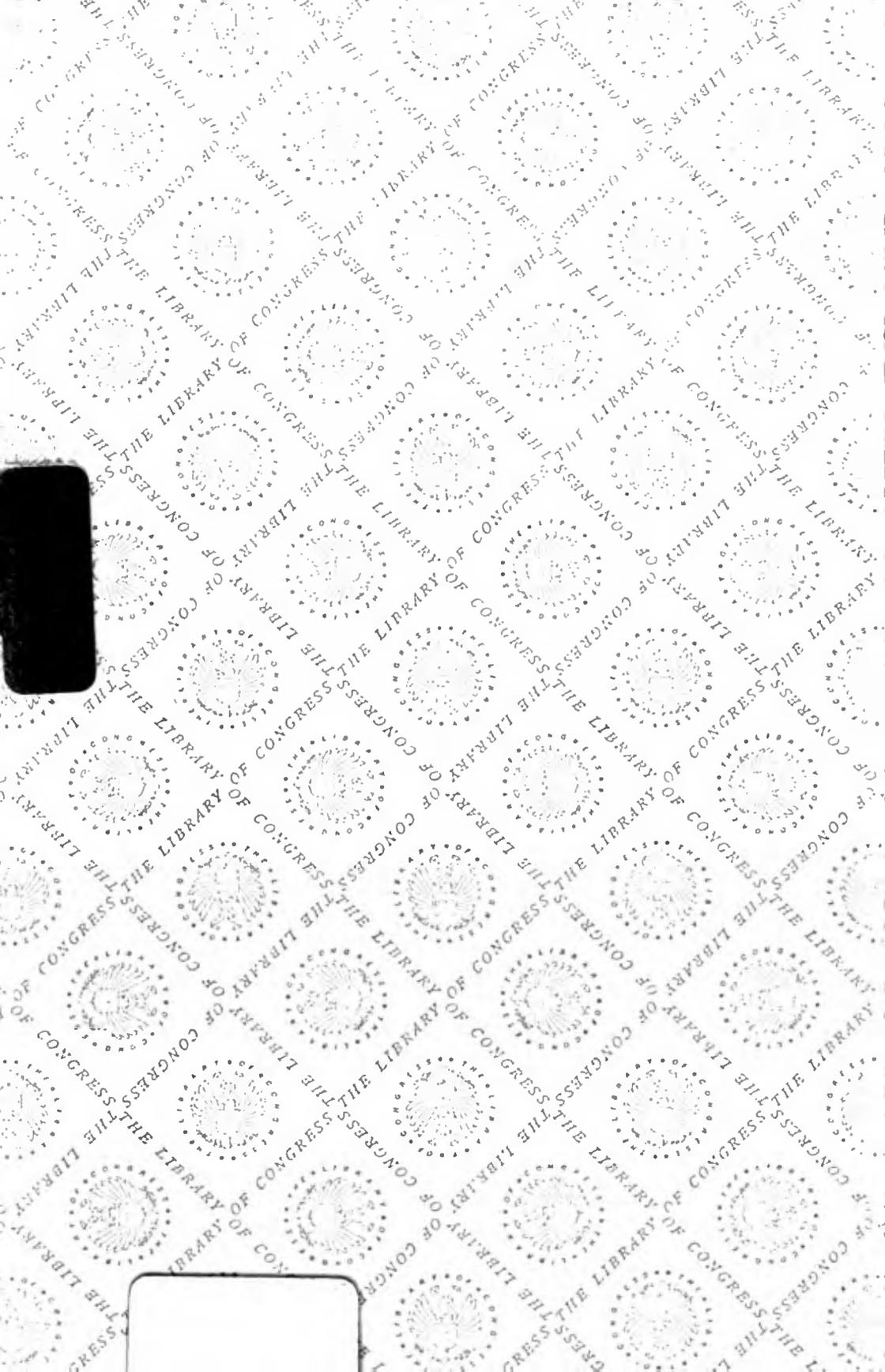
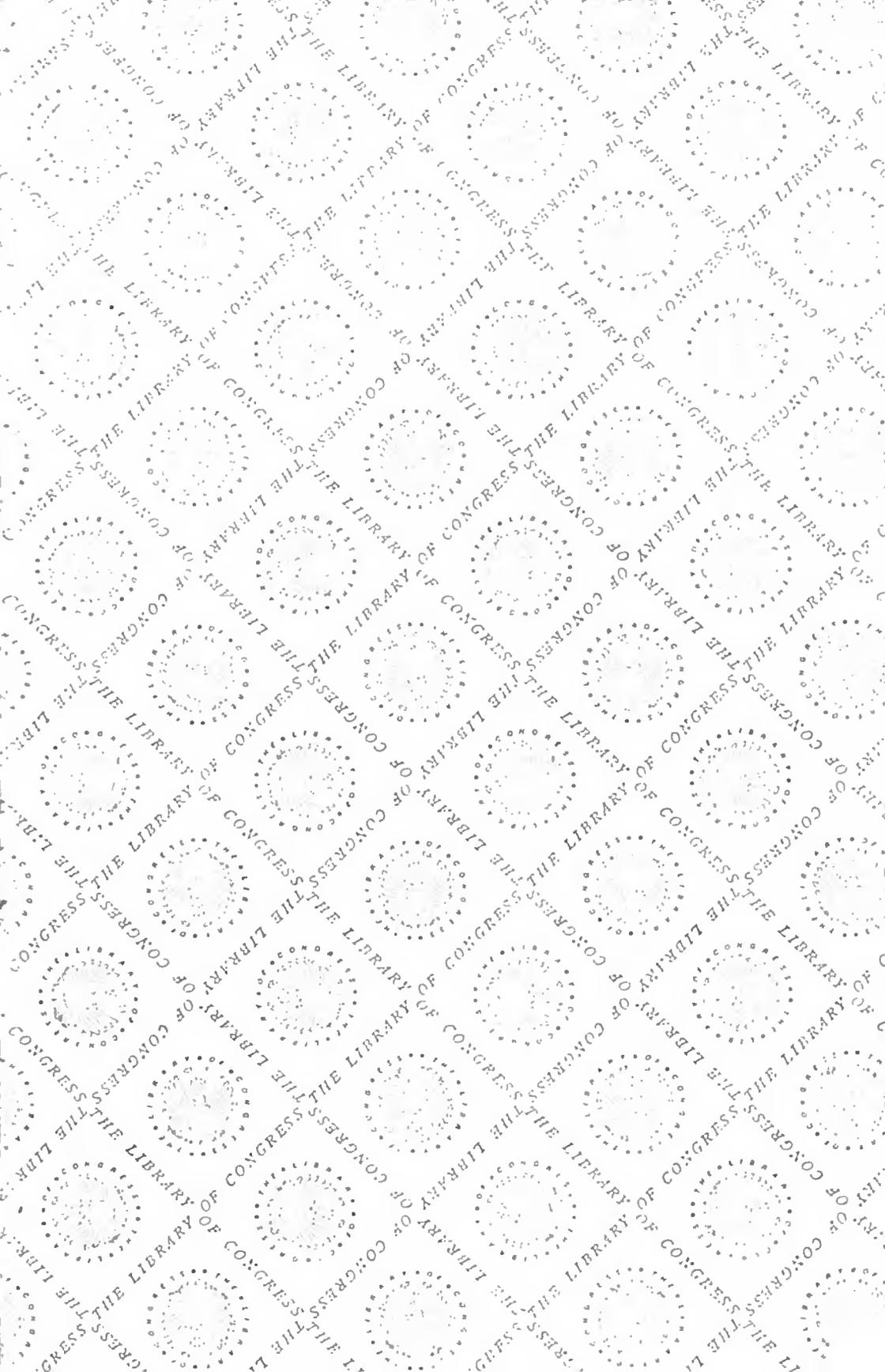


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*United States Congress, House Committee  
"on Interstate and Foreign Commerce"  
Subcommittee on the Health and Environment*

# NATIONAL DIABETES ACT OF 1973

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HEARINGS

BEFORE THE

SUBCOMMITTEE ON

PUBLIC HEALTH AND ENVIRONMENT

OF THE

COMMITTEE ON

INTERSTATE AND FOREIGN COMMERCE

HOUSE OF REPRESENTATIVES

NINETY-THIRD CONGRESS

FIRST SESSION

ON

**H.R. 4882**

**(and all identical bills)**

BILLS TO AMEND THE PUBLIC HEALTH SERVICE ACT TO  
EXPAND THE AUTHORITY OF THE NATIONAL INSTITUTE  
OF ARTHRITIS, METABOLISM, AND DIGESTIVE DISEASES  
IN ORDER TO ADVANCE THE NATIONAL ATTACK ON  
DIABETES

---

JULY 27 AND AUGUST 1, 1973

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**Serial No. 93-46**

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Printed for the use of the  
Committee on Interstate and Foreign Commerce



U.S. GOVERNMENT PRINTING OFFICE

WASHINGTON : 1973

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## American Diabetes Association:

Connelly, J. Richard, executive director.
Crofford, Dr. Oscar B., vice chairman, committee on research, and member, board of directors.
Davidson, Dr. John K., consultant to the public affairs committee and member, board of directors.
Entzweiler, Dr. Donnell D., chairman, committee on diabetes in youth, and member, board of directors.
Field, Dr. James B., member, board of directors.
Heffner, Dr. George P., member, board of directors.
Tannenbaum, Myles H., member, committee on public affairs.

## ORGANIZATIONS REPRESENTED AT HEARINGS—Continued

- Commonwealth of Pennsylvania Committee on Diabetes and Blindness:  
 Patz, Dr. Arnall, professor of ophthalmology, director, Diabetic Retinopathy Center, Wilmer Institute, the Johns Hopkins Hospital, and member, board of directors, National Society for the Prevention of Blindness.  
 Schwarz, Dr. Richard H., professor of obstetrics and gynecology, University of Pennsylvania School of Medicine, director, the Jerrold R. Golding Division of Fetal Medicine, and member of the Commonwealth of Pennsylvania Committee on Diabetes and Blindness.  
 Stenzler, Carl, chairman.
- Diabetes Research, Inc., Dr. Heskell M. Haddad.
- Health, Education, and Welfare Department:  
 Burton, Benjamin T., Ph. D., Associate Director, National Institute of Arthritis, Metabolism, and Digestive Diseases.  
 Lamont-Havers, Dr. R. W., Deputy Director, National Institute of Arthritis, Metabolism, and Digestive Diseases.  
 Zapp, Dr. John S., Deputy Assistant Secretary for Legislation (Health).
- Joslin Diabetes Foundation, Inc.:  
 Chick, Dr. William.  
 Ferguson, Edward C.  
 Mason, John.  
 Mowbray, James H.  
 Orr, Miss Barrie.  
 Robertson, Mrs. Clifford P.  
 Sears, Frederick F.  
 White, Dr. Priscilla, director.  
 Wilson, Miss Chris.  
 Younger, Dr. Donna.
- Juvenile Diabetes Foundation, Robert Kronowitt, chairman, board of directors.  
 National Federation of the Blind, John F. Nagle, chief, Washington office.

