

of our responsibility as Members of Congress and the keepers of the public purse to be watchful that such excesses do not occur.

However, we know from experience that the taxpayers' dollars are not always wisely spent and I regret to inform my colleagues that I have information indicating that this has happened again.

The case in point is a \$75 million research project, initiated 10 years ago by the National Institute of Neurological Disease and Blindness (NINDB). NINDB is part of the National Institutes of Health, which comes under the Department of Health, Education, and Welfare.

The study covers 60,000 pregnant women and their offspring and was the subject of an evaluation by a blue-ribbon committee which filed a report critical of the project.

Among other things this report reflected two glaring deficiencies. First, millions of dollars were authorized for a project which now appears to have been poorly defined and improperly constructed. Second, there has been an absence of congressional oversight in ascertaining whether taxpayers' funds are being effectively utilized in connection with the study.

Steps apparently are being taken by NIH authorities to correct the problems identified in the evaluation report. However, Mr. Speaker, such action probably has come too late. Conclusions, based in part on 10 years of questionable statistics, always will remain suspect.

My attention was drawn to this study by the Dayton Daily News, an outstanding Ohio newspaper, and its astute medical reporter, Miss Jayne Ellison. I would like to commend Miss Ellison and the Dayton Daily News for their diligence and public service in this matter.

The newspaper published a comprehensive story on the study and the evaluation report in its editions on September 22, 1967.

For the information of my colleagues, I hereby insert the full text of the account in the RECORD:

**A NATIONAL INSTITUTES OF HEALTH STUDY MAY HAVE WASTED \$75 MILLION**

(By Jayne Ellison, Daily News staff writer)

Congressman Charles W. Whalen Jr. (R-Ohio) today charged that a \$75 million federal health research project was "poorly defined" when begun 10 years ago and that stop-gap salvage attempts have "probably come too late."

He scored a study involving 60,000 pregnant women and their offspring, which has drawn the fire of a blue-ribbon evaluating committee.

The committee's report, filed in May 1966, has been suppressed until now.

It was prepared as an evaluation of a project begun in 1957 in 16 American hospitals, under the title of "collaborative perinatal research program" of the National Institute of Neurological Disease and Blindness (NINDB).

**CRITICIZED FROM START**

The project has been criticized by scientific investigators almost since it began.

The Daily News sifted through reports and consulted top medical authorities in uncovering the ad hoc Gordon committee findings.

Dr. Harry Gordon, dean of the Albert Einstein college of medicine, New York, chaired the evaluating committee. Also serving was Nobel laureate Dr. Frederick G.

**A NATIONAL INSTITUTES OF HEALTH STUDY MAY HAVE WASTED \$75 MILLION**

(Mr. WHALEN (at the request of Mrs. HECKLER of Massachusetts) was granted permission to extend his remarks at this point in the Record and to include extraneous matter.)

Mr. WHALEN. Mr. Speaker, we are all concerned about how effectively the Federal Government uses the hard-earned tax money of its citizens.

We would like to think that none of it is wasted or used improperly. It is part

Robbins, dean of Western Reserve university school of medicine.

Project weaknesses found by the evaluating committee were:

Children's hospital, San Francisco, and Yale university, pulled out of the project because "these institutions could not fulfill their commitment to the program."

Too few women were enrolled in the study in the first weeks of pregnancy.

Design for genetic studies was found unsuitable and "does not justify the program's existence."

Some principal investigators drifted away from the research and left work to project directors.

Too many institutions, too many study cases.

Data collected were uneven and differed, even within the same institutions.

There was no strong direction for the project.

Too much information was collected in the collaborating institutions which detracted from items of primary interest.

Some institutions were a year behind in editing material required by the Perinatal Research board of NINDB.

Institutions did not have competent staffs, despite funding to train them, to pursue some aspects of the project.

No technical solution is possible to solve the problem of collected data of questionable quality.

Originally, the giant project began to study conditions or events from conception to pregnancy which affect the baby at birth. At this time, the study encompasses cerebral palsy, epilepsy, mental retardation, defects of speech, hearing and vision, organic behavioral diseases, and reading and learning deficiencies as they relate to the period between conception and the early months of life.

Plans are also under way to follow children through age seven or beyond.

#### ENORMOUS UNDERTAKING

Enormity of the undertaking reflects in the four million cards, with about 30 million "bits of information" yet to be evaluated.

Committee chairman Dr. Gordon refused to comment on the report when contacted by The Daily News.

The NINDB rose to its own defense, after the committee report was delivered to Dr. James A. Shannon, director of the National Institutes of Health.

Dr. Richard L. Masland, NINDB director, admitted "there are differences in the quality and completeness (of data) between institutions and within single institutions at different times."

"We have greater faith in the quality of the data—or in the extent of usable data—than is implied by the committee's report," he wrote.

The Gordon ad hoc committee urged that a strong research scientist head the project. Dr. Masland replied that this wasn't feasible on a temporary basis and proposed a small working committee to review data analyses already completed and to direct evaluation of data base as recommended.

