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DIABETES RESEARCH AND TRAINING AMENDMENTS

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AND NATIONAL DIABETES ADVISORY BOARD

EXTENSION ACT OF 1979

DOCUMENTS

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HEARING
BEFORE THE
SUBCOMMITTEE ON
HEALTH AND SCIENTIFIC RESEARCH
OF THE
COMMITTEE ON
LABOR AND HUMAN RESOURCES
UNITED STATES SENATE

NINETY-SIXTH CONGRESS

FIRST SESSION

ON

S. 451

TO AMEND THE PUBLIC HEALTH SERVICE ACT TO REVISE AND
EXTEND THE PROGRAMS OF THE NATIONAL INSTITUTE OF
ARTHRITIS, METABOLISM, AND DIGESTIVE DISEASES WITH
RESPECT TO DIABETES, TO REVISE AND EXTEND THE AU-
THORIZATIONS FOR THE NATIONAL DIABETES ADVISORY
BOARD, AND FOR OTHER PURPOSES

FEBRUARY 26, 1979

Printed for the use of the Committee on Labor and Human Resources



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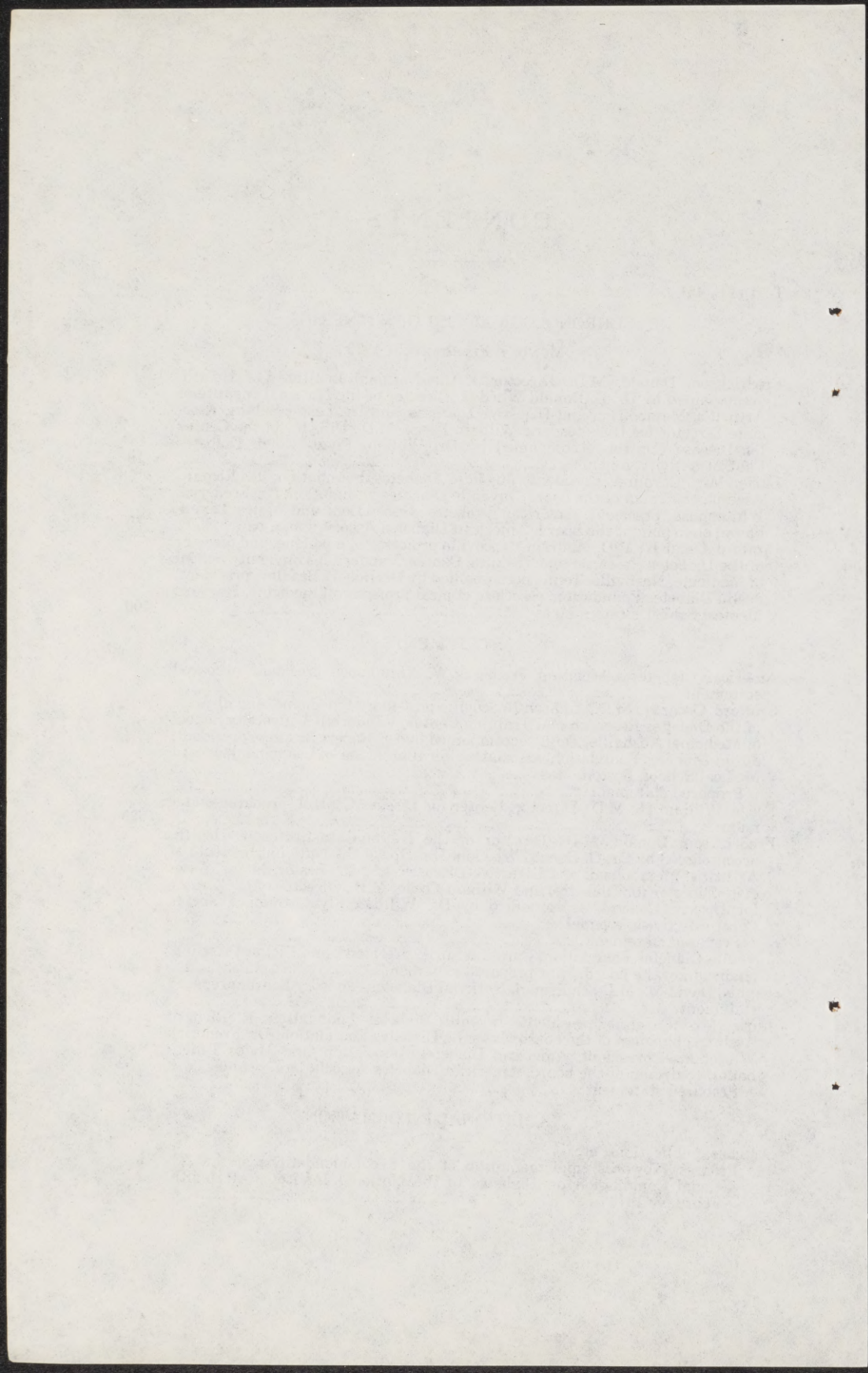
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DIABETES RESEARCH AND TRAINING AMENDMENTS AND NATIONAL DIABETES ADVISORY BOARD EXTENSION ACT OF 1979

MONDAY, FEBRUARY 26, 1979

U.S. SENATE,
SUBCOMMITTEE ON HEALTH AND SCIENTIFIC RESEARCH,
OF THE COMMITTEE ON LABOR AND HUMAN RESOURCES,
Washington, D.C.

The subcommittee met, pursuant to notice, at 10:05 a.m., in room S-207, the Capitol, Senator Richard S. Schweiker presiding pro tempore.

Present: Senator Schweiker.

Senator SCHWEIKER. The Health and Scientific Research Subcommittee of the Labor and Human Resources Committee will please come to order.

I am pleased to be here this morning to conduct the Subcommittee on Health and Scientific Research hearing on the progress of Federal diabetes programs.

Diabetes is one of the most serious health problems facing Americans today. It afflicts perhaps as many as 10 million people in this country. Its disabling, sometimes fatal, complications include heart disease, kidney failure, stroke, diabetic neuropathy, gangrene leading to amputation, and blindness. The life expectancy among people with diabetes is approximately one-third less than that of the general population. The incidence of diabetes is increasing to the point that the average American born today has about a one in five chance of developing the disease. Disproportionately, it strikes the aged, the poor, and minority groups.

There is no cure for diabetes.

In late 1975, the National Commission on Diabetes presented these grim facts in its report to the Congress. Since that time, there has been growing awareness among Federal health policy-makers and the public of the devastating impact of diabetes and its complications, and an increased emphasis on diabetes-related research, education, and training programs at the Federal level.

As the ranking Republican on the subcommittee, and now on the full Human Resources Committee, I have long been an advocate of strengthening the Federal commitment to the fight against diabetes and its complications.

And as the author of diabetes legislation, now law, I want to learn more about how our current diabetes programs are working. I am anxious to hear how our programs can be improved.

The new diabetes legislation pending before this subcommittee which I have introduced provides a basis for this hearing.

[The text of S. 451, the bill referred to, follows:]

1 (b) Whenever in this Act an amendment or repeal is
2 expressed in terms of an amendment to, or repeal of, a sec-
3 tion or other provision, the reference shall be considered to
4 be made to a section or other provision of the Public Health
5 Service Act.

6 (c) Whenever in the amendments made by this Act the
7 title "Director" is used, the reference shall be considered to
8 be made to the Director of the National Institute of Arthritis,
9 Metabolism, Diabetes, and Digestive Diseases unless other-
10 wise indicated.

11 NATIONAL INSTITUTE OF ARTHRITIS, METABOLISM,
12 DIABETES, AND DIGESTIVE DISEASES

13 SEC. 2. (a) Section 434(a) is amended by inserting
14 "Diabetes," after "Metabolism," each place it occurs.

15 (b) Section 434(b) is amended to read as follows:

16 "(b)(1) There are established within the National Ar-
17 thritis, Metabolism, Diabetes, and Digestive Diseases Advis-
18 ory Council a subcommittee on diabetes, a subcommittee on
19 arthritis, a subcommittee on digestive diseases, and a sub-
20 committee on kidney diseases. The subcommittees shall be
21 composed of members of the Council who are outstanding in
22 the diagnosis, prevention, and treatment of diabetes, arthritis,
23 digestive diseases, and kidney diseases, respectively. The
24 subcommittees shall review applications made to the Director
25 for grants for research projects relating to the diagnosis, pre-

1 vention, and treatment of diabetes, arthritis, digestive dis-
2 eases, and kidney diseases and shall recommend to the full
3 Advisory Council those applications and contracts which they
4 determine will best carry out the purposes of this part. The
5 subcommittees shall also review and evaluate the diabetes,
6 arthritis, digestive diseases, and kidney diseases programs
7 under this part and recommend to the Council such changes
8 in the administration of such programs as they determine are
9 necessary.

10 “(2) The Advisory Council, taking into account the rec-
11 ommendations of the subcommittees, shall review the appli-
12 cations made to the Director for grants for research projects
13 and recommend to the Director for approval those applica-
14 tions and contracts which the Council determines will best
15 carry out the purposes of this part, and shall recommend to
16 the Director such changes in program administration as it
17 determines are necessary.”.

18 ASSOCIATE DIRECTOR FOR DIABETES

19 SEC. 3. Section 434(d) is amended to read as follows:

20 “(d)(1) There is established within the Institute the po-
21 sition of Associate Director for Diabetes, who shall report
22 directly to the Director, except as provided in paragraph (4).

23 “(2) Acting through the Associate Director for Diabe-
24 tes, the Director shall—

1 “(A) carry out programs of support for research
2 and training in the diagnosis, prevention, and treat-
3 ment of diabetes mellitus and related endocrine and
4 metabolic diseases, and

5 “(B) establish programs of evaluation, planning,
6 and dissemination of knowledge related to research and
7 training in diabetes mellitus and related endocrine and
8 metabolic diseases.

9 “(3) The Associate Director for Diabetes shall have pri-
10 mary responsibility for all diabetes-mellitus-related activities
11 supported or conducted by the National Institutes of Health,
12 shall serve as an information resource and contact point for
13 public and private agencies with respect to such activities;
14 and shall report and make specific recommendations to the
15 Director of the National Institutes of Health with respect to
16 the functions described in paragraph (4) on a regular basis.

17 “(4) After consultation with appropriate Federal agen-
18 cies, the Associate Director for Diabetes shall be responsible
19 for—

20 “(A) development, through the Diabetes Mellitus
21 Coordinating Committee, of a coordinated plan for the
22 National Institutes of Health with respect to diabetes-
23 related research; training; and data and information
24 collection, analysis, and dissemination;

1 “(B) development of sound management ap-
2 proaches for diabetes-related activities within the Na-
3 tional Institutes of Health;

4 “(C) collection and evaluation of epidemiological
5 data with respect to diabetes;

6 “(D) identification of research opportunities in
7 Federal diabetes-related activities, including specific
8 recommendations for means to take advantage of such
9 opportunities;

10 “(E) coordination of information dissemination ac-
11 tivities with respect to diabetes; and

12 “(F) preparation and submission to the Director of
13 the National Institutes of Health of an annual, coordi-
14 nated budget for all diabetes activities supported by the
15 National Institutes of Health, including specific recom-
16 mendations with respect to fiscal issues relating to
17 such activities.”.

18 DIABETES RESEARCH AND TRAINING CENTERS

19 SEC. 4. Section 435 is amended by—

20 (a) redesignating subsection (b) as subsection (c),
21 and inserting the following new subsection (b):

22 “(b) In connection with training programs conducted in
23 accordance with subsection (a), the Secretary shall provide,
24 from the amounts authorized to be appropriated in subsection

1 (d), not to exceed ten training stipends through each center in
2 any fiscal year.”,

3 (b) redesignating subsection (c) as subsection (d),
4 striking the word “and” after “1979,” in subsection
5 (d), and inserting before the period “, \$14,000,000 for
6 the fiscal year ending September 30, 1981,
7 \$17,000,000 for the fiscal year ending September 30,
8 1982, and \$20,000,000 for each of the next three
9 fiscal years.”.

10 NATIONAL DIABETES ADVISORY BOARD

11 SEC. 5. (a) Section 436A(a)(1) is amended to read as
12 follows:

13 “(1) The following ex officio members: The Assistant
14 Secretary for Health or his designee, the Director of the National
15 Institutes of Health or his designee, the Director of the
16 National Institute of Arthritis, Metabolism, Diabetes, and Di-
17 gestive Diseases or his designee, the Director of the National
18 Heart, Lung, and Blood Institute or his designee, the Direc-
19 tor of the National Eye Institute or his designee, the Direc-
20 tor of the National Institute of Child Health and Human De-
21 velopment or his designee, the Director of the Center for
22 Disease Control or his designee, the Administrator of the
23 Health Resources Administration or his designee, the Admin-
24 istrator of the Health Services Administration or his desig-
25 nee, the Associate Director for Diabetes of the National In-

1 stitutes of Arthritis, Metabolism, Diabetes, and Digestive
2 Diseases or his designee, and the Chief Medical Director of
3 the Veterans' Administration or his designee.”.

4 (b) Section 436A(e) is amended to read as follows:

5 “(e) The appointed members of the Board shall be ap-
6 pointed for terms of three years each, except that, of the
7 appointed members serving on the date of enactment of the
8 Diabetes Research and Training Amendments and National
9 Diabetes Advisory Board Extension Act of 1979, six shall be
10 reappointed for terms of two years each.”.

11 (c) Section 436A(f) is amended by—

12 (1) striking the word “and” at the end of para-
13 graph (1) and inserting “, as amended and updated in
14 accordance with paragraph (2),”;

15 (2) redesignating paragraph (2) as paragraph (3)
16 and inserting the following new paragraph (2):

17 “(2) amend and make such changes in the Dia-
18 betes Plan as the Board determines are necessary to
19 insure its continuing relevance, and”.

20 (d) Section 436A(k) is amended by striking the “and”
21 after “September 30, 1979,” and inserting before the period
22 “, and each of the next five fiscal years.”.

23 (e) Subsection (l) is amended by striking “September 30,
24 1980,” and inserting in lieu thereof “September 30, 1985.”.

Senator SCHWEIKER. In my new position as the ranking Republican on the Labor-HEW Appropriations Subcommittee, I will soon be faced with the need to act on the President's budget for diabetes programs in 1980, after our hearings in that Appropriations Subcommittee.

So I am eager to find out what has been accomplished. The diabetes budget has tripled since the National Commission on Diabetes made its report to Congress in late 1975, and major legislation to improve program management and coordination, the National Diabetes Advisory Board Act, has been enacted. Has the board functioned well? What can we do to enhance its effectiveness?

The bulk of diabetes funds are spent through the National Institutes of Health. Although the lead institute is the National Institute of Arthritis, Metabolism and Digestive Diseases, diabetes activities cut across many institutes. I am hopeful that our witnesses today will examine what we have gotten for our money in terms of research breakthroughs, and what the NIH has done internally to help insure that our efforts pay off.

The Center for Disease Control has begun to implement another of the national commission's recommendations with the establishment of State diabetes control programs.

Today's hearing combines legislative and oversight functions of our subcommittee. I look forward to the witnesses' observations on my new diabetes bill, the Diabetes Research and Training Amendments and National Diabetes Advisory Board Extension Act of 1979.

Before we proceed, I would like to take this opportunity to acknowledge the support of my colleagues on the full Human Resources Committee and the Health Subcommittee—particularly Senator Williams, chairman of the full committee; Senator Kennedy, chairman of the Health Subcommittee; and Senator Javits. As cosponsors of past diabetes legislation, they have contributed a great deal to our effort. I also want to express my appreciation to Senator Kennedy for his assistance in scheduling this hearing.

We will have as our first panel of witnesses Dr. Donald Fredrickson, Director of the National Institutes of Health, accompanied by Dr. G. Donald Whedon, Director of the National Institute of Arthritis, Metabolism and Digestive Diseases, and Dr. Lester Salans, Associate Director for Diabetes.

Dr. Fredrickson and his colleagues are responsible for research programs in diabetes

I would also like to welcome Dr. William Foege, Director of the Center for Disease Control, accompanied by Dr. William Flynt.

STATEMENT OF DR. DONALD FREDRICKSON, M.D., DIRECTOR OF THE NATIONAL INSTITUTES OF HEALTH, ACCOMPANIED BY DR. G. DONALD WHEDON, DIRECTOR OF THE NATIONAL INSTITUTE OF ARTHRITIS, METABOLISM AND DIGESTIVE DISEASES; AND DR. LESTER SALANS, ASSOCIATE DIRECTOR FOR DIABETES; AND WILLIAM FOEGE, M.D., DIRECTOR OF THE CENTER FOR DISEASE CONTROL, ACCOMPANIED BY DR. WILLIAM FLYNT, CHIEF, DIABETES CONTROL ACTIVITY, A PANEL

Dr. FREDRICKSON. Mr. Chairman, thank you for the opportunity to be here this morning to discuss the progress of NIH in the area of diabetes research and related activities.

I have a statement which I should like to paraphrase, if I may, rather than read it in its entirety.

Senator SCHWEIKER. Without objection, we will put your entire statement in the record, Dr. Fredrickson.

Dr. FREDRICKSON. As you have noted, Mr. Chairman, the National Diabetes Mellitus Research and Education Act was passed in 1974, and the first submission of the long-range plan by the National Commission on Diabetes occurred in 1975. I think we have made considerable strides in expanding and coordinating our research and manpower development with respect to diabetes. In this undertaking we have also profited from the advice and recommendations of the National Diabetes Advisory Board which has been most energetic in assisting us in implementing those recommendations of the Commission which are related to the NIH's goals and mission.

I have, Mr. Chairman, a longer statement which is a more detailed summary of many of the activities which I will briefly touch and if you wish, I will be very glad to submit that also for the record.

Senator SCHWEIKER. We would like that, and without objection, it will be included in the record.

Dr. FREDRICKSON. Let me turn briefly to a summary of program development since the beginning of this expanded and accelerated effort toward the solution of the enormous diabetes problem in this country

As you noted, Mr. Chairman, the funding for research in this area has tripled since 1976. In that year the total level was \$42.5 million. In 1979 we will spend approximately \$124 million in the diabetes area with over half of this total funded through the National Institute of Arthritis, Metabolism, and Digestive Diseases (NIAMDD). The quality of the applications remains high, and the response to our first NIH-wide program announcements soliciting research grant applications spanning the full range of diabetes-related research has been excellent. Expansion has taken place not only in fundamental disciplines, such as endocrinology, metabolism, immunology and genetics, but also in many clinical areas dealing with the various complications associated with diabetes, such as diabetic retinopathy and disorders of the vascular and nervous system.

Clinical and laboratory research training has burgeoned as well. We have increased the numbers of national research service awards, research career development awards, and clinical investi-

gator awards in the area of diabetes and have initiated new diabetes special emphasis research career awards (SERCA) designed to encourage qualified individuals in the early stages of their post-graduate medical careers to develop research skills and interests in specific aspects of diabetes. In the NIAMDD, the primary source of support for diabetes-related training, the number of NRSA fellowships and traineeships in diabetes increased from 29 in fiscal year 1976 to 201 in fiscal year 1978.

The NIAMDD now supports 11 centers in diabetes at approximately \$9.5 million, including three Diabetes-Endocrinology Research Centers and eight Diabetes Research and Training Centers (DRTC). These centers offer a unique opportunity for interaction and coordination between investigators from various scientific disciplines and between traditional biomedical research activities, health care delivery, and education. All of the eight DRTCs have been created since 1977.

In the area of education and information dissemination, we are active in a number of ways. A National Diabetes Information and Education Clearinghouse has been initiated at the NIAMDD and will work closely with governmental and nongovernmental groups to foster the development and dissemination of education materials in diabetes to health professionals, patients, and the public. Each of the eight Diabetes Research and Training Centers have active information programs for physicians and allied health personnel who provide primary care to diabetes patients through model care demonstration programs in the centers and through outreach programs in the community. In addition, the NIH together with the NIMH will soon announce a new program focusing on research on the behavioral and psychosocial aspects of diabetes.

Having highlighted some of our program accomplishments since the submission of the National Commission's report, I would like to mention some of the scientific advances which have been made in our understanding of diabetes and its treatment. For example: the utilization of recombinant DNA technology to produce rat, and more recently, human insulin; the very recent achievement in the rat animal model, of transplanting pancreatic islets, the body's normal source of insulin, across genetic lines without immunologic rejection; the demonstration that certain genetic factors, the HLA antigen system, are associated with some types of diabetes but not others; studies in both laboratory animal and man which suggest that viral infections may result in extensive pancreatic islet cell damage and may cause insulin-dependent diabetes in animals with certain genetic backgrounds; and the demonstration that photocoagulation is effective in inhibiting the progression of the vision threatening complication of diabetic retinopathy, a major advance in the treatment of what is now the leading cause of new blindness in this country.

While we do not yet have all the answers we are seeking with respect to diabetes and its complications, I believe we are making progress. I can assure you, Mr. Chairman, we will continue to explore all possible avenues with respect to this major health problem.

Before closing, I want to bring to your attention an additional effort which I believe is of great importance to our continued

success. Diabetes is unique in that research directed toward its causes, prevention and cure involve the research responsibilities of practically all the Institutes of the National Institutes of Health. Research in diabetes thus requires special coordination in program planning and management. To build on the accomplishments in the Inter-NIH Diabetes Mellitus Coordinating Committee, established in 1977, I instituted in January of this year the Trans-NIH diabetes program which will strengthen the lead role of the NIAMDD for NIH activities and provide a sharper focus for program activity and greater accountability among all NIH components. I believe this mechanism will satisfy the need for both the strong leadership and flexibility required to fully exploit current research opportunities and meet the challenges that lie ahead.

Mr. Chairman, that completes my statement. I will be glad to answer any questions you may have this morning.

[The prepared statement and summary of activities supplied by Dr. Fredrickson follows:]



FOR RELEASE UPON DELIVERY

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH
BETHESDA, MARYLAND 20014

STATEMENT BY

DONALD S. FREDRICKSON, M.D.

DIRECTOR

NATIONAL INSTITUTES OF HEALTH

ON DIABETES

BEFORE THE

SUBCOMMITTEE ON HEALTH AND SCIENTIFIC RESEARCH

SENATE COMMITTEE ON HUMAN RESOURCES

FEBRUARY 26, 1979

Mr. Chairman and Members of the Subcommittee:

Thank you for the opportunity to be here today to talk about NIH's progress in the area of diabetes research and related activities. Since the passage of the National Diabetes Mellitus Research and Education Act in 1974 and the submission of the Long-Range Plan by the National Commission on Diabetes in 1975, we have, I believe, made significant strides in expanding and coordinating our research, manpower development, and education and information efforts to combat diabetes. In this undertaking, we have also profited from the advice and recommendations of the National Diabetes Advisory Board, a group which has been most energetic in assisting us in implementing those recommendations of the Commission which are related to the NIH's goals and mission.

With your permission, I would like to highlight some of our accomplishments in implementing the Long-Range Plan.

I will turn first to the area of program development.

- o The overall funding level for NIH research and related activities in diabetes has tripled since 1976. In that year, the total level was \$42.5 million. In 1979 we will spend approximately \$124 million in the diabetes area with over half of this total funded through the National Institute of Arthritis, Metabolism, and Digestive Diseases (NIAMDD). The quality of the applications remains high, and the response to our first NIH-wide Program Announcements soliciting research grant applications spanning the range of diabetes-related research has been excellent. Expansion has taken place not only in fundamental disciplines such as endocrinology, metabolism, immunology and genetics, but also in many clinical areas

dealing with the various complications associated with diabetes, such as diabetic retinopathy and disorders of the vascular and nervous systems.

- o Clinical and laboratory research training has burgeoned as well. We have increased the numbers of National Research Service Awards, Research Career Development Awards, and Clinical Investigator Awards in the area of diabetes and have initiated new Special Emphasis Research Career Awards (SERCA) designed to encourage qualified individuals in the early stages of their postgraduate medical careers to develop research skills and interests in specific aspects of diabetes. In the NIAMDD, the primary source of support for diabetes-related research training, the number of NRSA fellowships and traineeships in diabetes increased from 29 in FY 1976 to 201 in FY 1978.
- o The NIAMDD now supports 11 centers in diabetes at approximately \$9.5 million, including three Diabetes-Endocrinology Research Centers and eight Diabetes Research and Training Centers (DRTC). These Centers offer a unique opportunity for interaction and coordination between investigators from various scientific disciplines and between traditional biomedical research activities, health care delivery, and education. All of the eight DRTC's have been created since 1977.
- o In the area of education and information dissemination, we are active in a number of ways. A National Diabetes Information and Education Clearinghouse has been initiated at the NIAMDD

and will work closely with governmental and nongovernmental groups to foster the development and dissemination of educational materials in diabetes to health professionals, patients, and the public. Each of the eight Diabetes Research and Training Centers have active information programs for physicians and allied health personnel who provide primary care to diabetes patients through model care demonstration programs in the Centers and through outreach programs in the community. In addition, the NIH together with the NIMH will soon announce a new program focusing on research on the behavioral and psychosocial aspects of diabetes.

Having highlighted some of our program accomplishments since the submission of the National Commission's Report, I would like to mention some of the scientific advances which have been made in our understanding of diabetes and its treatment. For example:

- o the utilization of recombinant DNA technology to produce rat, and more recently, human insulin;
- o the very recent achievement in the rat animal model, of transplanting pancreatic islets, the body's normal source of insulin, across genetic lines without immunologic rejection;
- o the demonstration that certain genetic factors, the HLA antigen system, are associated with some types of diabetes but not others;
- o studies in both laboratory animal and man which suggest that viral infections may result in extensive pancreatic islet cell

damage and may cause insulin-dependent diabetes in animals with certain genetic backgrounds; and

- ° the demonstration that photocoagulation is effective in inhibiting the progression of the vision threatening complication of diabetic retinopathy, a major advance in the treatment of what is now the leading cause of new blindness in this country.

While we do not yet have all the answers we are seeking with respect to diabetes and its complications, I believe we are making progress. I can assure you, Mr. Chairman, we will continue to explore all possible avenues with respect to this major health problem.

Before closing, I want to bring to your attention an additional effort which I believe is of great importance to our continued success. Diabetes is unique in that research directed toward its causes, prevention and cure involve the research responsibilities of practically all of the Institutes of the National Institutes of Health. Research in diabetes, thus, requires special coordination in program planning and management. To build on the accomplishments of the Inter-NIH Diabetes Mellitus Coordinating Committee, established in 1977, I instituted in January of this year the Trans-NIH Diabetes Program which will strengthen the lead role of the NIAMDD for NIH activities and provide a sharper focus for program activity and greater accountability among all NIH components. I believe this mechanism will satisfy the need for both the strong leadership and flexibility required to fully exploit current research opportunities and meet the challenges that lie ahead.

I would be pleased to answer any questions you or members of the Subcommittee may have.

PROGRESS TOWARDS IMPLEMENTATION OF THE RECOMMENDATIONS OF THE

NATIONAL COMMISSION ON DIABETES

TO THE

NATIONAL INSTITUTES OF HEALTH

(prepared February, 1979)

National Institute of Arthritis, Metabolism and Digestive Diseases (NIAMDD)

1. Increase support of research in basic endocrinology, metabolism and nutrition, and application of the results of such research to the study of diabetic defects and the causes, prevention and cure for diabetes.