# NATIONAL DIABETES ACT OF 1973

FRIDAY, JULY 27, 1973

HOUSE OF REPRESENTATIVES,  
SUBCOMMITTEE ON PUBLIC HEALTH AND ENVIRONMENT,  
COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE,  
*Washington, D.C.*

The subcommittee met at 10 a.m., pursuant to notice, in room 2322, Rayburn House Office Building, Hon. Paul G. Rogers, chairman, presiding.

Mr. ROGERS. The subcommittee will come to order, please.

This morning the subcommittee will begin consideration of the need for legislation to advance research efforts as to the cause, effect, and prevention and treatment of diabetes mellitus.

This subcommittee has some knowledge in the area of the adequacy of research efforts into the causes and prevention of many diseases and in the course of obtaining this knowledge, the committee has learned that no research effort in any field can be entirely adequate to the task.

Nevertheless, there are instances in which legislation has been helpful in redirecting research efforts in badly underfunded areas and I think examples of recent efforts are in the field of cancer, heart disease, multiple sclerosis, and digestive diseases.

The purpose of today's hearing is to determine the extent of the present effort to treat and prevent diabetes whether or not it begins to be adequate to meet the task and, if not, whether legislation can be designed to alleviate it adequately.

Without objection, the text of the bills to be covered in this hearing and the agency reports thereon shall be printed at this point in the record.

[The text of H.R. 4882 and all identical bills and the agency reports, thereon follow:]



1           (2) that it is the fifth leading cause of death from  
2           disease, and that it is the second leading cause of new  
3           cases of blindness;

4           (3) that the complications of diabetes mellitus lead  
5           to many other serious health problems;

6           (4) that uncontrolled diabetes significantly de-  
7           creases life expectancy;

8           (5) that the citizens of the United States should  
9           have a full understanding of the nature of the impact of  
10          diabetes mellitus;

11          (6) that there is convincing evidence that the  
12          known prevalence of diabetes mellitus has increased dra-  
13          matically in the past decade;

14          (7) that the present level of knowledge of therapy  
15          of diabetes mellitus has not provided solutions to many  
16          difficult problems and especially in the delivery of health  
17          care to those who are economically and educationally  
18          deprived;

19          (8) that the severity of diabetes mellitus in chil-  
20          dren and most adolescents is greater than in adults,  
21          which in most cases involves greater problems in the  
22          management of diabetes mellitus;

23          (9) that the attainment of better methods of diag-  
24          nosis and treatment of diabetes mellitus deserves the  
25          highest priority; and



1 standing of which is essential to solution of the problem of  
2 diabetes.

3 “(2) It is the purpose of the program to expand,  
4 intensify, and coordinate the activities of the Institute respect-  
5 ing diabetes and related endocrine and metabolic diseases.  
6 The program shall be coordinated with the other programs  
7 conducted or administered by the research institutes of the  
8 National Institutes of Health to the extent that such institutes  
9 have responsibility respecting such diseases. The program  
10 shall provide for—

11 “(A) investigation into the epidemiology, etiology,  
12 prevention and control of diabetes, including investiga-  
13 tion into the social, environmental, behavioral, nutri-  
14 tional, biological, and genetic determinants and influences  
15 involved in the epidemiology, etiology, prevention and  
16 control of diabetes;

17 “(B) studies and research into the basic biological  
18 processes and mechanisms involved in the underlying  
19 normal and abnormal phenomena associated with dia-  
20 betes including abnormalities of the skin, gastrointestinal  
21 tract, kidneys, eyes, and nervous system. The studies and  
22 research shall also include evaluation of influences of  
23 other endocrine hormones on the etiology, treatment, and  
24 complications of diabetes.

25 “(C) research into the development, trial, and

1 evaluation of techniques and drugs used in, and ap-  
2 proaches to, the diagnosis, treatment and prevention of  
3 diabetes;

4 “(D) establishment of programs that will focus and  
5 apply scientific and technological efforts involving bio-  
6 logical, physical and engineering science to all facets  
7 of diabetes;

8 “(E) establishment of programs for the conduct and  
9 direction of field studies, large-scale testing and evalua-  
10 tion and demonstration of preventive, diagnostic, ther-  
11 apentic, rehabilitative and control approaches to diabetes;

12 “(F) the education and training of scientists, clini-  
13 cians, and educators in the fields and specialties requisite  
14 to the conduct of programs respecting diabetes; and

15 “(G) patient, public and professional education  
16 relating to all aspects of diabetes.

17 “(b) (1) The plan required by subsection (a) of this  
18 section shall be developed within two hundred and seventy  
19 days after the effective date of this section, and be trans-  
20 mitted promptly to the Congress. Such plan shall set out  
21 the staff requirements and resources necessary for the Na-  
22 tional Institute of Arthritis, Metabolism, and Digestive Dis-  
23 eases to carry out the program and recommendations for  
24 adequate funding levels for the program.

1       “(2) In the development of the plan, attention will be  
2 given to means to assure continued production of funda-  
3 mental new knowledge which would form the basis of future  
4 advances in the understanding, treatment, and control of  
5 diabetes. Specific recommendations will be made on the  
6 proportion of the effort devoted to the production of new  
7 knowledge which would be expected to occur as the result  
8 of individual projects undertaken in the Nation’s and the  
9 world’s biomedical research laboratories generally and that  
10 which would be anticipated as arising from the research  
11 conducted in the centers under section 437.

12       “(3) The Director of that Institute shall as soon as  
13 practicable after the end of each calendar year prepare in  
14 consultation with the Council and submit to the President  
15 for transmittal to the Congress a report on the activities,  
16 progress and accomplishments under the program during  
17 the preceding year and a plan for the program for the  
18 succeeding five-year period.

19       “(c) In carrying out the program, the Director of the  
20 National Institute of Arthritis, Metabolism, and Digestive  
21 Diseases, under policies established by the Director of the  
22 National Institutes of Health and after consultation with the  
23 Council and without regard to any other provisions of this  
24 Act may, if authorized by the Council, obtain (in accord-  
25 ance with section 3109 of title 5, United States Code, but  
26 without regard to the limitation in such section on the num-

1 ber of days or the period of such service) the services of not  
2 more than ten experts or consultants who have scientific or  
3 professional qualifications.

4 "DIABETES PREVENTION AND CONTROL PROGRAM

5 "SEC. 436. (a) The Director of the National Institute  
6 of Arthritis, Metabolism, and Digestive Diseases, under  
7 policies established by the Director of the National Institutes  
8 of Health, and after consultation with the Council, shall  
9 establish programs as necessary for cooperation with other  
10 Federal health agencies, State, local, and regional public  
11 health agencies, and nonprofit private health agencies, in  
12 the prevention, control, and evaluation of diagnosis and treat-  
13 ment of diabetes, appropriately emphasizing the prevention,  
14 control, diagnosis and treatment of such diseases in children.

15 "(b) There is authorized to be appropriated to carry  
16 out this section \$25,000,000 for the fiscal year ending  
17 June 30, 1974, \$35,000,000 for the fiscal year ending  
18 June 30, 1975, and \$45,000,000 for the fiscal year ending  
19 June 30, 1976.

20 "NATIONAL RESEARCH AND DEMONSTRATION CENTERS  
21 FOR DIABETES

22 "SEC. 437. (a) (1) The Director of the National In-  
23 stitute of Arthritis, Metabolism, and Digestive Diseases may  
24 provide for the development of not less than fifteen centers

1 for basic and clinical research into, training in, and demon-  
2 stration of advanced diagnostic, prevention, and treatment  
3 methods for diabetes.

4 “(2) The centers developed under paragraph (1) of  
5 this subsection shall, in addition to being used for research,  
6 training, and demonstration projects, be available for the  
7 following prevention program for diabetes:

8 “(A) programs to develop improved methods of  
9 detecting individuals with a risk of developing diabetes;

10 “(B) programs to develop improved methods of  
11 intervention against those factors which cause individ-  
12 uals to have a high risk of developing diabetes; and

13 “(C) programs to develop health professions and  
14 allied health professions personnel highly skilled in the  
15 prevention and control of diabetes.

16 “(3) (a) Centers developed under this subsection may  
17 be supported under subsection (b) or under any other  
18 applicable provision of law.

19 “(b) The Director of the National Institute of Arthritis,  
20 Metabolism, and Digestive Diseases, under policies estab-  
21 lished by the Director of the National Institutes of Health  
22 and after consultation with the Council, may enter into co-  
23 operative agreements with public or nonprofit private agen-  
24 cies or institutions to pay all or part of the cost of planning,  
25 establishing, or strengthening, and providing basic operating

1 support for, existing or new centers (including centers  
2 established under subsection (a)) for basic or clinical re-  
3 search into, training in, and demonstration of, advanced  
4 diagnostic, prevention, treatment and control methods for  
5 diabetes. Funds paid to centers under cooperative agree-  
6 ments under this subsection may be used for—

7 “(1) construction, notwithstanding section 405;

8 “(2) staffing and other basic operating costs, in-  
9 cluding such patient care costs as are required for  
10 research;

11 “(3) training, including training for allied health  
12 professions personnel; and

13 “(4) demonstration purposes.

14 Support of a center under this subsection may be for a period  
15 of not to exceed five years and may be extended by the Di-  
16 rector of the National Institute of Arthritis, Metabolism, and  
17 Digestive Diseases for additional periods of not more than  
18 five years each, after review of the operations of the center  
19 by a scientific review group established by the Director. As  
20 used in this section, the term ‘construction’ does not include  
21 the acquisition of land.

22 “INTERAGENCY TECHNICAL COMMITTEE

23 “SEC. 438. (a) The Secretary shall establish an Inter-  
24 agency Technical Committee on Diabetes which shall be re-  
25 sponsible for coordinating those aspects of all Federal health

1 programs and activities relating to diabetes to assure the  
 2 adequacy and technical soundness of such programs and ac-  
 3 tivities and to provide for the full communication and ex-  
 4 change of information necessary to maintain adequate co-  
 5 ordination of such programs and activities.

