Study of NIH Gets Under Way

The biomedical research community is feeling hard-pressed to defend the traditional organization of basic research against the demands of special interest groups and their congressional supporters

An Institute of Medicine (IOM) study of the organizational structure of the National Institutes of Health (NIH) got off the ground recently with an open hearing at which representatives of a number of professional health societies seized the occasion to plead their special causes.

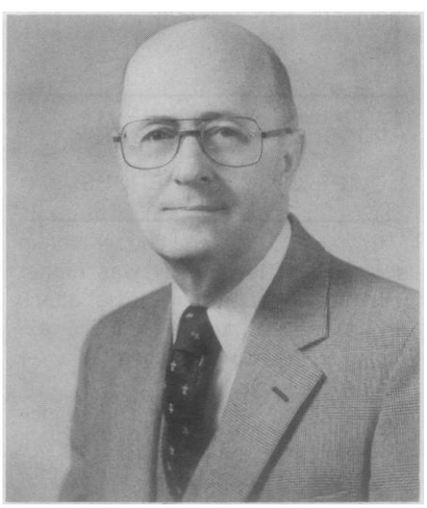
NIH's concern about mounting congressional pressure to satisfy the demands of special interest groups with earmarked funds and new institutes lies behind the IOM study. "Bills proposing changes or additions to the NIH have been introduced at every recent session of Congress," an IOM background statement notes. "While some regard such organizational changes as a way to emphasize research in neglected areas, others see them as administratively costly and scientifically ineffective." The NIH administration is squarely in the latter camp. The congressionally mandated, $792,000 IOM study, was initiated by the NIH (Science, 16 September, p. 1163).

The likely establishment of a new arthritis institute, coupled with a score of provisions in a pending House bill introduced by Representative Henry A. Waxman (D–Calif.), constitute the immediate impetus for the study. The Waxman bill would greatly extend congressional control over the management of research (*Science*, 19 August, p. 726). Those who oppose further restructuring of NIH along "disease-of-the-month" lines hope that new legislative forays into NIH can be held in abeyance until the IOM study is completed at the end of 1984.

Virtually no one in biomedical research really thinks the NIH budget, at roughly $4 billion a year, is adequate. But because it is not likely to increase substantially, the question becomes one of how it will be distributed and by whom—scientists or legislators. Many of those who appeared before the IOM's NIH committee, chaired by James D. Ebert, president of the Carnegie Institution of Washington, tended to favor decision-making by scientists along with structural changes in NIH that would guarantee a generous flow of money into areas of their own interest.

For example, Melvin H. Van Woert, speaking for the National Organization for Rare Disorders (NORD), testified that NORD members feel rejected because they lack the political clout necessary to command big money. Referring to the NIH policy giving "especially high priority for funding of basic research," Van Woert said, "In general, this seems a prudent policy" except in the case of rare disorders. He proposed a change favoring more research and drug development for orphan diseases.

Bobby R. Alford, representing the Association of Academic Departments of Otolaryngology, called for "change in a very substantial manner," when he advocated creation of a National Ear, Nose, and Throat Institute.



James D. Ebert

Assessing the organization of NIH

David Satcher, president of the Association of Minority Health Professions Schools, testified that NIH has a duty to provide greater support for research at the schools he represents.

William F. Bridgers, president of the Association of Schools of Public Health, said the country needs to establish Centers for Research Demonstration on Health Promotion and Disease Prevention—25 are mandated in the Waxman bill—and also recommended "a new institute at NIH, literally a national institute of health, of public health, of health preservation, or some similar title."