The NIAMDD budget for support of diabetes research increased from approximately \$19 million in FY 1976 to \$41.4 million in FY 1977, \$58.9 million in FY 1978 and roughly \$67.8 million in FY 1979. These funds have been used to support basic diabetes, endocrine, metabolic, and nutrition research not only in the Institute's Diabetes Program, but also diabetes-related research in the Endocrine, Metabolic Diseases, Nutrition and Kidney Programs of the NIAMDD. Approximately \$12 million of the FY 78 diabetes funds were allocated to diabetes-related research in the NIAMDD's Endocrinology, Metabolic Diseases and Nutrition Programs. In addition, the Institute increased its support of basic and applied research in its Endocrine, Metabolic Diseases and Nutrition Programs from non diabetes funds from \$62 million in FY 76 to \$64 million in FY 77, \$79.5 million in FY 78, and approximately \$92.1 million in FY 1979.

New programming efforts have been initiated in order to stimulate additional research. In FY 1977 the Institute received 420 applications in response to its first diabetes Program Announcement spanning the range of diabetes research. In FY 1978 the Institute, together with 7 other Institutes co-sponsored (for the first time at NIH) an NIH-wide Program Announcement soliciting research grant applications spanning the range of diabetes-related research. Over 100 applications were submitted during the first round in FY 1978. A revised Announcement was reissued in the summer of 1978 and the initial response has been excellent: roughly 250 applications have so far been received in FY 1979. Thus, although the full impact of the Announcements cannot yet be determined the initial response has been very rewarding.

In the fall of 1978, the NIAMDD together with seven other NIH Institutes issued an NIH-wide Program Announcement entitled The Epidemiology of Diabetes. This announcement solicits applications for research grants, individual National Research Service Awards (Fellowships) and Special Emphasis Research Career Awards in the area of diabetes-related epidemiologic research. The initial response to this announcement has been positive: 29 new applications have been submitted for the first round of review.

2. Increase support of research in nutrition relating to diabetes and to obesity in persons with diabetes, and increase the number of obesity centers to 3 to encourage such research and to train manpower in this area.

Support for research in nutrition and obesity relating to diabetes has increased substantially. In FY 76, NIAMDD supported 16 projects at a funding level of \$841,499; in FY 77 these figures were 30 and \$2,170,261 respectively and in FY 1978 support of this further increased to 38 projects and \$3,084,606. The NIAMDD support of obesity research in FY 77 was approximately \$1.178 million and in FY 1978, roughly \$2 million. This is an area of research specifically identified in the NIH Program Announcement. The Institute has recently announced a new program, Nutrition Health Resource Core Centers, in which obesity research will be a significant component.

3. Increase support for research efforts in diabetic microangiopathy.

During FY 77, the NIAMDD increased its support of research efforts directly relating to diabetic microangiopathy to a total of \$690,950, and in FY 78 to roughly \$1,320,000. A portion of these funds support research on diabetic nephropathy. The NIH Diabetes Program Announcement specifically identified microangiopathy as an area of current research interest. Research on microangiopathy in the eye is supported by the NEI (\$13.7 million in FY 79)

4. Initiate and support (with the NHLBI) a five-year study to assess the effect of treatment of juvenile-onset diabetes on the development of micro- and macrovascular complications.

The NIAMDD and NHLBI established a committee which met regularly during the past year to consider the feasibility of and plan the clinical trial. This advisory group recommended that such an undertaking was both ethical and feasible and recommended that the Institutes proceed with a phased type clinical trial. The initial phase of this trial will test the feasibility of creating two groups of diabetic patients differing significantly in their blood glucose concentrations as the result of "tight" vs. "business as usual" treatment regimens. In October 1978 a Sources Sought Announcement was issued soliciting the interest and capabilities of institutions to participate in this program. 75 responses to this Announcement have been received. The Sources Sought Announcement is preliminary to a Request for Proposals (RFP) for the conduct of the feasibility phase of the study, Phase I. It is anticipated that this RFP will be issued by the NIAMDD in March, 1979. Phase II, the full scale clinical trial, will proceed after the conclusion of Phase I, and only if the latter demonstrates that it is feasible to create two populations of blood glucose concentration through different treatment of randomized patients.

5. Expand on-going intramural research programs related to diabetes.

Support of the NIAMDD's intramural research program related to diabetes has been expanded from \$2.5 million in 1976 to \$3.8 million in 1978. The Institutes' Intramural Diabetes Research Branch is recognized as one of the world's leading and most productive laboratories studying the mechanism of insulin action in health and disease. In addition to this expansion, intramural research on diabetes in the Pima Indian at the Epidemiology and Field Studies Branch in Phoenix has received new and increased support: in FY 1977 a Human Diabetes Program involving the collaborative efforts of many of the leading intramural and extramural scientists in diabetes was initiated in Phoenix.

6. Increase its support for research manpower training in diabetes and related endocrinologic and metabolic disorders.

During FY 77, the NIAMDD established a Manpower Development Program for diabetes, endocrinology and metabolic diseases in order to facilitate and coordinate increased programming efforts in these areas. An ad hoc advisory group was convened to review existing research manpower development support and to identify specific areas of need for future emphasis. It was agreed that a significant increase in support of research training would be required, and, in this regard, a Program Announcement inviting applications for institutional and individual National Research Service Awards, Research Career Development Awards and Clinical Investigator Awards was issued in FY 1977. The initial response has been favorable with a substantial increase in the number of fellowships and training grant applications received and awarded. Thus, for the NIH as a whole the number of diabetes related RCDAs awarded has increased from 23 in FY 76 to 74 in FY 78. The number of diabetes related fellowship and training awards increased from 37 in FY 76 to 144 in FY 78. More dramatic is the fact that within the NIAMDD, the primary source of support for diabetes related research training, the number of trainees (NRSA fellowships and training awards) has increased from 29 in FY 76 to 201 in FY 78. A similar increase has occurred in RCDAs awarded by the Institute over this time period. The Manpower Program Announcement was reissued late in 1978 and the initial response has been gratifying.

The Institute has also developed two new programs. The NIAMDD and the NHLBI have jointly sponsored a new Special Emphasis Research Career Award (SERCA) designed to encourage qualified individuals in the early stages of their postgraduate medical careers to develop research interests and skills in the metabolic, endocrinologic and cardiovascular aspects of diabetes. Eight SERCAs have been awarded to date. A new SERCA is soon to be announced in which the NIAMDD and NICHD will jointly sponsor an award entitled "Special Emphasis Research Career Award: Diabetes Mellitus: Obstetrical, Perinatal and Pediatric Aspects." Currently

The NIAMDD and the NIA are exploring a SERCA on diabetes and aging. The NIAMDD and the Fogarty International Center have recently announced a Senior Investigator Award in Diabetes which will enable Senior U.S. researchers to study diabetes related problems in foreign laboratories and hospitals for a period of up to one year. All of these new awards emphasize multidisciplinary training.

The NIAMDD announced late in FY 1978 a new diabetes research grant program entitled "New Investigator Research Award in Diabetes." This award is aimed at young new investigators and will provide research grant support for studies in diabetes and related areas. The initial response of 38 applications for the first receipt date has been most encouraging.

7. Establish an ad hoc advisory panel on transplantation and artificial devices and, commensurate with the panel's recommendations, increase support of research efforts on transplantation of the pancreas or islet cells and development of artificial devices.

The NIAMDD has sponsored workshops on Pancreatic Islet Transplantation (November 29-30, 1977) and Artificial Devices for the Control of Blood Glucose (May 17, 1976, and December 1-2, 1977) for the purpose of identifying the current state of the art and future research objectives in these areas. Based on these workshops and additional input from the scientific community, the NIAMDD has developed a comprehensive, systematic program of research support for transplantation and artificial devices. Increased support has already begun as evidenced by the fact that in FY 77, the Institute allocated approximately \$1.7 million (14 research grants) for research in pancreatic islet transplantation and artificial devices, and in FY 1978 approximately \$3.8 million for 56 grants in these areas. The 1978 NIH-wide Diabetes Program Announcement specifically identifies pancreatic islet transplantation as a high priority research area. In addition, in 1978 the Institute issued a request for proposals (RFP) for research and development of artificial devices. 15 full proposals were submitted and underwent peer review in late FY 1978. To date two contracts have been awarded: The Mayo Foundation (\$264,119.) and The University of Minnesota (\$344,897.); three more awards are expected to be made in FY 79.

8. Establish Diabetes Research and Training Centers.

Eight Diabetes Research and Training Centers (DRTC) have been awarded by the NIAMDD: University of Chicago; Washington University, St. Louis; University of Michigan; University of Indiana; Albert Einstein University; Joslin Research Center; Vanderbilt University; and the University of Virginia, Charlottesville. The Institute has reissued a Program Announcement for DRTC applications with multiple receipt dates, rather than a single deadline as in the past. The guidelines for the DRTCs have been revised for further clarification and to allow for planning for, and phasing in, the training and information transfer components of these multipurpose centers. In addition to the DRTC program, the Institute continues to support the Diabetes and Endocrinology Research Centers (DERC). Currently three such centers are supported: University of Washington, Seattle; the University of Pennsylvania, and the University of Iowa. The

Seattle; the University of Pennsylvania, and the University of Iowa. The Institute plans to continue to support and expand this program. Current total support of diabetes centers by the NIAMDD is approximately \$9,475,073.

9. Assemble a National Diabetes Data Group as a standing committee in the Office of the Associate Director for Diabetes of the National Institute of Arthritis, Metabolism and Digestive Diseases.

The National Diabetes Data Group was established by the Associate Director for Diabetes, NIAMDD in 1977 with responsibility to foster the collection, analysis and dissemination of data on diabetes. Leaders from several federal agencies (NIH, CEC, NCHS) as well as individuals from the private sector with expertise in diabetes research, epidemiology, nutrition and socioeconomics serve as members of the National Diabetes Data Group. In addition, the American Diabetes Association, the Juvenile Diabetes Foundation, and the National Diabetes Advisory Board have representatives on the Data Group. This collaboration should result in integration and coordination of national resources for development of diabetes data. Several initial activities of the Data Group deserve brief mention.

The Group identified the need for increased epidemiological research and manpower in diabetes; consequently in FY 1978 the NIAMDD, together with seven other NIH Institutes issued a Program Announcement soliciting applications for research grants and training awards in this area.

The Data Group convened, in May 1978, leading experts in the international diabetes community to help develop an improved classification of diabetes. The resulting proposed classification is now being widely disseminated in the international diabetes community in an effort to obtain a broad consensus; the revised classification will then be proposed for adoption.

The Data Group sponsored a Symposium on the Epidemiology of Diabetes at the October 1978 National Meeting of the American Public Health Association.

In April 1977, the Food and Drug Administration released a study that questioned the adequacy of the insulin supply in the United States within the next decade. In addition, the Food and Drug Administration asked the National Diabetes Advisory Board to perform a comprehensive analysis of current and future insulin supply and demand. The Board in turn established the ad hoc Insulin Study Committee to explore whether a shortage of insulin could occur in the United States within the next 20 years. Perhaps the most significant conclusion of the Committee's study is that based on the evidence presented regarding present and future conditions, no shortage of insulin is anticipated in the next 20 years. The Committee based its conclusions, in large part, on an extensive analysis of insulin supply and demand data conducted

by the National Diabetes Data Group. The Committee recommended that the National Diabetes Data Group be charged with the responsibility for reporting, analyzing and assembling data pertaining to the supply and demand of insulin on an appropriate periodic basis.

The Data Group has taken the lead and been actively involved in assessing the validity of data on diabetes from the Health Interview Survey (HIS) of the National Center for Health Statistics. That survey is the sole national survey which provides data on incidence and prevalence of diabetes. The Data Group has also begun a preliminary analysis of diabetes related data from the Health and Nutrition Examination Survey (HANES) now being conducted and is helping to establish priorities for editing and publishing the data which bear upon diabetes and its complications so that timely availability is assured. The Group is also helping NCHS to design its future surveys.

As recommended by the National Commission on Diabetes, a compilation of the most recent data of diabetes has been prepared (by Drs. Peter Bennett, Paul Entmacher, Jean-Pierre Habicht, Harvey Knowles and Mrs. Louinia Mae Whittlesey). This document has just been published and will be distributed to lay, scientific and governmental audiences.

10. Establish the National Diabetes Information and Education Clearinghouse with responsibility for its activities delegated to the Office of the Associate Director for Diabetes.

The National Diabetes Information and Education Clearinghouse was established by the Associate Director for Diabetes, NIAMDD in 1978 for the purpose of fostering the development and dissemination of quality and effective educational materials in diabetes to the professional, patient and public. The Clearinghouse will work closely with all governmental and non-governmental agencies, groups and individuals in this program. Several meetings with individuals and groups from both the government and private sector have already been held. A group of consultants with expertise in diabetes, education and information transfer have been convened to advise the Clearinghouse and this group held its first meeting in October, 1978. One of the first opportunities for innovative educational projects has recently been identified. In cooperation with the National Library of Medicine, the NIAMDD plans to explore the possibility of developing a "computer textbook" on diabetes for the practicing physician that can be updated monthly to provide a current, comprehensive resource. The "textbook" could be read through computer terminals already available at medical teaching institutions and libraries across the country. The Clearinghouse's initial plans also include the development of annotated bibliographies covering a wide spectrum of diabetes educational and informational materials.

11. Establish research resource facilities to maintain research materials and animal models and provide economical and

efficient services necessary to meet the needs of diabetes research.

An ad hoc advisory group was established in 1977 to advise the NIAMDD regarding the implementation of the Commission's recommendation regarding animal models. A sources sought announcement was issued in July, 1977 requesting information about existing animal models with some proven reproducible characteristics which mimic the features of human diabetes mellitus. 28 responses were received which included information on 22 colonies which could be considered in this category. A Program Announcement soliciting applications for the further development of promising new animal models for diabetes research was issued in FY 1978. Several responses have been received and new awards have been made in FY 1979. The NIAMDD has awarded a large Program Project Grant to five investigators for the further characterization and study of diabetes in the Chinese Hamster (5 investigators - \$676,002).

An RFP for procurement of abnormal insulins and insulin analogues for distribution to qualified investigators for research involving receptor studies and studies of insulin bioactivity was issued in FY 1978. Proposals for the production and dissemination of such materials as guinea pig antiserum, Somatomedin, IGF I, IGF II, chicken insulin, desoctapeptide insulin have been received and several new awards have been made. Gastric inhibitory polypeptide has been purchased for distribution to qualified investigators to study its effects on release of insulin from pancreatic islet cells. An RFP has been issued in order to stimulate continued production of this material. An NIAMDD sponsored workshop will be held in February 1979 to consider the possibility of supporting the production and dissemination of other diabetes research materials and facilities.

12. Sponsor interdisciplinary workshops, symposia and conferences on diabetes and its complications to encourage cross-fertilization of ideas and cooperative research efforts.

The NIAMDD has sponsored a number of workshops including: a conference on the Etiology and Pathogenesis of Insulin-Dependent Diabetes Mellitus which focused on the epidemiologic, viral, immunologic and genetic aspects of the syndrome (with the Juvenile Diabetes Foundation); a conference on Glycosylated Hemoglobins in Diabetes (with the American Diabetes Association); a workshop on Pancreatic Islet Cell Transplantation; a workshop on Artificial Devices for the Control of Blood Glucose Concentration; a workshop on the development of a new classification of diabetes; the second annual Diabetes Day for physicians and scientists covering a broad range of topics of current clinical interest in diabetes; a national symposium on the Epidemiology of Diabetes; and a workshop on Research on the Behavioral Aspects of Diabetes. Several additional workshops are planned.

The proceedings of most of these workshops and conferences have been published and widely disseminated, or are in the process of being prepared for publication. The Institute has co-sponsored a number of additional workshops with other NIH Institutes and the Fogarty International Center including: a Task Force Analysis and Recommendations for Public Action on Obesity; the Second International Congress on Obesity; a workshop on Basic Studies of Somatomedin and Other Growth Factors.

13. Review all available research information resources in order to develop a system to provide a complete and up-to-date source of information on on-going proposed research relating to diabetes.

The Office of the Associate Director for Diabetes has begun to identify the various sources of scientific research information available regarding diabetes mellitus. In addition to professional journals, books and indices, automated data storage and retrieval systems existing at the NIH are being identified and evaluated as sources of information. The latter includes: 1) IMPAC (Information for Management Planning and Coordination), a system dealing with the administrative aspects of NIH extramural programs; and 2) the CRISP system, a comprehensive system developed and maintained to make possible the rapid retrieval and dissemination of up-to-date scientific information on PHS-sponsored projects. Quick on-line or off-line extraction of these data are possible through the use of a sophisticated query software facility. IMPAC and CRISP may be linked for provision of additional data as needed.

In addition, NIH's DRG publishes a two volume research grants index containing information extracted from CRISP. These are available from the U.S. Government Printing Office and are generally to be found in most medical and university libraries.

The Annual Reports of the Interagency Diabetes Mellitus Coordinating Committee which was chaired by the Associate Director for Diabetes, NIAMDD, contain a complete compendium of diabetes-related research projects and activities comprising the total Federal effort in diabetes, as well as information on seven major diabetes subject categories and thirty-five subtopics that cut across all Federal agencies. This enables a determination of both the actual and relative levels of the total Federal effort in each of these areas as well as identification of which agencies are supporting such efforts. Furthermore, these Reports permit identification of areas being supported by more than one agency. Such data will be helpful in promoting cooperation, coordination, and efficiency in the National Diabetes Program.

The Office of the Associate Director is currently attempting to modify

the existing NIH data storage and retrieval system to provide more detailed information regarding subcategorization of diabetes-related activities supported by NIH funds and to deal with areas of overlapping concern. The Institute is working with other NIH Institutes through the NIH Diabetes Coordinating Committee and with the National Diabetes Advisory Board in this effort.

Finally, the NIAMDD's own program analysis capabilities are being expanded by adding categories to the scientific data base which will facilitate the prompt and sophisticated retrieval of information needed by the scientific and lay communities as well as by other agencies and legislative bodies. It is anticipated that other NIH Institutes will develop similar capabilities.

The establishment of the National Diabetes Information and Education Clearinghouse provides a central focus for the coordination of many of these activities.

14. Be alert and receptive to the sponsorship of evaluation studies pertaining to diabetes treatment and education as part of the NIH's competitively awarded research programs.

Within the newly initiated Diabetes Research and Training Centers are components, shared resources and feasibility studies, which relate to diabetes treatment and education. The guidelines indicate that the cores, or shared resources must have clearly stated objectives with a systematic plan for how the objectives will be met. Feasibility studies in this area must contain a statement of objectives, the plan of approach, and plans for assessing an evaluation. Thus, in planning for the DRTC program, the NIAMDD has a strong commitment to studies with evaluation components in this area. In addition, the NIAMDD diabetes program staff will be maintaining close liaison with the CDC in their newly created Diabetes Control Programs. In those states where there is both a CDC contract and a DRTC, efforts are being made to establish a liaison.

In the area of regular research grants, the NIAMDD will continue its commitment to high-quality programs relating to evaluation of diabetes treatment. Evaluation studies of education may or may not fall within the purview of the NIH, but in all cases would be viewed with interest and concern for funding resources for high quality programs.

National Heart, Lung and Blood Institute (NHLBI)

1. Increase support of research in heart disease, peripheral vascular disease, atherosclerosis, hypertension, and blood coagulation that related to diabetes morbidity and mortality, and increase support for those research studies already underway which are unique to diabetic macroangiopathy.

The National Heart, Lung, and Blood Institute has continued to support the program and research on cardiovascular disease in relation to diabetes mellitus that was expanded by two Requests For Applications (RFA's) announced and funded in FY 1976 and 1977. These announcements led to the funding of an additional 48 regular research grants at a cost of about \$3.2 million dollars per annum. Some of these grants are now completing their committed period of award and more will do so in the next year or two. Renewal applications are anticipated. In addition, existing programs of research in which there are components directly related to diabetes and its cardiovascular effects have continued. These include the acquisition of information through regular grants, Specialized Centers Of Research (SCOR's), epidemiological studies in communities and cohorts, the Lipid Research Clinics, and certain intervention trials. In aggregate, the diabetes related expenditures for FY 78 were \$13,609,000, and are estimated to be \$14,200,000 in FY 79.

In addition, the NHLBI has joined with the NIAMDD in sponsoring a Special Emphasis Research Career Award for the interdisciplinary training of experts in aspects of both diabetes and cardiovascular disease. The initial experience with this program saw the funding of 8 awards, of which 4 were supported by NHLBI. The program has been reannounced.

2. Initiate and support (with the NIAMDD) a five-year clinical study to assess the effect of treatment for juvenile-onset diabetes on the development of micro and macrovascular complication.

The NHLBI has actively participated in the deliberations of the ad hoc Advisory Group convened to advise the NIH on this matter. Progress in this joint effort with the NIAMDD has been described under that Institute's section. The Institute plans to continue to advise the NIAMDD during its conduct of the study.

National Eye Institute (NEI)

1. Increase support of research on the causes and treatment of diabetic retinopathy.

Support of research on the causes, treatment and prevention of diabetic retinopathy and other ocular complications of diabetes within the NEI increased from approximately \$5 million to over \$9 million in 1977, \$12,085 million in FY 78 and an estimated \$13,750 million in FY 1979. The funds are supporting a wide array of studies ranging from biochemical and physiological investigations designed to elucidate the detailed pathogenic events associated with diabetes eye diseases in general to clinical trials of new treatments for diabetic retinopathy in particular. Especially noteworthy are: 1) the Diabetic Retinopathy Study which has established the effectiveness of photocoagulation in the treatment of proliferative diabetic retinopathy; 2) the launching of a new multicenter clinical trial - the Early Treatment Diabetic Retinopathy Study--to determine the value of systemic aspirin, alone or in combination with other drugs in preventing progression of the disease and to determine the best timing during the course of the disease for administration of photocoagulation therapy. The design and planning phases of the study have been completed and patient recruitment is expected to begin by July, 1977. 3) The Diabetes Retinopathy Vitrectomy Study to evaluate the efficacy of vitrectomy when performed in the first six months after vitreous hemorrhage; 4) the development of a preliminary protocol for the clinical evaluation of chemical substances which inhibit the enzyme aldose reductase and thus have potential value for treating complications in the lens, peripheral nerve, and retinal vasculature of diabetes. The research base for this new initiative received its principle contributions from the NEI intramural program: and 5) announcement of a new Program of support for Studies on Vascular and Circulatory Abnormalities of the Retina including Diabetic Retinopathy. These basic studies will be continued and modestly expanded.

The recently issued NIHwide Diabetes Program Announcement specifically identified research into the causes, natural history treatment and prevention of diabetic retinopathy as an area of high priority. The NIHwide Epidemiology of Diabetes Announcement specifically identified research in the epidemiology of diabetes and in the study of the prevalence and incidence of specific complications with welldefined populations of diabetes.

2. Expand training fellowships and special awards in the area of diabetesrelated studies.

Support for training and career development of investigators has been maintained at previous levels, but a continued need for more post residency ophthalmologists to become involved in diabetes research has been identified. The Institute is intensifying its efforts to redress this imbalance by making greater use of the training opportunities associated with its contractsupported cooperative clinical trials and by placing greater emphasis on the Academic Investigator Award as a support mechanism for emerging clinical scientists. In addition the NEI has

initiated a program which utilizes the Institutes intramural facilities for the training of physician scientists.

National Institute of Child Health and Human Development (NICHD)

1. Increase support of basic and clinical research on pregnancy and diabetes, and sponsor a followup study of infants of mothers with diabetes.

The NICHD diabetes budget has increased from about \$2 million in FY 1976 to \$5.0 in FY 77, \$6.7 million in 1978 and roughly \$7.5 million in FY 1979. The Institute is continuing and expanding its support of research projects related to diabetes. In December 1976 the NICHD issued a Request for Applications for new research grants (RFA) concerning "Diabetes in Pregnancy: Effects on Mothers and Offspring." This RFA focused primarily on diabetes and fetal development; diabetes in pregnancy; contraceptive steroids and diabetes, and obesity and diabetes. Approximately 23 applications were received in response to this RFA. Research on pregnancy and diabetes was identified as an area of high priority in the NIH-wide Diabetes Program Announcement. In FY 1979 the NICHD issued an RFP dealing with "Genetic Linkage Analysis of Juvenile Diabetes" and so far has made one award in this area (\$194,500).

In addition, several new Major Research Program (MRP) grants have been initiated by the Institute in its efforts to implement a long-range plan to prevent complications in pregnancy due to diabetes and problems of infants born to diabetic mothers. Within a six-month period beginning July 1, 1977, four MRPs were awarded. These are multi-disciplinary projects funded originally for five years with an option for renewal for an additional five years. The MRP's resemble Centers in that they guide a concentrated research effort toward the solution of a major perinatal health problem and are multi-disciplinary in approach. Like Center grants they involve several component subprojects and entail a large commitment of research funds. The four MRPs in the area of diabetes will expend a total of approximately \$2,323,442 in their first year of operation.

The specific purposes served by the MRPs in diabetes are: (1) To undertake a comparative prospective longitudinal investigation of diabetic and normal pregnancies and to explore many aspects of the problem of diabetes in pregnancy and its effect on the immediate and long-term outcome of the offspring and the mother; (2) To develop tools which will permit the antenatal detection of abnormal fetal metabolism in diabetic pregnancies, identification of the mechanisms involved, and ultimately the prevention of aberrant development and brain damage by appropriate antenatal intervention; (3) To study abnormal carbohydrate metabolism from a developmental standpoint; and (4) To study the physiologic and psychologic development of infants of diabetic mothers.

The NICHD has sponsored or co-sponsored several diabetes-related workshops

including: Early Detection of Potential Diabetes; a Task Force Analysis and Recommendations for Public Action in Obesity, Studies of Somatomedin and Other Growth Factors, and

2. Sponsor a long-term clinical study on the effects of infant feeding on the development of obesity and diabetes.

The Institute funds 2 large studies which are concerned with the relationship of infant feeding to later onset of obesity and diabetes. One of the investigations deals with the effects of breast feeding and milk formulae of various compositions on infant growth and body composition during the first year of life. The other investigation deals with the precursors and determinants of obesity. This project is a consortium of seven longitudinal studies of child growth which includes analysis of dietary factors in infancy and childhood. Applications for this entire area were specifically requested in the NIH-wide Diabetes Program Announcement.

3. Expand training fellowships and special awards in the area of diabetes-related studies.

The NICHD and NIAMDD have developed a joint SERCA focusing on pregnancy, perinatal and pediatric aspects of diabetes.

National Institute of Neurological and Communicative Disorders and Stroke (NINCDS)

1. Increase support for basic research relating to peripheral neuropathy, stroke and other neural disorders prevalent in diabetes.

The NINCDS diabetes-related budget increased from a 1976 level of \$1.606 million to approximately \$1.85 million in FY 77, \$3.3 million in FY 78 and roughly \$3.9 million in FY 1979. The Institute specifically solicited applications for research in this area in the recently released NIH-wide Diabetes Program Announcement. The NINCDS, in collaboration with the Muscular Dystrophy Association, held an international workshop dealing with normal and abnormal nerve development; mechanisms of peripheral neuropathies; metabolic and diabetic neuropathies; and the biology of nerve; mechanisms of repair and regeneration. The NINCDS also supports research on cerebral vascular disease.

2. Expand training fellowships and special awards in the area of diabetes-related studies.

In FY 77 approximately \$356,000 were granted to 22 training fellowships and special awards in the area of neurobiology and muscle disease and it is hoped that such training might encourage trainees to pursue research in a variety of specialized fields including those related to diabetes.