6 “(b) The Director of the Institute shall serve as Chair-  
 7 man of the Committee and the Committee shall include  
 8 representation from all Federal departments and agencies  
 9 whose programs involve health functions or responsibilities  
 10 as determined by the Secretary.”

11 CONFORMING AMENDMENTS TO THE PUBLIC HEALTH

12 SERVICE ACT

13 SEC. 4. Section 431 (a) of the Public Health Service  
 14 Act is amended by striking out “and metabolism” and  
 15 inserting in lieu thereof “diabetes and metabolic diseases”.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,  
 Washington, D.C., July 16, 1973.

HON. HABLEY O. STAGGERS,  
 Chairman, Committee on Interstate and Foreign Commerce, House of Repre-  
 sentatives, Washington, D.C.

DEAR MR. CHAIRMAN: This letter is in response to your request of March 21,  
 1973, for a report on H.R. 4882, the National Diabetes Act of 1973.

The bill would provide the authority for the Director of the National Institute  
 of Arthritis, Metabolism, and Digestive Diseases to:

Develop a plan for a National Diabetes Program designed to expand,  
 intensify, and coordinate the activities of the Institute and other NIH In-  
 stitutes respecting diabetes and related endocrine and metabolic diseases.

Establish diabetes prevention and control programs in cooperation with  
 various health agencies funded at \$25, \$35, and \$45 million for the next  
 three fiscal years.

Develop not less than 15 National Research and Demonstration Centers  
 for basic and clinical research into, training in, and demonstration of, ad-  
 vanced diagnostic, prevention, and treatment methods for diabetes.

In addition, H.R. 4882 would require the Secretary of Health, Education, and  
 Welfare to establish an Interagency Technical Committee on Diabetes to coordi-  
 nate all Federal health programs and activities relating to diabetes.

Adequate legislative authority already exists to support a multifaceted attack  
 on diabetes, and such an attack is now being mounted effectively by the Na-  
 tional Institute of Arthritis, Metabolism, and Digestive Diseases. H.R. 4882  
 would be duplicative of authority already vested in the Secretary of Health,  
 Education, and Welfare.

While we share a concern for the problem of diabetes, we strongly disagree that this bill would contribute to a scientific advance in dealing with the problem. We believe that research in diabetes and related areas is already being given priority consistent with research opportunities available and their relationship with other Federal research priorities. A new categorical disease program is not warranted, and the need for an Interagency Technical Committee on Diabetes has not been demonstrated.

We therefore strongly recommend that H.R. 4882, the National Diabetes Act of 1973, not be enacted.

We are advised by the Office of Management and Budget that there is no objection to the presentation of this report from the standpoint of the Administration's program.

Sincerely,

FRANK C. CARLUCCI, *Acting Secretary.*

EXECUTIVE OFFICE OF THE PRESIDENT,  
OFFICE OF MANAGEMENT AND BUDGET,  
*Washington, D.C., July 20, 1973.*

HON. HARLEY O. STAOERS,  
*Chairman, Committee on Interstate and Foreign Commerce, House of Representatives, Washington, D.C.*

DEAR MR. CHAIRMAN: This is in response to your request of March 21, 1973, for the views of this Office on H.R. 4882, a bill "To amend the Public Health Service Act to expand the authority of the National Institute of Arthritis, Metabolism, and Digestive Diseases in order to advance the national attack on diabetes."

In its report to your Committee, the Department of Health, Education, and Welfare states its reasons for recommending against enactment of H.R. 4882. The Department expresses the view that research in diabetes is already being given priority consistent with research opportunities available and that a new categorical disease program is not warranted.

We concur with the views expressed by the Department in its report. Accordingly, we recommend against enactment of H.R. 4882.

Sincerely,

WILFRED H. ROMMEL,  
*Assistant Director for Legislative Reference.*

Mr. ROGERS. Our first witness this morning is our former colleague on this side and now a most distinguished Senator from the State of Pennsylvania, the Honorable Richard S. Schweiker, who has been most active in the health field. He is the ranking minority member on the committee on the Senate side which handles health problems. He is most knowledgeable and is the author of S-17, the National Diabetes Research and Education Act.

The committee is very pleased to welcome you and certainly will be pleased to receive your statement at this time.

#### STATEMENT OF HON. RICHARD S. SCHWEIKER, A U.S. SENATOR FROM THE STATE OF PENNSYLVANIA

Senator SCHWEIKER. Thank you very much, Mr. Chairman. I greatly appreciate this opportunity to present to you and the subcommittee a brief statement regarding the need for a national diabetes program as embodied in the bills you are presently considering. I personally want to thank you for holding these hearings and for your interest and leadership in the health field. I have enjoyed working with you in my new assignment on the Senate side very much.

At the outset, I want to commend this subcommittee for scheduling these hearings. I know you will receive outstanding testimony from a number of individuals and organizations who can speak for the Na-

tion's diabetics expressing their gratitude that this committee is examining the problem of diabetes. May I add my voice to theirs and say that I am encouraged by this action and I look forward to the enactment of legislation that inaugurates a much needed national diabetes program.

This subcommittee is no doubt aware that the Senate Health Subcommittee earlier this year conducted a hearing on the problem of diabetes. The subcommittee, on which I am pleased to serve as the ranking Republican, currently has before it two bills which seek to expand and accelerate the national effort against this major health problem.

I have introduced S. 17, the National Diabetics Research and Education Act, a followup to a bill I offered during the last session of Congress, which was the first legislative proposal in recent history to address itself to the problem of diabetes. Its purpose is to expand and coordinate the research effort against diabetes and to advance patient, professional, and public education activities to alert Americans to early indications of diabetes and to emphasize the significance of early detection, proper control, and the complications which evolve from the disease. Under this proposal, a national task force on diabetes, to include lay persons, would be established to formulate a long-range plan to combat diabetes. Also, the feasibility of operating model diabetes research, treatment, and education clinics for detection, intervention, and development of manpower would be tested.

Senator Gale McGee has introduced the National Diabetes Act of 1973, S. 648, which expands the authority of the National Institute of Arthritis, Metabolism, and Digestive Diseases to develop a plan for a national diabetic program and to establish centers for basic and clinical research into diabetes and the development of advanced diagnostic, prevention, and treatment methods for diabetes.

The two proposals form the basis upon which the subcommittee will recommend an appropriate measure to be passed by the Senate. We anticipate the passage of a bill this session.

Mr. Chairman, in looking at the problem of diabetes we are referring to a disease which by conservative estimates affects 5 million Americans. There are some estimates as high as 10 to 12 million. For each diagnosed diabetic there may be as many as three or four people undiagnosed, who carry an inherited factor for the disease. Since there is a genetic factor involved and the number of diabetics is increasing it has been estimated that by 1980 one in five people will have diabetes or its trait. Statistics on diabetes are vague because diabetes is not a reportable disease. Nevertheless, it is the fifth leading cause of death in the United States. It is probably second or third if you consider the fact that diabetes is the major factor causing many chronic and disabling illnesses, primarily cardiovascular, renal, hypertensive, and neurological. The man who dies of a heart attack is listed in the death statistics as a victim of heart disease, but many times he has actually died from diabetes which caused the heart attack and the vascular disease. The same is probably true in cases of kidney disease, stroke, and so forth. Also, diabetes has become a major cause of blindness in our country.

Federal concern and action is necessary because the growing geometric progression of new diabetics per year, nearly a 10-percent increase annually, presents a significant public health problem which cannot be ignored.

In my judgment, the problem of the incidence of diabetes is one to which we have not addressed much attention. Until 1921 and the discovery of insulin the diabetic did not survive. Since then diabetics have survived longer and have been producing children with diabetes or with a strong inherited factor for diabetes. Also, the diabetic now lives long enough to encounter inevitable complications of diabetes which involve the eyes, the blood vessels, and the kidneys.

If we are to face the facts squarely we must realize that the discovery of insulin was not a cure as was felt originally but was only a first step. It is ironic that since 1921 diabetes has come to nearly dominate the medical scene yet so little is being done to solve the mysteries of this illness.

In terms of its economic impact, the loss from disability, premature death, and sickness in the diabetic population is conservatively considered to be at least \$2 billion annually. Yet we spend less than \$10 million annually in support of all aspects of research in diabetes. During the Senate hearing it was stated that we are spending approximately \$1.60 per diabetic per year. I regret that this figure is being reduced to \$1.25 with the cutbacks at NIH.

A statement prepared by the National Institute of Arthritis, Metabolism, and Digestive Diseases for initial presentation to the House Appropriations Committee this past spring contained the sentence: "Today with proper treatment, most diabetics can lead a normal life." Mr. Chairman, I have received numerous letters from physicians, biomedical scientists, researchers in the field of diabetes, and diabetics challenging that statement. Some consider it "an extraordinary lack of understanding \* \* \*." Others have referred to it as "at best debatable and at least incorrect."

What I wish to point out is that from the Federal perspective diabetes is being neglected.

The customary method in recent years to create an affirmative program involving a greater national commitment has been to allocate more money to the task. In the case of specific health problems, the recommendation is often "more money for research." In this instance, it is necessary for the subcommittee to examine the state of science with respect to diabetes to see if a breakthrough is possibly at hand.

Are we simply to add large sums of money into research and can such sums be spent productively? Since adequate funds have not been available, research in diabetes has been neglected. Consequently, our knowledge of the causes or origins of diabetes and its long-term effects on the human body is deficient. How must we proceed? Certainly the Federal role and responsibility must be determined and very clearly defined.

I submit that the first priority is clearly to raise the research allocations to find the cause of diabetes, to provide new methods of treatment, to intervene in the complications of diabetes, and to find possible cures.

A second major priority should be the establishment of a central agency to coordinate all education, research, and treatment of diabetes. This central agency would be responsible for the coordination of all research in the field of diabetes and the initiation and evaluation of new research projects. The central agency would be responsible for

setting up regional research and training centers established strategically and geographically to service the Nation's diabetic population. These regional centers would be under the control and direction of the central agency, but might function as an integral part of an established, ongoing medical center. They would, however, be a separate entity budgeted by the central agency and reportable to the central agency.

Clearly, the National Institute of Arthritis, Metabolism, and Digestive Diseases can and should assume this responsibility.