The arguments in favor of creating specific disease-oriented centers or institutes have not changed much over the years since the NIH proliferated into the 11 institutes of today. Frederic C. McDuffie, representing the Arthritis Foundation which has lobbied so successfully for a new National Institute of Arthritis and Musculoskeletal Diseases, summed it up when he said new institutes should be created when there is a problem that afflicts large numbers of citizens (36 million Americans have arthritis) which seems amenable to treatment because of progress in basic research (in this case, immunology). Given need and scientific opportunity, the added ingredient is effective lobbying. "We have to adapt to the political system and be opportunistic," said McDuffie of the arthritis lobby's efforts to win more money and attention for arthritis research. "It is," he said, "the American tradition" as far as doing business with Congress is concerned. And, although he argued for the creation of a "trans-NIH office" within the office of the NIH director to be sure that developments in one area are transferred as applicable to research in another, McDuffie acknowledged that had there been such a clearing house within NIH, the Arthritis Foundation would still have lobbied Congress directly for a greater share of the NIH dollar. When worthy causes are competing for limited dollars, politics count.

Counterarguments in what turned out to be a rather predictable public debate were mounted by representatives of the more interdisciplinary professional groups and those whose members are basic researchers. Speaking for the American Society for Microbiology, Riley D. Housewright called a new arthritis institute an "unwise and unnecessary expense" administratively, and urged that the broad legislative mandate under which NIH was created be retained unchanged. The microbiologists, joining the Association of American Medical Colleges (AAMC) opposed Waxman's efforts to redesign the NIH administration to give Congress more say in day-to-day decision-making. Citing the many strengths of the NIH as it is, he adopted an "If it ain't broke, don't fix it" posture. AAMC representative Robert M. Berne, noting what is seen as increasing congressional involvement in NIH, said that "With the advent of the cancer legislation [in 1971] and of the new heart legislation in 1972, a need for periodic renewals of expiring legislation was created. Meeting the need has become the

occasion for an increasing number of mandated directives and limitations on the heretofore flexible managerial prerogatives of [the NIH]. Further legislative interference, he said, would likely "hobble a . . . remarkably successful government organization."

The American Medical Association submitted a position paper along similar lines.

But Robert Rosenzweig, new president of the Association of American Universities (AAU) took a somewhat different tack. Looking back to the 1950's when former NIH director James A. Shannon led the institutes to prominence with strong support from congressmen John Fogarty and Lister Hill, Rosenzweig sees NIH as an institution that has never been free of Congress. Rather, it is the nature of congressional involvement that is at issue. Rosenzweig called for a new "set of arrangements" with members of Congress, including Waxman, to assure funding for basic research as well as support for prevention, new therapy, and the like.

Rosenzweig stated there is "no reason to believe that the present organization of NIH and the present arrangements for congressional involvement in biomedical research policy are the best ones possible." To a large extent, he noted, the present NIH organization "just grew." Said Rosenzweig, "The creation of disease-based institutes may have some scientific basis, but its political logic is even more compelling; one can find reasons why two institutes [cancer and heart] are authorized in law with time and dollar limits and the others are not, but they are not reasons of science policy; a case can be made for the value of each of the existing disease-based institutes, but the logic of those cases leaves one defenseless against equally compelling cases on behalf of other serious diseases."

Although the IOM committee has stated its intention of dealing with the organizational structure of NIH independent of political considerations, Rosenzweig pointed out that when $4 billion is at stake, there are no questions untouched by politics. Implicitly arguing against the position that decision-making should be left primarily to scientists, he testified that ". . . we cannot succeed [in preserving the strengths of NIH] by telling potential allies in the Congress that they cannot be trusted with science policy because they do not understand its sensitivity to political manipulation."

The IOM study is expected to be the most comprehensive review of the NIH since the analysis by the President's Biomedical Research Panel in 1976, which covered the bases but had little identifiable effect on policy. Now the IOM has its shot. One IOM study panel, headed by Maclyn McCarty, professor emeritus at Rockefeller University, will review NIH's organizational history, including an analysis of the establishment of new institutes in the past and the current status of those that split off—such as mental health.

A panel on the current organization of NIH, chaired by Samuel O. Thier, chairman of medicine at Yale, will try to figure out how decisions about research are actually made, including the role of NIH staff and its advisory committees. Among other matters, it will also look at the structure of agencies, such as the National Center for Health Statistics and the National Institute for Occupational Safety and Health, that have been proposed as additions to NIH. "We'll have to define the proper mission of the NIH," says Thier.

