

A New Arthritis Institute Nears Approval

Despite protests by NIH director Wyngaarden, Congress likes the idea, especially in an election year

Over the opposition of the director of the National Institutes of Health (NIH), Congress is on the verge of approving the creation of another institute within the agency, this time for the study of arthritis. When the proposal to establish an arthritis institute was introduced in Congress last spring, its chances of passage seemed remote. But because of masterful lobbying by a powerful combination of supporters, the legislation has picked up strong momentum in the House and Senate. Former NIH director Donald Fredrickson says glumly, "I take a dim view that the proposal can be stopped."

makes little administrative, fiscal, or scientific sense. NIH director James B. Wyngaarden claims that the start-up overhead costs alone for an arthritis institute would total at least \$4 million to \$5 million. That money would be allocated at the expense of biomedical research, given the budget constraints at NIH during recent years. He says that research money for arthritis and musculoskeletal diseases has increased from \$27 million in 1976 to more than \$61 million in 1981.

Wyngaarden argues that the formation of a separate institute by disease category runs counter to a trend in biomedical

the proposal has a good chance of winning.

Although Wyngaarden and the Reagan Administration's position has the backing of the American Medical Association, the Association of American Medical Colleges, and the Federation of American Societies for Experimental Biology, the advocates of an arthritis institute have been much more persuasive on Capitol Hill for a variety of reasons. The most obvious is that the proposal is extremely difficult to oppose in an election year and because "on the surface it is a meritorious idea," Wyngaarden says. A lobbyist for the proposal puts it this way, "It's a motherhood and apple pie issue."

The legislation also has weighty support from key legislators. It has bipartisan sponsorship in the Senate from Barry Goldwater (R-Ariz.), who had a hip replacement last year, and Alan Cranston (D-Calif.). The two senators introduced the bill. On the House side, Claude Pepper (D-Fla.), a veteran legislator and chairman of the Select Committee on Aging, is championing the measure. Add to this the support of the Arthritis Foundation, the American Academy of Orthopedic Surgeons, the American Association for Retired Persons and Retired Teachers, and others such as Justin Dart, a member of the Reagan "kitchen Cabinet."

Another key figure in the extraordinary success of the proposal is philanthropist Mary Lasker. It was at Lasker's behest last year that her close friend Claude Pepper introduced a bill to create an arthritis institute.

The bill lay dormant until this spring when the proposal was taken up as an amendment to the NIH reauthorization bill (H.R. 6457). It then survived an intricate minuet of political maneuvering over a 4-week period in the Energy and Commerce Committee. At one point, it seemed destined to fail when advocates for diabetes research clouded the picture by pressing for their own institute.

Lasker and arthritis research lobbyists, however, were out in full force. The night before the committee voted on the amendment, Lasker telephoned more



James B. Wyngaarden

A new institute makes little administrative, fiscal, or scientific sense, he says.

Marjorie Sun

Arthritis research at NIH is currently conducted under the auspices of the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases. Proponents of a new institute argue that arthritis and musculoskeletal research should be wrested from this hodgepodge and granted greater visibility by having its own identity. They say that its creation is justified by the fact that 37 million Americans suffer from arthritis and musculoskeletal diseases. A separate institute would make it easier to attract financial support from Congress and the private sector. They note that the National Commission of Arthritis and Related Musculoskeletal Diseases recommended in 1976 that a new institute be created.

NIH contends, however, that the addition of another institute to the existing 11

research to study basic principles underlying the origins of disease. NIH officials also point out that proponents of the arthritis institute do not quote accurately the 1976 national commission report. The panel recommended that a new institute be established "when feasible," citing the tight federal budget at the time. Furthermore, according to Wyngaarden, the formation of another institute invites the proliferation of others. "Where does it stop?" he asks.

Legislation in the House containing the arthritis institute proposal has passed through committee and is ready to be taken up on the floor, probably after recess. The Senate Labor and Human Resources Committee held a hearing recently on similar legislation but has not yet voted on the measure. But according to Senate staff aides and NIH officials,

than a dozen members to solicit their vote. The next day, 13 May, the committee approved the amendment by a margin of 11 to 2. All looked well until Representative Thomas Luken (D-Ohio) proposed an amendment to create a new diabetes institute.

At this point, Representative Henry Waxman (D-Calif.), chairman of the committee's health and environment subcommittee sought to block the formation of both institutes. According to a subcommittee aide, Waxman is basically satisfied with the current NIH framework, but reluctantly went along with the arthritis amendment when its passage became inevitable. Faced with the possibility of two new institutes, the subcommittee chairman did not want to be in a position of having to choose one proposal over the other.

To Waxman's dismay, the committee voted handily in favor of a diabetes institute. But Waxman quickly called for quorum. There was none. By his simple maneuver, the diabetes proposal was down the drain.