I believe a specific plan or program should be formulated, an approach found in all the legislative proposals. However, I suggest that the entity which draws up this "game plan" include lay persons, particularly parents of diabetic children. The scientific and medical participants should represent the various disciplines involving diabetes, cardiology, ophthalmology, neurology, neuropathy, and genetics, to mention a few.

In addition, I recommend that the committee consider the creation of an Associate Director of NIAMDD for diabetes who would chair a committee of representatives of each of the Institutes at NIH which deal with problems relating to diabetes. No such formal apparatus exists at present, and the Director of NIH should be required to establish such a committee. The coordination of efforts at NIH dealing with this disease would be improved if such a provision were included in the legislation.

Mr. Chairman, thank you for permitting me to present to the committee some of my thoughts on this serious problem. I purposely have been brief since you will be receiving testimony from the experts and professionals in the field as well as from those who live with this disease.

I am confident this hearing signals a beginning of a major national assault against diabetes. Whatever legislative measure emerges as a result of these hearings and the deliberations of the subcommittee, it will provide the blueprint for finding a way to more effectively deal with this problem. In my judgment, the Nation's diabetics, who up to now may have felt neglected by their Government, are entitled to a commitment to increase the effort against this disease and thus increase the chances for making some real progress in the detection and treatment of diabetes and, hopefully at some point, its control and cure.

I look forward to joining you, Mr. Chairman, and your colleagues in a House-Senate conference, to work out the final form of the law we will enact. We cannot legislate a cure for diabetes, but we can certainly establish a framework for a more effective diabetes program and provide the support necessary to carry out such a program.

Mr. ROGERS. Thank you very much, Senator Schweiker, for an excellent statement, which I think has placed this problem in proper perspective.

This committee will go over your suggestions and give them the most serious consideration, and I am hopeful that we can work out some program that would be effective in this fight.

Also, I think both of our committees better have a little visit with Mr. Weinberger and Mr. Carlucci to see if we can convince them. I am sure you share that feeling.

Senator SCHWEIKER. I think that may be the more difficult job.

Mr. ROGERS. You may be right.

Thank you for being here, you have been most helpful and we will continue to keep in touch. Thank you.

Senator SCHWEIKER. Thank you, Mr. Chairman.

Mr. ROGERS. The next witness is the Honorable William A. Steiger, Member of Congress from Wisconsin, our distinguished colleague who has been a driving force for action in this area. He has great experience in this field. He has given me a few of his personal experiences, and so we know that he is an expert, and the committee is delighted to welcome him here and will be pleased to receive the benefit of his testimony.

I might say as chairman that he and particularly Mr. Vander Jagt have been constantly after this committee to do something, and so we are doubly grateful to you for helping us get to this.

**STATEMENT OF HON. WILLIAM A. STEIGER, A REPRESENTATIVE  
IN CONGRESS FROM THE STATE OF WISCONSIN**

Mr. STEIGER. Thank you, Mr. Chairman. I do not have a prepared statement, and I hope the Chair will forgive the fact that I did not put something together. I, too, will be brief, as was Senator Schweiker.

Congressman Vander Jagt and I and the other 98 cosponsors of the legislation in the House are deeply grateful to you for your willingness to have these days of hearings, and I am hopeful that out of it will come information and the right questions so that whatever we do is rational.

I have more than a passing interest in what we do about diabetes. I have been a diabetic for 22 years and have watched with interest not only the new approaches made in the field of diabetes, but frankly, the problems. Thus, my approach will be a little different in terms of what I perceive to be some difficulties with which we are faced in the field of diabetes.

The statistics are known: \$8.2 million spent in the last fiscal year; diabetes is the fifth leading cause of death by disease; and the fact that there exists considerable misunderstanding among the medical community, parents, diabetics, and among the general population as to what diabetes is all about.

It was once assumed that with the discovery of insulin, and those new developments in the field that are not insulin but are pills which have the effect of insulin in reducing blood sugar, that the diabetic no longer faced many problems. I think clearly that is not the case.

If possible, Mr. Chairman, I would like to include, as a part of my statement, an article from the New York Times, which rather dramatically discusses the death of Jackie Robinson who had died apparently of a heart attack when, to many doctors, the basic cause of his death was diabetes and its complications.

Mr. ROGERS. Without objection, it is made a part of the record following your statement [see p. 18].

Mr. STEIGER. That article pinpoints some of the side effects of diabetes and some of the problems. I would, Mr. Chairman, make three points:

One, that there are inadequate funds for research in this field. Diabetes is multidisciplinary; it does not affect just one part of the

body but clearly has profound implications throughout the human body.

The amount of money we are now spending is too low, given the fact we are close to some important developments—in the implantation of a pacer for the control of insulin going into the bloodstream, thereby enabling the blood sugar level to be reduced, and in the ability to better determine whether or not a young person will have diabetes in his or her lifetime. These thresholds we are approaching require an accelerated effort in this field on the part of both the public and the private sectors, and I think the Federal Government should provide a degree of leadership. A greater interdisciplinary approach would be exceedingly beneficial to those who have diabetes, in enabling them to lead a better life, and it would also help us determine more clearly how to prevent the disease in the future.

Second, we need to give far greater attention to what diabetes is all about. This partially is a problem of the medical field. It is partly a problem of what information is available to diabetics, to the parents of diabetics, and to their wives and husbands who live and work with the diabetic.

I have been absolutely amazed by the outpouring of correspondence that has come into my office, as I know it has come to your office and Congressman Vander Jagt's office, from those who are diabetics across this country, in response to the new initiatives.

But what has been even more interesting to me has been in meeting in the sixth district of Wisconsin more and more people who are diabetics and who are searching for better answers to the problems they face.

As I see the problems of a man 45 years old fired from his job because he is a diabetic, then I have to sit back and ask, "What kind of an attitude makes it possible for that man to lose a job because of a disease, not well-controlled, which made it in the mind of one employer impossible to keep him on that job?"

Such a human tragedy ought not to happen, and it is a part of the role of this committee, as it is a part of the role of each of us individually, to make certain there is clarity in where we go and what we do.

Third, Mr. Chairman, I do not pretend, in offering this testimony or in offering H.R. 4882, to say there is a single answer to this problem. The subcommittee has an incredibly good record in responding to serious problems in the health field. You have to work with Mr. Weinberger and OMB and Mr. Carlucci, and all I would say, Mr. Chairman, is I believe the foundation for an expanded research effort must come through the Institute of Arthritis, Metabolism, and Digestive Diseases.

Dick Schweiker is correct in defining an approach that can be used, but in the end it will be up to you and the members of your committee to make the best judgment you can about the specifics of the legislation.

None of us pretends to know all of the solutions to this problem. I hope that from the 2 days of hearings you are scheduling to deal with this—the testimony you will hear from the American Diabetes Association, from the Joslin Foundation, from the Juvenile Diabetes Foundation, and from the youth committee of the Joslin Foundation—that

will gain only better understanding of the weaknesses in what we now do, and the ways to strengthen future efforts in diabetes research.

The need is critical and I think the approach we have proposed, by and large, makes sense. I can but hope that out of this will come an agreement between both the House and Senate that an expanded research effort in the field of diabetes will produce great benefits, not only to those who now have diabetes, but to those who do not have it but who can be better served because of what we do this year.

Thank you.

[The New York Times article referred to follows:]

[From the New York Times, Sunday, Oct. 29, 1972]

#### DIABETES IS CALLED BASIC CAUSE OF ROBINSON'S DEATH

(By Lawrence K. Altman)

The immediate cause of Jackie Robinson's death last week at age 53 was apparently a heart attack. But to many doctors a more fundamental process was involved: diabetes and its complications.

The former Brooklyn Dodger's heart attack, which came after a decade of failing health, was his third since 1968, two of the Manhattan specialists who cared for him said in interviews. These two previous attacks had left him with need for cardiology care to treat his congestive heart failure.

The Dodger second baseman had also consulted several other kinds of specialists in the 20 years he knew he had diabetes because during this interval Mr. Robinson had developed most of the conditions that can complicate the endocrine disease.

The first black major leaguer lost the sight of one eye and was becoming progressively blind in the other, despite treatments with a laser beam. A week ago today, he suddenly lost even more sight from a hemorrhage in his "good" eye.

In 1961, his knee, already damaged by arthritis caused by the trauma of sliding around the bases on the playing field, was further injured by a serious infection. The staphylococcal bacteria that caused the knee infection also poisoned his blood system with a near fatal case of septicemia and temporarily threw his diabetes out of control until antibiotics and more insulin helped him recover.

#### DISCOMFORTING SYMPTOMS

Mr. Robinson also suffered from burning sensations and other pains in his legs that had resulted from a combination of diabetic damage to the nerves and arteries in his legs. So discomfoting were these symptoms, his doctor said, that Mr. Robinson had to give up golf.

Also, his blood pressure was abnormally high for many years. Though hypertension can be another complication of diabetes, Mr. Robinson's physician said they considered it an unassociated problem in his case. Cardiologists have reported that hypertension is found with unusually high frequency among blacks.

Endocrinologists say they believe that diabetes is the result of inadequate production of insulin by the pancreas gland, which is situated deep in the abdomen. Insulin controls the amount of sugar in the blood. But because the body's chemical pathways are so complex and intertwined, diabetes affects protein and fat metabolism as well as that of sugar and other carbohydrates.

Other doctors said that Mr. Robinson's case vividly illustrates the types of medical problems with which many of the 200 million diabetics in the world must live.

Diabetes knows no geographic borders as it affects people of all races around the globe. In the United States, 2 per cent of the population, or four million people, are said to have diabetes. Its symptoms can include fatigue, unusually frequent urination, excessive thirst and increased appetite in the face of weight loss.

#### VALUE OF INSULIN

For more than 50 years, insulin injections have staved off early death for millions of diabetics lives for decades, whereas those born before insulin's discovery survived just months.

Nevertheless, a diabetic's life expectancy is about two-thirds that of a non-diabetic at any age. Doctors at the Joslin Clinic in Boston reported recently, for example, that a 30-year-old diabetic could expect to live another 30 years, whereas a 30-year-old nondiabetic could expect to die in 42 years.

The price from the complications made possible by the advance of insulin therapy is vast. Economists say that each year diabetics spend \$2-billion for such items as physician fees to regulate the insulin doses, hospital beds to care for diabetic coma and insulin shock, nursing care to help skin ulcers heal and prevent gangrene of the toes and legs, pills, seeing-eye dogs and live-in help to care for blind diabetics. Diabetes ranks behind cataracts and glaucoma as the third leading cause of blindness in Americans.