A third panel, led by Steven C. Beering, president of Purdue, will study alternatives to NIH's present structure. Among the issues the Beering panel will examine are the relationship between the extramural and intramural programs at NIH, the relative importance of "scientific opportunity" and "burden of ill-

Pressure for Trauma Institute

Trauma surgeons are the latest group to campaign for a new institute within the National Institutes of Health (NIH). The idea of a trauma institute has been around for years. It now has the support of Representative William Lehman (D–Fla.), chairman of the House appropriations subcommittee on transportation. Transportation Secretary Elizabeth Dole has evinced interest, and the surgeons hope eventually to have their arguments bolstered by a National Academy of Sciences (NAS) report recently commissioned by the Department of Transportation (DOT).

The idea for a trauma institute was first endorsed by the NAS in a 1966 report entitled "Accidental Death and Disability: the neglected disease of modern society." There are now 110,000 trauma deaths a year—half on the road and half of the total involving alcohol. During the 1970's, dramatic progress in treating trauma was made with the upgrading of emergency medical service (EMS) networks around the country, made possible by passage of 1973 legislation and enhanced by knowledge gained from the Vietnam war.

Neurosurgeon Ayub Ommaya of Georgetown University, who has been consulting with DOT, says that now that the treatment of trauma has become a recognized specialty, the next step is to recognize that research on the whole phenomenon deserves a niche of its own. He says that trauma, unlike other diseases, has lacked a public constituency; but now traffic safety and rehabilitation experts, as well as the insurance industry, favor creation of an institute.

The federal government now spends about $150 million on trauma-related research. About two-thirds of it is sponsored by various NIH institutes, primarily the National Institute of General Medical Sciences.

According to NIH Director James B. Wyngaarden, the current setup is appropriate. The heart institute studies heart trauma, the neurological disease institute investigates trauma of the nervous system, and so forth; "you don't have trauma in vacuo," he says. Besides, "supposition that a new institute means more funding is not borne out by history."

Trauma surgeons argue that a new institute would be desirable even if it meant no more funds because it would supply visibility, direction, and coordination to the whole field. The NIH attitude, they believe, betrays a lack of understanding of the nature of the field. They see trauma as a "disease" that is preventable and curable. It has its own etiologies in which youth and alcohol figure prominently.

What is sorely needed in addition to more coordinated basic research, say the surgeons, is more research on the epidemiology and prevention of trauma, as well as auxiliary fields such as biomechanics. David Boyd of the University of Maryland Hospital and former director of the government's EMS programs, adds that a new institute could promote needed evaluation of EMS programs and organizational development. "Trauma care is organization," he says.—**CONSTANCE HOLDEN**

ness" as criteria for setting research priorities, and the way research is managed at other institutions including the National Science Foundation, industrial laboratories, and foreign national research institutes.

Unknown at present is the extent to which congressional action may overtake the IOM study and whatever policy recommendations it makes. Passage of Waxman's bill, which once looked like a sure thing, is now more iffy, largely because of growing support for an opposing bill from Representatives James T. Broyhill (R–N.C.) and Edward R. Madigan (R–Ill.). The Broyhill-Madigan bill has the backing of the Reagan Administration, the AAMC, and the AMA, among others. There is speculation at present that no major new NIH legislation will pass this year, with Congress settling for a relatively simple bill to maintain the status quo—something which has happened several times in recent years. But the matter is by no means foreclosed.

—BARBARA J. CULLITON

Mixed Marks for Berkeley Materials Center

A DOE panel's recommendations could threaten construction of the synchrotron light source that was to be NCAM's centerpiece

A Department of Energy (DOE) panel set up last March to review the proposed National Center for Advanced Materials (NCAM) at the Lawrence Berkeley Laboratory has turned in its report card. NCAM's marks are decidely mixed.