But Waxman was still left looking as though he favored the arthritis amendment over the diabetes measure. It so happened that his objection to the creation of more institutes was shared by the subcommittee's ranking minority member, Edward Madigan (R-Ill.). When it came time to vote on the issue, Madigan opposed the diabetes amendment, but in a most unusual way. He voted for it. According to an aide, he wanted to prove how all too easily new institutes can be concocted at the whim of Congress.

That night a Madigan aide came up with a politically acceptable solution to block the creation of an arthritis institute. His boss and Waxman immediately seized upon it. Wyngaarden said he would do anything to support it. Suddenly the arthritis lobbyists saw the promising future of their own institute fading.

The Madigan proposal was this: an amendment would impose in effect a 2-year moratorium on the creation of any new institutes at NIH. During that period, the Institute of Medicine would conduct an 18-month study to review the present structure of NIH and then make recommendations. The moratorium extends for 6 months after the study is released, to permit congressional review of the report.

With the prospect of an arthritis institute slipping away and the status quo maintained, the arthritis and diabetes groups struck a compromise. The arthritis lobbyists successfully argued that if arthritis research were extricated from

Mary Lasker's Latest Pet Project

To many, philanthropist Mary Lasker is the grande dame of the National Institutes of Health (NIH), while others may say she is the enfant terrible. In any event, she has taken on as her latest pet project at NIH the creation of a new arthritis institute. As in the past, Lasker has been busy pushing her cause and she is outspoken in her support of the arthritis institute proposal. "She has been all over the Hill," said a Senate aide.

She finds the arguments against the institute quite shallow. She dismisses the contention that the federal budget is too tight to warrant a new institute. "The cost of creating a new institute is peanuts," she said in a telephone interview. "It is ridiculous not to have a separate institute for arthritis. Everyone assumes there is a finite amount of money. This is a rich nation." She cites the fact that the budget of the National Heart, Lung and Blood Institute has ballooned from \$10 million in 1972 to \$559 million in 1982. "If that's static, I'll eat my shoe."



Mary Lasker

"It is ridiculous not to have a separate institute for arthritis."

It is much easier to get money for research when a project is identified by disease, she argues. She is baffled that NIH director James B. Wyngaarden opposes the formation of an arthritis institute. Lasker, a member of the NIH director's advisory board, says, "Is it going to be more work for the directors?" Wyngaarden had no specific comment. "We've tried to make as dispassionate an argument against the proposal as we can," he said.

She challenges Wyngaarden's contention that biomedical research has reached a stage where common biological principles are more important in the study of disease than the division of the institutes along disease categories. Lasker charged, "How else would NIH have gotten \$51 billion of the total accumulative NIH budget over the years if it hadn't been divided by disease? If NIH officials know how to do it, let them do it." An NIH budget official said, however, that the total budget adds up to \$45 billion.

Asked about the proposal that the Institute of Medicine review the NIH structure, she said, "I don't mind it. It depends on who's on the committee." But the arthritis institute should be established now, she said.

There is little reason not to establish more institutes, she said. "I think there is no problem with proliferation of institutes as long as there is proliferation of disease."

Although the arthritis proposal already has tremendous momentum, there is a slim chance that it could be blocked if legislation goes to conference. Lasker has been known to pull out all the stops to convey her opinion. In the annals of NIH history, she is most known for her lobbying effort to get the Nixon White House to declare a "war on cancer," with vastly increased funds and administrative independence for the National Cancer Institute. A column by Ann Landers, in favor of the Lasker measure, created a ground swell of grass roots support that was considered critical to passage of the National Cancer Act of 1971. Who knows what is up Lasker's sleeve if the arthritis institute proposal should falter?

—M.S.

the present institute, diabetes research would virtually be left with its own institute anyway. The diabetes organizations found the reasoning acceptable and stopped pressing for their own institute. In fact, they have now thrown their support behind the arthritis institute legislation. A diabetes lobbyist says, "Even though we don't get our own institute, we come pretty darn close."

There were several factors underlying the acquiescence of the diabetes groups. During the past few years, the budget for diabetes research at NIH has expanded by about 400 percent to \$131 million in 1981. Diabetes research also has had consistently strong support by Secretary of Health and Human Services Richard Schweiker, who was very active on behalf of diabetes research when he was a U.S. senator. It received a token salute from the Administration during the past year when the institute's name was changed to include "diabetes" and when the institute was elevated to bureau status within the department. Moreover, for the first time in the history of the 31-year-old institute, a diabetes researcher—Lester Salans—was appointed in June to head the institute. With all this activity, the two major national diabetes organizations, which had earlier been divided on whether to press for a separate institute, decided to jettison their efforts for a new institute.