Yet Americans do not view diabetes with the same degree of concern that they do diseases like cancer for which Congress appropriated \$377.5-million in this fiscal year.

#### SMALL EXPENDITURES CITED

The National Center for Health Statistics lists diabetes as the seventh-leading cause of death among Americans. It is also a major contributor to cardiovascular disease (heart attacks and strokes), the nation's leading killer.

Despite these staggering statistics, diabetes experts point to the relatively small Federal expenditures to find better treatments. The main Federal basic research program in diabetes at the National Institutes of Health in Bethesda, totalled \$8.2-million last year.

Diabetes specialists say they are still mystified about the disease that has been known since ancient times. Among the myriad unanswered questions scientists hope to resolve are:

Why does arteriosclerosis occur so much earlier in life among diabetics, making heart attacks and strokes so much more common than among nondiabetics?

Precisely how is diabetes inherited?

What causes the bodies of some diabetics like Jackie Robinson to become so severely ravaged within 20 years, whereas other diabetics who have had the disease for twice as long escape the severity of many of the same complications?

Why does diabetes—in a pattern distinct from arteriosclerosis—selectively damage the smallest arteries, particularly those in the eye, kidney, nerves and skin? After 20 years, only one diabetic in 10 is said to escape such damage to the retina in the back of the eye. Yet why can some see well and others go blind? Electron microscopists suspect that the clues lie in the portion of the arteries called the basement membrane, which becomes unusually thick as a result of deposits of substances called collagen and mucoproteins. Why does this pathological process often begin before blood and urine tests disclose that a patient has diabetes?

Why do diabetics have more difficulty combating bacteria—like Jackie Robinson's staph knee infection—than nondiabetics?

Why do cells of diabetics age much faster than those of other people? Researchers at the University of Washington at Seattle, one of the leading centers of diabetes investigation, discovered recently that cells taken from diabetics, when made to grow artificially in test tubes in laboratories, age much faster than do those from nondiabetics. Precisely how these cell changes produce diabetic damage is what teams of researchers elsewhere in the world are trying to learn.

When basic and clinical researchers find the answers to these and other questions, they say scientific information ultimately will be valuable not only to the families of diabetics like Jackie Robinson, but also to tens of millions of nondiabetics who suffer from arteriosclerosis. And because so much is unknown in medicine, these doctors also say that such scientific knowledge perhaps will influence treatment of other diseases.

Mr. ROGERS. Thank you so much.

The committee will consider the question you have made and hopefully we can design legislation that will begin to meet the need in this area and the committee is grateful for your being here.

Mr. STEIGER. Thank you for giving me this chance.

Mr. ROGERS. Without objection, the Chair wishes to place in the record, as though read, statements submitted by Congressmen Peter W. Rodino, Jr., of New Jersey, John J. Rhodes of Arizona, George E. Brown, Jr., of California, John Melcher of Montana, Lou Frey, Jr., of Florida, and William Lehman of Florida.

**STATEMENT OF HON. PETER W. RODINO, JR., A REPRESENTATIVE  
IN CONGRESS FROM THE STATE OF NEW JERSEY**

Mr. RODINO. Mr. Chairman, at the outset, I wish to thank you and all the members of your subcommittee for giving me the opportunity to present this statement at this time. The hearings you are conducting are of such vital importance to the health and lives of so many citizens both in the United States and throughout the world that I felt compelled to emphasize my intense interest and my deep appreciation for the work you are doing here today. I am, by no means, an expert on diabetes, nor am I a member of the medical profession. Over the past days, I have been following closely the testimonies of many of the distinguished individuals who have addressed you and the information they have gathered, shared and explained has shocked and distressed me.

The lack of relevant knowledge in understanding diabetes must be erased. I'm certain that to the majority of men and women throughout this country, the various signs, effects and treatments for such disorders as cancer and heart disease are fairly well known. But the awareness of diabetes, the extent to which this disease has afflicted our people and the damaging deterioration and loss of life which may result from its onset, is severely lacking. How many times have we heard that diabetics are really quite fortunate; with a vigilant diet, a mere injection once a day and plenty of exercise, a full, normal life can be led. In later years, additional complications may arise, but with the discovery of insulin, all fears regarding the control of the disease have been set to rest. Perhaps the most frightening aspect of diabetes lies in the strength of these myths and in the pervasiveness of these deceptions that all is well and that further research is not imperative. If nothing else, if through these hearings, the citizens throughout this land recognize the gravity of this naive, we will have taken a progressive step toward closing the abyss over the complex, mysterious nature of this disease. I certainly intend to bring the information I have learned from these hearings to the immediate attention of my constituents. And, it is my hope that a great many members of this body will do the same.

I believe, of all the prepared statements before this subcommittee, the extemporaneous, brief, yet jarring words of Gary Kleiman capture the essence and the urgency of the actions we must pursue. Gary, 20 years old, the first freshman to make the Syracuse University tennis team and a diabetic for 13 years, sat before you on August 1, now totally blind in one eye and with 30 percent vision in the other, fighting for the preservation of his remaining sight and for the continued functioning of his deteriorating kidneys. For 12 years, Gary was perfectly fine, a role model in his community for other diabetics. On the 13th, in his own words, he became a statistic, joining the thousands of partially or totally blind diabetics throughout this country. He won't pick up a tennis racket for the Syracuse team again, and with the relentless deterioration of his entire body in the coming months and years, I shudder to think of the shattered hopes and the possible pain, suffering and limited time which remains for him—unless we act.

Gary's presence alone has shown us the crucial need to greater research to control diabetes. According to Dr. Lamont-Havers, Associate Director of extramural programs at the National Institute of Metabolic Diseases, as of today, no cure exists for diabetes. Insulin can stop the symptoms of this disease, but not its complications. And, the long term complications of diabetes, those affecting the blood vessels, kidneys, peripheral nerves and eyes, cannot be prevented or adequately treated. Gary's case has demonstrated that it is the very suddenness with which this disease may flare up which causes the greatest amount of worry for those who suffer from it and which makes the line between the healthy diabetic and the severely handicapped diabetic a shadowy line indeed.

In August of last year, the National Eye Institute, in a news release from the Department of Health, Education, and Welfare, stated that of all patients who suffer from diabetes in the first 10 years, 50 percent show some signs of retinopathy; of those suffering for 15 years, 75 percent show some degree, and of those with diabetes for 25 years, 95 percent show signs of retinopathy. Carl Stenzler, chairman of the Committee on Diabetes and Blindness cited in his August 1 testimony that 250,000 diabetics die of heart failure and that by the year 2000, 574,000 will be either partially or totally blind. Mr. Stenzler advised that there are not 5 but 10 million diabetics, one-half of whom do not even realize they have the disease. And, of these 10 million men and women, 50 percent will suffer kidney failure, stroke, blindness, amputations, or death within 27 years of the outset of the disease. Dr. Schwartz of the University of Pennsylvania Medical School remarked that a pregnant, diabetic woman will probably be blind or dead before her child reaches maturity. According to statistics from the National Institute on Arthritis and Metabolic Diseases, one-quarter of the entire earth population carries the hereditary genes for diabetes and by 1975, it is estimated that 1 in every 25 persons will be diabetic.

These are not merely numbers, obscure predictions or ill-founded prognoses. These are facts—facts which in many cases decree the chances of life or death for 12 million people. And, Gary, in his own words, closed his statement before this subcommittee with the hope that he will not become, in the next 10 years, a final statistic.

Robert Kronowitz, chairman of the Juvenile Diabetes Foundation, attested before you that all money for research is to run out by November of this year and after years of research and progress, all developments are on the verge of termination.

Over and over again, it was emphasized to me and to all the members of this subcommittee that diabetes affects every age; it does not discriminate; its exact cause is entirely unknown; and that it cannot be prevented, and—it cannot be controlled—no effective way of arresting vascular degeneration has yet been found.

As a cosponsor of H.R. 7440, it is my hope that the successful and expeditious passage of this legislation will bring us the needed research to actually stop this gradual blood vessel deterioration and save the life of Gary and all whom he represents. I wish to extend every effort to assist in finding the difficult yet crucial path leading to diabetes control and to make those myths of safety and health for all afflicted by this disease into a reality.

**STATEMENT OF HON. JOHN J. RHODES, A REPRESENTATIVE IN  
CONGRESS FROM THE STATE OF ARIZONA**

Mr. RHODES. Mr. Chairman, thank you for this opportunity to make a statement concerning the bill which I have cosponsored, H.R. 7440, the National Diabetes Act of 1973.

This bill would create a specific national diabetes program that would benefit the 5 million Americans a year who are afflicted with this terrible disease. Diabetes is the fifth leading cause of death and the second leading cause of blindness in our country today. Diabetes decreases the life expectancy, by approximately 30 percent of anyone afflicted and a sad fact is that it strikes children and adolescents more severely than adults. There is convincing evidence that diabetes has increased dramatically in the last decade. It has recently been discovered that diabetes is 5 times as common among school-aged children than previously supposed.

Better methods of diagnosis and treatment must be developed and should be given the highest priority. Study and research into the basic biological processes and mechanisms of diabetes are urgently necessary for an all out attack on this disease. The National Institute of Arthritis, Metabolism, and Digestive Diseases, with expanded authority under this bill would conduct field studies, large-scale testing and evaluation, in a first step toward conquering diabetes.

In addition to research, the bill would authorize establishment of 15 centers throughout the country for training in, and demonstration of advanced diagnostic, prevention, and treatment methods for diabetes. These centers will also concentrate on developing improved methods of detecting individuals with a risk of contracting diabetes, and research into methods of prevention for those high risk individuals. Also, the centers will start programs to train health personnel in prevention and control of diabetes.

I am hopeful that favorable consideration will be given to this bill. Testimony before this committee has already indicated that breakthroughs in conquering this disease are around the corner. We must provide the resources that will make diabetes a disease of the past.

**STATEMENT OF HON. GEORGE E. BROWN, JR., A REPRESENTATIVE  
IN CONGRESS FROM THE STATE OF CALIFORNIA**

Mr. GEORGE E. BROWN, Jr. Mr. Chairman and members of this subcommittee: I am grateful for the opportunity to present my views in favor of H.R. 4882, a bill to amend the Public Health Service Act. H.R. 7440, a bill I am cosponsoring, is identical to H.R. 4882. This legislation would provide the needed expansion of the authority of the National Institute of Arthritis, Metabolism, and Digestive Diseases in order to intensify the attack upon diabetes.

