Congress Readies AIDS Funding Transfusion

Moves to double spending on AIDS reflect progress but also enormous problems in combating the disease

Eighteen months ago, Secretary of Health and Human Services Margaret Heckler announced at a packed press conference that the cause of AIDS had been found. She predicted that test kits to screen blood donations for the AIDS virus would be available in 6 months and that a vaccine would be ready for testing within 2 years. Although she was off by only a few months in her projections for the blood test, the upbeat message of her press conference has been replaced in recent months by grim warnings from politicians and scientists alike that efforts to combat the virus that is widely believed to be the primary cause of AIDS will be long and difficult.

These warnings are coming in spite of—and in a sense because of—remarkable progress in understanding the causes and spread of AIDS. In the short time since the disease was first recognized in 1981, a new virus has been identified and linked firmly to the disease, its genetic sequence has been determined, and antibodies to it can be detected by means of a simple blood test. However, notes William Haseltine of Harvard's Dana-Farber Cancer Institute, "The second phase of discovery promises to be much more arduous than the first. We have now progressed into the broad sea of the unknown."

The virus, first isolated by scientists at the Pasteur Institute in France and at the National Cancer Institute in Bethesda, Maryland, has turned out to be an enigmatic organism, both in its genetic structure and its interactions with the body. "Given our present state of knowledge of this new virus . . . we know that it will take a stroke of extraordinary good fortune for us to develop either an effective vaccine or therapy," says Haseltine.

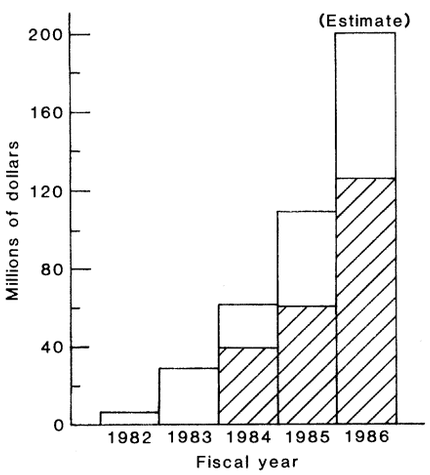
Similarly, the Public Health Service, in a battle plan for the prevention and control of AIDS published last month, acknowledges that "it is unlikely that a vaccine or therapy to substantially limit transmission will be generally available before 1990" and anticipates that the virus will continue to spread at an increasing rate for at least another 2 years. The goal set out in the plan is to slow down the increase in the number of AIDS cases—now more than 13,000 in the United States and doubling each year—by 1990, and to halt transmission of the virus completely by 2000.

The War on AIDS

This is the first article in a series about research on AIDS. Next: the discovery of the AIDS virus and subsequent disputes over patents and priority.

Achieving even these goals will require enormous infusions of funds and talent into programs ranging from fundamental biological research to public education. But the grim fact is that, even if the goals are achieved, there are likely to be upwards of 100,000 cases of AIDS in a few years' time. Not only will that devastate some high-risk communities, but, with treatment costs estimated to be around $100,000 per person, it will also place an immense burden on the health care system.

Small wonder, therefore, that the Administration has announced that AIDS is its number one health priority. But the number one health priority has found itself in conflict with the number one economic priority: to reduce the size of the federal deficit. The Administration has repeatedly forwarded to Congress budget requests that fall short of what officials in the Department of Health and Human Services (HHS) have said are needed. Moreover, the White House Office of Management and Budget (OMB) has generally argued that increased support for AIDS should be obtained by taking funds from other activities.



Congressional appropriations for AIDS

Shaded areas represent Administration requests, including budget amendments, forwarded to Congress. [Source: Office of Technology Assessment and Department of Health and Human Services]

Last year, for example, following Heckler's announcement that a virus had been found to be the cause of AIDS, Edward N. Brandt, Jr., then the assistant secretary for health, sent a memorandum to Heckler recommending that an additional $20 million be requested for fiscal year 1984, and $36 million for 1985. The requests were never sent to Congress, however. Similarly, earlier this year, James O. Mason, the director of the Centers for Disease Control (CDC) and acting assistant secretary for health, surveyed the agencies' needs and concluded that an additional $45.7 million was required. Heckler asked OMB to request the funds from Congress, but OMB declined.

Heckler then used her authority to reprogram some funds from existing activities and on 19 July sent Congress a budget amendment to shift another $37.8 million that had been requested for a variety of other health programs in 1986 into work on AIDS. The big winner in the shuffle would be the Centers for Disease Control, whose budget for AIDS would climb from around $20 million in fiscal year 1985 to $45 million in 1986. AIDS research funded by the National Institutes of Health (NIH) would increase from $61 million to only $70 million.

Not surprisingly, basic researchers funded by NIH felt they were not getting a fair shake and some began to lobby quietly on Capitol Hill for a massive infusion of money into fundamental research on the disease. At the same time, public anxiety about AIDS was increasing and it was becoming apparent that large sums would be needed to test potential antiviral drugs. Mason therefore conducted yet another survey of funding needs and on 15 September, Heckler asked OMB to request a further $70 million from Congress for fiscal year 1986, the bulk of it for NIH. So far, however, OMB has not responded.

Mason pointed out in an interview

with *Science* that the Administration is caught in a difficult position because funding needs are becoming evident faster than the usual budget mechanisms can cope with them. He argues that sufficient funds are being provided through supplemental requests, reprogramming, and negotiations between the executive branch and Congress.