Dr. Stuart Sessions, deputy director of the National Institutes of Health, was told The Daily News had a copy of the Gordon committee report and Dr. Masland's response.

"Being aware of the criticism, Dr. Shannon deliberately undertook to have an analysis of the program to identify the problem areas and see what recommendations the group (Gordon ad hoc evaluation committee) could make," Dr. Sessions said.

"You will notice he selected committee members who have no association with the project."

#### CONTROLS TIGHTENED

He agreed that Dr. Masland's response was defensive.

"Information that we now have appears clearly evident that all parties are now more

comfortable with the soundness of the data base," Dr. Sessions said. "There has been a general conclusion that it is pretty sound and will go forward without jeopardy."

"Some aspects will be run, as they say in the Navy, as a lighter ship."

Dr. Sessions denied that the beleaguered collaborative project got out of hand. He said instead that it became a question of how much could be added to the original design without damaging the original intention.

Call to Dr. Masland's office were directed to the NINDB public information office.

A spokesman said, "It may take a year to evaluate the material on the collaborative study."

"The magnitude of this hasn't been fully appreciated yet," he said. "It is fantastic. They tried to enroll enough women to get significant numbers and it is now the largest study of its kind in the world."

"One of the real weaknesses was in the collaboration between institutions. It made it difficult to keep a tight rein. Human nature as it is, some hospitals didn't have rigid controls."

"I felt some of the Gordon committee were biased. Everyone is interested in mothers and babies and they want information."

According to the spokesman, all collaborating institutions were changed from grants to contracts July 1, 1967, to tighten controls.

#### NO SUCCESS OR FIASCO

NINDB, a satellite of the National Institutes of Health, is part of the Department of Health, Education and Welfare.

Dr. George Silver, assistant acting secretary for health and scientific affairs, was asked if the Gordon committee report didn't make the collaborative study look like a fiasco.

"Well," he said, "the ad hoc committee report is over a year old. It was a fair report, but the committee was prejudiced against collaborative studies."

"It is not as critical as it appears to be. There are bugs."

"Can you say 'fiasco' before the data evaluation is made?"

"You can call it a fiasco or a big success when the report is in."

According to Dr. Silver, the research thus far is "positive." He concurred with Dr. Sessions that the evaluation "isn't really such severe criticism."

Is the project an albatross.

"We don't know that yet," he replied. (Copyright, 1967, The Daily News)

#### WHO DID EVALUATION, HOW WAS MONEY SPENT?

Who were members of the ad hoc committee who evaluated the \$75 million research project in 14 American hospitals?

Two of them were Dr. Harry Gordon, dean of the Albert Einstein college of medicine in New York and Dr. Frederick G. Robbins, dean of Western Reserve university school of medicine.

Dr. Gordon was chairman of the committee, whose members included:

Dr. William M. Allen, obstetrics and gynecology, Washington university school of medicine; Dr. Leslie B. Arey, anatomy, Northwestern university school of medicine; Dr. Alfred L. Baldwin, psychology, New York university.

Dr. Arthur L. Benton, neurology, State University of Iowa; Dr. Joe Robert Brown, neurology, Mayo clinic; Dr. Robert W. Deisher, director, child health division, University of Washington.

Dr. Wilfrid Dixon, University of California school of medicine, Los Angeles; Dr. F. Clark Fraser, genetics, McGill university; Dr. Brian MacMahon, epidemiology, Harvard university; Dr. Edith Potter, pathology, University of Chicago Lying-in hospital.

Dr. R. L. Schiefelbusch, director, University of Kansas bureau of child research, and

Dr. Harry M. Zimmerman, laboratory division, Montefiore hospital, Bronx.

The ad hoc committee was reinforced during the evaluation by a select group of 31 specialists from medical schools, hospitals and health departments. They were chosen for recognized abilities in areas covered by the collaborative study, such as epidemiology, genetics, neurology, speech and hearing pathology, child development, child health and obstetrics and gynecology.

How was the \$75 million spent?

According to the Gordon ad hoc committee report, costs for the Perinatal Research branch within NINDB, are \$2.7 million per year.

Then, awards were made to the collaborating institutions on an annual basis. Boston Lying-in hospital, for example, received over \$5 million during the 10 years, plus overhead expenses of either 15 or 20% annually in a number of years. University of Minnesota received over \$3 million, with similar amounts going to the other institutions in the study.

Participating institutions are:

Boston Lying-in hospital; Children's Medical center, Boston; Pennsylvania hospital, Philadelphia; Children's hospital, Philadelphia; Institute for Health Sciences, Providence, R.I.; University of Minnesota.

New York Medical college (Metropolitan hospital); Medical college of Virginia; University of Oregon Medical school; Johns Hopkins hospital; Charity hospital, New Orleans; Columbia university; Children's hospital, Buffalo, and University of Tennessee.