Mr. Chairman, I am sure that you are aware of the gravity of this problem; nearly 5 million Americans suffer from this disease; diabetes mellitus is the fifth leading cause of death by disease, and it is the second leading cause of blindness. In its more severe form, diabetes develops rapidly to a state of metabolic derangement called keto-acidosis which can result in coma and death. In its less severe form, the disease results in accelerated degeneration of the arteries. Unfortunately, a

number of authorities have pointed to the increasing incidence of this disease.

Although the Egyptians recognized and described diabetes 3,500 years ago, there is still great room for progress in improving treatment techniques and preventing the onset of the disease. As late as 1968, Dr. Ronald W. Lamont-Havers could write: Today, nearly a half century (after the discovery of insulin) during which period the prevalence of diabetes has increased steadily, inexorably, throughout the world, despite improved research and treatment measures, no responsible authority believes that we have the answer—or are even close. Mr. Chairman, I think we can do better than this.

Pursuant to the passage of legislation currently before this subcommittee, a national diabetes program would be developed and presented to Congress by the NIAMDD. I believe such action would provide the greatest potential for an attack upon diabetes. It would expand funding of current activity, coordinate the efforts to find a solution, and provide for effective dissemination of new findings. This action is a necessary step in solving a critical problem.

Mr. Chairman, I appreciate this opportunity to appear before you on this important matter, and I commend the subcommittee for its diligence in pursuing this subject.

#### **STATEMENT OF HON. JOHN MELCHER, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MONTANA**

Mr. MELCHER. Mr. Chairman and members of the committee. I am pleased to have the opportunity to support H.R. 4882, a bill to advance a national attack on diabetes.

There is a great discrepancy between the nature and incidence of this disease and the amount of Federal support available for research. Diabetes affects the third largest number of children of any disease in the United States, is the leading cause of blindness, and is the fifth largest killer in the United States. With the possible exception of lung cancer, the incidence of diabetes is increasing faster than any other disease. In addition to blindness, diabetes is a leading factor in many other diseases—heart problems, stroke, cardiovascular disease, kidney disease, and premature aging. In spite of all this, 20 other diseases receive more Federal research support than diabetes.

The Federal allocation to diabetes research last year was \$8 million, the lowest allocation to any major disease. The funding proposed in H.R. 4882 will allow \$25 million in fiscal year 1974 and more in the next 2 years for programs necessary to control diabetes and to conduct research into its cause and cure. In addition, the money would be available for improving methods of detecting high-risk individuals, prevention, diagnosis, treatment and education about this disease which affects so many but about which so little is actually known.

A constituent of mine writes:

I have been a diabetic for 13 years and wish to tell you that help for the individual diabetic is indeed hard to come by. I am appalled at the ignorance of the majority of diabetics I have talked to. They know practically nothing about their disease or how to care for themselves. Further, help is just not available, at least in this part of the country. You get a few minutes of a busy doctor's time, then you are entirely on your own caring for a complicated disease that will affect every minute of the rest of your life. Not for a minute

of the day or night are you free of the necessity of regulating your diet, your medication, your exercise, your emotional health. Then you have the ignorance of the general public to combat. The general public needs a great deal of educating concerning this disease, which many of them are going to have to deal with sometime during their own lifetime, either in the case of their own health, or that of a member of their family. It is an expensive disease to live with and many victims just do not have the financial resources to properly deal with it, even if they knew how. Serious complications often result, even if the disease is well controlled. Please support this legislation (H.R. 4882) and give us the help we so desperately need. Perhaps a cure can be found for the millions of people who live with this disease.

The cause and cure for diabetes are still as unknown today as 50 years ago when insulin was discovered. Insulin is not a cure but a medication and does not stave off the eventual ravages of this disease. In addition to the 1 million children and young adults dependent on insulin shots 1, 2 or 3 times daily, there are 5 to 11 million diabetics taking oral medication or who control diabetes through diet.

There are many exciting possibilities for curing diabetes. For example, an artificial pancreas has been developed but not miniaturized. Another possibility is transplantation of the parts of the pancreas which produce insulin.

It is my fervent hope that a cure can be found in the near future. Enactment of H.R. 4882 will be a step in that direction.

#### **STATEMENT OF HON. LOU FREY, JR., A REPRESENTATIVE IN CONGRESS FROM THE STATE OF FLORIDA**

Mr. FREY. An 8-year-old girl carries a hypodermic needle with her to school in her lunchbox each day.

The hypodermic needle is used to inject insulin in her thigh, and her lunchbox contains special foods because she, a diabetic, cannot eat the food served in the school cafeteria.

Her problem is not an uncommon one. In fact, there are an estimated 4 million other Americans with diabetes.

Sure, they can live with it and with medication they can enjoy normal lives, but looking forward to daily injections of insulin is not particularly heartening for anyone, especially if you are only 8 years old.

Adequate research into the causation of diabetes might have prevented this little girl's plight and saved thousands of lives.

While funding for cancer and heart disease research is not adequate, it's still almost 46 times as much as we spend on diabetes.

Diabetes is the seventh leading cause of death and the second leading cause of blindness in America.

There has been little since the discovery and application of insulin 50 years ago, in significant breakthroughs in a knowledge of the causative mechanism of the disease or toward its cure.

Last year 3.8 million persons were diagnosed to have diabetes while an additional 2 million persons were estimated to suffer from undiagnosed diabetes.

This makes a total of almost 6 million persons who are diabetics.

Of course, diabetes is not unique to America. One out of every four persons in the world is estimated to carry the hereditary gene for diabetes.

These figures do not include those who die from diseases to which their diabetes has contributed.

Diabetes is a hereditary disorder involving an inability to metabolize carbohydrates normally. Women, all persons over 40, obese persons and those who have diabetes in the family are more susceptible to diabetes.

The majority of research of diabetes is conducted by the National Institute of Arthritis, Metabolism and Digestive Diseases.

The total budget of that Institute will be cut from an estimated \$139,806,000 in fiscal year 1973 to an estimated \$133,608,000 in fiscal year 1974.

Of this budget, an estimated \$7.1 million is allocated for diabetes program in fiscal year 1974.

Since diabetes reached its peak in funding in 1972 with \$8,182,000, the funds allocated have been on a steady decrease.

We propose an increase in the funding level for a Federal diabetes program. These funds should be applied to the diagnosis and symptomatic control of the disease.

This bill would provide the needed prevention and control programs, and develop a national diabetes program under the National Institute of Arthritis, Metabolism and Digestive Diseases.

It would also establish at least 15 centers for training and demonstration programs related to advanced diagnostic, prevention and treatment methods.

The many thousands of people who have diabetes need not be handicapped—if their diabetes is kept under control.

But the keys to success are early discovery and continuing medical supervision.

#### **STATEMENT OF HON. WILLIAM LEHMAN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF FLORIDA**

Mr. LEHMAN. Mr. Chairman, I appreciate the opportunity to testify in support of H.R. 4882, a bill to expand the authority of the National Institute of Arthritis, Metabolism and Digestive Diseases to advance the national attack on diabetes.

Last year marked the 50th anniversary of the discovery of insulin. Unfortunately, despite that great discovery, disabilities associated with diabetes have not been effectively combatted. While it's been shown that the level of sugar in the blood can be controlled by proper diet and medication, here is no proof that such control will prevent the onset of heart disease, blindness, and other problems common to diabetics. Diabetes is the second leading cause of blindness, and a leading cause of heart disease, kidney disease, vascular deterioration.

Today there are 155,000 diabetics who cannot see well enough to work. The National Eye Institute reports that 15 to 20 percent of all new blindness is caused by diabetes. The Harvard School of Public Health projects 573,000 diabetic blind persons by the year 2000. And it is estimated that in 27 years, diabetic blindness will exceed all other causes of blindness put together. It is important to note here that most diabetic blind cannot be taught braille. Neuropathy, diabetes attacking the nerves, makes the sense of touch negligible.

Fifty percent of those blinded by diabetes will be dead from kidney disease, heart disease, or brain damage in 5 to 10 years. Diabetics are 3 to 4 times more likely than others to develop heart trouble or suffer strokes, the Nation's leading killer.

A diabetic's life expectancy is roughly two-thirds that of a non-diabetic. The average duration of life for children under the age of 10 who develop diabetes is 30 years. For adults, it is about 17 years after the age of onset.

Thirty-five thousand Americans die each year from diabetes, and more than 50,000 from diseases to which their diabetes has contributed. Not surprisingly, diabetes is now the fifth leading cause of death in the United States.

Approximately 4½ million persons in the United States have diabetes. One person in 20 is either an actual or potential diabetic. There are approximately 325,000 new cases each year. By 1975, it is estimated that 1 in every 25 persons will be diabetic.

About 600,000 of the U.S. diabetics are children. Data from a new Michigan survey of more than 1 million children reveal that 1 child out of every 587 has diabetes. This is in sharp contrast to more traditional estimates of 1 out of every 2,500.

It is significant to point out that the annual cost to the economy each year due to diabetes, including medical costs, drugs, and loss of manpower, is estimated at \$2 billion. The Federal allocation for fiscal year 1974 for diabetes programs will be a little over \$7 million. This is a decrease of almost \$1 million from fiscal year 1970.

It is clear to me from the figures I have cited above that our present efforts in this area are totally inadequate. The bill before this subcommittee is vital. It would authorize \$105 million over the next 3 years for a national attack on diabetes. Research on the disease is now at a crucial stage, and I urge your subcommittee to give this bill favorable consideration.

Mr. ROGERS. Our next witness is Dr. John S. Zapp, Deputy Assistant Secretary for Legislation (Health), Department of HEW, and he is accompanied by R. W. Lamont-Havers, Deputy Director of the National Institute of Arthritis, Metabolism, and Digestive Diseases and Benjamin Burton, Associate Director NIAMDD.

We welcome you gentlemen and we are pleased to receive your statement.

**STATEMENT OF DR. JOHN S. ZAPP, DEPUTY ASSISTANT SECRETARY FOR LEGISLATION (HEALTH), DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE; ACCOMPANIED BY DR. R. W. LAMONT-HAVERS, DEPUTY DIRECTOR, NATIONAL INSTITUTE OF ARTHRITIS, METABOLISM, AND DIGESTIVE DISEASES; AND BENJAMIN T. BURTON, PH. D., ASSOCIATE DIRECTOR, NIAMDD**

Dr. ZAPP. Thank you very much, Mr. Chairman, and you have introduced my witnesses this morning so I will move immediately into my statement.