National Institute of Dental Research (NIDR)

1. Increase its support for research efforts on the dental complications of diabetes.

The NIDR's diabetes-related research budget has increased from \$400,000 in FY 76 to \$728,000 in FY 77, \$823,000 in FY 78 and approximately \$1,059,000 in FY 1979. The Institute's intramural division supports a major research program on viruses and experimental models of diabetes mellitus. Progress in this important area of diabetes research by this, a leader among such laboratories in the international scientific community, has been impressive. Recently investigators in this laboratory have isolated a virus from the pancreas of a child with acute diabetes mellitus which was found to destroy beta cells grown in tissue culture.

National Institute of Allergy and Infectious Diseases (NIAID)

The NIAID diabetes-related budget in FY 77 was approximately \$2 million, in FY 78 increased to \$2.3 million and in FY 79 to roughly \$3.9 million. The Institute is expanding its support of research in the area of infectious agents (particularly viruses) and immunology as they relate to the onset of juvenile-onset type diabetes and in the area of allergy to insulin. Its intramural program supports laboratories researching the immunology of insulin. The Institute is exploring the feasibility and mechanism of support for an HLA typing serum bank.

National Institute on Aging (NIA)

The NIA's support of diabetes related research has grown from \$490,000 in FY 76 to roughly \$1.877 million in FY 1979. The NIA, through its Gerontology Research Center in Baltimore actively conducts an intramural program of research on diabetes related problems. NIA and NIAMDD are currently developing a SERCA on Diabetes and Aging.

NEW COOPERATIVE INITIATIVES AMONG NIH INSTITUTES AND
BETWEEN THE NIH AND THE CDC

1. In FY 1977 eight Institutes of the NIH issued a NIH-wide Program Announcement soliciting applications for research grants in diabetes and related areas spanning the range of diabetes-related topics. The first receipt date deadline was March 1, 1978, at which time the number of applications received by several Institutes was significantly greater than in the past, most notably the NIAMDD and NHLBI. This Program Announcement was revised and reissued in the summer of 1978 and the response has so far been encouraging.
2. The NIH issued a program announcement sponsored by eight Institutes soliciting applications for epidemiological research in diabetes. A similar announcement is being prepared soliciting applications for training awards in the area of diabetes-related epidemiology.
3. The NIAMDD and NHLBI have initiated a new manpower development award entitled Special Emphasis Research Career Award - Diabetes Mellitus: Cardiovascular, Endocrinologic and Metabolic Aspects, in order to encourage research in the early stages of their careers to pursue research in these areas. The goal is to create a pool of highly qualified investigators with expertise in the cardiovascular, metabolic and endocrinologic aspects of diabetes mellitus for a future role in research, teaching and clinical care. Program announcements and guidelines for the programs were released late in FY 77, 16 applications were received for review by the mid-February deadline and of these 7 awards have been made jointly by the two Institutes. The NICHD and the NIAMDD have recently developed a SERCA award focusing on pregnancy and perinatal aspects of diabetes. A similar award is being developed by NIAMDD and NIA.
4. Several NIH Institutes, the National Institute of Mental Health and the National Diabetes Advisory Board jointly organized a workshop on the behavioral aspects of, and need for, behavioral research in diabetes, held in Bethesda in October 1978. A national conference on this subject is anticipated for 1979. The NIMH and NIH are jointly developing a Program Announcement soliciting applications for research on the behavioral aspects of diabetes. That announcement will issued early in 1979.
5. The emerging and increasing coordination and cooperation between the CDC and the NIAMDD has been encouraging. In states where CDC Control Programs and NIH DRTCs co-exist, communication and cooperation has been effected. This includes the CDC Control Programs and NIH DRTCs in New York, Michigan, and Illinois and Missouri. Collaboration and cooperation have not only been effected between the CDC and NIH but between these two Federal agencies and the State Health Departments in these three states. The CDC works closely with the NIAMDD on the Data Group and the Clearinghouse.

6. Several DRTCs are considering collaboration programs with the Indian Health Service (HSA) for the training of health personnel needed in its new model diabetes care program. The DRTCs offer a unique resource for interaction between traditional biomedical research and health care delivery.

7. An Intra-NIH Diabetes Mellitus Coordinating Committee comprised of 12 NIH B/I/Ds has been established and has met on a regular basis since mid-1977 in an attempt to establish a central focus for the planning and coordination of diabetes programs within individual Institutes. The four new joint initiatives described above have been generated from this Committee. In addition, the Committee has addressed questions such as joint funding between Institutes, DRG Referral Guidelines, multidisciplinary workshops and diabetes budgets. The Coordinating Committee is currently attempting to develop an improved and more flexible data storage and retrieval system for NIH supported diabetes projects. The Director, NIH has recently expanded the responsibilities of the Committees.

THE NATIONAL DIABETES ADVISORY BOARD

In October 1976, the Congress established the National Diabetes Advisory Board (P.L. 94-562) with the mandate to:

- Review and evaluate the implementation of the Long-Range Plan to Combat Diabetes formulated by the National Commission on Diabetes.
- Advise and make recommendations to the Congress, the Secretary of Health, Education and Welfare, and the heads of other appropriate Federal agencies with respect to the Long-Range Plan and with respect to the guidelines, policies, and procedures of Federal programs relating to diabetes.
- Report its findings annually to the Congress and the Secretary.

In establishing the Board, Congress assigned it advisory rather than operational responsibilities.

Twenty-three members were appointed in early 1977 (12 public members and 11 representatives of Federal agencies) and the Board has since met at regular intervals. The Board submitted its First Annual Report in 1978 which summarized its assessment of the major developments in diabetes research, multidisciplinary centers, health care, education, control programs and in the private sector, and its priorities for the future in each of these areas. The Second Annual Report is currently in preparation and will be submitted to the Congress and the Secretary of Health, Education and Welfare in early 1979.

The National Diabetes Advisory Board serves as the National and sole focus for reviewing, evaluating and advising with respect to the entire Long-Range Plan to Combat Diabetes as it concerns diabetes research, treatment and education throughout all agencies of the Federal government, the public and the private sector. Furthermore it serves as a catalyst for coordination of effort among each component of the diabetes community.

The National Diabetes Advisory Board has since its inception been a source of support and valuable advice to NIH's diabetes programs and in particular to the Associate Director for Diabetes, and to the various Federal agencies responsible for implementing the Long-Range Plan to Combat Diabetes. The Board has contributed significantly to several NIH diabetes-related activities including:

- The creation of the Inter-Institute NIH Diabetes Coordinating Committee.
- The development with NIAMDD of revised and improved guidelines for the multi-disciplinary Diabetes Research and Training Centers.
- The development with NIAMDD, NHLBI and NICHD of two Special Emphasis Research Career Awards in Diabetes, one focusing on cardiovascular, endocrinologic and metabolic aspects and the other on the obstetrical, perinatal and pediatric aspects of diabetes.

- ° Support of NIAMDD's development of the National Diabetes Data Group and National Diabetes Information Clearinghouse and in the definition of their roles.
- ° A study of the adequacy of insulin supplies in the United States by an ad hoc Insulin Study Committee.
- ° Stimulation of interest in research on the behavioral and psychosocial aspects of diabetes and participation with NIH in the sponsoring and convening of a national conference on this subject in 1979.
- ° Fostering increased collaboration between NIH and other Federal agencies in diabetes related activities of mutual interest such as in the interaction between the DRTCs and the state control programs of CDC, and between the DRTCs and the developing Indian Health Service model health care projects.

In addition to these and other contributions to NIH programs the Board has contributed significantly to the activities of several other agencies and groups within the Federal, public and private sectors.

Senator SCHWEIKER. Thank you, Dr. Fredrickson. We will ask Dr. Foege to present his statement before we ask questions.

I want to say that you have presented an impressive list of accomplishments. I assume the research efforts you outlined have been funded in one way or another through NIH, is that correct? These are the scientific breakthroughs that NIH has had a hand in?

Dr. FREDRICKSON. I think that is basically true, that the root of each of these accomplishments or their extension thereafter has been NIH funded.

Senator SCHWEIKER. I think that is quite an impressive list. I commend you and Dr. Whedon and Dr. Salans because I know you all had something to do with the climate and program structure that helped produce these achievements.

Now we will hear from Dr. Foege.

Dr. FOEGE. Thank you. With your permission, I will summarize my statement.

In May 1977, after we received money for diabetes control programs, we advertised an RFP for demonstration projects. At that time we set out four long-term objectives. One was to reduce excess hospitalization of diabetics by 50 percent. Currently diabetics spend three to four times as much time in hospitals as nondiabetics.

Second, we set the objective of reducing coma deaths among persons with juvenile diabetes by 50 percent.

Third, reduce lower limb amputations by 10 percent and, fourth, eliminate excess perinatal mortality associated with pregnancies of diabetic women.

Ten States were awarded phase 1 contrast funds.

Senator SCHWEIKER. Would you repeat the last objective?

Dr. FOEGE. The last objective was to eliminate excess perinatal mortality.

Senator SCHWEIKER. Could you explain that in more detail?

Dr. FOEGE. Perinatal mortality includes stillborn infants and deaths among babies within the first week of birth. We know that perinatal mortality among infants of diabetic mothers is about four to five times that which occurs among nondiabetic mothers. We think much, if not all of this, is preventable with proper prenatal and postnatal care.

Ten States have completed phase 1 at an average cost of \$160,000 per State. These 10 States have accomplished the following as part of their phase 1:

They have established baseline morbidity and mortality data.

They have established baseline data for care resources.

They have determined the major reasons for the increased morbidity and mortality observed among their diabetic populations.

They have established an advisory group. Lastly based on these efforts they have developed an intervention plan.

As part of this first phase the States have obtained new data documenting previously unknown or assumed levels of morbidity. Three pieces of information are of special concern.

One, they have found that amputations occur at the rate of about 7 lower limb amputations per 1,000 diabetic per year, which is about 35 times the rate that would be expected in nondiabetics. If this can be extrapolated to the Nation, it means that there are

about 34,000 lower limb amputations per year with hospital costs alone of \$100 million.

The second interesting and very significant finding is that they have found that the rate of ketoacidosis is about five times as great for people who are eligible for medicaid as for other individuals.

Third, it has been found that the readmission rate to hospitals is about six times as great for persons eligible for medicaid versus people who use Blue Cross/Blue Shield.

The States listed the following four factors as most commonly contributing to diabetes, morbidity. Fragmented and uncoordinated effort among groups concerned with diabetes. Second, inadequate patient education. Third, inadequate professional education. Fourth, inadequate data bases with which to measure convincingly the magnitude of the problems and improvements brought about by intervention.

Nine of the ten States have now been funded for phase 2. The 10 State will be funded in March, at an average cost of about \$265,000 per State per year. In phase 2, State intervention activities include developing educational programs for patients and professionals and a followup system to reach diabetic patients in their homes.

One State has planned an epidemiologic study of hospitalization for ketoacidosis to find out whether there are particular high risk groups, and if so, why.

An integral part phase II will be evaluation. Initially evaluations will be in terms of process, for example whether education programs are developed as planned and if so how many persons attend. Eventually—after 2 or 3 years—the States will be looking at such outcome measurements as hospitalization, ketoacidosis, amputations and perinatal mortality.

In addition to the contracts with the States, we have been working in a number of other areas. We have worked with the ADA, NIAMDD, and other groups to hold, a workshop on screening in diabetes. We have been working with the Indian Health Service as they develop their five model programs. The Indian population has a higher rate of diabetes than the remainder of the American population and special efforts are now underway to reduce morbidity and mortality among this group.

Senator SCHWEIKER. How does the rate among Indians compare to the rate among black. I know the black population has a higher incidence, too.

Dr. FOEGE. The prevalence rate among Indians is even higher. For Indian populations as a whole, it is about twice that of non-Indian population. But there are particular tribes where the prevalence rate is as high as 20 percent. In at least one tribe 45 percent are reported to have diabetes. It is a very significant problem in the Indian population.

Senator SCHWEIKER. Has your work proceeded far enough that you are able to isolate any genetic or environmental factors that could account for the high rate as yet?

Dr. FOEGE. We have not. But I think this fits in nicely with the testimony of Dr. Fredrickson regarding the possible associations between HLA antigen typing, other genetic backgrounds, and viral infections that may lead to a high prevalence of diabetes in certain groups.

We have also been working with other States that do not have contracts. We responded to requests from 15 States for consultations in the last year. We have been working with the American Hospital Association and have in the past year developed a patient teaching manual. We have developed a contract with the Rand Corp. to determine measures that can be used to evaluate educational programs in terms of the best outcome. The CDC Laboratory has been working with the National Eye Institute in their study of eye complications and with the National Center for Health Statistics on the diabetes segment of the Health and Nutritional Examination Survey. In the very near future we will be signing contracts with two more States.

We believe that the diabetes program has provided a prototype for how one introduces public health principles to chronic disease control.

I believe this is one of the most exciting recent public health programs that CDC has have been involved in, and I am optimistic that we are on the way to demonstrating reductions in morbidity, mortality, and costs.

That concludes my statement, Mr. Chairman. I will be happy to answer questions.

Senator SCHWEIKER. Let me say that I feel CDC has done an outstanding job in this area. When the proposal for State Diabetes programs first came through my legislation, it was obviously just an embryo of an idea. I feel CDC not only picked up the idea, but has worked to perfect it in a very critical, sophisticated way. I am delighted to see what has been accomplished with rather limited resources, and also with the fact that you have made the diabetes program a classic case of what can be done with chronic disease control.

I want to compliment your leadership and the CDC, because I think CDC has done an outstanding job with very limited funding in this area.

Dr. FOEGE. Thank you very much.

[The prepared statement of Dr. Foege follows:]



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
CENTER FOR DISEASE CONTROL
ATLANTA, GEORGIA 30333
TELEPHONE: (404) ~~333-3311~~ 329-3311

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STATEMENT BY

WILLIAM H. FOEGE, M.D.

DIRECTOR, CENTER FOR DISEASE CONTROL

on

DIABETES CONTROL PROGRAM

before the

SUBCOMMITTEE ON HEALTH AND SCIENTIFIC RESEARCH

U.S. SENATE

FEBRUARY 26, 1979

Mr. Chairman, and members of the Subcommittee, I am pleased to appear before you to discuss the Center for Disease Control's diabetes control program.

As you know, the National Commission on Diabetes in its report to Congress on December 10, 1975, recommended establishment of a series of state or more locally based diabetes control programs under the Center's stewardship. In making the recommendation, the Commission recognized that the effectiveness of health services provided by divergent care sources to patients with diabetes is often diminished because of inadequate planning, coordination, and evaluation of effort.

The Commission envisioned that the systematic application of public health disease control methods to diabetes through CDC-sponsored programs would improve coordination among health agencies and organizations at the local level. These programs would also assist in compiling data about needs, services and resources for use locally and nationally. In response to the Commission's recommendations, the Congress has appropriated resources since 1977 to support this CDC demonstration effort. I would like to review the background for this CDC diabetes control program and to share some of its accomplishments since 1977 with you.

First, the use of diabetes control in the public health setting should be distinguished from the definition of "control" by the medical specialist who uses the term in relation to blood sugar levels for individual patients. In public health, diabetes "control" means achieving the lowest possible levels of diabetes morbidity and mortality in a community applying current scientific and medical knowledge about the management of the disease.

Planning, evaluation, epidemiology and surveillance are time-tested public health disease control techniques. Their application to diabetes, coupled with interventions tailored to current knowledge of the management of diabetes, can be expected to result in reduced morbidity and mortality. These same techniques have achieved a marked reduction, and in some cases eradication, of such diseases as smallpox, poliomyelitis, measles and tuberculosis. While far more modest, the following long term goals were established by the CDC program at the outset of the diabetes control demonstration projects in order to monitor their progress:

- (1) Reduce excess days of hospitalization among persons with diabetes by 50% (5.5 hospital days per year for diabetics versus 1.5 hospital days per year for nondiabetics)
- (2) Reduce by 50% deaths associated with diabetic coma in juvenile diabetics
- (3) Reduce lower extremity amputations among persons with diabetes by 10%
- (4) Eliminate the 10-fold excess in perinatal mortality associated with pregnancies of diabetic women

These goals are based upon studies reporting that such results are attainable where persons with diabetes receive appropriate instruction in self-care and have ready access to high quality care by physicians and other professionals who can assist diabetic patients with the proper management of their disease.

To accomplish this, the diabetes control program staff has devoted its resources to three major activities since the program's inception: 1) procurement and technical support of 10 state-based

diabetes control demonstration project contracts; 2) coordination and collaboration of these efforts with those of other Federal, state and local agencies and groups; and 3) CDC-based epidemiologic studies and special evaluations.

Diabetes Control Demonstration Projects

A Request for Proposal (RFP) for the community diabetes control demonstration project contracts was released on May 24, 1977. A total of 29 states responded to the solicitation, which was sent to the health departments of the 50 states, the District of Columbia, and the Commonwealth of Puerto Rico.

In the first or planning phase of the contract, each state was required to collect and assess baseline morbidity, mortality, and care resource data; to identify major problems in terms of excess diabetes morbidity and mortality; to establish an advisory group and framework for improving coordination among community resources. Based on these efforts, the states would develop an intervention plan for improving diabetes control that would be approved by CDC for implementation during the second phase of the contracts.

On September 28, 1977, contracts were awarded to the state health departments of Colorado, Georgia, Illinois, Maine, Michigan, Mississippi, Nebraska, New York, Rhode Island and South Carolina. These states comprise 25% of the U.S. population. The project states were also assigned a CDC diabetes control advisor to monitor performance and *PROVIDE* TECHNICAL AND administrative guidance.

The 9-12 month planning phase has been completed in all states, at an average cost of \$160,000 per state.

A report, summarizing baseline morbidity, mortality, and care resource data collected in the 10 states during the first year's activities, was prepared and disseminated in November 1978 to all state health departments and to other components of the diabetes community including the Diabetes Data Group, the Diabetes Mellitus Coordinating Committee, and the National Diabetes Advisory Board. Many findings contained in this report were previously unknown or assumed but not confirmed.

- In three states, for example, the annual rate of amputations among patients with diabetes was 7 per 1000. The average hospital cost of each diabetes-related amputation was reported at about \$3000. These data, when applied to the entire United States, indicate that over 34,000 diabetes-related amputations occur each year with hospital costs alone of some \$100,000,000.
- Compilation of data from seven of the states reveals that the rate of diabetic ketoacidosis is approximately five times greater for diabetes patients receiving Medicaid payments than those paid for from other sources.
- Georgia and Nebraska data suggest that the annual readmission rate is six times greater for Medicaid eligible diabetics than for diabetics insured by Blue Cross/Blue Shield, and data collected from three pilot project areas in Illinois show that the average number of hospital days per person per year is three to four times greater for diabetics than non-diabetics.

Although these findings are preliminary and must be further refined, they are helping us to define the nature and extent of the public health problem and will enable use to devise appropriate interventions.

As part of the planning process, each project state was asked also to identify those factors which contributed to the problems and resulted in excess diabetes morbidity and mortality. The most common factors specified by the states were:

- (1) fragmented and uncoordinated efforts of responsible and interested groups;
- (2) inadequate patient education;
- (3) inadequate professional education, and
- (4) absence of adequate morbidity and mortality data.

In summary, Phase I of the demonstration projects enabled the states to focus upon diabetic populations having the highest rates of hospitalization, ketoacidosis, amputation, and other complications of diabetes and to tailor a plan for appropriate interventions during phase II for improving the health status of those populations.

In Phase II, for example, third party payors in Maine are involved in the planning, implementation, and evaluation of a hospital-based patient education and follow-up system. Nebraska is conducting an intensive education program using existing home health agencies to extend patient education into the home and to supplement hospital-based education programs. In Illinois there is a cooperative venture between the state health department and the NIH-sponsored diabetes research and training center at St. Louis' Washington University to provide a quality diabetes education program to hospital-based nurse educators. A Rhode Island project is an epidemiologic study of ketoacidosis in order to determine appropriate interventions to reduce the frequency of this complication among juvenile diabetics.

New York is implementing regional model programs to demonstrate the effectiveness of comprehensive patient education and the team treatment approach to reducing adverse clinical outcomes related to diabetes.

The Phase II implementation plans of 6 states were funded in September 1978, 3 in January 1979, and the 10th will be funded by the end of this month. The average annual cost of the plans funded to date is \$265,000. Of the funds obligated to date for Phase II, 44% is for specific interventions including patient or professional education, 21% is for improving the epidemiology and the quality and usage of data by the state projects, and the remaining 34% is committed to continued support of the state advisory coordinative efforts and the surveillance, planning and evaluation functions.

All states have built-in evaluation components as an integral part of each project. Evaluation will center about four health status indicators as measures of project effectiveness and progress toward the long term goals: 1) rates of hospitalization among diabetics; 2) rates of DM ketoacidosis hospitalization admissions; 3) rates of amputations of lower extremities among diabetics; and 4) perinatal mortality rates associated with diabetes in pregnancy.

During the first year of implementation, evaluation will of necessity center about process rather than outcome measures. Furthermore the lack of adequate morbidity and mortality data in some of the states necessitates the use of interim evaluation measures while better data are being developed. The number of courses provided or persons trained, content of education programs, or number of visits patients make to a care center are examples of indirect process measures. Our intent is to

relate these interim evaluation measures to changes in disease outcomes and to document whether persons with diabetes, as expected, are better off with than without diabetes mellitus project interventions.

National Collaborative Activities of CDC

Administrative and technical support of the state projects have comprised only a portion of the CDC diabetes effort. In addition, CDC has pursued an active role at the national level in working with the various other organizations and groups recommended in the Long Range Plan to Combat Diabetes. These include the National Diabetes Advisory Board, Diabetes Mellitus Coordinating Committee, the Diabetes Data Group, the Diabetes Information and Education Clearinghouse, and the NIH Research and Training Centers (DRTC). The health departments of the three project states (Illinois, Michigan, and New York) with Diabetes Research and Training Centers are coordinating their activities with these DRTC's. The Rhode Island project is also collaborating with an NICHD-funded Center at Brown University in a statewide study of diabetes-related, perinatal mortality.

In another cooperative effort, CDC sponsored with NIH and the American Diabetes Association, a diabetes screening workshop in Atlanta in May 1978. At this workshop participants evaluated the present status of diabetes screening and developed recommendations for community-based diabetes detection activities, particularly in regard to other funding priorities for a community's diabetes program.

In addition, CDC's Diabetes Control Program is assisting the Indian Health Service (IHS) with the development of the 5 Model Diabetes Control Centers funded by Congress in 1978. This week an interagency

agreement between CDC and IHS was completed assigning a CDC diabetes public health advisor to the IHS project headquarters in Albuquerque. The assignee, drawing upon the first year of CDC's experience with the state projects, will assist the IHS project director with program planning, implementation, evaluation, and administration.

Other CDC activities have included on-site consultations to health departments of 15 non-contract states which have requested epidemiologic and planning assistance in establishing a diabetes control program. Through the Bureau of Health Education, CDC has supported contracts with the American Hospital Association to determine among other items the extent of hospital-based diabetes education programs and with the Rand Corporation to define measures that can be used to quantify behavioral changes as an effect of patient education. Through other interagency agreements between the National Center for Health Statistics and the National Eye Institute of NIH, and the CDC Bureau of Laboratories, we are providing laboratory support for the diabetes segment of the Health and Nutrition Examination Survey and a study of diabetic retinopathy.

Epidemiological Studies and Special Evaluations

Epidemiological studies and special evaluations are an integral part of state projects. Most of these activities have evolved in response to special requests or problems from the demonstration projects. In Mississippi, for example, CDC staff participated in design and conduct of a study comparing underrecording of diabetes mortality

on death certificates as well as a study of hospital admissions for ketoacidosis and amputations. A community-based program in Illinois for the screening of pregnant women was identified which provides an available data base for evaluating the efficacy of diabetes screening during pregnancy.

Future Plans

With the FY 1979 diabetes appropriation, CDC will award 2 new state contracts. These will be funded at about the same level and managed similarly to the initial 10. A diabetes control public health advisor will also be assigned to monitor the contract and provide technical assistance. The RFP for the new contracts was mailed in December 1978 to those states presently without diabetes projects, the District of Columbia, and the Commonwealth of Puerto Rico with a response deadline of March 16. Despite the small number of anticipated new contracts, to date 12 states (California, Maryland, Minnesota, Missouri, New Jersey, Ohio, Pennsylvania, Texas, Utah, Washington, Wisconsin, West Virginia) and the District of Columbia have formally stated their intention to respond.

The diabetes effort with the project states is providing a model that can be used by the states for developing prevention programs. The state projects in diabetes also assist the states in developing their staff capacities for epidemiology, planning, evaluation, and coordination. These efforts, combined with the use of morbidity and mortality data to plan epidemiologically-sound intervention activities, will become an integral part of effectively managing a variety of other disease control and prevention programs.

This concludes my testimony. I shall be glad to address any questions which you have.

Senator SCHWEIKER. Now, we will go to some questions.

Dr. Fredrickson, I understand you have formed your own NIH Diabetes Coordinating Committee. I guess that is part of what you call your trans-NIH diabetes program?

Dr. FREDRICKSON. Yes and no, Mr. Chairman. The Diabetes Coordinating Committee for NIH was formed in 1977, as a subcommittee of the interagency Diabetes Mellitus Coordinating Committee which encompasses several Federal agencies. We have found that Committee to flourish, but what we have done is to add to the nature of that coordination effort a strengthened role at the NIH for the Associate Director for Diabetes and Endocrinology and Metabolic Disease, Dr. Salans. We have strengthened his role with respect to coordinating diabetes programs of all the Institutes at NIH, and have made certain, above all that he has access to one on a regular and continuing basis. I view this kind of coordination as essential and we have now given Dr. Salans a more specific charge for overseeing all the activities at NIH relating to diabetes research. We have strengthened his role somewhat in this move within the last month.

Senator SCHWEIKER. What does this new structure do? Why was it needed in addition to the already existing Diabetes Mellitus Coordinating Committee? You have answered part of that question, but I want to ask it for the record.

Dr. FREDRICKSON. I think it does several things, Mr. Chairman. The role which Dr. Salans had as Chairman of the NIH Diabetes Coordinating Committee did many of the essential things that are necessary to ensure that a person have as much awareness as is generally possible at NIH regarding the activities within many Institutes relating to a single problem. But here we have made him responsible also for the information which is assembled from the various Institutes. It is he who will have the last word about data with respect to the Institute activities.

We will thus give him a role which has previously been carried out by central NIH budget officers as opposed to a program manager. We have also asked him to increase activities with regard to information and to oversee programs with respect to gathering epidemiologic data. This will provide, then, a strengthened information resource and a focal point for contacts with other agencies and organizations.

Perhaps, above all, I have made it very clear to all the Institutes that I do expect regular input from Dr. Salans which will include his own views to me of where there may be gaps and that I will hold him responsible for making certain that the Director of NIH is aware of opportunities for diabetes research in any of the biomedical sectors covered by other Institutes. I think with his judgment and knowledge of the field and my powers of persuasion, we can together be a very important instrument for maintaining program balance and moving the cutting edge of knowledge forward as far as possible.

Senator SCHWEIKER. Do you think we should continue both coordinating committee groups, or should we phase one out, in your judgment?

Dr. FREDRICKSON. I think it is essential that we maintain the NIH Coordinating Committee. The Interagency Committee is neces-

sary to have in place, but it is more of a mechanism for exchanging information than it is for developing a program in diabetes research.

Senator SCHWEIKER. You are saying they serve two different purposes?

