"The committee is unwilling to assume that negative mouse data necessarily outweigh the consensus of a variety of short-term tests. . . . All the evidence needs to be taken into account, and the decision based on the weight of evidence in each case."

Because there is no simple single test that provides a yes/no answer, the committee recommends at two-tiered approach. The first tier consists of a series of microbial and cell culture tests, a positive in two or more of which labels a chemical as a presumed mammalian mutagen. A single positive sends the chemical to the second tier, which involves fruit flies.

This screening through a two-tiered battery of short-term tests constitutes the first of five levels in a proposed mutagen assessment program. "In most cases, the outcomes of such tests wll be sufficient to support industrial or governmental control." If a simple mutagen/nonmutagen answer is insufficient, assessment moves onto a second level, that of hazard characterization. This depends on being able to measure the degree of mutagenic potency expressed.

Level three looks to data from carcinogenicity tests that might aid in judging mutagenic hazard. And if uncertainty still exists, one of several possible mouse tests can be undertaken, which constitutes level four. Information from these tests, together with other data, should be enough to estimate the risk associated with the chemical. The NAS committee took risk assessment no further than this, but pointed out that calculations involving probable exposures and weighing of benefits could eventually yield a risk/benefit analysis. Parenthetically, the committee also observes that those bearing the risks often are not those who accrue the benefits.

Although the report has only just been published, its findings have been in the hands of the Environmental Protection Agency, which was the contracting agency, since mid-December. EPA, however, sees no apparent urgency for its perusal. The agency's first public foray into mutagenicity risk assessment was at the end of 1980, with the publication in the *Federal Register* of proposed guidelines on the topic. Following public review and comment, the guidelines went to the agency's scientific advisory board for further review and revision.

The NAS report, which confirms and extends much of what was contained in the original proposal, will be an important source of information for the final revision of the guidelines. In the unlikely event that the delays that have hampered progress to date do not continue, new guidelines are due by the end of 1983.

—ROGER LEWIN

Waxman Bill Seen as Threat to NIH

Is NIH panel chairman just trying to tidy up statutory authority, or would changes undermine agency's traditional status?

Representative Henry A. Waxman (D–Calif.), chairman of the House authorizing subcommittee for the National Institutes of Health (NIH), is pushing ahead with legislative changes that would substantially increase the direct influence of Congress—particularly of Waxman—in NIH affairs.

Waxman heads the health and environment subcommittee of the House Energy and Commerce Committee. The panel is expected to act favorably on Waxman's bill, H.R. 1555, which would extensively revise the authority under which NIH operates. Critics in the biomedical research community believe that the changes proposed threaten the flexible authority under which NIH has traditionally operated and which agency advocates see as the key to its research excellence. Waxman and his associates say this is not the case and that the bill is designed to bring needed order to an administrative tangle caused by the rapid growth of NIH programs

In 1980, Waxman sought successfully to legislate time and dollar limits for NIH. This time, his proposals stop well short of that, but some critics say the changes would make it easier later to require periodic reauthorization of NIH.

Waxman consolidated his control of the subcommittee in the 4 years since he won the chairmanship after a bruising contest (*Science*, 30 March 1979, p. 1319). In the same period he has become a major force in House handling of environmental and health issues.

Waxman served a three-term political apprenticeship in the rough-and-tumble California state legislature before coming to Congress in 1974, and in Washington has proved himself an effective practitioner of quid pro quo politics. An unabashed liberal, Waxman represents a Los Angeles district which includes Hollywood and Beverly Hills, and his skill in tapping his politically and financially liberal constituents and directing their contributions to the campaigns of like-minded colleagues in Congress has bolstered his influence in the House.

The long-term concern of NIH partisans centers on Section 301 of the venerable Public Health Service Act that sets forth the research status of NIH. It is unique in giving NIH "open-ended" authority. This means that most NIH institutes do not come before Congress periodically to have their statutory authority renewed and escape the full force of special interest pressures.

Reasonable or not, underlying the resistance to recodification is a conviction that the special protection of its open-ended authority is crucial to NIH. NIH is seen as particularly vulnerable to the powerful "disease constituencies" and other special interest groups that abound in the health field. NIH advocates recognize the power of appeals in behalf of suffering patients. They see the consequences of opening NIH to standard authorization politics as the fragmentation of NIH into an incoherent collection of special interest enclaves. An old NIH nightmare is the vision of recodified NIH institutes facing periodic reauthorization bouts that would turn into legislative free-for-alls in committee and on the floor. Pessimists see the signs of trouble already in the reported glut of amendments being readied for H.R. 1115.

After taking over the subcommittee chairmanship, Waxman in 1980 sought to end NIH's open-ended authorization. This met the strong opposition from the Carter Administration, NIH officials, and biomedical researchers and the organizations that represent them, notably the Association of American Medical Colleges. Waxman dropped the provi-

sion in subsequent years, but the medical research lobby doubts that Waxman has dropped the idea.

This year, the focus of concerns about so-called recodification is Waxman's proposed revisions of Title IV of the parent act that defines the responsibilities of NIH and the individual national institutes. Overall, the bill would extend the authority for the two institutes requiring reauthorization—the National Cancer Institute (NCI) and the National Heart, Lung, and Blood Institute (NHLBI)—and spell out the responsibilities of the other institutes. The bill also calls for creation of a National Institute of Arthritis and Musculoskeletal Research. An arthritis institute appears headed for congressional approval this year after being stymied last year.