It is again a pleasure to appear before the committee.

Mr. ROGERS. The committee is always delighted to see you, Dr. Zapp. We have gotten to where we almost consider you a member of the committee we get to see you so much and we welcome you.

Dr. ZAPP. Thank you, Mr. Chairman. We are here to present the views of the Department on H.R. 4882, the National Diabetes Act of 1973. While your interest as well as that of the members of the subcommittee in this disease is commendable, Mr. Chairman, we, the Department, question the advisability of the enactment of this categorical legislation to conduct research and control activities as a means of expressing that concern, a concern which we all share.

#### DIABETES MELLITUS

I would like to describe briefly for you the nature and scope of diabetes and the public health problem it represents, and our current research and other activities in this area.

Diabetes, which affects millions of Americans, is a complicated disease for which there is no known cure. Diabetes ranks seventh on the list of diseases causing death in the United States. Diabetes has been known for some time to be a hereditary disorder. As a result of the body's inability to metabolize carbohydrates normally (which, in turn, is based on impaired production or activity of the hormone, insulin), the diabetic is unable to convert dietary carbohydrates properly into the stored form, glycogen, or to utilize them normally for the energy required for body functions.

Thus, the carbohydrates, in the form of glucose, accumulate in the blood and, because of their high concentration, overflow into the urine. As the disease progresses, abnormal carbohydrates metabolism becomes associated with a noticeable derangement in the metabolism of fats and proteins.

In its severe form—occurring more frequently in juvenile diabetes—the untreated disease rapidly progresses to a grave metabolic disorder, ketoacidosis, which may result in coma and death unless controlled by insulin administration and specific supportive therapy. Although the disease can be fatal unless properly treated, in most cases it can be well controlled. It is important to recognize that today, with proper treatment, most diabetics can lead a near-normal life. Despite control of clinical symptoms, however, and the usual ability to hold in check the abnormal blood sugar level, in too many cases the long-term complications of diabetes develop progressively and affect the blood vessels, peripheral nerves, kidneys, and the eyes. As a result, patients in whom the disease developed in early life usually have an abbreviated life-span and suffer progressive disability from the complications of the disease, usually beginning in early middle age.

In its less severe form the so-called "maturity-onset diabetes," disease gradually emerges in later life. This type of diabetes usually does not require treatment by daily insulin injection; in most cases, a diet which reduces the patient's body weight to the lean side of normal and which avoids sugars suffices to maintain the patient free of direct clinical symptoms. Nevertheless, even here patients will progressively suffer from complications such as accelerated degeneration of the blood vessels and thus may be subject to premature heart disease and a decreased life expectancy.

## CURRENT ACTIVITIES OF THE NATIONAL INSTITUTES OF HEALTH

As you know, Mr. Chairman, and as previous witnesses have mentioned, the National Institute of Arthritis, Metabolism, and Digestive Diseases (NIAMDD) is the Institute at the National Institutes of Health which bears responsibility for research and research training support in diabetes. In addition, studies in diabetes with particular reference to the ocular complications are supported by the National Eye Institute. A major reason for the establishment in 1950 of the NIAMDD was to focus the national research effort on the problem of metabolic diseases, among which diabetes is the most widespread and important. Since its establishment, the Institute has underwritten a major effort in research related to diabetes. The current effort directly related to diabetes is around \$8 million annually, the overwhelming majority of which is used to fund diabetes research at university centers, medical schools, and hospitals throughout the country.

In addition, it is important to point out that the Institute expends in similar fashion even larger sums in support of primarily fundamental research in endocrinology (\$19.5 million) and metabolism (\$32.4 million) which are the basic research bases from which diabetes is likely to be understood and conquered. Without the breakthroughs in these areas, the final solution to the problem of diabetes will not be possible.

In an effort to facilitate rapid communication of research efforts to researcher and practitioner alike, to assist ongoing research, and to avoid possible duplication of effort, the NIAMDD is publishing monthly one-of-its-kind "current-awareness" index—the Diabetes Literature Index—which is distributed widely to diabetologists and provides references to the latest publications of research results in diabetes originating anywhere in the world. One may liken this effort in coordination of the latest knowledge about the disease to constant communications from a central data bank on diabetes. In addition, the Institute, through its information office, provides the lay public with brochures and information on the disease and, with the aid of radio spot announcements, informs the public of their availability.

Because of the special nature of diabetic retinopathy, a progressive disorder of the blood vessels of the retina stemming from diabetes, and a leading cause of blindness in this country, research on this particular complication of diabetes is supported by the National Eye Institute.

Among these studies, the NEI is currently supporting a 10-year, \$5 to \$7 million study which will eventually involve approximately 1,800 patients at 15 clinical centers across the country (current annual cost \$1.2 million). The primary objective of this cooperative study is to determine whether photocoagulation helps preserve vision in patients with diabetic retinopathy, and which type of instrument—the xenon arc photocoagulator or the argon laser—provides the greatest beneficial effect.

In addition to this special cooperative study, the NEI supports a number of other studies related to more fundamental aspects of diabetic retinopathy.

## DESCRIPTION OF THE PROPOSED LEGISLATION

Mr. Chairman, H.R. 4882 would authorize the Director of the National Institute of Arthritis, Metabolism, and Digestive Diseases to:

Develop a plan for a national diabetes program designed to expand, intensify, and coordinate the activities of the Institute and other NIH Institutes respecting diabetes and related endocrine and metabolic diseases.

Establish diabetes prevention and control programs in cooperation with various health agencies funded at \$25, \$35, and \$45 million for the next 3 fiscal years.

Require development of not less than 15 national research and demonstration centers for basic and clinical research into training in, and demonstration of, advanced diagnostic, prevention, and treatment methods for diabetes.

In addition, the bill would require the Secretary of HEW to establish an Interagency Technical Committee on Diabetes to coordinate all Federal health programs and activities relating to diabetes.

## DEPARTMENT POSITION

We strongly urge, Mr. Chairman, against enactment of H.R. 4882. In spite of the highly recognized and laudable intent of the sponsors of the proposed bill, adequate legislative authority already exists to support a multifaceted attack on diabetes, and such an attack, in balance with other national priorities, is now being mounted effectively by the NIAMDD. H.R. 4882 is wholly duplicative of authority already vested in the Secretary of HEW. While we share with you and many others a concern for diabetes, we strongly disagree that this bill would contribute to a scientific advance in dealing with the problem.

A large coordinated research effort is already mounted in the field of diabetes as well as in the closely related fields of metabolism and endocrinology from which much of the newer knowledge concerning the mechanisms underlying the disease is expected to evolve. We believe that research in diabetes and related areas is already being given priority consistent with research opportunities available and their relationship with other Federal research priorities.

For these reasons, Mr. Chairman, a new categorical disease control program is not warranted. It would unnecessarily add another program to the labyrinth of existing programs, each of which is capable of stirring emotions and creating unfulfilled expectations. Moreover, the need for an Interagency Technical Committee on Diabetes has not been demonstrated.

I wish to thank you, Mr. Chairman, for the opportunity to appear before the committee and give our testimony on the proposed legislation.

I will be happy with my colleagues to try to answer any questions that you or perhaps other members of the subcommittee later on may have.

Mr. ROGERS. As I understand your testimony, the Department opposes the legislation and you feel we are doing an adequate job and no emphasis needs to be given to this.

Dr. ZAPP. I would say, Mr. Chairman, we oppose the bill. We think the authority that the bill proposes to give the Department has already been vested in the Department by Congress. I don't think anyone of us could ever say that with a disease that effects this many people you could have an adequate amount of funds for it, but in relationship to the funds available and research available for other disease priorities and health problems, Mr. Chairman, we feel that the problem of diabetes has been adequately addressed by the Department.

Mr. ROGERS. What is the total budget for the Institute?

Dr. ZAPP. The fiscal 1974 proposed budget, Mr. Chairman, is \$133,608,000.

Mr. ROGERS. How much of that goes to diabetes?

Dr. ZAPP. Well, directly, Mr. Chairman, you have about \$7.2 million that would be proposed for expenditure specifically for diabetes in this coming year.

[The following figures were subsequently received for the record:]

REVISED BUDGET FIGURES—1973 OBLIGATIONS AND 1974 BUDGET

Revised budget figures not available at the time of the hearing show the following figures for diabetes:

1973 estimated obligations, \$7,859,000; 1974 President's budget, \$8,489,000; increase, \$630,000.

NOTE.—These figures and the following remarks reflect the budget charts prepared in January 1973.

Mr. ROGERS. Is that a reduction this year over last year?

Dr. ZAPP. That would be a slight reduction, Mr. Chairman.

Mr. ROGERS. About \$1 million?

Dr. ZAPP. Approximately.

Mr. ROGERS. So you are reducing specific funds for diabetes rather than increasing them?

Dr. ZAPP. The funds that would be going to actual diabetes are not as large in projected fiscal 1974 budget as they were in the last fiscal year.

Mr. ROGERS. It is a decrease, isn't it?

Dr. ZAPP. That is correct.

Mr. ROGERS. How does it jibe with all of what the administration is going if you are actually decreasing funds? I am not sure I understand.

Dr. ZAPP. I would have to say, Mr. Chairman, it is a matter again within the Institute which does have a slight decrease over the last fiscal year of some \$6 million. It went from \$139.8 million to \$133.6 million, and also within that is an increased effort as a result of congressional interest and activity in the field of digestive disease.

Mr. ROGERS. How much is that increase?

Dr. ZAPP. Digestive diseases?

Mr. ROGERS. Yes.

Dr. ZAPP. The increase in digestive disease is about \$2 million, Mr. Chairman.

Mr. ROGERS. Well, that does not show on the sheets I have. In fact, mine show it as about—well, you are including nutrition in that?

Dr. ZAPP. You are correct, Mr. Chairman.

Mr. ROGERS. There is a slight increase. No, rather it is a decrease there, too, is it not? That is from \$24 million down to \$23,768,000, is that correct?

Dr. ZAPP. Dr. Lamont Havers informed me that the budgets are not that recent.

My understanding, from discussing this with him, setting aside the funds for training grants, which obviously is a separate issue, which we discussed with you many times, the research effort in the field of digestive diseases has increased over the last fiscal year.