Dr. FREDRICKSON. Yes; they do.

Senator SCHWEIKER. Last month you wrote a memo describing how you wanted to organize the trans-NIH diabetes program. What you wrote is reflected in my new diabetes bill. One of the points you made in your memo is that the Associate Director for Diabetes, with his expanded responsibilities, would be given additional resources.

What additional resources have been provided so far? What did you have in mind?

Dr. FREDRICKSON. What I had in mind, Mr. Chairman, is that I would like to provide up to three positions to this office to enhance the activities that Dr. Salans is intending to undertake with respect to this new role of coordination and also improve the coordination and data-gathering resources that he hopes to set in place. Thus far, we have not been able to provide those positions to the Institute for that purpose. I hope this year, at least, one new position may be added. We are at a time when positions indeed are scarce for all the many needs that we have for them.

Senator SCHWEIKER. I realize your control of staff resources is somewhat limited by OMB-imposed ceilings on positions. This is a battle we have to fight with OMB in the Appropriations Committee. I appreciate your concern.

Dr. Fredrickson, what does it mean when an institute becomes a bureau? What factors go into the administrative decision to make this kind of organizational change?

Dr. FREDRICKSON. Two of the Institutes, actually three in a sense, if we include the National Library of Medicine, of the NIH family are bureaus, Mr. Chairman. The decision is one that can be made by the Director of NIH with the concurrence of the Department.

Basically what happens is that it allows for a step up, an escalation of titles, and the formal opportunity to create so-called divisions. Division structures then emerge in bureaus as they are not in the standard table of organization for institutes.

What happens also is the opportunity to increase the grade of a few individuals within the administrative structure, a problem which is a double-edged sword because it may enhance the capacity of the Institute—it may—but it also gives that bureau a different competitive position with respect to its sister Institutes and possibly for key administrative people.

But, as you may know, Mr. Chairman, we have examined over the last several months the question of whether the NIAMDD should be a bureau, and I came to the conclusion that it was a decision that would result in unhappiness with respect to the rest of the NIH family. Questions would arise about what would be the next bureau, how soon that should follow. But, more importantly, I fail to find in my analysis that there would be the true functional enhancement that one would like to see in taking this step with respect to conversion of the NIAMDD to a bureau.

Senator SCHWEIKER. One thing that occurs to me, and I understand the problem you have outlined in terms of the competitive positions of the different institutes, but it occurs to me that maybe we should set some dollar figure as a criterion, so that when an institute grows to a certain point in terms of dollar expenditures it would become a bureau. That way you are not singling out any particular institute. You are simply realizing the facts of life in terms of what the institute's growth has meant in terms of managerial and administrative problems that are a little heavier than those of some of its peers. Would it be feasible to consider the total dollar volume activity of an institute in deciding bureau status, since dollar volume is a rough indicator of the level of managerial and administrative responsibilities, which I assume is one of the reasons for making an institute a bureau?

Dr. FREDRICKSON. I would think, Mr. Chairman, that is a reasonable suggestion for the kind of criterion or standard that might be used, if we could be convinced that the conversion of an institute to a bureau really did make that much difference in ability to handle its programs more effectively. I must question that after a number of years of studying this very problem, I have been in bureaus and I have been in institutes, and I am not convinced they were markedly different in their ability to handle programs on the basis of that designation. I think it would be more desirable if we were able to convert offices to divisions without the need to create bureaus. I have actually been exploring that administrative move because there is some enhanced value to the title of division.

Senator SCHWEIKER. Do you need legal authority to do that? Would you like legislative authority to do that?

Dr. FREDRICKSON. I do not believe I need it, Mr. Chairman. In fact, one of my other activities today is to follow up on some leads I have already set in motion to see whether that is possible without any further legal authority. I should be glad to reserve the opportunity to come back were I to find that useful.

Senator SCHWEIKER. How would you view the establishment of Division of Diabetes, Endocrinology, and Metabolic Diseases within NIAMDD?

Dr. FREDRICKSON. I would do it today if it did not require us to create a bureau.

Senator SCHWEIKER. As you see it, that gives you all the advantages of the change without many of the disadvantages involved in creating a bureau?

Dr. FREDRICKSON. That is correct.

Senator SCHWEIKER. I might ask Dr. Whedon, would you like to comment on this? I realize you are in a difficult position. I know we are among friends and can be candid.

Dr. WHEDON. I am in a difficult position. Frankly I do think that Dr. Fredrickson in his opening remarks and answer to the question you have just raised did cite a number of the advantages that we see within our Institute from elevation to bureau status. But I think the keyword is cooperation within NIH, and we do not want to urge any precipitous action. I hope this will ultimately be worked out.

Senator SCHWEIKER. I know Dr. Fredrickson has been cooperative in many of these areas. I appreciate that and I agree that intra-NIH cooperation is something we want to keep on an even keel.

I would like to ask you a few more questions.

Dr. Whedon, how is the NIAMDD Advisory Council now organized, in a nutshell?

Dr. WHEDON. The act of 1972 which lengthened the name of our Institute to include the words Digestive Diseases also required that we have a subcommittee or special committee of council for digestive diseases. This occurred at the time when we were gathering steam, so to speak, in our budget responsibilities and our responsibilities for arthritis and diabetes, and we decided that we would proceed and reorganize our Institute into four main groupings of our 10 program areas, groupings called clusters, and that we would have an associate director in charge of the extramural activities of each of these four clusters, and that we would informally reorganize our council so that we have actually in being, and have had now for about 3 years, a subcommittee of council for each of our four main groupings.

Senator SCHWEIKER. Would you list those four groupings for the record?

Dr. WHEDON. The one that was legislatively set up in digestive diseases covers nutrition as well. We have grouped together diabetes, endocrinology, and metabolism. The third grouping is arthritis, bone, and skin diseases. The fourth is kidney diseases, and with it, in a way that is not unusually logical but nevertheless workable, hematology. So we have hematology and kidney diseases as our fourth. We have a subcommittee of council for each of these four groupings.

Senator SCHWEIKER. Dr. Fredrickson, what is your thinking about the advisability of providing a very limited number of stipends through the diabetes research and training centers as my bill proposes?

Dr. FREDRICKSON. Certainly, Mr. Chairman, I believe that research, both clinical and laboratory training in research is a very important element in all of our programs. I think that training in diabetes is highly desirable. I would hope that and presume that this stipend authority would also be awarded under the regulations of the NRSA for I feel creation of a thicket of different training authority at NIH may lead to enormous confusion especially with regard to the setting up of special categorical training areas under any other means.

Senator SCHWEIKER. Under existing law, we already require the DRTC's to have training programs. The approval processes for the centers and the National Research Service Awards take place at separate times and involve separate reviewing bodies, so that requiring training stipends to come through NRSA gets to be an administrative problem, does it not? It sounds like it could create something of an administrative nightmare, I would guess.

Dr. FREDRICKSON. I think there is also the other side of the coin, Mr. Chairman. I believe we may have some nightmarish problems on the other side if they were to be different authorities. If I might, I would just add one comment about training in general.

We currently are heavily engaged in attempting to create the most integrated kind of training program possible at NIH so that we have a total NIH training fabric which is not simply the patchwork of different institutes or categorical programs. I feel this is important because I think that we are at this time of austerity going to have to be examining extremely carefully program by program and position by position the allocation of training funds for pre- and post-doctoral training. So that again I do plead for the institution of any new training programs we have done in a way that will enable us to integrate them into this total NIH program.

Senator SCHWEIKER. Is there a way to do it so that we can meet the objectives of the bill in providing stipends and still meet your NIH program objectives? I am not necessarily against doing that. I am questioning whether there might be a way to do that to mutual satisfaction.

Dr. FREDRICKSON. I think what we need to consider is, first of all, the opportunity to adjust the number of positions that might be funded by these centers for this purpose against the total of the training activities of NIH. I think we need to do that for every one of our programs, particularly in these times of austerity. I would say that this, from an administrative standpoint, is the most important. I think we also need to consider whether we could use the NRSA authority for the training you propose in the sense that it will certainly afford less confusion to the community at large. But I would have to consider, Mr. Chairman, whether we might be able to offer you some compromise or means of achieving both objectives.

Senator SCHWEIKER. I wish you would consider it further. I recognize your concerns, and I think there might be a way to work something out that would be satisfactory to you and also meet the objectives of my bill.

When the National Diabetes Advisory Board was first proposed, there was some fear expressed that it would complicate the work of NIH officials, particularly Associate Director for Diabetes.

How has the Board worked? Dr. Salans, do you feel it has been a help or hindrance to you in your job as Associate Director?

Dr. SALANS. Senator Schweiker, I feel that at all levels in which I have had an opportunity to work with the Board and part of the Board, there has been a most positive and helpful relationship.

Senator SCHWEIKER. Do you feel it has in any way circumvented or supplanted the management prerogatives and authority of NIH, specifically NIAMDD and diabetes program officials?

Dr. SALANS. No; I feel, in fact, the Board has been very useful in advising not only my office but other components of NIH and other Federal agencies. It has been a very useful positive part of the long-range plan.

Senator SCHWEIKER. Do you feel there is a need to change the Board's membership as this bill proposes or otherwise? Would you or Dr. Whedon like to comment on that?

Dr. WHEDON. Well, the changes that I understand are proposed in the legislation would be to add the Director of the National Institute of Child Health and Human Development and to remove the representative of the Secretary of Defense.

I think these are relatively minor changes in membership. I would have no comment except that I think it is certainly appropriate for the Director of Child Health and Human Development to be a member of the Board.

Senator SCHWEIKER. Do you have any suggestions beyond that?

Dr. WHEDON. I have not thought deeply about this. I do not have any other suggestions. Perhaps Dr. Salans does.

Dr. SALANS. No; I think the composition is reasonable as it is, and the more flexibility that the Secretary has in appointing members, without concern as to whether there is expertise in a particular area of diabetes or science, the better it is.

Senator SCHWEIKER. I might ask any of the three of you, Dr. Fredrickson, Dr. Whedon, or Dr. Salans, whether you have any other comment on the bill that we have not covered what is in it or not in it?

Is there anything else you think we should focus on that I have not asked about?

Dr. WHEDON. I would just like to amplify my answer to a question you asked me a few moments ago about committees and subcommittees of the Council. That is a section in the proposed bill.

I think we should go on record as opposing it on the basis that we really already have or are doing what is proposed in the bill. We have four committees of Council. Further, we do not know that the structure and responsibilities of this Institute will always remain the same. So it would be more flexible for us if we did not have written in law four specific committees of the Council.

Senator SCHWEIKER. Dr. Fredrickson, do you have any other comment?

Dr. FREDRICKSON. Mr. Chairman, the administration has not had an opportunity to study this bill, and it does not have official position.

I would like to give one or two impressions of my own.

Senator SCHWEIKER. Please do.

Dr. FREDRICKSON. I must preface it by saying that I think all of these are commendable moves for commendable objectives. Certainly nobody in my view, Mr. Chairman, in the Congress has done more than you to see that we have reached this current stage of illumination and expansion of the diabetes program. We, as well as the constituents who are particularly interested in this disease, have reason to be grateful for it. I say this because I do want to emphasize that I think we have achieved a great deal without certain of these elements appearing in the statute. There is merit to the argument that Dr. Whedon has made about flexibility. To be more specific, I would find it difficult to have an Associate Director for Diabetes named by law when I think we have already achieved virtually everything which that position possibly could represent, and which I think is intended to be represented in the proposed statute. This has been done without the legislation itself.

I say this because I fear there may be a rash of proposals for Associate Directors to be created for a variety of other conditions or diseases. I certainly would like the flexibility to experiment with the new role of Dr. Salans, perhaps thus even enhance it. Perhaps we might even go beyond the authority of the proposed law when I see that the dynamics of interaction between and among the Insti-

tutes will allow it, but I do think it would be of great advantage to us to have the opportunity to achieve the objectives here without statutory language.

Senator SCHWEIKER. Dr. Fredrickson, I understand your concern but, of course, arthritis and digestive diseases already have associate directors named by law.

Dr. FREDRICKSON. Yes. But I think you have it already in diabetes. In the sense that you have it, I was seeing here an enhanced role or change in that function as represented by current designations.

Senator SCHWEIKER. Let me give some historical background, for the record. When my legislation on this issue first came up, the position of Associate Director for Diabetes, was mandatory. I yielded to make it discretionary in conference between the House and the Senate. This was 3 or 4 years ago.

I just wonder if the program and position have not come of age enough so that the Associate Director for Diabetes should take its place alongside of arthritis and digestive diseases as a permanent feature.

Dr. FREDRICKSON. Well, certainly, in a functional sense, it has arrived. It is there already, Mr. Chairman, without the statutory language. I suppose, Mr. Chairman, at the risk of saying too much, I do have trouble with a seven letter acronym NIAMDDD.

Senator SCHWEIKER. Can you suggest a way to put Diabetes in the name without seven letters?

Dr. FREDRICKSON. I have thought about this myself and so have the Institute Directors. There has been a great variety of proposals. None of them has an esthetic quality that was overwhelming. I do not know of a way to do it except by deletion, and obviously there is a great hazard and some loss to be incurred if that were to be the way of adding Diabetes to the name.

I do understand that. And I have not found a satisfactory solution.

Senator SCHWEIKER. Well, you will notice that my bill adds Diabetes in a way that preserves the acronym exactly the same. We are adding another disease to the title, but we still keep the NIAMDDD. It is pronounced the same. I could see that if we threw a monkey wrench into it and made it unpronounceable, that might cause some problems, since in most of our work we use the abbreviation of the Institute's name anyway.

Is the change I've proposed really a handicap?

Dr. FREDRICKSON. Well, it is all in one's point of view, Mr. Chairman.

Senator SCHWEIKER. Dr. Salans, what do you think are the most promising leads for future diabetes research? What areas should we be looking at, and directing our resources to, based on your experience?

Dr. SALANS. I think, Senator Schweiker, that Dr. Fredrickson in his opening remarks, and in the material that he provided for the record, has highlighted those areas. The exciting advances he described in the area of recombinant DNA technology not only has potential for synthesizing or producing insulin for diabetics, but also for a host of other hormones and proteins relating to other serious conditions.

At the same time I think that technology may in fact permit the opportunity to study gene regulation of cell function; if I might be permitted to be somewhat loose, to study the so-called diabetic gene.

A second area that he described concerns the hereditary aspect of the various forms of diabetes, and our ability now to decipher some of the genetic patterns of inheritance of different types of diabetes. Such advances hold great potential for providing insight into the possibility that certain genetic patterns predispose individuals to susceptibility to factors in the environment which may produce clinical diabetes, such as infections with viruses, or perhaps other toxic agents. There is a need to relate those genetic patterns to potentially causative agents for certain types of diabetes.

Dr. Fredrickson described to you an area of research I believe is a major advance of considerable importance, that having to do with the area of pancreatic islets transplantation. As you know the major problem has not been with the technology of transplanting islets from one to another animal and improving the diabetes, but maintaining those islets in the new animal for a long enough period of time without immunologic rejection.

Dr. Paul Lacy at Washington University, St. Louis, has just recently demonstrated that by manipulating the system with which he works in the rat, that he can transplant pancreatic islets from one strain of rat to another without undue immunologic rejection over a long period of time. The potential that this holds in the future is considerable.

The mechanism by which insulin produces its action on cells, how it gets the cell to use glucose, how it keeps the cell from releasing its stored energy, is another area where there has been a great deal of progress over the last few years. Researchers now are able to study the specific components of the cell through which insulin produces its effects, and results in the metabolism of glucose.

I think these, as well as some clinical advances, such as those focusing on the factors that are responsible for the chronic complications of diabetes are areas of tremendous potential and great excitement.

We are just beginning to make progress in this area. I am very confident that we will be able to make more progress. What I would like to stress finally is that progress in these areas in diabetes impact not only on diabetes, but on processes which are fundamental to all diseases, or to most diseases that man suffers. I think progress in these areas in diabetes has already and will continue to have further impact on other aspects of human disease.

Senator SCHWEIKER. I would like to ask either Dr. Whedon or Dr. Salans to respond to the next question. We hear a lot about the problem of attracting clinical investigators into the research field. Does this pose special problems for the diabetes effort?

Dr. WHEDON. Well, it is my feeling that it is a general problem across all of the areas of our responsibility. I suspect it is a problem for the other Institutes as well. There is the matter of lack of stability from year to year in the funding of research.

We particularly have a lack of stability in the whole training support mechanism by authorization and by budget support. This is discouraging to young men and women coming through medical school, getting their clinical or Ph. D. training, and electing to have a career, a lifetime career, in developing the new knowledge that we all need to have a better product with which we can improve the care and management of disease.

So it is a general problem, but diabetes has certainly shared in it. We have made special efforts. Many new training programs that Dr. Salans can describe have been introduced by us at the suggestion mainly of Dr. Salans, but with the advice and help of the advisory board. These I think stand to help the situation of training within diabetes substantially.

Senator SCHWEIKER. What percentage of the diabetes research budget is devoted to research training, and how does this compare with other fields of research? Do any of you have the figures on that?

Dr. SALANS. The overwhelming majority of funds that NIH expends on diabetes is directed toward research, and even more specifically toward the support of research grants. A relatively smaller portion of those funds go for research training and an even smaller proportion of it goes to the support of activities referred to as information transfer or education of physicians, patients and public.

At the NIAMDD, for example, roughly 90 percent of the funds expended on diabetes go for direct support of investigator initiated research grants, while 5 to 10 percent support training and manpower development.

Dr. WHEDON. I would just add that in looking quickly down the table for the fundings of our programs, that just looking at each of our major program areas—arthritis, diabetes, and digestive diseases, and kidney-urology—the figure for training is about 10 percent of the figure for research grants. There is a little variation from program to program, but not very much.

Senator SCHWEIKER. Let us turn to CDC, Dr. Foege, has the State diabetes control project program been successful in generating interest and resources from outside the Federal Government?

Dr. FOEGE. I believe the answer to that is definitely yes. Last year we provided about \$1.3 million to States for the contracts or in other ways. We have noted at least \$1 million that the States themselves have put into this. We think we are approaching now \$1 from the State for every dollar from the Federal Government.

Senator SCHWEIKER. That is very impressive. What will be the effect of the President's budget proposals on the CDC diabetes effort?

Dr. FOEGE. As you know, I am committed to seeing this effort continue, because I believe it is a demonstration beyond diabetes. We would hope, as we have done in the past several years, to use other CDC resources, for instance, in health education, and in laboratory support, so that we would find other ways to continue projects. We would also attempt to get the States to contribute a larger share of the total project.

Finally, we are hoping that the prevention formula grants, which will be used in fiscal year 1980, might provide a certain amount of support for the diabetes program.

We are committed to continuing these demonstration projects in fiscal year 1980.

Senator SCHWEIKER. Do you have a figure, if you are not able to use funds from other program sources, as to what the cut might mean in your diabetes program?

Dr. FOEGE. I do not have a figure, but what we have decided is, with the fiscal year 1980 budget we will use that money for core support program, that is management of the program, the evaluation, epidemiology and surveillance. Where we cut back would be in the area of patient education or professional education.

At the present time about 55 percent of the total money is spent on the core money, and 45 percent on the patient professional education and health care delivery. What we would do is limit our funds to the core program.

Senator SCHWEIKER. If you do that, will that mean you will be able to add any new State projects, or not?

Dr. FOEGE. We will add on two States in 1979. We will not add additional States in fiscal year 1980.

Senator SCHWEIKER. We have a figure here, from the President's budget, proposing a cut from \$2.6 million in 1979 down to \$1.5 million in 1980. Is that approximately correct? Now, again, I realize what you are saying about flexibility of some other health education or prevention funding, which maybe you could use for diabetes.

Dr. FOEGE. That is correct.

Senator SCHWEIKER. I have some questions on positions and funding for the program for the next 3 years, but I think I will leave that for my Appropriations Committee to cover.

Do you think it would be useful to have a representative of the State health departments on the National Diabetes Advisory Board?

Dr. FOEGE. I believe that that would be a very good addition, because as we see the demonstration projects becoming stronger, I see a day in the very near future, when all 50 States would want to have diabetes programs. I think it would be wise to have State health officers, or representatives of the group on the board.

Senator SCHWEIKER. How has CDC worked with the advisory board? What has that relationship been?

Dr. FOEGE. I think we have had very good and close relationship. I would echo the comments made by NIH, this has been totally positive influence in the entire diabetes area.

Senator SCHWEIKER. Do you feel there is any need for authorizing legislation specifically establishing the CDC diabetes program?

Dr. FOEGE. I believe in the long run there may be some difficulties with perpetrating programs on the basis of contracts. I believe there might be a point at which a project grant authority complementing the prevention formula grants would be a useful step.

Senator SCHWEIKER. All right.

Unless any of you have further comments on any of the questions this morning that we did not give everybody a chance to respond to, I guess we should move on to the next witnesses. I want

to thank the panel very much for your testimony. I appreciate your cooperation and support, and thank you for being here.

Dr. FREDRICKSON. Thank you.

Senator SCHWEIKER. For our next panel the subcommittee is pleased to welcome Mrs. Caroline Lurie, president, Juvenile Diabetes Foundation; Mr. Richard Aszling, chairman of the board, Juvenile Diabetes Foundation; Dr. Frederick Whitehouse, president, American Diabetes Association; and Mr. Myles Tanenbaum, chairman of the board, American Diabetes Association.

We will proceed in the order we called you. Please go ahead with your statements.

STATEMENTS OF MRS. CAROLINE LURIE, PRESIDENT, JUVENILE DIABETES FOUNDATION; R. RICHARD ASZLING, CHAIRMAN OF THE BOARD, JUVENILE DIABETES FOUNDATION; DR. FREDERICK WHITEHOUSE, PRESIDENT, AMERICAN DIABETES ASSOCIATION; AND MYLES TANENBAUM, CHAIRMAN OF THE BOARD, AMERICAN DIABETES ASSOCIATION, A PANEL

Mrs. LURIE. Senator Schweiker, I will submit the full testimony, if that is all right with you.

Senator SCHWEIKER. We will include it in the record without objection at the conclusion of your testimony.

Mrs. LURIE. I am Carol Lurie, president of the Juvenile Diabetes Foundation. I am delighted to have accompanying me today the chairman of the Juvenile Diabetes Foundation's Board, Richard Aszling.

I must admit that in sitting and listening to the testimony before us I found an unbelievable air of excitement. I started to think back 5 years ago when Mrs. Lee Ducat sat here, and you introduced legislation to establish the National Commission on Diabetes. I wonder if you are aware, as I am, of what has happened? Of what you did? I would like to ask you a question. Are you aware of what you accomplished?

Senator SCHWEIKER. I am certainly encouraged by what I have heard from the first panel, but I am delighted to hear it from you, Carol.

Mrs. LURIE. You created something where there was nothing and that was quite an accomplishment. If I was wearing a hat, I would tip it to you right now.

Thank you, from the families and parents and members of the Juvenile Diabetes Foundation, thank you very much.

Senator SCHWEIKER. Thank you. You can always ask a question like that.

Mrs. LURIE. We are here today to express our strongest possible support for the Diabetes Research and Training Amendments and National Diabetes Advisory Board Extension Act of 1979, which would extend the legal operating authority of this vital advisory body for another 5 years, and accomplish several other important objectives.

How far have we come since 1974? Five years ago, prevention and cure of diabetes and its complications were mere pipedreams in the minds of the parents of diabetic children. Three years ago, the recommendations of the National Commission on Diabetes were merely thoughtful and insightful ideas committed only to

paper. Today, after the NDAB has been in operation for less than 700 days, the Nation's 10 million diabetics and their families have more than a glimmer of hope.

Listen to all the things that were brought up this morning. There is an Intra-NIH Coordinating Committee, the National Diabetes Data Group, and the National Diabetes Information Clearinghouse. The National Diabetes Advisory Board has catalyzed these important developments. And, in a giant step toward meeting Congress' mandates, the board will sponsor a National Summit Conference this fall to assess the extent to which the long range plan has been implemented and to review scientific advancements which have been made in the diagnosis and treatment of diabetes and progress toward curing and preventing diabetes and its complications.

The National Diabetes Advisory Board serves as the sole national focus for review, evaluation and advice with regard to the entire Federal diabetes effort. It has, in a short period of time, made great strides in the development of a unique capacity to advise and catalyze the coordination of the research activities of 11 component Institutes of the National Institutes of Health, the National Institute of Mental Health, the Indian Health Service, the Emergency Medical Services Division of the Health Services Administration, the Veterans Administration and the Department of Agriculture.

The NDAB and the diabetes program have demonstrated, in an exemplary fashion, that assorted Federal, State and private agencies can interlock and interface their activities to mesh significant new and existing programs designed to serve the specific needs of our diabetic population.

Ten States are now developing community-based diabetes control demonstration projects instituted by the Center for Disease Control. The Indian Health Service is implementing five model diabetes care projects on Indian reservations; diabetes has a prevalence rate of as high as 60 percent on some Indian reservations. Diabetes Research and Training Centers are operational in eight different States.

Major research programs (MRP's) of the National Institute of Child Health and Human Development initiated in four States investigate aspects of the diabetic pregnancy and the infant of the diabetic mother. And, voluntary health organizations, such as the Juvenile Diabetes Foundation and the American Diabetes Association, which cooperate with the various established programs, have chapters in every State of the Union.

In sum, the National Diabetes Advisory Board has served as an essential catalyst which has facilitated the creation of a truly national diabetes program—a dynamic research, education and control network which has established programs which are now just beginning to serve the needs of this country's 10 million diabetics.

Diabetes research was the primary thrust of the long range plan since research holds the ultimate key to control, prevention and cure of diabetes. JDF applauds Congress for substantially augmenting Federal financial support for diabetes research in the past several years. The NDAB has monitored with scrutiny diabetes projects proposed, approved and funded by each Institute in NIH;

the quality of applications funded and not funded; and trends in research activities.

As you well know, I am not a medical professional and the JDF is not a professional organization, but we do have an eminent 18 person medical advisory board which is an integral part of our organizations. Personally, I do know that tremendous progress is being made to expand research aimed at the complications of diabetes—blindness, heart disease, neurological disorders, kidney disease, et cetera.

Moreover, elaborate multidisciplinary projects involving diabetologists, epidemiologists, geneticists, immunologists and virologists are now in progress and could represent potential breakthroughs in virological causes of diabetes and prevention. Transplantation of islet cells and the pancreas, successfully accomplished in animals, embody the potential to discover a cure for diabetes. And, the recominant DNA research this year has represented a great breakthrough. Human insulin produced in the laboratory offers the diabetic the hope for a purer insulin and a better quality of life while we await the discovery of a cure or a means of preventing the disease.

The Federal diabetes effort, an infant program just a half-decade ago, has matured. Research support has increased dramatically as has the potential for breakthrough. The national effort to combat diabetes is developing into a model—a dynamic model—through the healthy and energetic cooperation of Federal, State and voluntary health agencies represented and working together on the National Diabetes Advisory Board. Moreover, the Federal research effort, funded by Congress and implemented by the National Institutes of Health, has been the beneficiary of substantial input and guidance from the Board.

We are only a quarter of the way down the road.

I would now like to turn the next part concerning our exact recommendations over to Dick Aszling, and then I might have another word to say when he is finished.

Senator SCHWEIKER. Go ahead, Mr. Aszling.