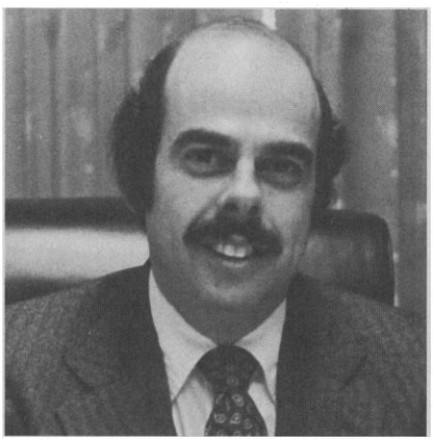
Waxman is also expected to offer several substantive amendments including a proposal to set aside 1 percent of the NIH budget for research into the prevention, diagnosis, and treatment of diseases that pose a public health emergency. The initiative is inspired by concern over the outbreaks of the so-called acquired immunodeficiency syndrome (AIDS) for which homosexuals, drug users, and Haitians are identified as high-risk groups (*Science*, 7 January, p. 42).

A committee analysis of H.R. 1115 points out that the authority for NIH has not been revised since the 1940's and "contains a number of redundant, outdated or contradictory provisions." Waxman's amended Title IV would prescribe the duties of the NIH director for the first time, provide for appointment of assistant directors for disease prevention for NIH and for each separate institute, and set up a uniform system of advisory boards that would apparently have a degree of management responsibility greater than that held by the current advisory councils.

Administration opposition to Waxman's proposals was expressed in 23 February hearings before his subcommittee by Health and Human Services (HHS) assistant secretary for health Edwin N. Brandt, Jr. In his testimony, Brandt objected to proposed changes in both management and organization of NIH, saying, "in neither case are sweeping changes scientifically or administratively necessary." He noted that the proposed revisions would delete all references to Section 301 and "would create organizations and procedures that are too rigidly defined and, in fact, represent an attempt to micro-manage the NIH."

Proponents argue that detailed authorization provisions in the case of NIH would breed instability. Donald S. Fredrickson, a recent NIH director, now a vice president of the Howard Hughes Medical Institute, says in behalf of open-ended authority that it allows "NIH administrators to move swiftly to take advantage of scientific opportunities."

Brandt said at the hearing that the Administration will submit a bill providing a 5-year extension for those programs that require action. He argued that



Representative Henry A. Waxman

Growing influence in NIH affairs

no major changes should be made affecting NIH authority before completion of a study now getting under way by the Institute of Medicine (IOM) of the National Academy of Sciences. The study was initiated to deal with questions raised by the proposed arthritis institute and other mooted additions to NIH, but is expected to offer broad recommendations on NIH management and organization.

Waxman is not the first to question NIH's sui generis operating arrangements. President Lyndon Johnson exerted heavy pressure on NIH to pay more heed to practical applications of research. Through the 1960's, former North Carolina Representative L. H. Fountain used his Government Operations subcommittee's oversight powers to prod NIH into accepting greater accountability. But NIH's unique status has been supported by influential patrons in Congress. The first real breach came during the Nixon Administration when NCI and NHLBI were established with periodic reauthorization required.

Weighing in favor of recodification is a widening acknowledgement that Title IV needs untangling. The IOM study is increasingly cited as a possible source of an acceptable formula for change. Robert Rosenzweig, the new president of the Association of American Universities is one who takes the view that changes in NIH authority are thinkable. Rosenzweig, a former Stanford vice president, says, "I'm not arguing for the status quo. A change in authority may be wise, but it should follow serious study, not precede it."

By congressional lights, Waxman's view that NIH should follow the rules set down for other federal research agencies is not unreasonable. The fact that such a change would give Waxman greater clout as a chairman is seen as going with the territory.

Except on the recodification matter, Waxman seems to be regarded, on balance, as pro-NIH by the biomedical research community. Subcommittee staff argue that recodification is not a serious factor in current deliberations, and researchers should be concerned with Waxman's efforts to resolve issues important to them such as those affecting fetal research, animal welfare, and payment of overhead costs for research.

The immediate prospect for Waxman's version of the NIH bill are favorable despite the House Minority leadership's espousal of a simple extension of authority called for by the Administration. Waxman can count on a majority in his subcommittee strengthened by departures and additions in the new Congress. Passage by the House of a similar measure last year indicates friendly treatment in full committee and on the House floor. In the Senate the odds are reversed. In the last Congress, the gap was so wide between House and Senate versions of an NIH bill that a conference was never arranged. Another impasse is possible.

Waxman, however, is a formidable congressional operator. His success last year in defending the Clean Air Act from industry efforts to reduce air quality standard earned bravos from environmentalists and grudging respect from industry lobbyists. His efforts brought him into conflict with the chairman of his parent Commerce Committee, Representative John D. Dingell (D–Mich.), who favored relief for the beleaguered auto companies of his home state. This year Waxman is reported willing to accept some relaxation in standards affecting autos in return for tougher controls on power plant emissions thought to figure prominently in acid rain problems.

It is this capacity for political give-and-take that worries NIH advocates, or rather that it should be applied to NIH. The Waxman bill may not complete the journey through the legislative process in this Congress to make its full impact on NIH, but Waxman himself seems likely to play a continuing and increasingly influential role in NIH's future.

—JOHN WALSH