House Battles over NIH Legislation

Representative Waxman's bill is focus of a debate about how much control Congress should have over scientific decisions

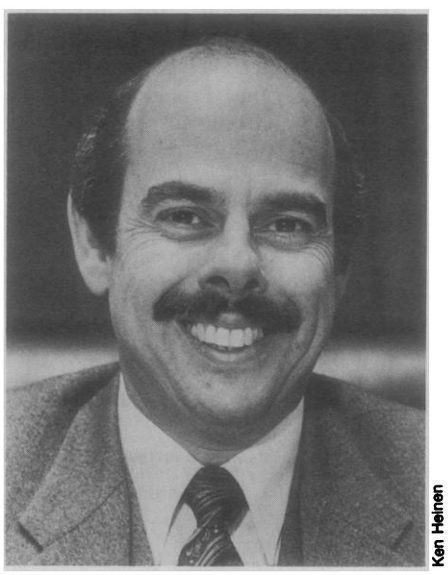
An intense political battle in the House of Representatives over control of the National Institutes of Health (NIH) took an unanticipated turn in the past few weeks when two Republican congressmen launched a late but potentially successful attack on a controversial NIH bill sponsored by Representative Henry A. Waxman (D–Calif.). A full House vote on the measure, which had been expected to come to the floor this month, has been deferred; no action will be taken until Congress reconvenes in September from summer recess. Thus, Waxman has time to refortify support for his position, but opposing forces also have time to amass support of their own. A month ago observers were betting that Waxman's bill would easily win House approval. Now those bets are off.

The issue, which for political purposes is being framed in relatively stark terms, is this: Who should be in charge of scientific decision-making at NIH—Henry Waxman or NIH administrators and peer review panels?

Waxman, who is considered a savvy and ambitious member of the House, is chairman of the subcommittee that authorizes funds for NIH.* For the third year in a row, he has introduced legislation that would give Congress—and his subcommittee in particular—unprecedented control over NIH by spelling out in great detail just what kind of research it should undertake and how it should be managed.

During House debate, Representative Edward R. Madigan (R–Ill.) called Waxman's legislative emphasis on management details ". . . a prime example of the wrong approach" to fostering basic research. His colleague, Representative James T. Broyhill (R–N.C.) said ". . . those who have responsibilities for administering NIH are far better qualified than those of us on the House floor, operating in a political environment like this, to make the determination as to where NIH dollars go." Broyhill calls the Waxman bill, which has the support of a large number of voluntary health organizations, "a political pork barrel which guarantees NIH's downfall."

When Congress reconvenes, Madigan and Broyhill will introduce a substitute to the Waxman bill that provides the same high-funding levels that Waxman wants with far fewer strings. The funding levels in the Madigan-Broyhill substitute may be key to its potential success. The dollar amounts that Democrat Waxman would authorize for NIH total almost one-half billion dollars more than the President requested for the fiscal year 1984 budget. Not only have Republicans Madigan and Broyhill decided to go along with Waxman on this but the Administration itself has given tacit approval of the increased funding as a tactic for defeating what is seen as Waxman's power grab for NIH.



Ken Heinen

Henry A. Waxman

His bill is seen as a power grab for NIH.

On 25 July, the day Waxman's bill was first debated in the House, the Office of Management and Budget (OMB) approved a formal "statement of administration policy" in support of the Madigan-Broyhill substitute because it contains "none of the heavily prescriptive requirements" of the Waxman bill. The Administration's mild statement that it "prefers that the substitute's excessive funding levels be reduced" is generally interpreted as the next best thing to OMB's acceptance of higher funding for NIH. According to a congressional aide, Madigan and Broyhill are hoping to win bipartisan support by eliminating dollars from the discussion and "focusing the debate on the issues of control and management of NIH."

In truth, the current controversy is simply an extension of a debate that goes back at least to 1971 and passage of the National Cancer Act, which gave the National Cancer Institute (NCI) special administrative status within NIH, along with added millions of dollars for research. People have been decrying the "politicization of biomedical research" ever since. The difference now is the degree to which Waxman would further that politicization.

For example, under the cancer act, NCI now depends on periodic congressional reauthorization in order to legally stay in existence. By contrast, legal authority for most of the other institutes is vested in section 301 of the Public Health Service Act which gives NIH permanent operating authority. Waxman's bill (H.R. 2350) would not only reauthorize NCI and certain other programs that are up for renewal but also would undermine section 301 by requiring that each of the NIH institutes come up for periodic reapproval by Congress.† Since coming to the health subcommittee chairmanship in 1979, Waxman has repeatedly stated his desire to see all the institutes governed by the same set of rules. On the House floor last month, he said that his bill—known as the Health Research Extension Act of 1983—"contains a nonsubstantive, technical redraft . . . of the Public Health Service Act." Administration officials would argue with his description of it as "nonsubstantive."

In addition to providing legally necessary reauthorizations, Waxman's bill provides for 17 completely new activities within NIH. Like the Madigan-Broyhill substitute, H.R. 2350 authorizes the creation of a new National Institute of Arthritis and Musculoskeletal Diseases, an idea widely favored in Congress and opposed by NIH director James B. Wyngaarden and others in the Administration

*Subcommittee on health and the environment of the Committee on Energy and Commerce.