Mr. ASZLING. First, let me repeat our extreme gratitude at being invited to come here today and make this statement. My principal role will be to report that we vigorously endorse and support your bill, and to make some specific comment about recommendations. At the risk of repeating, I would like to state again that we believe the National Diabetes Advisory Board has a consistent record of unique achievement over the past 2 years. It has tracked congressional appropriations aimed at the establishment of vigorous diabetes education, treatment, control and research programs. The communication lines and the programmatic tracks have been laid. We are at a crucial junction. We must not lose the momentum already established. This subcommittee and this Congress must provide for the diabetes movement to continue to grow and mature in an orderly, well-guided manner in the coming decade.

I regret that, for the time being, diabetes is still with us. We have made some dents in its devastating impact, but most of our work remains to be done. This legislation provides for a 5 year extension of the National Diabetes Advisory Board. We support this extension. And, we particularly applaud the amendment to the

Public Health Service Act that would authorize the Board to review, evaluate and amend the long range plan to assure its continuing relevance. This would allow the Board to modify the long range plan and appropriately revise and update its recommendations to the Congress and the multitude of Federal agencies who support diabetes activities. Also, it would permit the Board to allow for the advances that are anticipated to take place in the next few years.

Some may argue that, in today's Proposition 13 political climate, a 5-year extension is inappropriately lengthy. However, time for a diabetic is measured differently. Five years of clinical research in the laboratory is not a luxurious amount of time. Five years in the life of a diabetic can bring on physical and emotional chaos, can bring on cardiovascular disease, blindness, kidney failure, neurological diseases, and amputation—all at a frighteningly accelerated pace. Five years can bring our young people from a normal life situation to death. An extension of this vital board for a minimum of 5 years is absolutely essential.

JDF supports, as well, the proposed amendments regarding the composition of the NDAB. The Director of the National Institute of Child Health and Human Development should be added as a member of the board, for diabetes' impact on maternal and fetal health is a growing priority within this Institute, and, indeed, is an unfortunate fact of diabetic life.

We would recommend as well that some provision be made for input to board deliberations of several additional agencies, including the National Institute of Allergy and Infectious Diseases, the Institute of Aging, the National Institute of Dental Research, the National Institute of General Medical Sciences, the National Institute of Mental Health, the U.S. Department of Agriculture, and the Food and Drug Administration. This objective could be accomplished by designating officials of these agencies as ad hoc, nonvoting members of the board. We believe strongly that the board should be composed of a majority of public members, researchers, diabetics, and parents of diabetics.

Senator Schweiker, we applaud the section in your bill which would place "diabetes" within the title of the National Institute of Arthritis, Metabolism and Digestive Diseases.

Senator SCHWEIKER. The name change does not bother you?

Mr. ASZLING. Not at all.

At the risk of creating a laundry list on the label, we would like to see this done, to give diabetes the emphasis it deserves as the third leading killer disease in the United States.

We do not believe, however, that this goes far enough. We propose that this subcommittee and the Congress afford NIAMDD "bureau status." NIAMDD is the third largest Institute within NIH in terms of the size of its budget. The larger Institutes, the National Heart, Lung and Blood Institute and the National Cancer Institute, which provide support for research in heart disease and cancer, the first and second leading killers in the United States, have already been afforded bureau status.

NIAMDD's budget in fiscal year 1979 will exceed \$300 million for the first time. The Institute supports research in over 100 diseases. Elevating this vital Institute to bureau status would greatly facili-

tate the administration of programs of the National Institute of Arthritis, Metabolism and Digestive Diseases.

JDF would also like to offer support for the expansion of the responsibilities of NIAMDD's Associate Director for Diabetes. The diabetes research effort involves over \$100 million in Federal funds. Because diabetes research spans all of NIH, it is imperative that the Associate Director have sufficient authority to adequately direct this important Federal initiative. The Associate Director for Diabetes should be statutorily responsible for:

Developing a coordinated NIH plan to address the needs and opportunities in diabetes research, research training, data collection and analysis, and information transfer;

Preparing for the Director of the National Institutes of Health on an annual basis a coordinated diabetes budget for all of NIH, developed through consultation with individual NIH Directors; and

Reporting to the Director of NIH on a regular basis the progress and problems of NIH diabetes research.

Congress, in Public Law 93-354, authorized the establishment of Diabetes Research and Training Centers (DRTC's) to accelerate the transfer of research information to health professionals. We enthusiastically support this program and Congress mandate to combine high-quality research with additional facilities and resources to accelerate the development of improved methods of clinical care and to transfer this information to physicians and allied health personnel who provide primary care to patients with diabetes.

There are currently eight centers, supported at a level of about \$8 million, representing 7 percent of the total diabetes budget. JDF believes that an expanded and continued effort would enable these centers to increase innovative programs in patient care, patient education, and public education through more effective liaison with Federal, State, and private health agencies. We vigorously support the 5-year extension of the authorities of the DRTC's as provided in the proposed legislation.

Thank you very much, Senator. We appreciate the privilege of addressing this important subcommittee.

Mrs. LURIE. Can I say three more things?

Senator SCHWEIKER. Certainly.

Mrs. LURIE. I know it is in our written testimony, but I think there are three people that should be mentioned very loud and very clearly, with JDF's gratitude, and the diabetes movement's gratitude.

One is to Dr. Oscar Crofford, chairman of the National Commission on Diabetes, and to the members of the commission. Thank you for providing us with the masterful long-range plan, a document which has been the blueprint for the successes of the last few years, and which will continue to be our hope for the future.

Another is Dr. David Kipnis, chairman of the National Diabetes Advisory Board, to whom goes our heartfelt thanks for making a new creation a working miracle.

Another is Dr. Lester Salans, Associate Director for Diabetes, NIAMDD, to whom we are eternally grateful. He has innovatively and aggressively guided and administered the diabetes effort during the past 2 years.

And then I know I am supposed to be very, very calm and collected, and sit here because I am before a congressional committee, but you have got to know something. I have deep emotion, and a lot of fear, because I do not want to see the effort that came about 5 years ago stopped in any way, shape or form, and I thank you for the courage you had, your committee had, and which has to continue, because you have given all the world hope. Do not let it stop now.

Thank you for listening.

Senator SCHWEIKER. Thank you.

[The prepared statement of Mrs. Lurie follows:]

TESTIMONY OF
THE JUVENILE DIABETES FOUNDATION

Presented by

Mrs. Caroline Lurie, President

and

Mr. Richard Aszling, Chairman of the Board

to the
Subcommittee on Health and Scientific Research
of the
Senate Committee on Human Resources

Re: "The Diabetes Research and Training Amendments
and National Diabetes Advisory Board Extension Act of 1979"

Room 4232, Dirksen Senate Office Building

February 26, 1979

Senator Kennedy, Senator Schweiker, and Members of the Subcommittee:

I am Carol Lurie, President of the Juvenile Diabetes Foundation. I am delighted to have accompanying me today the Chairman of JDF's Board of Trustees, Richard Aszling.

The Juvenile Diabetes Foundation is an international, voluntary health organization dedicated to supporting and furthering research and education in diabetes. Today, we appear before you on behalf of our Board of Directors and our entire membership and their families with over 100 chapters throughout the United States, Canada, and Israel.

DIABETES AND THE NDAB

Five years ago, Senator Schweiker, you introduced legislation to establish a National Commission on Diabetes. Mrs. Lee Ducat, Founder and Past President of JDF appeared before this Subcommittee then and stated: "The picture is bleak for the diabetic. He must live dependent on an insulin bottle, a syringe, and an alcohol swab for life. He faces a grabbag full of dreadful complications and shortened life expectancy. There are few educational materials and few doctors and nurses who truly understand the disease. There has been no change in fifty years since the discovery of insulin. There are few, if any, treatments for the complications. The public is generally unaware of the real problems of diabetes. Funding for diabetes research is at the bottom of the list of all serious diseases."

Awareness of these sobering facts lead Congress to create the National Commission on Diabetes (P.L. 93-354) and to charge it with the responsibility of developing a Long Range Plan to Combat Diabetes. The Commission developed such a plan and, as its primary recommendation, urged Congress to establish a National Diabetes Advisory Board with a mandate to advise Congress and the Secretary of the Department of Health, Education and Welfare on the implementation of the Plan, to propose changes as needed, and to report annually to Congress regarding the national research effort in diabetes and the development of programs in diabetes health care, control, and education.

Again, the diabetes community came to you to seek enactment of a bill which would create this Board. And, again, you, this Subcommittee, and the Congress responded by establishing the National Diabetes Advisory Board as part of "The Arthritis, Diabetes, and Digestive Disease Amendments of 1976" (P.L. 94-562). We are here today to express our strongest possible support for "The Diabetes Research and Training Amendments and National Diabetes Advisory Board Extension Act of 1979," which would extend the legal operating authorities of this vital advisory body for another five years, and accomplish several other important objectives.

How far have we come since 1974? Five years ago, prevention and cure of diabetes and its complications were mere pipedreams in the minds of the parents of diabetic children. Three years ago, the recommendations of the National Commission on Diabetes were merely thoughtful and insightful ideas committed only to paper. Today, after the NDAB has been in operation for less than 700 days,

the Nation's 10 million diabetics and their families have more than a glimmer of hope. They know that progress is being made. As the National Commission on Diabetes recommended, funding for diabetes research has been expanded. An Intra-NIH Coordinating Committee has been created. The National Diabetes Data Group and the National Diabetes Information Clearinghouse are operational. There are now 8 Diabetes Research and Training Centers which are conducting diabetes research, training physicians and allied health personnel in diagnosing and treating diabetes, and educating the public regarding diabetes. The National Diabetes Advisory Board has catalyzed these important developments. And, in a giant step towards meeting Congress' mandates, the Board will sponsor a National Summit Conference this fall to assess the extent to which the Long Range Plan has been implemented and to review scientific advancements which have been made in the diagnosis and treatment of diabetes and progress toward curing and preventing diabetes and its complications.

The National Diabetes Advisory Board serves as the sole national focus for review, evaluation, and advice with regard to the entire federal diabetes effort. It has, in a short period of time, made great strides in development of a unique capacity to advise and catalyze the coordination of the research activities of 11 component Institutes of the National Institutes of Health, the National Institute of Mental Health, the Indian Health Service, the Emergency Medical Services Division of the Health Services Administration, the Veterans Administration, and the Department of Agriculture.

The NDAB and the diabetes program have demonstrated, in an exemplary fashion, that assorted Federal, state and private agencies

can interlock and interface their activities to mesh significant new and existing programs designed to serve the specific needs of our diabetic population. Ten states are now developing community-based diabetes control demonstration projects instituted by the Center for Disease Control. The Indian Health Service is implementing five model diabetes care projects on Indian reservations; diabetes has a prevalence rate of as high as 60% on some Indian reservations. Diabetes Research and Training Centers are operational in 8 different states. Major Research Programs (MRPs) of the National Institute of Child Health and Human Development initiated in 4 states investigate aspects of the diabetic pregnancy and the infant of the diabetic mother. And, voluntary health organizations, such as the Juvenile Diabetes Foundation and the American Diabetes Association, which cooperate with the various established programs, have chapters in every state of the Union. In sum, the National Diabetes Advisory Board has served as an essential catalyst which has facilitated the creation of a truly national diabetes program -- a dynamic research, education and control network which has established programs which are now just beginning to serve the needs of this country's 10 million diabetics.

Diabetes research was the primary thrust of the Long Range Plan since research holds the ultimate key to control, prevention and cure of diabetes. JDF applauds Congress for substantially augmenting Federal financial support for diabetes research in the past several years. The NDAB has monitored with scrutiny diabetes projects proposed, approved and funded by each Institute in NIH; the quality of applications funded and not funded; and trends in research activities.

As you well know, I am not a medical professional and the JDF is not a professional organization, but we do have an eminent 18 person medical advisory board which is an integral part of our organization. Personally, I do know that tremendous progress is being made to expand research aimed at the complications of diabetes -- blindness, heart disease, neurological disorders, kidney disease, etc.. Moreover, elaborate multidisciplinary projects involving diabetologists, epidemiologists, geneticists, immunologists and virologists are now in progress and could represent potential breakthroughs in virological causes of diabetes and prevention. Transplantation of islet cells and the pancreas, successfully accomplished in animals, embody the potential to discover a cure for diabetes. And, the recombinant DNA research this year has represented a great breakthrough. Human insulin produced in the laboratory offers the diabetic the hope for a purer insulin and a better quality of life while we await the discovery of a cure or a means of preventing the disease.

The Federal diabetes effort, an infant program just a half-decade ago, has matured. Research support has increased dramatically as has the potential for breakthrough. The national effort to combat diabetes is developing into a model -- a dynamic model -- through the healthy and energetic cooperation of federal, state and voluntary health agencies represented and working together on the National Diabetes Advisory Board. Moreover, the Federal research effort, funded by Congress and implemented by the National Institutes of Health, has been the beneficiary of substantial input and guidance from the Board. The Juvenile Diabetes Foundation offers the following recommendations vis-a-vis the proposed legislation.

RECOMMENDATIONS

The National Diabetes Advisory Board has a consistent record of unique achievement over the past two years. It has tracked Congressional appropriations aimed at the establishment of vigorous diabetes education, treatment, control and research programs. The communication lines and the programmatic tracks have been laid. We are at a crucial junction. We must not lose the momentum already established. This Subcommittee and this Congress must provide for the diabetes movement to continue to grow and mature in an orderly, well-guided manner in the coming decade.

I regret that, for the time being, diabetes is here to stay. We have made some dents in its devastating impact, but most of our work remains to be done. This legislation provides for a five year extension of the National Diabetes Advisory Board. We support this extension. And, we particularly applaud the amendment to the Public Health Service Act that would authorize the Board to review, evaluate, and amend the Long Range Plan to assure its continuing relevance. This would allow the Board to modify the Long Range Plan and appropriately revise and update its recommendations to the Congress and the multitude of Federal agencies who support diabetes activities. Also, it would permit the Board to allow for the advances that are anticipated to take place in the next few years.

Some may argue that, in today's Proposition 13 political climate, a five-year extension is inappropriately lengthy. However, time for a diabetic is measured differently. Five years of clinical research in the laboratory is not a luxurious amount of time. Five years in the life of a diabetic can bring on physical and emotional

chaos, can bring on cardiovascular disease, blindness, kidney failure, neurological diseases, and amputation -- all at a frighteningly accelerated pace. Five years can bring our young people from a normal life situation to death. An extension of this vital Board for a minimum of five years is absolutely essential.

JDF supports, as well, the proposed amendments regarding the composition of the NDAB. The Director of the National Institute of Child Health and Human Development should be added as a Member of the Board, for diabetes' impact on maternal and fetal health is a growing priority within this Institute, and, indeed, is an unfortunate fact of diabetic life.

We would recommend as well that some provision be made for input to Board deliberations of several additional agencies, including the National Institute of Allergy and Infectious Diseases, the Institute of Aging, the National Institute of Dental Research, the National Institute of General Medical Sciences, the National Institute of Mental Health, the United States Department of Agriculture and the Food and Drug Administration. This objective could be accomplished by designating officials of these agencies as ad hoc, non-voting members of the Board. We believe strongly that the Board should be composed of a majority of public members, researchers, diabetics, and parents of diabetics.

The Status of Diabetes Within NIAMDD

Senator Schweiker, we applaud the section in your bill which would place "diabetes" within the title of the National Institute of Arthritis, Metabolism and Digestive Diseases. This should assist in giving diabetes the visibility necessitated by its being the third leading killer in the United States.

We do not believe, however, that this goes far enough. We propose that this Subcommittee and the Congress afford NIAMDD "bureau status". NIAMDD is the third largest Institute within NIH in terms of the size of its budget. The larger Institutes, the National Heart, Lung, and Blood Institute and the National Cancer Institute (which provide support for research in heart disease and cancer, the first and second leading killers in the United States) have already been afforded bureau status.

NIAMDD's budget in FY 1979 will exceed \$300 million for the first time. The Institute supports research in over 100 diseases. Elevating this vital Institute to bureau status would greatly facilitate the administration of the programs of the National Institute of Arthritis, Metabolism and Digestive Diseases.

JDF would also like to offer support for the expansion of the responsibilities of NIAMDD's Associate Director for Diabetes. The diabetes research effort involves over \$100 million in Federal funds. Because diabetes research spans all of NIH, it is imperative that the Associate Director have sufficient authority to adequately direct this important Federal initiative. The Associate Director for Diabetes should be statutorily responsible for:

- developing a coordinated NIH plan to address the needs and opportunities in diabetes research, research training, data collection and analysis and information transfer;
- preparing for the Director of the National Institutes of Health on an annual basis a coordinated diabetes budget for all of NIH, developed through consultation with individual NIH Directors; and

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-- reporting to the Director of NIH on a regular basis the progress and problems of NIH diabetes research.

Diabetes Research and Training Centers

Congress, in P.L. 93-354, authorized the establishment of Diabetes Research and Training Centers (DRTCs) to accelerate the transfer of research information to health professionals. We enthusiastically support this program and Congress' mandate to combine high quality research with additional facilities and resources to accelerate the development of improved methods of clinical care and to transfer this information to physicians and allied health personnel who provide primary care to patients with diabetes.

There are currently eight Centers, supported at a level of about \$8 million, representing 7% of the total diabetes budget. JDF believes that an expanded and continued effort would enable these Centers to increase innovative programs in patient care, patient education, and public education through more effective liaison with federal, state, and private health agencies. We vigorously support the five-year extension of the authorities of the DRTCs as provided in the proposed legislation.

CONCLUSION

Senator Schweiker, Mr. Aszling and I have attempted to logically present to you our reasons for supporting this legislation to extend the authorities for the National Diabetes Advisory Board, extend the authorities of the DRTCs, and enhance the administrative role of the Associate Director for Diabetes. We have tried to highlight the accomplishments of the Board and the successes of the

diabetes program over the past five years. I must emphasize that this program has been strong and great for many reasons, but for one reason in particular -- the people who have implemented it have been great.

To Dr. Oscar Crofford, Chairman of the National Commission on Diabetes, and to the Members of the Commission, thank you for providing us with the masterful Long Range Plan, a document which has been the blueprint for the successes of the last few years, and which will continue to be our hope for the future.

To Dr. David Kipnis, Chairman of the National Diabetes Advisory Board, goes our heartfelt thanks for making a new creation a working miracle.

To Dr. Lester Salans, Associate Director for Diabetes, NIAMDD, we are eternally grateful. He has innovatively and aggressively guided and administered the diabetes effort during the past two years.

And to you, Senator Schweiker, goes our deepest gratitude. You have listened and you have responded to us, year after year, month after month, and day after day. We are proud of this program and we sincerely feel that you should rightfully share with us in our pride and derive great satisfaction in having been ours and our Nation's hero. You have given a real sense of hope to this country's millions of diabetics.

I wish that I could report to you that a cure for diabetes is at hand. Or, that we are only a year or two away from such a cure. At this time, I regret that I cannot. Diabetes is still the third leading cause of death in the United States, with some 300,000 deaths attributed to it annually. There are 600,000 new cases of

diabetes a year, about 2,000 new cases each day. Diabetes is the leading cause of blindness, heart disease, kidney disease and gangrene. Diabetes is accelerating in incidence in the black population and the female population. It is a disease which affects all stratas of our population equally, knowing no racial, ethnic, class or geographic barriers. It is estimated to cost the American economy \$6 billion per year.

1976, our bicentennial year, was the year that Congress proposed a unique solution to a unique problem. It created a National Board to coordinate and implement the Long Range Plan, a diabetes program to span all Institutes of NIH and other agencies of the government involved in education, training and research. We move to a new phase now in our quest to make diabetes a chapter in history -- the extension of the Board, a modest expansion of its mandate, bureau status for this vital Institute, and extension of the Diabetes Research and Training Center program.

Lee Ducat, Founder and Past President of JDF, reminds us of the apocryphal story of a young man who decided that he could outwit the wisest of wise. He approached the wise man and he said "Father, I have a bird in my hand. Is it dead or alive?" The young man had planned that if the wise man had said that the bird was dead, he would open his hands and let it fly. If the wise man pronounced the bird alive, he would squeeze his hands and produce the bird dead. The wise man looked at the young man and after a few minutes spoke, "The fate of the bird rests in your hands."

Senator Schweiker and Members of this Subcommittee, the fate of the diabetes effort does truly rest in your hands. In your support of prior diabetes legislation you set an example for the whole world to follow. We are prayerful that you will continue to

be courageous and forceful in taking the next step to rid our society of the dreaded disease.

On behalf of the Juvenile Diabetes Foundation and our constituency of hundreds of thousands, may I say that we are grateful for having had this opportunity to share our thoughts with you on a subject so close to our hearts.

Senator SCHWEIKER. Now we will hear from the American Diabetes Association. Dr. Whitehouse?

Dr. WHITEHOUSE. I am going to let Mr. Tanenbaum start first.

Mr. TANENBAUM. My name is Myles Tanenbaum. I am chairman of the board of the American Diabetic Association, and a resident of Bryn Mawr, Pa.

Senator SCHWEIKER. A good constituent, besides.

Mr. TANENBAUM. I would like to thank you, Senator Schweiker, for scheduling this hearing to give us all an opportunity to look at the broad issues of interest for those in the diabetes community.

Dr. Whitehouse and I have a formal statement on behalf of the American Diabetes Association's work, which I would like to have, with your permission, submitted.

Senator SCHWEIKER. Without objection, we will include your complete statement on behalf of ADA in the record.

Mr. TANENBAUM. Thank you.

This hearing provides us with a rare opportunity, not only to look forward, but to look back on what has happened. As I was coming down this morning, I recalled almost 6 years ago coming to the first hearing on the then Schweiker-McGee bill, and that hearing was, as I recall it, in the House, and you, Senator Schweiker, were the leadoff witness. You have been leading off for us ever since, I must say.

What struck me was that the second witness, and I am not sure you were there at the time, was a young Congressman by the name of William Steiger. Mr. Steiger had been a diabetic. He had juvenile onset type diabetes. He was a leader in Wisconsin American Diabetes Association unit, as well as here in the Congress. Unfortunately, Congressman Steiger is no longer with us. He is a gruesome statistic in the many statistics of mortality relating to diabetes.

Senator SCHWEIKER. Yes. I might interrupt and say he was a good friend of mine, and certainly he was very supportive of our diabetes efforts in the House. It was a great loss to the Congress.

Mr. TANENBAUM. The original concept of developing a long-range plan came out of the legislation that you had sponsored and was embodied in the commission study representing a strategy whereby there was an interdependence of the various Institutes of the National Institute of Health, as well as the involvement with NIH of CDC and Indian Health Services, as well as the Veterans' Administration and other constituent branches of Government.

Last, it evidenced a major interdependence between Government on the one hand and its partnership with the private sector. As the National Diabetes Advisory Board has grown in its work, and has produced its reports, I think the working together is evident, both in the report itself, as well as in the results that have been achieved.

We consider, that is, the American Diabetes Association, considers that the continuance of the National Diabetes Advisory Board is essential to provide the surveillance, and to bring to bear the combination of people that come from a wide range of interests, both in Government and private citizens who have a concern about diabetes, and to who by reason of the multidisciplines that are on that panel are able to help guide the efforts of the various Institutes, as well as the other agencies of Government.

For that we support your bill. As a matter of fact, we support your bill entirely, and all its other ramifications. We like the idea that diabetes is coming into the name of the Institute. It provides a broader public perception of the importance of that element. We would like better to see it stricken one day when it is no longer with us.

In addition, we support the legislative authority given to the position of the Associate Director for Diabetes, as well as the fact that you are reorganizing, as it were, the manner in which the Institute will operate.

There have been some issues raised concerning what has been referred to as bureau status concerning the Institute. I am appealing to you today from whatever background I have as an attorney, as a businessman, and very frankly, I cannot guide you, certainly no better than those people who testified earlier, as to how the Government bureaucracy could best function, and I could not tell you whether a bureau or institute, or whatever it is, is a better way for it to operate.

So, from that standpoint, I do not think we can be of any help. To the extent that we can urge on your committee the continuation of the effort, and the funding of dollars and more dollars, and when you hear today what has been said, and read the report of the National Diabetes Advisory Board, and see the progress that has been made, it really reflects the combination of those efforts with dollars provided in a very intelligent way, guided by the strategy of the long-range plan. For that we support the legislation.

In regard to the bureau, we cannot comment.

One further matter occurred to me again as I was coming down this morning. There will not be another eclipse of the Sun in this century, they tell us, on the North American Continent. They predict it will be the year 2017, that there will be another eclipse. Here we are sitting in this room today, and we could not have seen it even if it were not as overcast as it were outside, but I imagine it would have been a little darker by reason of the eclipse.

I started to think whether I would be around at the time of the next eclipse. As I did, I thought further, my two children, who have diabetes, I compared our differences in ages, and I wondered whether they would be here. They should be.

I would say listening to the hope that was expressed today by the scientists, reading the report, and with the support that you have given in your committee, I think they will be.

I thank you.

Senator SCHWEIKER. Thank you.

Dr. Whitehouse?

Dr. WHITEHOUSE. Senator Schweiker, my name is Fred Whitehouse. I am president of the American Diabetes Association. I am also a practicing internist at the Henry Ford Hospital in Detroit.

My remarks are sort of quasi extemporaneous. I typed up some of these after I finished the hospital rounds. I will read some of them, and make some of them off the top of my head. These remarks will supplement those of Mr. Tanenbaum, and sort of try to enter into the record a perception as an internist, as a practicing physician, seeing these things regarding progress in diabetes research in the clinical application.

About 75 percent of my patients are diabetics, from 8 to 80. One-third of them are black. It is a large metropolitan hospital. We have consultative practice in primary care. I have been in this practice for 25 years, since my training as a fellow at the Joslin Clinic. My decision to go into diabetes was the smartest thing I ever did professionally, because it has been extremely rewarding.

At the tender age of 12 I learned about some of the things that could happen relative to diabetes. During these 25 years, patients have asked me two different questions: What are they doing about diabetes, and what is new in the treatment?

In the first two decades of my practice my answers were diffuse. Since the Congress has authorized the National Diabetes Commission, and the National Diabetes Advisory Board, and the National Diabetes Research and Training Centers, and there has been a tremendous boost to research funds. I have been able to be more specific with my patients regarding what they are doing in research everywhere, and what is new in the treatment of diabetes. It was largely because of people like yourself in Congress that I have been able to do this. This permits a positive attitude within a physician's office relative to the patients and their families, particularly the new ones upon the scene.

There are a couple of things I would like to comment on. I think the National Diabetes Advisory Board and the Diabetes Research and Training Centers have gone a long way to permit this positive attitude, as well as CDC, and finally the information clearinghouse. In my own practice, Senator Schweiker, while I spend a fair amount of time talking about physical things, most of the time I spend in individual consultation with patients, relates to their emotional problems and how they go on improving the quality of their life in order to live with diabetes. This takes time, for any physician who is taking care of diabetics.

It is important that the beginning areas in mental health and psychological aspects of diabetes are pursued. This is one area where we can tell our patients with diabetes that things are getting started. We can learn how best to handle, and we can instill compassion within the people who are training to help the diabetics.

So that this practice will continue, and be accentuated, the American Diabetes Association supports reauthorization of the NDAB, and strengthening of the NIAMDD to permit increased visibility of diabetes. I like the idea of diabetes being in the title.

We further urge support within the Diabetes Research and Training Center of including addition of training grants under their aegis.

I would like to say here that one of the ways in which you can get people into research activities is to acquaint them early on to the care of diabetic patients. Take the Diabetes Research and Training Center, for instance, at the University of Michigan, which I am familiar with. Young people in medical school, and maybe in the third or fourth year, and can become involved in diabetes, and pretty soon they may either get into the clinical area or into the area of research. Early on you can capture their minds, as it were. This is one of the advantages of Diabetes Research and Training Centers.

