Congress Votes NIH a Big Budget Boost

But it also passes a bill establishing two new institutes and specifying in detail how NIH should be managed

Shortly before adjourning for the elections, Congress approved a record budget of $5.146 billion for the National Institutes of Health (NIH) in fiscal year 1985—a 14 percent increase over 1984 and $580 million more than the Reagan Administration requested. But it also approved some things NIH does not want, such as an arthritis institute, a nursing institute, and a temporary ban on some types of research on fetuses.

These measures were contained in a flurry of legislation passed by the 98th Congress in its dying days. They include an appropriations bill for the Department of Health and Human Services (HHS), of which NIH is a part; an authorization bill establishing policy for NIH—the first such authorization bill passed since 1980; and a separate item setting up centers for disease prevention at universities around the country. Congress has not approved so much legislation affecting biomedical research in years. But NIH officials wish Congress had adjourned without agreeing to some of these measures, and there is speculation that the authorization bill may be vetoed.

They are happy about the appropriations bill, however. Following a well-established tradition, Congress has ignored the Administration's parsimonious prescriptions for medical research and approved a huge increase for NIH. The Administration, partly on the assumption that Congress would add to whatever was proposed, asked for virtually no increase. But Congress's additions have exceeded most expectations.

The total should permit NIH to fund 6400 to 6500 new and competing grants in FY 1985 (which began on 1 October) up from about 5500 in 1984. This should provide some relief from the fiscal drought of the past few years, which has resulted in a large fraction of highly rated research projects going unfunded. In contrast, the Administration's budget request would have funded only 5000 new and competing grants, a number established during the Carter Administration as a minimum level to provide some stability in NIH's operations.

The appropriations bill also contains some $218 million for training grants, enough to support about 10,000 young researchers and to increase stipends by 4.3 percent. This is about $50 million above current levels, which have remained depressed for several years as a result of a legal technicality. Because Congress failed to approve an authorization bill for NIH in the past 4 years, authority for the training programs lapsed and the House of Representatives refused to appropriate new funds for them. Passage of the NIH authorization bill on 9 October provided the legal authority to put new money into training grants, however, and Congress came through with a big increase.

Included in the bill, according to a congressional staff analysis, is some $83 million, spread over several agencies, for monitoring, research, and treatment of AIDS (acquired immune deficiency syndrome). This is a substantial increase over current levels, thanks in large measure to an amendment proposed on the floor of the Senate by Senator Alan Cranston (D–Calif.) that added $14.6 million to the Administration's budget request for these activities. Cranston's amendment included an additional $11.2 million for the Centers for Disease Control, $2.6 million for the National Institute of Allergy and Infectious Diseases at NIH, and $822,000 for the National Institute of Mental Health. Curiously, Cranston's amendment did not add to the funds for the National Cancer Institute, which supported the work by Robert Gallo's lab that led to the discovery of a virus associated with AIDS.

> A veto would risk getting tighter restrictions on animal and fetal research next year.

Congress's generous treatment of biomedical research budgets is, however, accompanied by what many Administration officials view as excessive management of NIH's business from Capitol Hill. This trend is evident in the authorization bill, which was approved by Congress after a remarkable odyssey through the legislative process and some skillful maneuvering by its chief sponsor in the House, Representative Henry Waxman (D–Calif.).

The House passed its version of the bill last fall, but equivalent legislation was never brought to a vote in the Senate because of fears that foes of abortion, led by Senator Jeremiah Denton (R–Ala.), would insert a provision virtually outlawing research on fetuses. The Senate did, however, approve a bill in May to establish an arthritis institute at NIH, and that provided a legislative vehicle for Waxman to move the House bill forward. He got the House to attach its version of the NIH authorization bill as an amendment to the Senate's arthritis bill, and it was then left to a House-Senate conference committee to come up with the final legislation.

The whole effort was, however, almost derailed by continuing disagreement on fetal research. The House bill essentially would have put into law regulations governing fetal research that have been in place for almost a decade. In effect, they only permit research that is either intended to benefit the fetus or entails no added risk of pain or suffering to the fetus. The secretary of HHS is, however, permitted to grant waivers for projects that may put fetuses at risk if the project has passed ethical reviews at both the institutional and federal level. (The type of project that might qualify for a waiver is the testing of a vaccine on women scheduled to undergo therapeutic abortion. This was done with rubella vaccine in 1969 and the research showed that, contrary to results from animal studies, the virus can cross the placenta and infect the fetus.) Some Senate members of the conference committee, led by Denton and Orrin Hatch (R–Utah), wanted much stricter provisions, however, and the matter was deadlocked for weeks.

At the eleventh hour, a compromise was reached under which the House language was retained, but a 3-year moratorium was placed on the granting of waivers. In addition, a Biomedical Ethics Advisory Committee, which was also created by the legislation (see below), was instructed to examine the circumstances, if any, under which waivers should be granted. Less than 24 hours

later, the bill was approved by both the House and Senate.