With a compromise in hand, the arthritis and diabetes organizations sought to reverse the damage wrought by the Madigan amendment. Their next move was to persuade the committee to exempt the creation of an arthritis institute from the moratorium. They won. So the way things stand now, the House NIH reauthorization bill includes a provision calling for a ban on new institutes for 2 years while the Institute of Medicine conducts a review. With the exemption, however, Congress may establish an arthritis institute.

On the Senate side, the arthritis institute proposal is embodied in a bill by itself (S. 1939) and is not part of an NIH reauthorization measure. The Labor and Human Resources Committee held a hearing on the bill on 20 July. But two key senators on the committee, Orrin Hatch (R-Utah) and Edward Kennedy (D-Mass.), are not committed as yet. Again, Mary Lasker made a point to call committee members. She went so far as to visit Kennedy herself. But a Kennedy aide said that the senator wants to reexamine the overhead cost estimates projected by NIH which are disputed by arthritis institute supporters.

Hatch, who faces a tough reelection

race, seemed to lean toward favoring the proposal at the hearing, albeit hesitantly. A staff aide says that Utah constituents have mounted tremendous forces to back the bill. One thing is fairly sure, "Hatch will not lead the fight against the bill on the floor," the aide says. "It is very difficult to fight this." In the aide's opinion, the reasons for the new institute are not scientific. He also adds that with today's tight budget at NIH, the arthritis groups "can't expect to get more money with neon lights." The possibility of opening the floodgates to more institutes is worrisome to him.

There is speculation that the committee will not vote on the bill which already has 38 cosponsors. Some congressional aides predict that Goldwater will introduce the proposal as an amendment to the Senate's version of the NIH reauthorization bill. Once incorporated in this manner, the measure would have an easier time gaining approval.

At this point, there appear to be few options to halt the proposal. A Madigan aide says that the Illinois legislator is hoping that the arthritis exemption is kept out of the Senate bill, which would then provide a point of potential compromise when the reauthorization bills go to conference. A Waxman aide indicated that the subcommittee chairman is still not enthusiastic about the arthritis institute. The fact that the proposal was not in the original NIH bill suggests that the new institute "is not his favorite idea." A Hatch aide says that the Institute of Medicine study is "the only hope against this arthritis proposal." The other possibility, which is less likely, is that Congress may not get around to voting on the NIH bills during this session because it still has an extremely full calendar. This was the case 2 years ago. After elections, the arthritis proposal may have a more difficult time winning acceptance.

But right now, the momentum of the issue may be overwhelming. Wyngaarden says unhappily, "If the will of the people as expressed by Congress is to create an arthritis institute, then we'll make it the very best institute we can." The proposal for a review of NIH by the Institute of Medicine provides a reasonable alternative because it addresses a legitimate question that has been talked about for years but never tackled. Now that NIH has grown to a \$3.6-billion budget and has a sizable bureaucracy, the time seems ripe to review the way the institutes are divided up. Unfortunately, the Madigan amendment, though scientifically more rational, is not a magnet for votes by either politicians or their constituents.—MARJORIE SUN

Hawaiian Milk Problems Stir Little Action

Federal regulators recently decided not to intervene in a continuing dispute over the contamination of Hawaiian milk by heptachlor, a carcinogenic pesticide. The contamination was discovered in January by state officials, who delayed an announcement for several months and—in the eyes of some critics—worried more about the condition of the dairy industry than the health of the state's population. The state's behavior brought requests from Hawaiian citizens and scientists for federal intervention to limit public exposure and to monitor local dairies (*Science*, 9 July, p. 137).

Officials at the Environmental Protection Agency (EPA) expressed little sympathy for these concerns. "We believe that the Hawaii Department of Agriculture is doing an excellent job in investigating the Hawaii heptachlor milk contamination problem, and that they and the state Department of Health have the situation well under control," declared Edwin Johnson, EPA's director of pesticide programs, in a June letter recently received by *Science*.

Johnson also informed the Food and Drug Administration (FDA) that there was no reason to lower the federal limit on heptachlor in milk, thereby diminishing the continued exposure of Hawaii's citizenry. "A review of the pertinent data in our files indicates that no imminent hazard to human health will be posed by exposure at or near the current federal limit," Johnson said. "Chronic effects are not likely to result and even short-term or subacute effects are not anticipated." The FDA, citing this recommendation, told the state's health officials that the current limit (0.3 part per million) seems perfectly adequate, even though it is twice the limit already established by the World Health Organization.

Asked how he came to this conclusion, Johnson said that it was largely "intuitive" and "based on a quick cut." He noted that virtually everyone—in Hawaii and elsewhere—already has residues of heptachlor in their bodies. Consequently, he said, additional short-term exposure poses only a minor, incremental risk. In 1976, when most uses of heptachlor were banned,