If you capture them, they are interested in adult or pediatrics. We do need more emphasis on pediatrics. Too long have internists been involved in this primarily. Pediatricians need to be involved in this, both in training grants from NIH, and from DRTC's. We are glad within our organization to have pediatricians active as part of our professional membership.

In Detroit, I can tell you, my diabetic patients are making progress because of the National Eye Institute research with laser therapy. Laser beams are here to stay. They are going to be helping diabetics with eye problems. I can tell patients about the automatic insulin delivery systems—open loop, closed loop—and the progress that is being made in transplants. You heard from Dr. Fredrickson and Dr. Whedon this morning on the importance of physical exercise in controlling diabetes.

Senator SCHWEIKER. I read in the paper this weekend about the diabetes pump, the size of two packs of cigarettes.

Dr. WHITEHOUSE. I think that is one of the areas. With the closed loop, well, it measures blood sugar, and you have the open loop, delivering insulin automatically through a system, which you can get a low dose steadily, and when you are ready to sit down and have corned beef and cabbage, a hot fudge sundae, maybe you can punch a button and a little bit more insulin can be delivered.

These are areas still for the future. The point of research is hopeful, and there are various activities, so when you talk with patients who have to get two or three shots a day, and we talk about automatic delivery systems, it is an area, not a cure, but it is an area of further palliation. This brings up one further point, and that is, it is important that research be in two areas. Palliation, better ways of handling the problem now; but in the long run we need to support basic research which will wipe out the problem.

Your bill, and the appropriations that come from it now and in the future will be able to support both of those. The importance of physical activity on the control of diabetes, cardiovascular risk factors—all of these things have come out in an increasing way as a result of the last 5 years of increase in funding.

Some of these things have come out through the National Heart and Lung Institute. These other institutes play a role, too.

I think my friends with JDF are absolutely right when they talk about adding child health development, because of the importance to children. I do not want to overstate the case too much, but there have been good beginnings in research.

We need to, nevertheless, talk about basic research, as well as applied research, and we need to have physician scientists there. I think it has been a very good beginning. It is only still just a beginning. In my opinion, and the opinion of ADA, we want to maintain that. We think that the National Diabetes Advisory Board is the best chance of coordinating ability and leadership qualities within the Federal, State and private sectors.

With your permission, I want to add a little rhetoric in closing. That is, that President Roosevelt wrote a letter to Churchill during the dark days of 1940 and 1941, quoting Longfellow: "Sail on oh Ship of State, sail on oh country strong and great."

Churchill in the House of Commons wrote back, or spoke back to President Roosevelt, and said: "Give us the tools, and we will finish the job."

That is what the ADA wants. That is what JDF wants. That is what my patients want. That is what clinicians taking care of diabetics want. They want you, your Congress, and the constituents want us to have our research friends given the tools so they can finish the job, so we can finish the job.

I am ready for any questions.

[The prepared statement of Dr. Whitehouse follows:]

TESTIMONY OF

THE AMERICAN DIABETES ASSOCIATION

Before The

SUBCOMMITTEE ON HEALTH AND SCIENCE

Of The

SENATE COMMITTEE ON HUMAN RESOURCES

ON THE

"DIABETES RESEARCH AND TRAINING AMENDMENTS AND THE NATIONAL DIABETES
ADVISORY BOARD EXTENSION ACT OF 1979"

February 26, 1979

INTRODUCTION

Mr. Chairman, my name is Dr. Fred W. Whitehouse and I am President of the American Diabetes Association and I am accompanied by Myles Tanenbaum, Chairman of the Board of the American Diabetes Association. I am a practising physician in Detroit, Michigan in the field of internal medicine specializing in the care of diabetics including primary care for diabetics. Mr. Tanenbaum is here in his role as Chairman of the Board of the American Diabetes Association ("ADA") and is the father of diabetic children. As you know, the American Diabetes Association is an organization of consumers, scientists in the field of diabetes, and health care professionals who serve the diabetic. We thank you for this opportunity to testify on your legislation dealing with the extension of the National Diabetes Advisory Board and the Diabetes Research & Training Center program.

We would like to begin our testimony by providing you with our assessment of the various Federal programs dealing with diabetes which have been developed over the last 3 to 4 years. Included in our assessment is commentary on the National Diabetes Advisory Board and its role in the development of these and other programs related to diabetes.

RESEARCH AND RESEARCH TRAINING ACTIVITY

As you know, Mr. Chairman, measured in terms of expenditures, the research and research training effort in the field of diabetes and related research has increased dramatically during the past 3 fiscal years. The Report of the National Commission on Diabetes was issued in December of 1975 or mid-way through fiscal year 1976. Thus, the first fiscal year in which there was an opportunity to carry out the Diabetes Plan recommended by the National Commission was fiscal year 1977. In that year, approximately \$81 million was appropriated and expended for diabetes research and research training activity within NIH. This increase was approximately \$38 million more than the FY 1976 level. In the succeeding two fiscal years appropriations and expenditures within NIH increased to \$108 million and \$124 million, respectively with the current FY 1979 level being \$124 million. The rate of increase has therefore slowed with the increase in FY 1979 over FY 1978 being approximately 17% but there has still been substantial growth, obviously. The specific program areas involved with this growth have been research, research training and the support of Diabetes Research & Training Centers. All 3 of these areas have grown as the total amounts expended have grown. In FY 1979, training will be at approximately the level of \$4 million, Research & Training Centers at the level of \$11 million and research support through grants and contracts constituting the remainder or approximately \$110 million. There is, however, some support provided through these expenditures for the National Diabetes Clearing House for information dissemination and for the National Diabetes Data Group for the collection and analysis of epidemiologic data.

It should be noted that the rate of growth for research support and the Centers has approximately paralleled the rate of growth for NIH diabetes activity generally. It would seem that research training has, however, not paralleled this growth and

this is one of the areas in which we think there is a substantial need for increased effort in the future.

I am particularly interested in the major efforts with regard to diabetes research since the results of that research have a great deal to do with my capacity as a practising physician who treats diabetics to improve their condition. More important, research results may well eventually discover a cure for this disease so that terrible complications which I see regularly may be substantially reduced and eventually eliminated. It is my opinion that diabetes research has already been and will continue to be very relevant to the provision of health care. This is particularly true because of the training role which the Research & Training Centers play and the dissemination role of the National Clearing House but it is also true because of the effective management of the research program by NIH. In particular, we would like to pay tribute to Dr. Lester Salans, the Associate Director for Diabetes, Endocrinology and Metabolism for his efforts in managing this program not only within the National Institute of Arthritis, Metabolic and Digestive Diseases, but also in other Institutes of NIH. We also want to express our gratitude for the support which Dr. Whedon, Director of the NIAMDD has supplied to this program and to Dr. Frederickson for his leadership as Director of NIH. The development of the NIH Coordinating Committee on Diabetes and the so-called "trans-NIH" diabetes initiative have done much to improve the effectiveness of management of research in the diabetes field.

I would like to mention some specific areas of diabetes research that are of particular relevance from the perspective of those of us in the American Diabetes Association. We are very supportive of the basic research which is being carried out in NIAMDD and other Institutes of NIH dealing with matters such as genetics and viruses which are believed to have a great deal to do with the cause of diabetes. While the complications of diabetes are extraordinarily severe, and obviously merit research related to palliative procedures aimed at these complications, we believe that basic research is a very critical and high priority activity for NIH. In this respect, development of diabetes-related programs in Institutes such as NIGMS and NIAID, in addition to the basic research so effectively undertaken by NIAMDD, are very heartening.

Great strides have been made through support of research, particularly by NIAMDD, in the areas of transplantation of the pancreas and the development of artificial devices to administer insulin. Transplantation of the total pancreas or of the islet cells which produce insulin is an extraordinarily important development which, while not perfected, has progressed substantially and demands greater support. This activity plus the research on artificial devices to do the work of the islet cells obviously constitute a cure for this dread disease. A specific example of an artificial device which is being developed is the glucose sensor. There has already been developed a "closed loop" system in which a sensor to monitor blood glucose levels is implanted

along with a mini-computer to interpret the sensor's findings and a pump to deliver insulin at the appropriate stages of metabolism. This system is already in use on a research basis for non-ambulatory patients but needs to be experimented on an ambulatory population more fully. The second device, the "open loop" system, involves a device which delivers insulin on a pre-determined pattern not dependent upon a sensor and computer-pump system. The pump simply functions by using a catheter and by pumping on the pre-determined pattern which pattern has been established by a prior study with the closed loop device. The system is much smaller and much more easily usable. Additional research on both of these devices is necessary in order to provide for ease of application since there has been substantial tissue reaction to the implantation of these devices.

Research has already produced major results in areas of improved management of the complications of diabetes. These complications deal primarily with the large and small blood vessels, kidneys, eyes and nerves. As you are probably aware, the Diabetic Retinopathy Study has already demonstrated that photocoagulation is effective in reducing the risk of severe vision loss and in delaying the progress of retinopathy. These procedures are now ready for practice and are being used. However, further research is underway and needs to be supported which would attempt to show the effectiveness of photocoagulation and treatment in the very early stages of retinopathy to determine the optimum time to initiate treatment. Clinical studies are underway in these areas.

Another area of significant clinical trial affecting health care delivery is research going on at the NICHD dealing with diabetic pregnancies. A great deal more needs to be known about the effectiveness of degrees of control exercised with respect to pregnant women during various stages of their pregnancy particularly the first half of pregnancy. It is believed that such control might have very positive effects with respect to infant survival and congenital defects. Like the results already achieved with respect to diabetic retinopathy and treatment, this study may well provide indications of improved methods of care which would be extremely effective in reducing the costs and the human suffering of congenital defects and the loss of life of children born from diabetic mothers.

I would like to discuss briefly at this point the manpower training question. Support for the training of researchers in the field of diabetes and diabetes-related research is conducted by the NIAMDD. In fiscal year 1977, training support was \$2.8 million. The level of support increased in fiscal year 1978 by approximately 20% to \$3.4 million. In fiscal year 1979, the level is supposed to be at approximately \$4.1 million or an increase of about 20% once again. The percentage increase in training has not really kept pace with the expanded support for research although training support has increased fairly substantially. Also, the total level of training support, approximately \$4 million in fiscal year 1979 and \$3.4 million in

fiscal year 1978, is a very small proportion of the total research budget in those years which was about \$120 and \$102 million, respectively. Specialists in research and research manpower have often estimated that research training support should be at least at a level of about 8-10% of research support. The National Commission on Diabetes recommended levels that were about 8% of the total research budget for training activity. There is nothing more significant to the production of ideas that will improve mankind than fresh, creative minds. It is difficult in these times to get the best of young physicians, particularly, to enter a research career since the monetary rewards are so much less than those of practice and the costs of research training are fairly substantial. In this connection, we would urge that this Subcommittee request that the Budget and Appropriations Committees support substantial increases for research training in a fiscal year 1979 supplemental bill and in the fiscal year 1980 appropriations bill for all manpower training throughout NIH. Creating a larger pool of research manpower generally will be of great assistance to all fields of research and all disease interest groups.

It is well documented that there has been a sufficient decline in the number of scientists, at least physician scientists. The 1978 Report of the National Research Council entitled "Personnel Needs in Training for Biomedical and Behavioral Research" indicates a dramatic reduction in the number of physician-researchers who are "first-time" principal investigators of NIH research grants. The decline is from 44% in 1966 to 29% in 1977. This decline portends a major depletion for the future of this major resource for research and research utilization. During this period, for example, manpower training programs in specific areas have been eliminated by the Federal Government as well. Part of the problem results from the fact that training stipends are only at the level of approximately \$10-\$13,000 which is a level substantially less than what a physician receives in residency training. We hope that the stipend level will be increased at least to account for annual cost-of-living increases. In this same connection, we would urge that the Medical Scientists Training Program of the NIGMS be expanded since qualified applicants presently far outnumber the current trainee positions in this program. I think the program should be increased at approximately the levels recommended by the NDAB of about 10% a year. Another important need in the field of manpower training is for a "retraining of scientists" program in order to refresh and renew our existing pool of scientists.

RESEARCH AND TRAINING CENTERS

The Diabetes Research & Training Center program has been a success in our opinion and deserves further support. In the past few years there has been much criticism of the so-called "Centers" programs of NIH. In general, however, those criticisms have been leveled at the fact that "Centers" often are service providers and funds allocated to service provision through the NIH budget take away from research activity. To some extent, criticisms have also been leveled at the many "Centers" programs because many individuals feel that institutional support such as that provided

to Centers is not an efficient targetting of research resources. We beg to differ with those who criticize all "Centers" programs. The criticisms are often too general and do not recognize differences between types of "Centers" program activity. The Diabetes Research & Training Centers support only research and training activity. The investment in institutional support is very justified in our opinion as an expenditure of research resources because the Centers serve as major research utilization and dissemination vehicles. At the same time as many individuals criticize "Centers" programs, there is also a very high level of interest in the Congress and the Executive Branch in the entire field of research utilization and it is just that research utilization which the Diabetes Research & Training Centers are intended to and do provide. These Centers train health professionals in the newest of methods which research has often produced for caring for the diabetic. The Centers are regionally located so that professionals in various areas throughout a region can be trained at these Centers and go back to their practice better equipped to deal with their patient population. In Massachusetts, for example, the Joslin Clinic will train nurses and other health professionals who may serve rural areas in western Massachusetts, Vermont, New Hampshire and Maine. These same activities occur in other Centers. In addition, the Centers serve as resources to assist state health departments in the development of improved planning and programming for diabetes control. The major initiative is to have the Centers which are in states with CDC diabetes control programs work closely with these control programs to assist in their implementation. Likewise, some Centers will be engaged in the training of health paraprofessionals to participate in the extremely important and exciting model care program for diabetics being undertaken this year by the Indian Health Service. One of the major parts of this program is the training of paraprofessionals who are Indians to deal with the control and management of diabetes which occurs in a disproportionately high percentage of Indians.

CLINICAL RESEARCH CENTERS

The NIH research support also includes the support of Clinical Research Centers through the Division of Research Resources of NIH. These Centers are hospital facilities which provide 80% of the beds for clinical research trials and related activity throughout the United States. Without these Centers, clinical research could not exist. Unfortunately, these Centers have received very little support over the past few years for any activity. It should be noted, that there is no specific earmarking or categorization of Clinical Research Centers for the operation of research regarding specific diseases. The Centers provide a facility for clinical trials and whatever area of research the medical center in which the facilities are located may be involved with. In the course of the last decade, there has been a decline in the number of such Clinical Research Centers, beds and patient days in such Centers. In 1968, there were 91 such Centers with 1000 beds, whereas in 1979, there are 74 Centers with only 656 beds. Since 1972, a period of 7 years, there has been an increase of only \$9 million over base of \$42 million in support of this program.

That would represent about a 2-3% increase per year which is probably about 6% less than the going inflation rate in each of those years. We would recommend that there be a major expansion of support for the general Clinical Research Centers in order to make up for a depletion in this substantial resource. We believe that the health research community has overlooked the importance of these major Centers which serve all areas of research. Like the expansion in research training, expansion of these Centers is a generic expansion which will provide resources for improved research in all fields.

CENTER FOR DISEASE CONTROL

The diabetes effort over the past 3 fiscal years has not been solely in the area of research. Much has been done to improve the ability of Federal and state governments and the private providers to respond to the health care needs of the diabetic. Not only has research and research utilization produced some new practices and procedures that are already being utilized, but the diabetes control program supported by the Center for Disease Control has already produced some significant state efforts to improve the condition of the diabetic by improving health care programs. The CDC activity has been primarily focused upon planning within the 10 states which have received CDC contracts to determine the population with diabetes and the most significant incidence of complications and to attempt to improve the health care resources to minimize the problems of complications. It has already been established in some states that the cost of amputation resulting from diabetes may be as much as \$100 million nationally. Obviously, early and improved care for this population could substantially minimize that cost.

In fiscal year 1977, there were applications from 29 state health departments for CDC contract funds to assist state health departments in planning and developing programs to control the problems of diabetes. Contracts were awarded to 10 states. In 9 of those 10 states the planning function in which base line data is collected on morbidity and mortality and health care resources and problems identified as well as the development of a plan to improve the application of health care resources was completed. In addition to the contract funds provided, a CDC staff person has been assigned to each state to provide technical assistance and consultation. It is expected that approximately 10 to 15 states will qualify for additional support based on a recent RFP issued by CDC but resources will not be available to expand the program into those states.

We believe it is of the utmost importance to assist state health departments in building their capacity to provide for the prevention and management of chronic disease. We think that the diabetes control program is a model that may well be used in other areas. We are particularly excited by the prospect of an expanded program in all states dealing with the management and care of chronic disease which should result from the 1978

amendments dealing with health services. Under those amendments, a grant program of support to all state health departments to plan for and implement programs to prevent and manage chronic care was authorized. The Administration has requested \$18 million to support that program in fiscal year 1980. It is our hope that the Department of Health, Education & Welfare, state health departments, and voluntary agencies such as the American Diabetes Association may work in an effective partnership to implement improved programs along these lines.

Examples of what is occurring under current CDC contracts with state health departments are very encouraging with respect to the care of diabetics and with respect to improved systems for managing the care of chronic illness generally. For example, Nebraska has proposed and is implementing a program to expand the capacity of home health agencies to provide patient education in the home to diabetics and to supplement hospital-based education programs. Mississippi is developing a program which deals with improving the delivery of services to pregnant diabetic women.

MENTAL HEALTH CARE AND THE DIABETIC

One of the major items mentioned in the Long Range Plan developed by the National Commission on Diabetes and by the NDAB is the problem of behavioral and emotional disorders among diabetics. Obviously, this is a problem which may well occur with any severe chronic disease. Families as well as the individual with the disease are significantly affected. Yet, the mental health care system does not focus adequately on this particular problem. There is little attention paid to the delivery of mental health care to patients recently diagnosed as diabetic and to their families. This is a particularly important problem for the juvenile diabetic. It goes without saying, that the mental and emotional condition of the patient and his or her family has a great deal to do with the ability of the attending physician to assure an adequate program of care and a positive outcome. Much has been made by HEW of the need to link primary health care with the mental health system but that focus has been upon traditional mental illness such as psychosis and neurosis which conditions in patients may first appear in the office of a general practitioner of medicine. There has not been a similar effort to link mental health care with primary health care in order to deal with the mental and emotional problems of the severely physically ill such as the diabetic.

NIMH is just beginning efforts, many of which are to be in conjunction with the NIH, to focus upon such issues. We hope that this Subcommittee will recognize the value of such efforts and their relevance to all chronic disease and support us in assuring that such mental health problems are receiving adequate attention.

THE NATIONAL DIABETES ADVISORY BOARD

I would now like to comment upon the activities of the National Diabetes Advisory Board during the past 2-1/2 years. It is our opinion that the Board has been extraordinarily effective in stimulating initiatives with regard to research and services to the diabetic and in improving the programs operated by each of the sectors represented on the Board. As you know, the Board represents officials of the Federal Government and individuals representing the various health care disciplines involved with diabetes, the scientific community, research institutions which provide for diabetes research, and the voluntary health agencies which provide for both health care services and research such as the American Diabetes Association and the Juvenile Diabetes Foundation and the Pennsylvania Diabetes Institute as well as the National Heart Association. Without an organization like the NDAB, these various sectors would not come together at a sufficiently high level and with sufficient motivation to actually improve various program activities the way they have been improved. The ability of our organization to expand health prevention activity through its affiliates in conjunction with the CDC and those state health departments which are working with the CDC on diabetes control programs has been helped inordinately by the attention given this complicated issue of interagency activity by the NDAB. Similarly, the development of the Indian Health Service model care program for Indians depends upon significant private and Federal action which has been encouraged by this Board. Research activities by our organization have also been improved in their effectiveness through our interaction with the research leaders of the NIH. We see the continued use of the NDAB as a vehicle for assessing Federal, state and local research and service programs and recommending, as well as beginning the implementation of improvements in such programs as a very important factor in the long range effort to deal with diabetes.

COMMENTS UPON THE DIABETES RESEARCH & TRAINING AMENDMENTS AND NATIONAL DIABETES ADVISORY BOARD EXTENSION ACT OF 1979

I would now like to comment on the proposed legislation to extend and expand the existing authorities for the Diabetes Research & Training Centers and the National Diabetes Advisory Board. First, with regard to the Diabetes Research & Training Centers, we have already testified as to their importance. We certainly support the extension of the authority for financial assistance to such Centers. We also support the proposed amendment which would allow Centers to provide training stipends. This training stipend program would be for physicians and other health professionals who are being trained in the Centers and for research training. I think the stipend program is necessary particularly for those health professionals or agencies that cannot afford the training programs being offered. The National

Diabetes Advisory Board made particular reference to the need for expanding the training of minority health professionals. We think that this should be a priority of the newly recommended traineeship program. Certainly, there is a very high incidence of diabetes among minority populations particularly the racial minorities. Improving the training of health care professionals who are from minority backgrounds is one very significant way of attempting to deal with that problem. Priority in this training stipend program for those individuals or for individuals who practice in areas serving minority populations, whether the individual practitioners be racial minorities or not, would seem to make a great deal of sense and has been recommended by the NDAB. We think another amendment should be added to the Section of the Public Health Service Act authorizing support of Diabetes Research & Training Centers to make it clear that such Centers are to be supported by the Secretary and agencies to which he has delegated his authority consistent not only with the plan and recommendations of the National Commission on Diabetes to which the present law refers, but also with the recommendations of the National Diabetes Advisory Board. That rather technical amendment would be of substantial significance we believe.

With regard to the provisions continuing the authority for a National Diabetes Advisory Board we have the following comments. It is apparent from our testimony to this point that we believe the Board has been enormously successful in improving the management of programs in all sectors of our health care field: Federal, state and private. We think that a continuation of the Board for a period of 5 years as authorized in this bill makes a great deal of sense and we would support it fervently.

In connection with the Board, we are supportive of the suggested provision which would require the Secretary of HEW to reappoint 6 member from the existing Board in the first set of appointments to the new Board. Such continuity is particularly important.

Our comments on the other provisions of this bill dealing with the diabetes program within NIH are basically supportive of the provisions in the bill. We certainly support adding diabetes to the title of the National Institute of Arthritis, Metabolism & Digestive Diseases since diabetes is the largest program in the Institute measured in dollar terms. We would also support the provisions which make it clear that Associate Director is a required position and those provisions which provide new responsibilities to him for activity that cuts across the various Institutes of NIH. We believe that such cross-cutting activity should be carried out in consultation with the NIH Diabetes Coordinating Committee rather than, for example, the Interagency Diabetes Mellitus Coordinating Committee mandated by statute. With regard to the listing of new responsibilities, we would suggest that the activity dealing with the coordination of information dissemination specifically refer to such coordination being carried out by the Associate Director "through the National Diabetes Information Clearing House". The Clearing House is an existing program in NIH which was recommended in the diabetes Long Range Plan and which has received support by the Director of NIH and the

Director of NIAMDD as well as the Associate Director for Diabetes. It clearly should be the vehicle for such coordination and giving it a statutory reference would simply assure that it be such vehicle in future years.

STAFFING SUPPORT FOR NIH, CDC AND THE NATIONAL DIABETES ADVISORY BOARD

As a final comment, we would like to raise a very serious problem which is affecting all of NIH and the diabetes control program within CDC. We know that you, Senator Schweiker, have been very involved with this particular problem both in your role on this Subcommittee as well as in your position on the Labor-HEW Appropriations Subcommittee. Despite your efforts and those of others on this Subcommittee and the Appropriations Subcommittee, we still have a serious problem.

Management of research activity and the management of experimental contracts such as those which the CDC has undertaken in the diabetes control area require adequate staffing for their effectiveness. Unlike formula grant-in-aid programs to states and unlike forms of general and special revenue sharing, research activity and demonstrations with regard to the planning and management of health care require highly competent Federal staff to assist in the carrying out of these programs.

For fiscal year 1979, NIH was supposed to receive some 300 new positions to be allocated roughly in accordance with areas of research priority as reflected in the health statutes including the appropriations law. The additional 300 positions were actually specified in the Labor-HEW Appropriations law for fiscal year 1979. To date, to our knowledge, only 100 of those positions have been filled and yet no rescission under the Budget and Impoundment Act has been submitted to the Congress. In addition, with respect to the CDC diabetes control program, there were supposed to have been 20 additional positions in addition to the \$1 million for expanded programs in fiscal year 1979. It is our belief that none of those additional 20 positions have been provided.

There clearly seems to be a significant question with regard to whether the law dealing with impoundments applies to positions and staffing; and if it applies, whether it can be applied effectively. We certainly hope that the Congress will do whatever it can to assure that there is adequate staffing of NIH and CDC for its many very significant program activities which require highly competent peers for management. The substantial expansion of support for diabetes research and diabetes control programs in the past few years has not been met by the necessary increases in staffing to assure effective implementation of those programs. This is clearly true of other NIH research activity.

Mr. Chairman, we thank you for your indulgence and we hope that we have provided you with some useful information. We would be happy to respond to any questions now or to respond

to them in writing at a later date. We stand ready to work closely with this Subcommittee and with the Senate on the many issues affecting biomedical research, research training, health care delivery and related matters. In particular, we once again want to offer our assistance with regard to the legislation which has been discussed today because we think it is of great importance to the continuing efforts which have been so significant for the diabetics in this country.

Senator SCHWEIKER. Thank you for your testimony. I do have some questions. I will direct some of them to a specific group, and some to both groups.

I will start out with you, Dr. Whitehouse.

Why is the general clinical research centers program supported by NIH particularly important for diabetes research? You did mention this in ADA's prepared statement.

Dr. WHITEHOUSE. There are two types. One is diabetes research and training centers, which are the areas, such as at Vanderbilt and Chicago and Michigan. One of the reasons I think they are important is that academically they permit excitement, and they draw attention within the medical school area, they draw attention to the importance of diabetes. They sometimes will bring people into research in diabetes who have not thought about diabetes as an area of research. But because they cross, correlate, and the people are sitting down and talking to each other, as Mrs. Lurie commented, there may be somebody working in the blood area who never would have talked, or been interested in this, except it happened concerning research in diabetes training areas, but nevertheless it gives an opportunity for growth in research activities.

Another reason is the interrelationship between the academic area, medical school area and the community. The community can move into medical school, to DRTC, and learn how better to advise their diabetic patients back in the community. DRTC people can go out into the community and help improve the palliative care of the diabetic until the time comes when there is good research.

Then on top of that are the general clinical research centers. Here I think it points up the fact that diabetes is a keystone disease relative to study of interrelated metabolism within the body and enzyme functions, hormonal functions. These are detailed studies on human beings carried out at the several clinical centers, and may be related to diabetes, neuritis due to diabetes, ketoacidosis, may be related to other diseases related to diabetes, where there needs to be very careful studies done, and balanced studies, intake of food, intake of minerals, intake of nutrients and output of certain things.

These clinical research centers within teaching hospitals, separate from diabetes research and training centers, need also to be supported.

Senator SCHWEIKER. Now, we will ask both groups to comment on some of these issues.

Both of you commented on the bill in your statements, both informally and formally. My question is, are there any other observations that have come up in discussion that you want to make?

As I say, you both have already covered the bill fairly well. I am throwing the question open again to see if either group has any other comment about the bill, beyond what has been said. We will let JDF go first.