The establishment of a materials center at Berkeley, said the panel, "offers exciting opportunities for significant advances in this technologically important field. Realization of the opportunities will, however, require substantial alterations of the proposal. . . ." The most significant recommendation is that an $84 million advanced synchrotron light source that was to be NCAM's centerpiece be divorced from the proposal and considered separately. DOE has established a new committee to do this.

If there ever was a fast-track project, NCAM was it. With little or no review by the research communities affected, NCAM appeared in the Reagan Administration's fiscal year (FY) 1984 budget under the sponsorship of presidential science adviser George A. Keyworth, II (*Science*, 18 February, p. 827). Construction costs were to total $139 million over 6 years. An additional $127 million was slated for R & D related to synchrotron radiation production and to research projects that could start up during the construction period (operations and equipment).

But Congress switched the NCAM express to a siding during its spring and summer budgetary deliberations. The House Science and Technology Committee found itself deluged by letters from academic and industrial materials researchers. The angriest among the 80 or so letters were from the academics. They complained about the lack of advanced consultation, questioned whether a centralized research facility was more productive than individual principal investigators, and criticized the relevance of the synchrotron light source.

In response to the criticism and to salvage as much of NCAM as possible for FY 1984, DOE's director of energy research Alvin Trivelpiece appointed the panel whose findings are now in.* In his charge to panel chairman Albert Narath of Sandia National Laboratory, Trivelpiece asked for a report by the end of August. An informal progress report was forthcoming on 10 June.

Although Narath's interim report strongly recommended that $13.4 million of the requested $25.9 million in construction funds be approved, Congress did not follow suit. On 29 June, Congress sent to President Reagan a budget bill that allowed for only $3 million for NCAM construction (*Science*, 15 July, p. 246). The bill did include the full $9.1 million asked for operations and equipment, however.

As originally proposed, NCAM consisted of three laboratories (Surface Science and Catalysis, Advanced Materials Synthesis, and Advanced Device Concepts) and the advanced synchrotron light source. Also included in the NCAM initiative was a $13.8 million upgrade of the Stanford Synchrotron Radiation Laboratory.

Narath's panel was not asked to review whether NCAM was a good idea but to make recommendations for strengthening it. In its deliberations, the panel judged the proposal according to whether it:

- was relevant to advanced materials;
- had a realistic potential for significant impact on important U.S. industries;
- had program goals whose attainment required centralized research;
- made a contribution to a new or strengthened mission for the laboratory; and
- required resources that were not excessive in relation to the value of projected accomplishments.

The panel's overall judgment was that NCAM fell short: ". . . the NCAM proposal, considered in detail, does not adequately satisfy the criteria developed above."

The most serious deficiency, according to the report, was the combination of materials research and a synchrotron light source in a single package. The light source "requires a disproportionately large share of NCAM resources. It is therefore an inappropriate centerpiece which causes an unacceptable program imbalance." The recommendation was to split NCAM into two components, a materials research center, and a synchrotron radiation facility, each of which should be judged on its own merits.

With regard to the materials research center (Berkeley Center for Advanced Materials was a name suggested as appropriate), the panel found that there was some shoring up to do. The burden of the message is that BCAM must clearly state how it is going to gear itself to industrial style, technology oriented research rather than to university style basic research. With a substantial fraction of its staff holding faculty appointments at the adjacent University of California, the Berkeley Laboratory now tilts strongly in the latter direction.

Reflecting this concern is the panel's criticism that the proposed NCAM pro-

*Members of the panel were: D. R. Davies, National Institutes of Health; J. M. Deutch, Massachusetts Institute of Technology; J. L. Doyle, Hewlett-Packard; F. R. Gamble, Jr., Exxon; K. L. Kliewer, Argonne National Laboratory; J. A. Krumhansl, Cornell University; D. W. Lynch, Iowa State University; A. Narath, Sandia National Laboratory; W. D. Nix, Stanford University; H. W. Paxton, U.S. Steel; D. A. Pistenmaa, National Institutes of Health; P. E. Seiden, IBM; and H. G. Stever, Universities Research Association.