Congress, which is feeling the keen winds of public hysteria over AIDS, has certainly been responsive. Each year, the appropriations committees have upped OMB's budget requests, relying largely on what health officials in the Administration were asking for. Total appropriations for AIDS research and education have risen from $5.5 million in fiscal year 1982 to about $109 million in 1985. And legislation now working its way through Congress is expected to push total funds over $200 million in fiscal year 1986 (see chart).

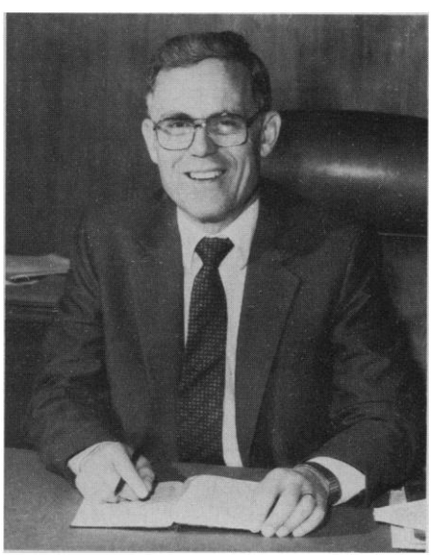
This avalanche of new money is contained in appropriations bills for HHS. One version, approved by the House of Representatives on 2 October, includes $190 million for AIDS programs in NIH, CDC, and the Alcohol, Drug Abuse and Mental Health Administration. The bill sticks closely to Heckler's 19 July amendment, except that an additional $70 million would be given to NIH, which would bring the agency's total AIDS funds to $140 million. In essence, the bill would dump the extra $70 million in the lap of NIH director James B. Wyngaarden, who would decide how it should be spent.

The Senate version, which has been approved by the Appropriations Committee and is awaiting floor action, contains $206 million for research and public education on AIDS and an additional $16 million for demonstration projects for alternative means of delivering care to AIDS patients. The latter is a modest attempt to come to grips with the staggering problems of dealing with the epidemic on the front lines of the medical care system. The bill would boost CDC's AIDS budget to $65 million, including an additional $10 million to open up more centers to test individuals for antibodies to the AIDS virus. NIH's budget would climb to $128 million, a figure arrived at after consultations with directors of individual NIH institutes, according to committee aides.

Whatever version of the legislation eventually emerges from Congress, it is clear that a huge infusion of funds is on the way. New people are, however, as urgently needed as new money. Although several federal laboratories moved quickly into AIDS research, they have been unable to hire new people because there has been a freeze on hiring at NIH. Moreover, there has not exactly been a stampede of university researchers into the field. "You can count on the fingers of one hand the first-rate laboratories [working on AIDS] outside the federal government," claims Haseltine.

Another problem, according to some observers, is a lack of strong central management of the AIDS effort. Consequently, the House Appropriations Committee has recommended that a permanent AIDS chief be appointed in HHS to plan and coordinate the war on AIDS.

Exactly how the new funds will be spent is unclear, but several programs will get major boosts. They include:



James O. Mason

Has requested an additional $115 million for AIDS in the past 6 months.

• *Public education.* In the absence of effective vaccines or therapies to control the disease, the only weapon to curb transmission of the virus and dampen public hysteria is effective information on how AIDS is and is not spread. In the past, the federal government has been sharply criticized for paying insufficient attention to public education, but educational efforts are now being sharply expanded. According to James Curran, who heads AIDS programs at CDC, at least $20 million will be spent on various education and risk reduction programs in 1986, mostly through CDC grants to state and local organizations.

• *Vaccine development.* The development of vaccines against the AIDS virus is turning out to be an extremely challenging task. The virus itself undergoes rapid genetic change, which may enable it to elude protection offered by a vaccine. Moreover, most people who are suffering from AIDS have high levels of antibodies in their blood, yet these antibodies do not generally appear to inhibit infection by the virus. Several vaccine approaches are now being tried, including injecting parts of the virus's protein coat into monkeys, but one scientist who is involved says that the amount of money for such efforts is "a joke." The bill now before the Senate would add $7 million to the vaccine program.

• *Drug testing.* NIH is gearing up to move a handful of potential antiviral agents into clinical trials. Four are currently undergoing small-scale toxicity testing. According to Anthony Fauci, director of the National Institute of Allergy and Infectious Diseases (NIAID), there is evidence that replication of the virus can be suppressed, but so far little evidence of clinical benefit to the patients. NIAID is planning to establish a network of institutions around the country so that promising compounds can be moved rapidly into more widespread trials. According to Mason, more than half the $70 million he recently requested from OMB would be channeled into research on therapeutic agents.

There is widespread agreement that much more needs to be understood about the biology of the virus and the natural history of the disease before effective therapies and treatment can be developed. For example, although it has long been known that the virus infects and kills a class of lymphocytes that play a key role in regulating the immune system, it has recently been found to infect a variety of other cells, including brain cells. The mechanism of infection is unclear and the range of disorders associated with the virus has yet to be determined. Moreover, the virus itself has some unusual features, including two genes whose function is unknown.

The progress of the disease in infected individuals is also unclear. According to extrapolations from blood test data, perhaps 1 million people in the United States have been infected with the virus. It is widely accepted that they are carrying the viral genes in some of their cells, but opinion is divided on whether disease will eventually be manifested in all infected individuals or whether other factors are necessary to trigger the virus into action.

Getting answers to all the research puzzles is going to take a lot of time, money, and scientific talent. The $200 million about to be approved by Congress for research and education on AIDS is clearly just one installment in what will be a long and expensive struggle to understand this disease.

—COLIN NORMAN