Mrs. LURIE. I have one large comment. I do not think it stems exactly from the bill. Yes; it does. We are talking about strengthening the Office of the Associate Director for Diabetes. How can you possibly do that when the additional resources Dr. Fredrickson proposes to add to Dr. Salans' staff are three people, and maybe you will have one? Is that what it means to strengthen an effort?

Senator SCHWEIKER. That is what it means according to the administration's view of strengthening the effort. The reason I did not get into that question in detail is because we are having a knock-down, drag-out fight with OMB in this area. The problem is fundamentally with OMB. We are going to have hearings on this issue in my Appropriations Committee.

We had mandated new NIH positions in the law, in the appropriation's law itself, so that the administration could not impound these positions, and they fought us tooth and nail. Rather than take the whole hearing on this problem today, we are going to make the positions issue a focus in the Appropriations Committee, because we have the clout there. I assure you that one new slot for a new trans-NIH program plan is not my idea of what an impressive resource capability is, and I did not pursue it earlier because we are going to make NIH positions the subject of a hearing in the Appropriations Committee.

Any other comments on the bill itself?

Dr. WHITEHOUSE. Only to underscore again what Mr. Tanenbaum has said, and that is we are supportive of the bill. We are supportive of the bill in such a way that it improves visibility of diabetes. It improves ongoing support of diabetes research, training and education, and all of these things that you attended initially in your first bill.

ADA is behind you four square.

Senator SCHWEIKER. I would like to ask both groups how you have been involved in Federal diabetes activities. In other words, what kind of links and communications have been established with you under the new set up, in terms of dealing with CDC, NIH, and other Federal agency programs?

Mr. TANENBAUM. Actually, it began with the Commission, and subsequently the Advisory Board, where our people, as well as other volunteers are members of those groups. Through that we can get feedback, and feed into those groups, as well as in their capacities as advisers in the various institutes.

With regard to CDC, in every single one of the States in which there is a CDC program, our affiliate organizations in those States have been coordinating with State health departments. The consequence has been that we have been able to derive, in support of our patient education programs in those States, and spread around in other affiliates a good deal of information that is already being gathered as baseline data concerning existing conditions on mortality and morbidity.

As well, it gives us an opportunity to feed back through those organizations the assistance of our professionals in regard to improving the care of diabetics.

Senator SCHWEIKER. I know ADA has had an interest in the establishment of State diabetes programs. Do you feel they are proceeding satisfactorily in terms of what CDC had done so far?

Mr. TANENBAUM. The programs in the States that have them are fine. As a matter of fact, with your assistance again, you jogged along the CDC to get moving on those programs, and they have picked up. They are working out very nicely.

Senator SCHWEIKER. The former CDC director was asleep, I might say, to put it mildly. Fortunately, Dr. Foege has taken an interest in diabetes and done a really good job.

Mr. TANENBAUM. After they got into it, CDC has really picked it up, and I think with enthusiasm. The problem is they do not have, with regard to that aspect of it, they do not have sufficient personnel. They have had their personnel requests impounded, as it were. Their announced program in regard to the five leading causes of morbidity and mortality in regard to funding programs leave diabetes, for whatever the reason, out of the running, because they do not include diabetes in the top five, notwithstanding the Commission's designation that diabetes is in fact the third leading cause of death, because the cause of death that would be evidenced on the death certificate, we fall out of that program, and from the standpoint of the manner in which it is progressing, we are pleased if they could get additional personnel.

Mrs. LURIE. The intermeshing I spoke about before, you now see members serving on NDAB, mutual conversations within NDAB and NIH, and you are beginning to see members serving on Diabetes Educational Clearinghouse. The including of information amongst people of the needed pamphlets, the needed educational materials, and it is a complete intermeshing which you never saw before.

You begin to hear that you have exploded the diabetes world, so that the amount of information that is required, the amount of information that comes at you, requests for information by a State, can you help us this way, can you help us that way, are the Government people even speaking at national conferences, Senators speaking at national conferences, and it is a complete—I use the word to death—but would you believe we are all one family. This is what is happening.

Senator SCHWEIKER. In light of Dr. Fredrickson's new NIH Coordinating Committee, and this question is for both of you, do you think there is also a need to keep the interagency Diabetes Mellitus Coordinating Committee?

Dr. WHITEHOUSE. I do not want to get involved in bureaucratic tar baby, or anything like that.

Senator SCHWEIKER. We do all the time down here. You might as well join in.

Dr. WHITEHOUSE. I am from the country I guess. Let me say that my view as a private citizen would be whatever way the job gets done the best is the way I would favor it. Now, when I first looked at these, and I am sort of unsophisticated relative to the National Institute of Health, but when I first looked at Diabetes Mellitus Coordinating Committee, and Trans-NIH, I wondered whether there was a lot of overlap, and maybe one could be phased into the other.

Honestly, Senator, I just have not studied it, and do not have enough depth of knowledge to know myself. I think the ADA position would be that the most efficient way of handling the interrelationship between the institutes to the purpose of the aim of the institutes, namely the support of diabetes, not only through NIH, but elsewhere, would be the way I would favor it.

I could talk with Dr. Salans or Dr. Whedon, or Dr. Fredrickson, and I am sure they would give me their own particular viewpoints. I could talk with others who are more sophisticated in the area than I am, because my area of expertise is primarily clinical practice. But I think whatever way happens to be worked out which would be the most efficient way from the standpoint of time and money would be the way I would propose they should go, whether it be Diabetes Mellitus Coordinating Committee, or Trans-NIH, whether they should be a bureau or not, as I think Mr Tanenbaum has addressed that point as well as I can.

Mrs. LURIE. One quick comment. Diabetes is a word that was not very famous at NIH for many years. It is a brand new word to them.

Senator SCHWEIKER. That is why we are having trouble writing it into law right now.

Mrs. LURIE. I think whether it be Diabetes Mellitus Coordinating Committee, or intraagency, I think is very important, the intraagency at NIH. For the first time the right hand knows what the left hand is doing. I do not think any of the other sister institutes, or any of the sister institutes knew the type of diabetes work which was being done.

I certainly think at the present time, until any other plan is initiated, this is very important to maintain.

Senator SCHWEIKER. Do you think there has been a change in public awareness? Your groups both deal with the public and the diabetic population. Has there been a change or increase in public awareness about the seriousness of diabetes since the Commission's report?

Dr. WHITEHOUSE. Do you want to comment on that, Myles?

Mr. TANENBAUM. As a matter of fact, the Commission report finally gave us the kind of information that we could reliably announce to the public concerning what we had believed previously, and only believed to be the seriousness in terms of mortality, morbidity concerning diabetes. That has enabled us, frankly, to enlarge our programs, and to attract, by reason of the public perception of the seriousness of the ailment a lot more in the way of campaign dollars that have enabled us to go back to the public with better public information programs.

I would say, of all the things that are in nontechnical area the outstanding element of what has happened is that the public is far more aware today than it ever was, and what they are aware of are fundamental facts, rather than just some misinformation, which had been the case previously.

Senator SCHWEIKER. Mr. Aszling?

Mr. ASZLING. I think we would concur in what our friends from ADA say. There is a gratifying increase in the level of public awareness and public understanding of diabetes. It is in large part, I suppose, due to stepped up areas within the Federal establishment as well as voluntary agencies. But there is a heck of a long way to go. We still, too frequently, run into the old phrase that I thought it was cured with insulin.

Senator SCHWEIKER. We have heard a lot about research in specific areas here this morning. I do not want to repeat it. I would like to ask you if there are any areas of diabetes research that we

should be pursuing that have not been discussed this morning, areas that we are overlooking?

Again, we already have covered quite a list of research opportunities, at least with respect to where the NIH has been, and where they are going. Are we missing anything that we ought to be doing? Should we be putting more emphasis on any area that we are not putting enough priority on? I'd like to hear from both groups.

Dr. WHITEHOUSE. Senator, I think some of the areas that were touched on, I believe, by Dr. Fredrickson, with respect to HLA. He talked about some of the genetic aspects. I think this area is going to be an area where much more emphasis is going to be needed in the future.

Not only, let us say, the split between juvenile onset diabetes, and some of the evidences of genes versus environment, and the adult onset, or non-insulin-dependent diabetes in the evidences of environment and genes. Within the group there is probably going to be a need to probe some of the genetic aspects of diabetes.

I think we are going to have to learn a little bit more about some of the nutritional nuances that exist.

Senator SCHWEIKER. I agree, Dr. Whitehouse. I think that has been a very neglected area.

Dr. WHITEHOUSE. We need to look into much more why, if you permit me a little levity here, am I good just because I appear slender, and is somebody else bad because they appear fat? No, probably not. The idea of the way that energy is utilized in the body, the driving force of appetite, from part of the brain—all of these things need involvement vis-a-vis diabetes. Nutrition is an overlooked area.

I spend a great deal of my time in trenches talking about nutrition. This is an area that needs looking into very carefully. I think a comment made about nutrition being in with digestive diseases because food gets in through the gut—well you can argue once it gets in there through that conduit, the rest of it is in an area of diabetes and metabolism, and you can dangle that over both of the areas, but nutrition, genetics, and other factors, toxic factors, particularly viruses, other areas that might play a role relative to diabetes—well there may be areas I am not aware of as a clinician which might come up tomorrow, which Dr. Crofford or Dr. Kipnis know more about, and I think you should ask them the same question.

I think the flexibility of the NIH and NIAMD, if you please, or the others need to be ready to open up and move into any areas which happen to show promise.

Mr. TANENBAUM. One area I am most concerned about that tends to be overlooked because it is essentially outside the mainstream of the concerns with regard to research has to do with mental health. It is in that area, and we are just now able to see some cooperation within IMH in this whole endeavor, but that is the area I think that has been probably most neglected in regard to emphasis in the way diabetics on a daily basis have very real problems, and their families do. It is not just limited to juvenile onset-type diabetics. With them it runs throughout their lives.

The problems of living with diabetics on a daily basis, and the problems evidenced in just family life, and things coming up under the heading of mental health areas are of particular concern that tend to be overlooked.

Senator SCHWEIKER. I did, incidentally, specify in the appropriations bill report last year that we should put more emphasis on this kind of work. The bill went through just at the tail end of last year, so there has not been enough time to implement it meaningfully.

I agree with your point, and we did put in appropriations report language on that particular area.

Mrs. LURIE. They have said it very beautifully. I would love to see a little more emphasis on the scientific endeavor.

Senator SCHWEIKER. Let me thank the panel very much for participating this morning. Your observations are very helpful.

Mrs. LURIE. Thank you.

Senator SCHWEIKER. Our last panel this morning, consists of two witnesses who represent present and past congressionally established diabetes advisory groups: Dr. Oscar B. Crofford, Addison B. Scoville Professor of Medicine, Vanderbilt University School of Medicine, Nashville, Tenn., and former chairman of the National Commission on Diabetes; and Dr. Robert Bradley, president, Joslin Diabetes Foundation; associate clinical professor of medicine, Harvard Medical School, Boston, Mass., and member of the National Diabetes Advisory Board.

Let me begin by saying that Dr. Crofford did an outstanding job leading the commission. Almost literally starting from scratch, the Commission on Diabetes brought forth a very scientifically sound and widely accepted product that has certainly been the blueprint for the progress we see here today.

Dr. Crofford, we are glad to see you back again, and commend you on what you helped to initiate. We will turn to your statement at this point.

STATEMENTS OF OSCAR B. CROFFORD, M.D., ADDISON B. SCOVILLE PROFESSOR OF MEDICINE, AND DIRECTOR OF THE DIABETES RESEARCH AND TRAINING CENTER, VANDERBILT UNIVERSITY SCHOOL OF MEDICINE, NASHVILLE, TENN., ACCOMPANIED BY DR. ROBERT BRADLEY, PRESIDENT, JOSLIN DIABETES FOUNDATION; ASSOCIATE CLINICAL PROFESSOR OF MEDICINE, HARVARD MEDICAL SCHOOL, BOSTON, MASS.

Dr. CROFFORD. Thank you very much, Senator Schweiker, for those kind remarks.

I have a brief statement that I will read into the record.

My name is Oscar B. Crofford. I am a doctor of medicine and serve as the Addison B. Scoville Professor of Medicine at Vanderbilt University Medical School in Nashville, Tenn. I was chairman of the National Commission on Diabetes when the long-range plan to combat diabetes was formulated. That plan made specific recommendations to the Congress, the National Institutes of Health, the Center for Disease Control, and a wide array of Government and non-Government agencies and organizations. The statements that follow represent my personal views of where we have succeeded and where we have failed to achieve full implementation of the

plan and what specific legislative actions are necessary for the plan to continue into the 1980's.

The Arthritis, Diabetes and Digestive Diseases Amendments of 1976 (Public Law 94-562) authorized establishment of the National Diabetes Advisory Board. Although this was a watered-down version of the legislative recommendation made by the commission, it contained the two essential elements of having the board submit its annual report to the Congress without prior administrative approval and a workable mechanism, for example, staff, money, authority to convene, et cetera, for the board to obtain the facts that it needs to develop a meaningful report. It is my strongly held opinion that the progress made in implementing the diabetes plan would not have occurred without an advisory board that is free from excessive Government influence and that is expected to review progress and report objectively to the Government, the Congress, and the general public. A cure for the complications of diabetes and a prevention for the disease itself have not been discovered. The long-range plan to combat diabetes must be continued and maintained up to date. Extending the term of the National Diabetes Advisory Board is my top priority recommendation for I view the board as the most essential element of the entire plan. I have reviewed those sections of S. 451 that pertain to the board and find them to be entirely satisfactory.

A second priority recommendation relates to the Diabetes Research and Training Centers program. In this instance the objectivity of my remarks could be challenged since I serve as the director of such a center. Nevertheless, I have had more years of experience in directing a diabetes center than anyone else and offer the following opinion based on that experience. The Congress and the National Institutes of Health should continue to display unwavering support for the Diabetes Research and Training Centers program. To do otherwise would have a devastating effect on the attitudes and morale of the new generation of research and health-care personnel that we are trying to recruit and train in the diabetes field. On-again, off-again Federal programs and policies have contributed to the research manpower shortage that now exists. The complications of diabetes are long-term problems whose solutions require long-term, stable research and training support mechanisms. We may hope but we should not expect the quick results from training centers that we expect from short-term, highly targeted research contracts. I am convinced that the Diabetes Research and Training Centers will make a substantial impact given 15 years of support and encouragement, but to hold them accountable for results prematurely will destroy the program continuity that we are all working so hard to establish. There will always be criticism of any "centers program." The Diabetes Research and Training Centers should not be confused with various health-care delivery centers, however. The critics of the diabetes centers program are unduly influenced by well-meaning but misinformed scientists who believe that diabetes centers are draining off scarce research funds and that their own research programs are thereby jeopardized. That is simply not true and the misunderstanding can be corrected by the language of the subcommittee report in the NIH section of the appropriation bill.

In S. 451, the authorization for the centers is reduced from \$20 million to \$14 million for fiscal year 1981. That is too large a reduction in the authorization. The reason that the centers program is not now spending up to the authorized limit is that the process for setting up the centers in the first place was not well handled by NIAMDD and to a lesser extent by the applicants. That process is now operating better and the authorization should be \$18 million for fiscal year 1981, with increases of 7 percent per year for each of the 4 subsequent fiscal years.

The provision for paying a limited number of training stipends from the funds authorized for centers is a well-conceived idea. It is ridiculous to set up training centers and then have the payment of training stipends from center funds be specifically prohibited. I support this aspect of the S. 451 enthusiastically and will be happy to work with Institute officials to develop guidelines for that aspect of the program if asked to do so.

Turning now to the National Institutes of Health, it is my opinion that 85 percent of the recommendations made to NIH have been or are now being carried out. The performance of the NIAMDD Associate Director for Diabetes, Dr. Lester Salans, has been truly outstanding and he deserves special commendation. I have reviewed those sections of S. 451 pertaining to the responsibilities of the Associate Director for Diabetes, especially the trans-NIH responsibilities. In my opinion all of these provisions are consistent with the diabetes plan and should be enacted.

In conclusion, Mr. Chairman, let me add my support to the provisions of S.451 and thank you for allowing me to appear as a witness this morning.

Senator SCHWEIKER. Thank you, Dr. Crofford.

Dr. Bradley?

Dr. BRADLEY. Thank you, Senator Schweiker, for inviting me here today. I am kind of a lameduck in a sense. Dr. Kipnis, chairman of the National Diabetes Advisory Board, was originally to have testified, but for reasons apart from weather, coming from St. Louis, was not able to make it. He has prepared testimony dated Thursday, February 22, 1979, which is a statement generally reviewing the progress which has been made in NDAB diabetes effort, and with it a statement relative to executive summary to the second annual report of the National Diabetes Advisory Board, which I believe is currently at the printers, and will be soon available.

I assume you have those.

Senator SCHWEIKER. Without objection, we will include both statements in the record.

Dr. BRADLEY. Thank you very much.

I would like to digress from the written word just a bit, perhaps also save some time, and hone in on a few points.

First of all, I have not actually read S. 451. What I have heard here in the last hour makes it sound very good indeed, if the substance is actually to increase support for the diabetes effort overall.

In a moment I will try to clarify that. There has been a good deal said about some of the progress in research relative to the commission's recommendations, some of which may have started before

the commission. I will not dwell a great deal on the individual examples of progress. They have been considerable.

One area which the board has been concerned about has to do with research manpower, and particularly the bringing into the effort of physician-scientists, the supply of which has fallen down sharply.

Dr. Crofford has just now alluded to one of the issues, namely on-again, off-again types of support, and I think this may be one of the problems. The area of education and control programs I would like to emphasize somewhat more because it is one of the portions of the National Diabetes Advisory Board effort for which I have been personally responsible. As a clinician practicing with diabetic patients for over 30 years, even though my formal title is president of Joslin Diabetes Foundation in Boston, I am particularly concerned that these programs turn out to be successful.

I have been impressed by the network of increasing professional interest, not only in terms of research, but in terms of activities having to do with health care and education.

Just to illustrate this, you have currently eight so-called PRTC's, two DERC's, and you have five Indian Health Service Model programs which do not relate to any of the others directly, but as I will show in a moment, may be critical.

You have 10 CDC programs already going through the planning phase and currently being implemented, with a plan to increase this activity. The interfaces between these are already becoming apparent.

I happen to be associate director of one of the DRTC's. We are already finding ourselves being challenged by Indian Health Services projects, and by CDC projects to provide training education for various people who could in turn go back to those communities and provide service there.

There is a very exciting ferment going on in this whole area. I think to halt it at the present time, or not to provide ongoing and hopefully increase support would be a tragedy to the whole program.

The other issue I would like to bring up about Indian Health Service is this. The thrust we have had in pushing this particular activity is that these could be a model demonstration type program of one sort, for example, for an underprivileged, poorly motivated population who have major health care needs in the diabetes area. Diabetes has great impact among American Indian populations.

The current service is one paid for, if you will, by hiring professionals, Indian Health Medical Service. Indian Medical and Health Service provides all the care. Our concept would be that one would try slowly but surely to educate the Indians so they in turn would provide health care, and then become the trainers of their own people—thus ultimately freeing up the Government from providing relatively disinterested people who are then assigned like an Armed Forces type person to a given area to carry on service.

If one can do this, and testing procedures have been put into recommendations, one might also apply a similar model to underprivileged populations, such as blacks, poor, et cetera, in various parts of the country. That would be something for the future, but

underscores the need for the effort to be broad-based throughout the Government—that is, not just in NIH.

But in answer to a prior question about the Diabetes Mellitus Coordinating Committee, which reaches outside NIH to other areas such as Health Services Administration, Health Resources Administration, et cetera I believe the Bureau of Community Health Services comes under HSA—hopefully, if a model demonstration program amongst Indians turns out to be successful, one might be able to imprint it through the Bureau of Community Health Services into other populations. That is longer range thinking. Clearly, one has not even approached the point at which this could be a reality as of the present time.

There are areas which I can see as a member of the Diabetes Advisory Board, we have not been able to address as yet, wherein a great deal of effort still is needed. If one asks the question in a given community of an individual: "What does diabetes mean to you?" more often than not, in our experience, mother had gangrene, or grandpa had gangrene. Why did he have gangrene? Because he had diabetes. What did he die of? He had a heart attack. Was that not diabetes? No; that was not diabetes. That was a heart attack.

I would like to emphasize that currently diabetes visibility has not reached the point at which the public at large recognizes the role of diabetes in producing fatal heart attacks, gangrene, and strokes. The reason diabetes is generally not rated as being No. 3 as a cause of death, but five, or six, or even eight depends on poor definition as to who has diabetes in the adult population. As yet the credibility of that very well-known report, at least to members of the Diabetes Commission, by Tokuhota in Pennsylvania has not yet reached the point where it is accepted by cardiologists and many others around the country. They are afraid to believe that it might be true. This is the reason No. 3 for diabetes as a cause of death has not reached the visibility which it deserves.

Now, I am speaking as an individual, and not as a member of a National Diabetes Advisory Board, and I would hope that we of the board would be getting into these questions before too long.

Senator SCHWEIKER. Dr. Bradley, as a member of the board, what do you think are the most important functions of the advisory board? Do you have any suggestions about how we should change its functions, or add supplemental functions, beyond what it does now? How would you analyze the present operation of the board?

Dr. BRADLEY. I think with all the things to be done, its functioning has been highly appropriate to the issues. There is no question that down the line the research effort is of critical importance. It has looked in great detail at not only the research effort in terms of the various thrusts of that research, and parts of NIH where such might be carried out, but also in terms of the manpower, as I indicated. They have definitely looked very hard at some of the health control and education programs.

As yet, they have not had a chance to focus on recommendations that might relate to some of the complications of diabetes, apart from general support of what the National Eye Institute is doing with its study relative to photocoagulation, and so on.

The trans-NIH investigator award has potential down the line. I expect once another year or two of activity in the Board has seen what looks to be good continuity of effort in some of the other areas that it will be able to devote itself more to vascular disease and other issues.

I was just going to say currently one of the big thrusts that we have had is trying to get at the issue of the psychosocial impact of diabetes. I think some progress is being made there, as has been indicated in the detailed report.

Senator SCHWEIKER. How would you assess the relationship among Federal officials carrying out Federal diabetes programs, scientists, and the lay, or consumer, members of the Board? How do they work and function together?

Dr. BRADLEY. I think they have worked well together. Primarily I would say because of the fact that Dr. Salans, as associate director, has done such a fine job of communicating, and also has been readily available.

That does not mean to point any fingers anywhere else. But the fact is that his role is key. As far as we can tell, well, last year I think he was the only person attending our many meetings for whom we decided to have a standing vote of applause for the work he has done. That is quite something coming from the private sector, for public officials, sir.

Senator SCHWEIKER. I guess that leads into my next question, which I'd like to direct to both of you. From your perspective, how do you assess the work of the Board vis-a-vis the private sector? Maybe you have already answered that question, but perhaps you would like to elaborate.

Dr. CROFFORD. Senator, I think the Board has done a good job. I was certainly struck by the testimony this morning, where for the most part, the administration witnesses were supportive of the activities of the Board, and commented that it would have been useful in an advisory role to them. The proposed changes in the composition of the Board are not of a major nature.

I think that it is important that the Board maintain a majority membership from the non-Government sector, and that will be maintained as laid out in your piece of legislation. I think they have worked very good together.

Dr. BRADLEY. I would be able to add one thought. I think it is true that thus far, and there are good reasons for this, a great deal of effort and thrust has been directed toward the issue of juvenile type diabetes, insulin-dependent type diabetes, and for obvious reasons.

The impact of diabetes day-to-day is the greatest in those people. I see no problem with that. Both in that area, and in the adult area, the issue of the education of professionals in terms of health care, how to take care of diabetes, what to look out for, and so on, not just education in terms of research techniques, which is another whole story, is a critical part of our thrust.

I think from my own experience with some of the education evaluation which has been put into DRTC's, and which has been frowned upon by many, I must say I am coming around to the point that I am beginning to be impressed that it is worthwhile.

We have already learned some things from our own component about the ways in which we teach people, and the qualifications of people who are doing some teaching, to realize that perhaps some major changes for the better can be made. If that is the case, maybe we can communicate the message about diabetes more effectively, not only to the diabetic population and their families, but also to the public.

Senator SCHWEIKER. Dr. Crofford, you mentioned that you felt the majority of the recommendations of the Diabetes Commission you headed were being implemented. Where do you feel we still have further to go to fully implement the recommendations? Where do you think we should put greater emphasis, in terms of priority or implementation, in order to achieve the goals of the Diabetes Plan?

Dr. CROFFORD. I think the major problem has been one of timing, rather than total disregard for the recommendations. Many of the programs are behind schedule because some of them were hard to set up in the first place. They had to recruit personnel to fill the spots to get these programs going. I think for the most part it is a question of being a little behind schedule. They are now going, and trying to catch up.

Some examples might be diabetes education clearinghouse, which has been referred to a couple of times this morning. That program has, for the first year—well a home for that program was not really identified. Then personnel had to be recruited. It is beginning to get into operation now, but still I think it is fair to say that the results from that program in 1979 are behind schedule from what was predicted in 1975.

The CDC program got off to a slower start than was anticipated. It is doing well now. I am really very optimistic for that diabetes control program through CDC.

Those are examples of sort of lagging behind, but with few exceptions, I think everybody is doing their best.

I would like to suggest two pieces of data that your staff might review in this regard. Certainly the second annual report of the diabetes board is forthcoming soon, and details step by step what the progress has been for all of the agencies and second, a document that Dr. Salans prepared for Dr. Fredrickson, which details from the perspective of the trans-NIH committee the progress that each of the NIH agencies and Institutes has made in implementing their plans.

Both of those, I think, provide a great deal of detailed background information for progress in implementing the plan, and perhaps should be included in the committee study pertaining to this legislation.

Senator SCHWEIKER. One final question, Dr. Crofford. Earlier, we asked our other witnesses if there were research areas we should be looking into that we have not been probing, or some areas that we have not pursued that should get higher priority. I would like to address the same question to you.

Dr. CROFFORD. I think all important research areas that I am aware of have been touched on by other witnesses this morning. I am pleased with the broad scope of the diabetes research program at the present time. I think it is a question of continuity of effort. I

do not really identify any specific areas that are being ignored at the present time.

Senator SCHWEIKER. Do you have any comments, Dr. Bradley?

Dr. BRADLEY. No. I think the biggest problem in getting at some of the research that one needs to do in the area of vascular disease and neurologic involvement is trying to find the appropriate models to study it. It is not a question of their not being interested in doing it, it is finding a device by which one can study these problems in the way that provides answers much more quickly.

Senator SCHWEIKER. All right.

I thank the panel very much.

[The prepared statement of Dr. Crofford, the summary statement referred to by Dr. Bradley, and additional material supplied follows:]

STATEMENT OF

OSCAR B. CROFFORD, M.D.

Addison B. Scoville Professor of Medicine, and
Director of the Diabetes Research and Training Center,
Vanderbilt University School of Medicine
Nashville, Tennessee 37232

PRESENTED AT A HEARING

Before the

SUBCOMMITTEE ON HEALTH AND SCIENTIFIC RESEARCH

of the

COMMITTEE ON HUMAN RESOURCES

UNITED STATES SENATE

96th Congress

1st Session

on

S. 451

Diabetes Research and Training Amendments
and National Diabetes Advisory Board Extension

Act of 1979

February 26, 1979

"The National Diabetes Mellitus Research and Education Act" (Public Law 93-354), signed by the President on July 23, 1974, directed the appointment of a National Commission on Diabetes, whose charge was to formulate a long-range plan of research and education to combat diabetes mellitus. The Commission submitted its report to Congress on December 10, 1975, and concluded its term on January 10, 1976.