†Among those activities requiring reauthorization are the National Cancer Institute, the National Heart, Lung, and Blood Institute, the Medical Library Assistance Act, and the National Research Service Awards—the current form of training grants.

as a bureaucratic burden that will not materially contribute to arthritis research. But Waxman's bill goes well beyond merely providing authorization for the new arthritis institute. It speaks in considerable detail to how it will operate, specifying, for instance, that there be a program for public dissemination of information to "discourage promotion and use of unapproved and ineffective" methods of diagnosis and treatment.

Among others, the Waxman bill includes provisions in the following areas:

- It contains specific items related to "diet therapy for kidney failure," research on spinal cord regeneration, sudden infant death syndrome, Alzheimer's disease, and sports-related disorders.
- It would establish a new National Commission on Orphan Diseases, comprised of ten specialists in rare diseases and five individuals who either have some rare disorder or represent a special interest group whose concern is focused on an uncommon disease. Waxman cites neurofibromatosis, or Elephant Man's disease, characterized by multiple tumors of the skin and cranial or spinal nerves, as an example of an orphan disease to which he would like NIH to devote more targeted attention. "In fact, concern over the adequacy of research in this area was a major impetus for creating this National Commission," he says.
- Acting in the belief that NIH has not paid sufficient attention to the prevention of disease, the bill requires establishment by 1986 of 25 geographically distributed Centers for Research and Demonstration of Health Promotion and Disease Prevention. (The United States has 23 schools of public health where most of these centers would likely be housed.) It also mandates the new position of assistant director for prevention within the NIH director's office and the creation of a prevention official within each of the NIH institutes. Further, NIH is required under the bill to produce a prevention plan that would include recommendations regarding epidemiology, the etiology of disease, especially as it relates to diet and other personal habits, and environmental factors.
- Cancer centers, which currently are established and funded at the discretion of NCI and its advisory board, would be written into law. According to Waxman, "the administration's proposed budget for fiscal 1984 would result in the defunding of 16 of the 20 cancer centers up for renewal in that fiscal year. . . ." (Funding levels in his bill would keep them going whether or not their existence as centers is established in law.)
- Centers devoted to research in mental retardation and in bioengineering are mandated in the bill, as is establishment of an administrative procedure for handling allegations of scientific fraud. A study on the safety of pertussis vaccination is mandated for completion by 1 April 1984. The bill calls for a National Academy of Sciences study on the commercialization of biotechnology. And it would establish a 15-member presidential commission on the human application of genetic engineering. These latter provisions, as well as the bill's language on scientific fraud, were included as part of negotiations with Representative Albert Gore, Jr. (D–Tenn.), who has taken a strong interest in these issues during the past couple of years.

James T. Broyhill (left) and Edward R. Madigan. Their bill provides the same funding levels as Waxman's but without the strings.

The Waxman bill enjoys the support of a number of specialized private health groups and is opposed by those that represent biomedical research institutions more generally. During debate on the House floor, Madigan challenged Waxman's assertion that his bill is vital to the future of NIH by saying: ". . . why is it that the Association of American Medical Colleges, the Federation of American Societies for Experimental Biology, the National Society for Medical Research, the American Physiological Society, the Association for Academic Health Centers, the National Institutes of Health, and the American Medical Association all oppose the gentleman's bill?"

Waxman countered with a list of his backers, calling them "equally impressive, if not more impressive" than those who have taken sides with Madigan and Broyhill. His list included the following groups: The American Cancer Society, the American Lung Association, the American Academy of Orthopaedic Surgeons, the Gluten Intolerance Group, the International Association for Enterostomal Therapy, and the Association of Schools of Public Health.

Waxman roundly denounced Madigan's suggestion that his supporters represent what "one would regard as special interest organizations. . . ." Said Waxman, ". . . it is surprising to think that people who are organized to fight diseases are viewed as a special interest group while the medical schools are not. . . ." This juxtaposition of groups on either side gets to the heart of one important aspect of what this fight is all about. Should NIH funds be distributed along Waxman's lines—something of an extention of the "disease-of-the-month" pattern of legislation that was prevalent for a while in the late 1970's—or should funding decisions be made more broadly along lines of developments in basic research? (Although Madigan has become a staunch supporter of the idea that NIH should be relatively unencumbered by congressional mandates, it is worth noting that he plans to introduce an amendment for the creation of a new national institute for nursing research.)

Reiterating the now familiar theme that research in one discipline may yield unexpected benefits in another if science is not too rigidly targeted, NIH director James B. Wyngaarden told *Science* he finds it "ironic" that this emphasis on doing research disease-by-disease is taking place "just when there's such a confluence of new knowledge at the science base." Wyngaarden clearly opposes the Waxman bill and calls the Madigan-Broyhill substitute a "far preferrable approach."