In addition to providing new authority for training programs, it renews the authorization for several NIH institutes. Among its other key provisions are the following:

Arthritis institute. The bill establishes a National Institute of Arthritis and Musculoskeletal and Skin Diseases at NIH. The new institute, which will incorporate many programs of the current National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases, has long been promoted by a variety of lobbies to give more political visibility to arthritis research. It has, however, been opposed by NIH director James Wyngaarden and other Administration officials as being an administrative burden that will not add to research. The legislation prescribes in detail how the institute should be established and operate. The appropriations bill does not, however, provide additional money for the new institute, which means that the costs of establishing it may have to come out of research funds.

Nursing institute. A provision, inserted in the House bill by an amendment offered by Representative Edward R. Madigan (R–Ill.) and reluctantly agreed to by Senate members of the conference committee, will establish an Institute of Nursing at NIH. Although the legislation is vague on what the institute will do, it is expected to incorporate much of the work of the current Division of Nursing in the Health Resources and Services Administration. The appropriations bill provides $5 million for the institute.

Laboratory animals. The legislation di rects NIH to establish guidelines for th use of animals in research much alon the lines the agency recently proposed In addition, it requires an exhaustiv study—by the National Academy of Sci ences if it is willing to undertake it—o trends in the use of lab animals, alterna tives to the use of animals in research and the financial impact of regulation requiring accreditation of institution conducting animal research. This provi sion is considerably less restrictive tha many proposals that have been makin the rounds on Capitol Hill.

Biomedical ethics. A 14-member Bio medical Ethics Advisory Committee wil be established to conduct studies of ethi cal issues arising from medical research Its primary focus initially will be o human genetic engineering and fetal re search, and it will report to a 12-membe board consisting of six senators and si members of the House.

Disease prevention. The legislation re quires the appointment of associate di rectors for prevention in the Nationa Cancer Institute, the National Institut of Child Health and Human Develop ment, and the Office of the NIH director A separate bill, approved by Congres on the same day, also establishes a Office of Disease Prevention and Healt Promotion in HHS and requires the es tablishment of 13 university-based cen ters for disease prevention.

Peer review. The director of NIH i required to establish procedures for "pe riodic, technical, and scientific peer re view" of intramural research at NIH.

Fraud. The legislation directs the sec retary of HHS to draft regulations settin out procedures that institutions mus take to investigate allegations of fraud i NIH-supported research.

Boards and committees. The legislatio establishes a variety of boards and com mittees to plan and coordinate work o lupus erythematosus, spinal cord injury health needs of the elderly, learning dis abilities, and orphan diseases.

Because so much of the NIH author zation bill is unpalatable to the Adminis tration, there has been speculation tha President Reagan may veto it. A vet would have little immediate impact o NIH because the training programs hav been funded by the appropriations bi and HHS already has authority unde another law to fund NIH institutes.

However, a veto would upset suppor ers of the arthritis institute in an electio year and it would run the risk of Cor gress approving much tighter restriction on animal and fetal research next year.

—COLIN NORMA

Universities Prevail on Secrecy

The long battle between the universities and the Department of Defense (DOD) over restrictions on the publication of academic research appears to have been resolved in the universities' favor—at least for the time being.

A memorandum written by Under Secretary of Defense Richard DeLauer, dated 1 October, specifies that no restrictions should be placed on the publication of unclassified fundamental research sponsored by DOD. The memo, which was sent to research chiefs in the Pentagon and establishes DOD policy on the matter, defines fundamental research to include virtually all DOD-supported research performed on university campuses.

DeLauer's memo clarifies and puts into effect a policy announced last May (*Science*, 8 June, p. 1081) that relies on classification as the primary means of controlling fundamental research publications. Announcement of the new policy effectively signaled an end to DOD's efforts to restrict dissemination of the results of unclassified but militarily sensitive research, but left open the question of how fundamental research would be defined. DeLauer's memo clarifies this.

The memo defines fundamental research as all unclassified research supported by DOD's 6.1 budget category—the category often referred to as basic research. It also states that "unclassified research performed on campus at a university and supported by 6.2 funding (the budget category that corresponds generally to applied research) shall with rare exceptions be considered 'fundamental,' " and therefore be exempt from restrictions.

The 'rare exceptions," according to the memo, would be "where there is a likelihood of disclosing performance characteristics of military systems, or of manufacturing technologies unique and critical to defense." In such cases, any restrictions on publication would have to be agreed by DOD and the university performing the work before a contract is signed.

A draft policy statement that would effectively establish DOD's new policy in all other federal agencies is currently under consideration in the White House. It would require agencies to determine before signing a research contract whether the work should be classified and to review periodically "all research grants or contracts for potential classification." According to this policy, no restrictions may be placed on unclassified fundamental research.

One concern that has been raised over this policy is that it could result in more work being classified. But university groups note that agencies are reluctant to classify academic projects because very few universities will undertake classified work.—COLIN NORMAN