

Research head for HEW

Though the Department of Health, Education and Welfare is the fountainhead of the United States' biomedical research effort, there has been little clear-cut interest in the world of research among the upper echelons of the department. The astounding growth of Federal support of basic biological research in the last two decades was fostered and charted largely by the National Institutes of Health, without much intervention from officials of the parent department. In 20 years the NIH, the arm of HEW that dispenses research funds, managed to increase its treasury from the neighborhood of \$1 million a year to \$1 billion a year. During that time the agency made its own policy regarding research support.

But times have changed. The money spiral has come to a halt. And a new Administration has come to Washington, bringing with it the management approaches applied to their affairs by major corporations.

The business approach is strongly goal-oriented. First, a problem is defined and a specific solution proposed. Then a timetable for moving toward that solution is drawn up. And finally, responsibility for carrying out policy is clearly assigned to an individual who can take credit if it succeeds and blame if it fails. "It is," says one HEW official, "a new and very hard-nosed approach."

With this assignment of line responsibility in mind, a new position has been created at HEW—deputy assistant secretary for research. Within 60 days officials plan to name the man who will fill the post directly under Dr. Roger O. Egeberg, Assistant Secretary for Health and Scientific Affairs. The new post was the brainchild of four men: Deputy Under Secretary Frederic Malek, Surgeon General Jesse Steinfeld, Dr. Egeberg and his top aide, Dr. James Cavanaugh.

They see the research deputy, who will inevitably draw fire from all sides, as a liaison between Government and the scientific community—a man whose chief role will be to construct and implement research policy within HEW and to look at areas in which HEW-supported work overlaps with that in other Federal agencies.

Says Dr. Cavanaugh, "We're looking for an individual with considerable experience in basic research, someone who understands science and the scientific community and who has its respect. All things being equal, if he were a Republican it would be great." But, he declares, "party affiliation is not the primary criterion involved by any means." The Administration has recently been under attack for allegedly introducing

partisan politics into scientific appointments (SN: 6/13, p. 572).

Sharing the Administration's science policy views, however, will be a criterion. Already, many of these views have been laid down. First, says Dr. Cavanaugh, is the Administration's dual commitment to continuing support of basic science and Government economies. "We want to stabilize the basic research budget for the next two years at the present level, which means an annual six percent increase if we're going to keep up with inflation," he says. Large numbers of scientists, pleading for continued expansion of Federal support of research, will not share the view that stabilization equals a real commitment to fundamental science; convincing them will be part of the new secretary's job.

What extra money does become available for science in the near future

DIABETES DRUGS

Battle over a study

During the last eight years, teams of scientists at 12 university medical centers conducted studies of 800 adults with asymptomatic diabetes. They sought to determine the causes of complications associated with the disease, primarily cardiovascular disorders, and to evaluate various standard forms of therapy (SN: 5/30, p. 526).

The results of the study indicated the blood sugar levels in individuals with asymptomatic, mild diabetes are not directly related to complications and mortality. But it was found that patients taking oral antidiabetes agents—the sulfonylureas sold as Orinase, Tolinase, Diabinese and Dymelor, given to lower blood sugar levels—were two and a half times as likely to die of cardiovascular complications as persons following other therapy regimens. And they received no benefits to outweigh that risk.

A direct cause-and-effect relationship between the agents and cardiovascular disease is only speculative at present. But the study's managers postulated that it could be the effect of a dangerous hypersensitivity to the drugs, which patients can develop in the course of long-term use.

Though information regarding this study by what is called the University Group Diabetes Program has been public for several weeks, the first formal presentation of the study came this week at the annual meeting of the American Diabetes Association in St. Louis. A storm of controversy followed.

Some physicians at the meeting argued that the university study contained insufficient data to back a direct link between oral antidiabetes drugs and cardiovascular complications.

Faced with conflicting views, out-

going ADA president Dr. Robert Hardin named an ad hoc committee, approved by the association's executive council, to draft an official comment. It issued a status quo report: "At this point the evidence presented does not appear to warrant abandoning the presently accepted methods of treatment of diabetes: diet, diet with oral agents, or diet with insulin as indicated."

Dr. Max Miller of Case Western Reserve University in Cleveland, coordinator of the university group, contends that the data are self-evident. In essence, he says, the study showed that the oral agents do not contribute to the patient's well-being and may have adverse effects during the course of prolonged use. Therefore, Dr. Miller says, he and his colleagues are challenging the conventional wisdom regarding treatment of asymptomatic diabetes.

In view of the university group's data, disputed or not, the Food and Drug Administration has proposed changes in the labeling of oral antidiabetes drugs. Dr. Edwin Ortiz of the agency's Bureau of Drugs anticipates new restrictions on what manufacturers can list as indications: that the agents be prescribed only for persons with frank clinical symptoms of diabetes and who cannot, or will not, take insulin. He also foresees changes in the warning statement. Those changes will reflect the new findings at least to the point of indicating the possible link between the drugs and the newly identified complications. The FDA is considering comments submitted by manufacturers and has solicited a copy of the ADA statement for evaluation. Final labeling revisions should be complete within a few weeks. □