Although the House fight over NIH can accurately be seen as a philosophical

battle over the best way to manage basic research funding, there are pure political elements to the battle as well. As chairman of the subcommittee on health and the environment, Waxman's power over NIH is of a second order. His committee "authorizes" funds for the institutes which, in congressional terms, means it plays only an advisory role vis-à-vis the powerful "appropriations" committee which actually makes the final, real decisions about how much money Congress is going to spend on something. But once a specific item is mandated in authorizing legislation, some level of funding is bound to follow. Here is where Waxman is trying to draw his strength. "If we are going to stand on the sidelines and merely hope the Appropriations Committee will protect these biomedical research priorities we think are important, I submit we are abdicating our responsibility," Waxman declares.

Current predictions are that the NIH bill will come up soon after Congress reconvenes, at which time the Madigan-Broyhill substitute will officially be introduced. Although House aides talk of trying to work out various compromises between now and then, it is anybody's guess how much either side may be willing to yield.

Then, once a House bill is passed, the issues will have to be fought over in House-Senate conference with Senators whose enthusiasm for the Waxman approach is decidedly lacking. The Senate version of the NIH authorization bill, introduced by Orrin G. Hatch (R–Utah), contains a provision for a new arthritis institute but is, in general, substantially less prescriptive and detailed than the Waxman bill.

Furthermore, the question of whether the Hatch bill will even come to a Senate vote is presently uncertain because of a "hold" that Bob Packwood (R–Ore.) has placed on it. Packwood opposes the legislative provisions to proscribe fetal research which are in the NIH bills. Unless some compromise is reached there, the bill may never make it out of committee.

It would not be the first time that Congress has simply been unable to resolve its differences over NIH. As Representative Madigan has noted, ". . . an NIH reauthorization bill has not been signed into law since December 1980 when the House and the other body reached a stalemate in conference and threw out both [House and Senate] bills, replacing them with a simple reauthorization" to keep NIH in operation without legislating a change in its way of doing business. It could happen yet again.—**BARBARA J. CULLITON**

Ruckelshaus Picks New EPA Team

Environmental Protection Agency (EPA) administrator William D. Ruckelshaus, in contrast to his predecessor, is selecting a team of senior officials with wide government experience. So far his choices for the agency's top posts have met with environmentalists' approval and have already bolstered morale within EPA.

While Anne McGill Burford brought in individuals who were Washington outsiders and were also mainly from industry, Ruckelshaus generally has chosen veterans of government, some of whom worked for Ruckelshaus when he was EPA administrator from 1970 to 1973.

Last week the Senate confirmed Alvin L. Alm as deputy administrator and Howard M. Messner as assistant administrator for administration. Alm, 46, a Democrat and now second in command at EPA, comes to the job from the Harvard Kennedy School of Government. He was EPA's chief of planning and management from 1973 to 1977. Later, he served as assistant secretary at the Department of Energy. Alm replaces John Hernandez, Jr., who plans to return to the University of New Mexico.

Messner served under Ruckelshaus in the early 1970's, and is taking on many of the same duties he had then, overseeing personnel and the budget. He was chairman of the government task force that led to EPA's creation. In recent years he has been a senior official at the Office of Management and Budget and, since February, he has been controller for the Energy Department. He succeeds John Horton, a wealthy entrepreneur from private industry.

Ruckelshaus had chosen others for top posts at the agency, but their nominations have not been formally submitted to the Senate by the White House as yet. Their confirmation is expected. Bernard D. Goldstein, chairman of the department of environmental and community medicine at Rutgers University, has been named to head EPA's office of research and development. He was a key witness for the federal government in 1977 when it pushed successfully for stricter regulation of benzene.

Josephine S. Cooper is slated to become the assistant administrator for external affairs, which puts her in charge of liaison with Congress, the public, and the press. For the past 2 years, Cooper has been on the staff of Senate majority leader Howard Baker (R–Tenn.) and helped to draft amendments to hazardous waste legislation. Her proposed changes would have strengthened the regulations, but more moderately than those recommended by environmental groups such as the Sierra Club. Prior to her Senate job, Cooper served at EPA for 10 years in a variety of posts, eventually rising to a senior position in the office of research and development.

The job of assistant administrator for water is to be filled by John Ravan, a former EPA regional administrator under Ruckelshaus. Joseph Cannon is expected to remain assistant administrator for air, one of the few holdovers from the Burford administration. Cannon was an opponent of Burford's attempts to relax rules requiring lower lead levels in gasoline

—**MARJORIE SUN**

Toxicology Labs to Bar Financial Conflicts

The nation's most prestigious toxicology laboratories are getting ready to impose a new code of ethics and a program of quality control on themselves. "I don't know quite how it's all going to work yet," says Harold Brown, Jr., executive director of the National Association of Life Science Industries (NALSI), the labs' Washington lobby. But NALSI officials have decided already that an important part of the new code will be a requirement that laboratory officers have no financial stake in the products they are testing.

"This is going to be difficult for us," Brown says, "because most of our people are entrepreneurs who believe in the business and like to invest in it." But the industry recognizes that it has a problem and must avoid even the appearance of a conflict of interest. "The question is, 'How much stock can you own?' Maybe it won't be zero," Brown thinks. Perhaps lab owners and operators will be asked to hold only "de minimis" shares in com-