkins scientist who discovered and patented the CD34 cell-selection technique. He also ordered CellPro to turn over to Hopkins and its partners 60% of "incremental profits" on sales of its CD34 machines while it awaits a decision

on its appeal. McKelvie also enjoined all U.S. sales of the CellPro machine, but held the injunction in abeyance until 3 months after Baxter wins approval from the FDA to market its device. Meanwhile, both McKelvie and Varmus have stated that they will monitor the need for CellPro's machine, and if they see evidence that patients who need this technology are not getting access to it, they will reconsider.

The hot potato now passes to FDA. On 24 July, an FDA advisory panel discussed Baxter's CD34 device and found it safe, but, according to the panel's chair, reached "no consensus" on efficacy. FDA has set no deadline for acting on the case.

—Eliot Marshall

INFECTIOUS DISEASES

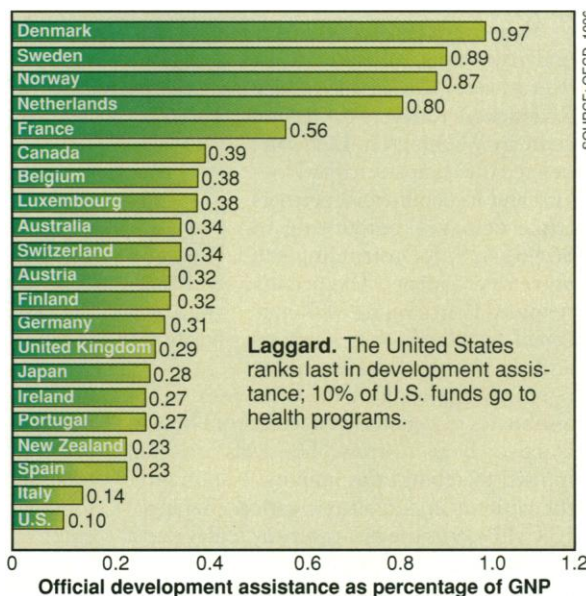
Congress Readies Injection of Funds

At a Senate hearing last May on the global spread of infectious diseases, Senator Patrick Leahy (D-VT) chided the U.S. government for treating "one of the most serious threats we face with the same kind of naïve optimism we did 20 years ago." Leahy, who persuaded the Appropriations Committee's Subcommittee on Foreign Operations to hold the hearing, included his colleagues in the blame: "Frankly, I am amazed that this topic has not received greater attention in the Congress." Those urgings have had an effect. Last month, the Senate passed an appropriations bill that earmarks \$30 million in the budget of the U.S. Agency for International Development (USAID) to combat infectious diseases. And last week, a House committee held a hearing on a bill that calls for the USAID to spend \$50 million "for targeted global programs to end infectious diseases."

Although USAID officials dislike Congress earmarking part of their budget in this way, they agree about the need to increase funding for emerging and reemerging infectious diseases such as malaria, tuberculosis, dengue, Ebola, and other plagues of poorer countries. Several prominent researchers are egging Congress on. "Let's face it, it's a real drop in the bucket, but it's a big drop," says Johns Hopkins University's D. A. Henderson, an epidemiologist whose past jobs have included leading the smallpox eradication program at the World Health Organization (WHO) and a stint at the White House's Office of Science and Technology Policy.

TB researcher Barry Bloom of New York City's Albert Einstein College of Medicine

says current U.S. efforts against infectious diseases are disjointed. "The power of medical science to make a difference, were it to address the problems of people in the poorest countries, is quite remarkable, and yet there is no leadership that is linking biomedical science to global equity in health or foreign policy." For evidence of the paltry U.S. spending on these efforts, Bloom points to a report he co-



authored for the Institute of Medicine earlier this year.* The report refers to 1996 data that ranked the United States dead last among industrialized countries in the proportion of the gross national product it spends on foreign aid (see graph), and it notes that only 10% of

* "America's Vital Interest in Global Health," Institute of Medicine, Board on International Health, is available on the Internet at <http://www.nap.edu/readingroom/books/avi>

the total goes toward health assistance.

A committee report accompanying the Senate bill says USAID should pass the money on to the WHO's Tropical Disease Research Program and its newly formed Division of Emerging and Other Communicable Diseases Surveillance and Control. The report also calls for giving some of the money to the Field Epidemiology Training Program of the U.S. Centers for Disease Control and Prevention (CDC). Henderson says the increase for disease surveillance is critical. "We're really investing very little money at the present time in anything that could be called surveillance," says Henderson. The CDC's Janis Videtto, who helps manage the \$1 million budget spent on training epidemiologists at 17 sites around the world, says additional money is "sorely needed."

Sally Shelton-Colby, USAID's assistant administrator for global programs, expressed misgivings about the legislation when she spoke at the House hearing last week, however. Although she agreed that the international community is not doing enough in this area, she noted that her agency spent \$320 million last year on infectious diseases, supporting such "fundamental prevention and control efforts" as family planning and economic development. Shelton-Colby said USAID could use new money to better monitor and fight TB, malaria, and the spread of drug-resistant pathogens, but she urged Congress to "resist the temptation to earmark funds," because it may force USAID to divert money from other equally important programs. "The committee should not be in a hurry to rob Peter to pay Paul," she said.

The fate of the House bill will be decided when Congress returns from its recess in the beginning of September. Then the House and the Senate will meet in conference to decide exactly how much money—if any—to devote to the effort.

—Jon Cohen