The National Commission on Diabetes was reestablished on April 22, 1976, by enactment of Public Law 94-278, which extended its term through September 30, 1976. The 1976 update of the Commission's Report was submitted to Congress on November 30, 1976.

Dr. Crofford served as the Chairman of the National Commission on Diabetes during both of its terms and was instrumental in formulating The Long-Range Plan to Combat Diabetes and the 1976 Update.

Since 1976 Dr. Crofford has observed the implementation of the Diabetes Plan from the perspective of a University based scientist-educator-physician and has participated in the Plan as the Director of the Diabetes Research and Training Center at Vanderbilt.

Mr. Chairman and distinguished members of the subcommittee:

My name is Oscar B. Crofford. I am a doctor of medicine and serve as the Addison B. Scoville Professor of Medicine at Vanderbilt University Medical School in Nashville, Tennessee. I was Chairman of the National Commission on Diabetes when The Long-Range Plan to Combat Diabetes was formulated. That Plan made specific recommendations to the Congress, the National Institutes of Health, the Center for Disease Control and a wide array of government and non-government agencies and organizations. The statements that follow represent my personal views of where we have succeeded and where we have failed to achieve full implementation of the Plan and what specific legislative actions are necessary for the Plan to continue into the 1980's.

The Arthritis, Diabetes and Digestive Diseases Amendments of 1976 (P.L. 94-562) authorized establishment of the National Diabetes Advisory Board. Although this was a watered down version of the legislative recommendation made by the Commission, it contained the two essential elements of having the Board submit its annual report to the Congress without prior administrative approval and a workable mechanism (i.e., staff, money, authority to convene, etc.) for the Board to obtain the facts that it needs to develop a meaningful report. It is my strongly held opinion that the progress made in implementing

the Diabetes Plan would not have occurred without an Advisory Board that is free from excessive government influence and that is expected to review progress and report objectively to the Government, the Congress and the general public. A cure for the complications of diabetes and a prevention for the disease itself have not been discovered. The Long-Range Plan to Combat Diabetes must be continued and maintained up to date. Extending the term of the National Diabetes Advisory Board is my top priority recommendation for I view the Board as the most essential element of the entire Plan. I have reviewed those sections of S-451 that pertain to the Board and find them to be entirely satisfactory.

A second priority recommendation relates to the Diabetes Research and Training Centers program. In this instance the objectivity of my remarks could be challenged since I serve as the Director of such a Center. Nevertheless, I have had more years of experience in directing a Diabetes Center than anyone else and offer the following opinion based on that experience. The Congress and the National Institutes of Health should continue to display unwavering support for the Diabetes Research and Training Centers program. To do otherwise would have a devastating effect on the attitudes and morale of the new generation of research and health-care personnel that we are trying to recruit and train in the diabetes field. On-again, off-again Federal programs and policies have contributed to the research manpower shortage that now exists. The complications of diabetes are long-term problems whose solutions require long-term, stable research and training support mechanisms. We may hope but we should not expect the quick results from training centers that we expect from short-term, highly targeted research contracts. I am convinced that the Diabetes Research and Training Centers will make a substantial impact given fifteen years of support and encouragement, but to hold them accountable for results prematurely will destroy the program continuity that we are all working so hard to establish. There will always be criticism of any "centers program." The Diabetes Research and Training Centers should not be confused with various health-care delivery centers, however. The critics of the Diabetes Centers program are unduly influenced by well-meaning but misinformed scientists who believe that the Diabetes Centers are draining off scarce research funds and that their own research programs are thereby jeopardized. That is simply not true and the misunderstanding can be corrected by the language of the Subcommittee report in the NIH section of the appropriation bill.

In S-451, the authorization for the Centers is reduced from \$20,000,000 to \$14,000,000 for FY'81. That is too large a reduction in the authorization. The reason the Centers program is not now spending up to the authorized limit is that the process for setting up the Centers in the first place was not well handled by NIAMDD and to a lesser extent by the applicants. That process is now operating better and the authorization should be \$18,000,000 for FY'81, with increases of 7 percent per year for each of the four subsequent fiscal years.

The provision for paying a limited number of training stipends from the funds authorized for Centers is a well-conceived idea. It is ridiculous to set up "Training Centers" and then have the payment of training stipends from

Center funds be specifically prohibited. I support this aspect of the S-451 enthusiastically and will be happy to work with Institute officials to develop guidelines for that aspect of the program if asked to do so.

Turning now to the National Institutes of Health, it is my opinion that 85 percent of the recommendations made to NIH have been or are now being carried out. The performance of the NIAMDD Associate Director for Diabetes, Dr. Lester Salans, has been truly outstanding and he deserves special commendation. I have reviewed those sections of S-451 pertaining to the responsibilities of the Associate Director for Diabetes, especially the trans-NIH responsibilities. In my opinion all of these provisions are consistent with the Diabetes Plan and should be enacted.

In conclusion, Mr. Chairman, let me add my support to the provisions of S-451 and thank you for allowing me to appear as a witness this morning.

EXECUTIVE SUMMARY

Three years have passed since the National Commission on Diabetes delivered to the Congress the Long-Range Plan to Combat Diabetes (Diabetes Plan). In the intervening period, the Congress, the Administration, and the public have recognized that diabetes is a major health problem which requires increased attention. As a result, new and innovative diabetes programs are now being planned and implemented in the areas of biomedical and behavioral research, research manpower development, disease control, and health care.

The National Diabetes Advisory Board - Activities and Continued Authorization

Congress created the National Diabetes Advisory Board to serve as the national focus for review, evaluation, and advice with respect to the Diabetes Plan. A major national effort has been initiated between the Federal agencies, private health organizations, state and local departments of health, and academic institutions to deal with the problems of a disease affecting over ten million people. The Federal effort alone involves eleven component institutes of the National Institutes of Health (NIH), the National Institute of Mental Health (NIMH), the Center for Disease Control (CDC), the Indian Health Service, and the Division of Emergency Medical Services of the Health Services Administration (HSA), in addition to portions of the Health Resources Administration, the Veterans Administration, the Department of Agriculture, and the Department of Defense. The Board serves as a catalyst for coordination of effort among each component of the diabetes community.

With the assistance of the Board, innovative and cooperative diabetes programs have been initiated which have increased the effectiveness of

Federal, state, and private health resources. Four examples of such coordinated programs are:

- Model Diabetes Care Program - Five project sites have been established by the Indian Health Service which is working closely with the Center for Disease Control and several Diabetes Research and Training Centers to train clinic staff and design appropriate clinical and epidemiological programs to reduce the incidence of diabetes complications in the highly susceptible Indian population.
- Community Diabetes Control Demonstration Projects - The Center for Disease Control is assisting state and local health agencies in ten project states to establish effective coordination with available resources such as the Diabetes Research and Training Centers and volunteer health agencies to reduce excess mortality and morbidity due to diabetes.
- Research Manpower Development - Two innovative Special Emphasis Research Career Awards, one focusing on the cardiovascular aspects and the other on the perinatal and pediatric aspects of diabetes, have been implemented as a cooperative program by three NIH institutes. These awards are part of the Board's efforts to reverse the serious decline in the number of physician-scientists engaged in biomedical research.
- Psychosocial and Behavioral Aspects of Diabetes - The National Institute of Mental Health and several institutes of NIH are developing a joint program announcement to stimulate interest in research on the psychosocial and behavioral aspects of diabetes. The Board has also joined these Institutes in co-sponsoring a conference on the subject to be held in May, 1979.

The Board has also catalyzed the following important developments in the past two years:

- Creation of the Intra-NIH Diabetes Coordinating Committee.
- Development of the National Diabetes Information Clearinghouse and the National Diabetes Data Group in NIAMDD.
- Development with NIAMDD of improved guidelines for the multi-disciplinary Diabetes Research and Training Centers.
- Cooperation of the National Diabetes Information Clearinghouse, the Division of Emergency Medical Services, HSA, and volunteer health organizations in an initiative to improve education for diabetic emergencies.

The Board's expertise and broad constituency enables it to respond uniquely and effectively to a wide variety of policy issues affecting the diabetes community. A striking example of this role was the Board's recent study of insulin supplies. A preliminary report issued in 1977 by the Food and Drug Administration seriously questioned the adequacy of insulin supplies during the next decade, and was referred to the Board by the Secretary, HEW for further assessment. The Board quickly established an ad hoc committee composed of its members and expert consultants and invited representatives of both U.S. and foreign pharmaceutical companies, the meat packing industry, and responsible Federal agencies to participate in the collection and analysis of data relating to the supply and demand for insulin. The credibility of the Board within both the Federal and private sector enabled this study to be conducted rapidly and in a refreshingly candid and open atmosphere. Within three months the first in-depth analysis of this subject had been completed. The Board's report, issued in April 1978, established that

insulin supplies were adequate through the end of the century and presented a reasonable set of guidelines by which the availability of insulin could be monitored effectively by both the Federal and private sectors.

The Board's ability to catalyze important developments and to respond promptly and effectively to public policy issues demonstrates the usefulness of the Board to the Congress, the Administration and the diabetes community. The statutory authorization for the Board currently extends through September 30, 1980. We recommend that the Congress extend the Board's activities for an additional five years. We further recommend that new members be appointed by the Secretary, HEW, to replace the current members at phased intervals to assure continuity of necessary experience and expertise.

Budget Recommendations

Although portions of the Diabetes Plan have been implemented, the effectiveness of these efforts in the prevention, treatment, and ultimate cure of this devastating disease depends on continued support by Congress, the Administration, and a concerned public. The Board has identified those areas in which the Federal effort should be expanded and emphasized in the next two years. Budget recommendations for these agencies are given in Table 1. Those recommendations differ from the distribution of funds originally recommended by the National Commission on Diabetes and reflect the Board's continuing assessment of relative needs and opportunities within the Diabetes Plan (Figure 1).

Personnel Position Recommendations

The implementation and continued progress of the Diabetes Plan is dependent upon sufficient personnel to plan and conduct the diabetes research, health care, and control activities described in this report. The Board has been informed that most of the new positions specifically mandated by the Congress in FY'79 for diabetes have not been made available

TABLE 1

Budget Recommendations of the National Diabetes Advisory Board,
FY 1980-1981

(\$ in thousands)

<u>Agency</u>	<u>FY 1979 estimate</u>	<u>FY 1980</u>	<u>FY 1981</u>
National Institutes of Health:			
NIAMDD	\$ 67,800	\$ 85,000	\$106,000
NHLBI	14,200	17,000	21,000
NEI	13,700	15,000	18,000
NICHD	7,500	10,000	12,500
NINCDS	3,900	5,200	6,500
NIDR	1,000	2,000	2,500
NIAID	3,900	5,800	7,000
NIA	1,900	2,500	3,000
NIGMS	1,500	1,500	1,700
NIEHS	100	500	700
DRR	8,400	11,500	14,500
Subtotal	\$123,900	\$156,000	\$193,400
Center for Disease Control	2,600	10,500	13,000
Indian Health Service	925	2,200	2,400
National Institute of Mental Health	*	1,200	1,500

* Diabetes portion of appropriation not specified

Figure 1

Comparison of Budget Recommendations for FY 1980 by the
National Diabetes Advisory Board and the National Diabetes Commission

(to be completed. similar to last year's)

Percentage of total budget to be displayed on graph. Figures will be:

	<u>NDAB</u>	<u>Commission</u>
NIAMDD	50.1 %	57.1 %
NHLBI	10.0	8.1
NEI	8.8	8.4
NICHD	5.9	5.6
NINCDS	3.1	1.5
<i>NIDR</i>	<i>1.2</i>	<i>1.2</i>
<i>NIAID</i>	<i>3.4</i>	<i>.4</i>
NIA	1.5	* <i>.4</i>
NIGMS	.9	* <i>.7</i>
NIEHS	.3	* <i>.2</i>
DRR	6.8	6.2
CDC	6.2	8.4
IHS	<i>1.7</i>	.9
NIMH	.7	.9

to the agencies due to the Administration's ceiling on total Federal employment. The Board recommends that Congress request a report from the Department of Health, Education, and Welfare and the OMB on the status of personnel positions for diabetes programs approved by the Congress in FY 1979. On the basis of current staff available for the diabetes programs, additional employment should be authorized in FY 1980 as shown in Table 2. These positions are urgently needed to provide patient care staff for the model Diabetes Care Program in the Indian Health Service, field service professionals required in the Community Diabetes Control Program of the Center for Disease Control, laboratory and clinical research personnel for the National Institutes of Health, as well as professional and support staff needed to plan and conduct clinical trials and other extramural grant and contract activities.

Table 2
Recommendations for Personnel Positions

<u>Agency</u>	<u>FY 1980</u>
National Institutes of Health:	
NIAMDD	15
NHLBI	5
NEI	5
NICHD	5
NINCDS	3
NIAID	3
NIDR	2
DRR	3
Center for Disease Control	15
Indian Health Service	25
National Institute of Mental Health	4

Bureau Status for the National Institutes of Arthritis, Metabolism
and Digestive Diseases

In recent years, the scope of major program responsibilities assigned to NIAMDD has increased dramatically without a corresponding adjustment in the internal organization of the institute. In the last three years, Congress has authorized accelerated initiatives in diabetes, arthritis and digestive diseases. The NIAMDD has proposed a reorganization which should provide not only for the most effective implementation of these expanded programs but also enhance its ability to improve program management in other areas of responsibility which include endocrinology, nutrition, and renal, metabolic, skin, bone and hematological diseases. The proposed plan would establish a bureau level organization for the NIAMDD and a division level organization for the institute's diabetes and related programs. We recommend that this plan be implemented.

Diabetes Research Program

Funds made available to NIH in FY 1978 and FY 1979 to implement the Diabetes Plan have increased the scope and depth of the diabetes research effort. Significant opportunities are now available for investigators in basic science disciplines not ordinarily identified with diabetes to apply their skill to such critical areas as the vascular, neurological and perinatal complications of diabetes as well as to the fundamental issues of causation, prevention, and cure of the disease. The following examples of recent advances reflect the diversity of scientific disciplines which have contributed to the diabetes research effort and which merit increased support.

- Recent studies have shown that the genetic pattern of inheritance of insulin-dependent diabetes (juvenile diabetes) differs from that in the non-insulin dependent form of the disease (maturity-onset diabetes).
- Human beta cells (insulin producing cells of the pancreas) have been grown in tissue culture and can be infected and damaged by several common viruses.
- New experimental techniques which decrease or prevent the immunologic rejection reaction common in transplantation provide hope for significant advancement in the treatment of diabetes by the transplantation of pancreatic islets.
- Artificial devices which monitor blood glucose and administer insulin automatically are currently being tested under controlled clinical conditions.

- Clinical trials of new therapies for diabetic retinopathy have demonstrated that photocoagulation is effective in reducing the risk of severe vision loss.
- A clinical trial of the efficacy of strict control of blood sugar in preventing the long-term complications of diabetes is being planned and a preliminary feasibility study will be initiated in the coming year.
- The effect of strict blood sugar control on reducing maternal and fetal complications in diabetic pregnancies is being studied in a clinical trial.
- Significant progress has been achieved in the production of human insulin through recombinant DNA technology which ultimately should result in a limitless supply of this essential hormone.

The Board's budgetary recommendations (Table 1) reflect the increased opportunities for new research advances represented by the accomplishments cited.

Development of Physician-Scientists

The diabetes research program is dependent upon an adequate supply of well trained research scientists in diabetes and related scientific disciplines. While the Board is concerned about the future availability of all research manpower there is a particularly acute and increasing shortage of medically trained investigators. The current number of these physician-scientists is inadequate and present manpower development programs will not correct this serious deficiency. Physician-scientists play a critical role in the translation of laboratory and field research

to the problems of the patient and the most productive clinical research is performed by investigators whose medical experience furnish the stimulus for their own studies.

The percentage of physician-scientists among new investigators receiving NIH research grants has dropped from 43.9% in 1966 to 28.8% in 1977. The number of medical school graduates pursuing advanced research training with NIH support has dropped from 4,600 in 1971 to 1,800 in 1977. This decline is due in part to Federal policies which severely curtail manpower training programs and effectively discourage medical school graduates from careers in biomedical research.

The Board has provided specific recommendations to correct the shortage of physician-scientists and eliminate present disincentives to research careers. The recommended budgets for the institutes of NIH include funds for current training programs and to implement the Board's new recommendations.

Multidisciplinary Centers

Two types of Centers are supported by the National Institute of Arthritis, Metabolism, and Digestive Diseases. The Diabetes Research and Training Centers (DRTC) provide special facilities to accelerate diabetes research and to transfer research advances with the least delay into more effective patient care. The number of DRTCs increased from five to eight during FY 1978. In addition, there are two Diabetes Endocrinology Research Centers (DERC), whose role is exclusively biomedical research. Each center provides investigators with core resources and short-term support for innovative pilot studies. Further expansion of the program is dependent upon demonstrated ability of

institutions to conduct research of the highest quality.

The National Institute of Child Health and Human Development recently established at four institutions a Major Research Program (MRP) which focuses on various aspects of fetal and maternal complications associated with pregnancies in diabetic mothers. Research in the area of diabetic pregnancies is a high priority since the outcomes of these high-risk pregnancies contributes significantly to the overall rates of infant mortality and morbidity in this country.

The General Clinical Research Centers (GCRC) of the Division of Research Resources are essential to the national diabetes research effort. Over 80% of all diabetes clinical research in the United States is conducted in these non-categorical, miniature research hospital facilities located throughout the country. The Board is distressed that clinical facilities supported by GCRC's have declined steadily over past years. This decline affects research in all diseases. Additional funds are urgently required to strengthen this program.

The Board's proposed budget for NIH includes funds to continue or strengthen these multidisciplinary center programs.

PSYCHOSOCIAL AND BEHAVIORAL ASPECTS OF DIABETES

Physicians and other professionals who work with diabetics are concerned about the frequency with which psychosocial and emotional factors seriously interfere with the therapy and daily life patterns of their patients, both young and old. The Board's first report to the Congress noted the absence of any significant Federal programs in this area and recommended that research and training efforts be undertaken by NIMH. The Congress subsequently directed NIMH to initiate diabetes-related behavioral and psychosocial research programs. In response, both NIMH and NIH will soon issue a joint program announcement to encourage research

applications and these two agencies are also planning a comprehensive conference on this subject.

These recent developments offer hope for progress, but the continued support of the Congress and the Administration is needed, to insure that these initiatives are continued and expanded. The Board's budget recommendations are based on the Board's judgement that NIMH should be the major source of support for activities in this subject.

Health, Care, Education, and Control Programs

The transfer of diabetes research accomplishments into improved disease prevention programs and patient services is an essential component of the Diabetes Plan. Significant progress has been achieved during the past year.

Diabetes Control Program. The Board has given its highest priority to a national diabetes control program directed by the Center for Disease Control working in close partnership with state and local health departments. Ten states have completed an initial planning phase and are beginning the implementation of innovative control programs. Many other states have expressed their desire to begin similar programs which are dependent upon additional funds.

Model Diabetes Care Program. The Indian Health Service has established the first five model projects designed to develop and evaluate methods to reduce the severity of diabetes and its complications. Diabetes is considerably more common in most Indian tribes than in the general U.S. population and a major portion of the health care expenses of the Indian Health Service is caused directly by diabetes. A total of ten model

model projects are considered necessary to evaluate adequately the effectiveness of a variety of treatment and prevention modalities.

Information, Education, and Related Programs. The National Diabetes Clearinghouse will coordinate the collection and evaluation of diabetes educational materials. The Emergency Medical Services has agreed to distribute appropriate educational literature to persons most likely to be involved in diabetic emergencies. The National Diabetes Data Group has developed programs to improve the collection and analysis of epidemiologic and other data related to the public health policy issues of diabetes. The Board's budget recommendation for NIAMDD reflect the importance which the Board gives to these activities.

Testimony Offered by David M. Kipnis, M.D.

Thursday, February 22, 1979

I am Dr. David M. Kipnis, Professor and Chairman of the Department of Medicine at Washington University School of Medicine and Physician-in-Chief at Barnes Hospital in St. Louis. I am here today as Chairman of the National Diabetes Advisory Board, which was established in 1976 by Congress to review and evaluate the implementation of a long-range plan formulated by the National Commission on Diabetes and to report annually to Congress and the Secretary of HEW recommendations for future policies, programs and budgetary requirements for the diabetes effort. The second Annual Report of the NDAB is currently at the printers and will be submitted to Congress within the next several weeks. The Executive Summary of that report is included with this presentation and provides a more detailed description of the accomplishments of the diabetes program since its inception along with specific recommendations as to future directions and budgetary requirements for research, scientific manpower development and control and educational programs. I will confine my comments to identifying the highlights of that report and focusing on those issues which the Board feels most important for your consideration.

Remarkable progress has been made on many fronts in diabetes research ranging from the most basic molecular level of investigation to the most clinically relevant issues of treatment. For example, in the past twelve months, recombinant DNA techniques have been successfully applied to the

production of human insulin by bacteria. It is anticipated that this breakthrough will lead to the production of human insulin in quantities sufficient to meet the needs of the diabetic population world-wide and alleviate our current dependency upon beef and pork insulin. Exciting new leads as to causative factors of certain forms of diabetes have come from epidemiologic and genetic studies. Recent data suggest that some forms of insulin-dependent diabetes - particularly in the young - may be associated with genetically determined altered immune reactions to certain virus infections which attack the pancreatic islets - those glands in the pancreas that produce insulin. Within the past several months, it has been reported that certain common viruses are capable of infecting human islets - findings which raise the possibility of preventing this disorder by the appropriate vaccination of individuals genetically predisposed to developing diabetes.

Progress has also been made in defining the fundamental mechanisms which cause the devastating long-term complications of diabetes affecting the eyes, kidneys, nerves and blood vessels, but this area demands much greater emphasis and effort. Clinical management of diabetes through the administration of insulin has proven life-saving for millions of patients, but the daily injection of insulin does not match the fine control of insulin secretion which the normal pancreas maintains. The amount of insulin required throughout each day changes from minute to minute in response to a huge number of variable factors which neither the diabetic patient nor his physician can adequately monitor or control

with present technology. Major emphasis, therefore, has been placed on the development of new therapeutic modalities for the improved control of the blood sugar level in diabetics. Remarkable progress has been made in this area and involves both islet cell transplantation and artificial devices which do the work of islet cells. Within the past year, islet cells have been successfully transplanted across major histocompatibility barriers and artificial devices capable of maintaining normal blood sugar levels have been clinically tested. Concomitant with these efforts, clinical trials of currently available treatment modalities in the prevention and/or amelioration of diabetic complications either have been completed, are in progress or are currently being planned. The demonstrated effectiveness of laser beam photocoagulation in the amelioration of diabetic proliferative retinopathy - the second most common cause of blindness in this country - is an excellent example of the accomplishments of these efforts.

The Board believes that Congress and the public should be pleased with the effective manner in which the diabetes research program has been implemented and the progress which has been accomplished to date. However, the Board feels that the diabetes research program is still in a growth phase and encourages Congress to maintain its current tempo of implementation.

One of the greatest concerns of the Board is the development of adequate research manpower to maintain the continued development of the diabetes research program. Continued progress in this effort is totally

dependent upon an adequate supply of well-trained research scientists in diabetes and related scientific disciplines. During the Board's ongoing review of the federal diabetes research programs, it has become increasingly evident that the current number of physician-scientists is inadequate and that present manpower development programs will not correct this serious deficiency. While the Board is concerned about the future availability of all research scientists with skills related to diabetes, there is a particularly acute and increasing shortage of medically trained investigators who are firmly grounded in both modern biology and clinical medicine. Indeed, the Board feels that this problem is not only of concern to the diabetes effort but is one which almost every other area of clinical research faces. The Board strongly recommends that Congress reassess its current training programs and provide both the funds and policy guidelines needed to assure a continued input of talented young people into this critically needed research manpower pool.

Another important element of the Long Range Plan in Diabetes was the development of institutional vehicles and administrative practices which would assure and catalyze effective co-ordination and cooperation among the multiple federal agencies involved in diabetes research, training programs, educational activities and control projects. The Board is pleased to report that these efforts have met with considerable success. For example, eight Diabetes Research and Training Centers have now been established and, although in their initial stages of evolution, are functioning already as major catalysts for the translation of research advances to clinical practice, and as training centers

for medical and paramedical professionals both for local services as well as to staff diabetes projects undertaken by other federal agencies (e.g. the Diabetes Model Care Units in the Indian Health Service). The Board recommends that authorization for these Diabetes Research and Training Centers be continued for an additional five years and that they also be authorized to utilize their funds for the training of physician-scientists for diabetes research.

Other co-ordinated activities which focus on the transfer of diabetes research technology into improved disease prevention programs and patient services are: 1) the community-based Diabetes Control Demonstration Projects developed by the Center for Disease Control which currently extends to ten states, 2) the Model Diabetes Care Projects implemented at five Indian reservations by the Indian Health Service, and 3) the diabetes education initiatives directed toward first responders to diabetic emergencies involving the Diabetes Clearinghouse and the Division of Emergency Medical Services. The Board is especially pleased with the collaborative efforts of these federal research agencies and state and local health agencies; this cooperation has resulted in the effective use of a limited supply of skilled manpower and financial resources. Of particular note is the CDC program which has not only been met with remarkable enthusiasm by state agencies, but has also engendered the commitment of state resources to complement limited federal appropriations - thereby maximizing the effectiveness of the federal program. The Board strongly recommends that Congress fully support these meritorious programs.

Some comment is in order concerning the Board's own activities and future role. Extensive Congressional debate about the role of the National Diabetes Advisory Board preceded its creation by enactment of P.L. 94-562. The past two years' experience of the Board has demonstrated the wisdom of Congress in assigning this body an advisory role rather than operational responsibilities. This policy decision has given the Board the freedom and flexibility needed to engage in candid discussions of research, health care, education and training programs with federal officials in a manner which would not have been possible had the Board been an operating agency of the Federal Government. The Board has been able to catalyze new programmatic developments such as the Model Diabetes Care Program in the Indian Health Service, the Community Diabetes Control Demonstration Projects of the Center for Disease Control, the National Diabetes Data Group and the National Diabetes Clearinghouse at NIAMDD, and cooperative ventures such as those involving the National Diabetes Information Clearinghouse and the Division of Emergency Medical Services. Of equal importance is the ability of the Board to respond to unanticipated developments critical to the welfare of the diabetes community. A particularly instructive example was the Board's recent study in response to a preliminary report issued in 1977 by the Food and Drug Administration which seriously questioned the adequacy of insulin supplies during the next decade. The credibility of the Board within both the Federal and private sectors enabled this study to be conducted rapidly, candidly, cost-effectively and in an open atmosphere. The final

report was issued in April 1978 and established that insulin supplies were adequate through the end of the century and presented a reasonable set of guidelines by which the availability of insulin could be effectively monitored by both Federal and private sectors.

We feel that the Board plays an important role in assuring the effective implementation of the diabetes program and responding to the needs of the national diabetic community and recommend its continuance be authorized for an additional five years. It is also recommended that the appointment of new members be staggered in such a fashion as to assure continuity of expertise.

Senator SCHWEIKER. This concludes our diabetes hearing this morning. The Subcommittee on Health and Scientific Research will stand in adjournment.

[Whereupon, at 12:15 p.m., the subcommittee adjourned, subject to the call of the Chair.]