Mr. ROGERS. It is not included in these charts.

Dr. LAMONT-HAVERS. Mr. Chairman, these tables were prepared in January. Since the beginning of the fiscal year, knowing that we had approximately \$19 million for competing research grants, we did assign approximately \$2 million off the top, as it were, to the other disease areas in order to fund the cooperative clinical studies in gallbladder, in gallstones, and some of the commitments in Crone's disease, and also to initiate a new digestive disease center as well as some other new additional digestive disease.

It does not show on that table.

Mr. ROGERS. But this shows a reduction of about \$1 million.

Dr. ZAPP. Yes.

Mr. ROGERS. So maybe you put \$1 million on the balance?

Dr. ZAPP. We put more than \$1 million more into digestive diseases. The overall increase in the NIAMDD fiscal year 1974 budget for digestive diseases is \$1.192 million. This represents an increase of \$1.590 million in the items of research grants, laboratory and clinical research, and research and development contracts, and a decrease of \$.398 million in the items relating to research training.

Mr. ROGERS. I would like you to submit all of those charts for an up-to-date chart because this indicates a decrease there, too.

Dr. ZAPP. I think we are both using budget sheets that show inaccurate information.

Mr. ROGERS. If you will let us have that, then it will be helpful.

[The following tables were received for the record:]

ANALYSIS OF CHANGES BY DISEASE CATEGORY—NATIONAL INSTITUTE OF ARTHRITIS, METABOLISM, AND DIGESTIVE DISEASES

[In thousands]

	1973 estimated obligations	1974 President's budget	Net change
Arthritis.....	\$13,737	\$12,015	-\$1,722
Bone.....	5,676	6,156	+480
Skin.....	4,433	3,944	-489
<b>Total.....</b>	<b>23,846</b>	<b>22,115</b>	<b>-1,731</b>
Diabetes.....	7,859	8,489	+630
Endocrinology.....	19,311	18,106	-1,205
Metabolism.....	29,774	27,908	-1,866
<b>Total.....</b>	<b>56,944</b>	<b>54,503</b>	<b>-2,441</b>
Digestive diseases.....	16,380	17,572	+1,192
Nutrition.....	7,807	7,811	+4
<b>Total.....</b>	<b>24,187</b>	<b>25,383</b>	<b>+1,196</b>
Kidney and urology.....	17,915	15,533	-2,382
Blood.....	11,581	10,323	-1,258
<b>Total.....</b>	<b>29,496</b>	<b>25,856</b>	<b>-3,640</b>
<b>Grand total.....</b>	<b>134,473</b>	<b>127,857</b>	<b>-6,616</b>
General research support grants.....	3,005	0	-3,005
Research management and program services.....	4,483	4,670	+187
Experimental training grants.....	719	585	-134
Other undistributed costs.....	625	496	-129
<b>Total estimate.....</b>	<b>143,305</b>	<b>133,608</b>	<b>-9,697</b>



1974 President's budget:

Asthma.....	8,664	318	917	1,996	80	40	12,015
Arthritis.....	5,635	97	404	1,996	20		6,156
Bone.....	2,513	148	945	2,234	100		3,944
Skin.....							
<b>Total.....</b>	<b>16,812</b>	<b>563</b>	<b>2,256</b>	<b>2,234</b>	<b>200</b>	<b>40</b>	<b>22,115</b>
Diabetes.....	6,331	297	360	1,166	85	250	8,489
Endocrinology.....	11,183	711	1,479	3,993	590	150	18,106
Metabolism.....	17,149	701	1,785	9,165	88	20	27,908
<b>Total.....</b>	<b>34,663</b>	<b>1,709</b>	<b>2,624</b>	<b>14,324</b>	<b>763</b>	<b>420</b>	<b>54,503</b>
Digestive diseases.....	11,116	702	1,333	1,425	2,421	575	17,572
Nutrition.....	6,398	262	1,360	791			7,811
<b>Total.....</b>	<b>17,514</b>	<b>964</b>	<b>1,693</b>	<b>2,216</b>	<b>2,421</b>	<b>575</b>	<b>25,383</b>
Kidney and urology.....	10,574	252	1,152	336	2,894	325	15,533
Blood.....	7,700	363	1,231	929	100		10,323
<b>Total.....</b>	<b>18,274</b>	<b>615</b>	<b>2,383</b>	<b>1,265</b>	<b>2,994</b>	<b>325</b>	<b>25,856</b>
Grand total.....	87,263	3,851	8,966	20,039	6,378	1,035	127,857
General research support grants.....							0
Research management and program services.....							4,670
Experimental training grants.....							585
Other undistributed costs.....							496
<b>Total estimate.....</b>							<b>131,608</b>

Mr. ROGERS. Now, could you describe the functions of the diabetes research and demonstration center?

Dr. ZAPP. I will refer that question to Dr. Havers.

Dr. LAMONT-HAVERS. Yes, sir.

The center concept would enable, hopefully on a regional basis, an increased effort in the development of knowledge from the level of fundamental research and clinical investigation through to its application to diagnosis, prevention, and therapy.

Mr. ROGERS. What is the budget for the research and demonstration center?

Dr. LAMONT-HAVERS. In the bill, sir?

Mr. ROGERS. Yes. For what you project it for?

Dr. LAMONT-HAVERS. Right, yes, sir, the one center which we are instituting with regard to diabetes is somewhat different.

The cost of the National Research and Demonstration Centers for Diabetes has not been determined. In comparison with similar types of centers in the heart and cancer programs, it could be assumed that, exclusive of construction, a very conservative estimate would be \$1 million for direct costs, per year per center.

The NIAMDD has initiated a Diabetes Research Center program this year on a much more modest scale. A decision to fund one such center has been made.

Mr. ROGERS. Is it located in Memphis?

Dr. LAMONT-HAVERS. No, sir, Nashville. This will be the question of having an environment of excellence in science.

Mr. ROGERS. What is its budget?

Dr. LAMONT-HAVERS. Its budget will be \$250,000 for the first year, which will be both direct and indirect costs.

Mr. ROGERS. How many people will be involved?

Dr. LAMONT-HAVERS. That I don't know offhand.

[See statement of Dr. Oscar B. Crofford, p. 61, this hearing, for details.]

Mr. ROGERS. You can't get too many for \$250,000.

Dr. LAMONT-HAVERS. I was going to explain the concept of that center which is quite different from what I thought you were asking.

The concept of the diabetes research center which the Institute will be initiating will be the fact that in an environment of excellence in science, the introduction of a relatively small amount of money, \$250,000, will enable the center to accumulate core facilities to take a quantum jump as far as research efforts are concerned. Therefore the \$250,000 will be to improve core facilities of equipment, personnel, this sort of thing, as well as enable them to undertake new initiatives much more easily than at present.

Mr. ROGERS. How do they take new initiatives without any money?

Dr. LAMONT-HAVERS. That is what the \$250,000 is for.

Mr. ROGERS. The \$250,000 is for initiatives?

Dr. LAMONT-HAVERS. Part is for new initiatives.

Mr. ROGERS. How much of the \$250,000 will be new initiatives?

Dr. LAMONT-HAVERS. Most of the money which will be given in the first year at least will be for core support.

Mr. ROGERS. What do you mean "core support?" Salary?

Dr. LAMONT-HAVERS. Enabling the environments to get common equipment and facilities.

Mr. ROGERS. It is for equipment then, the \$250,000?

Dr. LAMONT-HAVERS. Facilities and core personnel.

Mr. ROGERS. I am not sure I understand that. What can you get for \$250,000? You are going to get equipment, you are going to get personnel and new initiatives?

Dr. LAMONT-HAVERS. Yes, sir.

Mr. ROGERS. Now, I want a breakdown of that. I am not sure I can understand how you do it all on \$250,000.

Dr. ZAPP. Mr. Chairman, I think there is something we discussed earlier this morning that should be pointed out. This is not projected in my understanding as a fully federally supported research or diabetic research center.

It is a supplement to what is going on. You should recognize in the diabetes field the NIH support is only about 35 to 45 percent of the national effort. What we are trying to do in an area that has expertise is to put some consistent core money in to maintain a critical mass and develop this as a supplement to the Foundation.

Mr. ROGERS. It reminds me of the supplement vitamin "C." They say if you take too much of that and you don't get much effect.

Dr. ZAPP. When you have a center like this getting funds, a variety of sources are putting money into it.

Mr. ROGERS. Well, wait, give it to us for the record, what exactly is going to happen there and how much personnel and what goes for equipment and what new initiatives and what other support it has and how many people are involved, just give us a rundown for the record.

Dr. ZAPP. I will be pleased to.

[The following information was received for the record:]

*Details of First Year's Budget (Direct Costs only) of 1 P17 AM 17026-01—  
Diabetes Research Center*

Core support :

Personnel costs.....	\$36, 550
Equipment .....	62, 402
Supplies .....	33, 500
Protein chemistry laboratory contracts.....	8, 000
Alterations and renovations.....	3, 000
Other expenses.....	1, 700
	<hr/>
	145, 152
	<hr/>

New research initiatives :

Personnel .....	36, 103
Equipment .....	10, 008
Special services.....	26, 770
	<hr/>
	72, 881
	<hr/>
	218, 033

Sixteen individuals are being supported in whole or in part on this project. Seven new initiatives will be undertaken.

Mr. ROGERS. Can we get it in a week?

Dr. LAMONT-HAVERS. One of the witnesses you will be hearing today will be the principal investigator on that project.

Mr. ROGERS. Good, I think you should give to the committee a breakdown of the work done in diabetes, the funding, what research, and now, if there are any major thrusts or encouraging signs on the horizons that we are pursuing or are we just plodding along?

[The following information was received for the record:]

## DIABETES

The year 1972 marked the fiftieth anniversary of the discovery of insulin, the hormone that means life for many diabetic individuals. Prior to the discovery of insulin a diagnosis of diabetes in the early years of life was equivalent to a death warrant. Today, most diabetics can control their major clinical symptoms, marry and reproduce, and obtain gainful employment. Despite the *appearance* of a favorable medical outlook for the diabetic patient, however, progressive changes occur primarily in small blood vessels which may lead to serious complications in the kidneys, the nervous system, the eye and the cardio-vascular system.

Modern diabetes research is focused upon finding the cause of the disease, which affects more than four million Americans. Much of this research is devoted to studies on insulin, how it is produced and released, and how it does its vital work. Scientists believe that this and related fundamental research is the key to understanding diabetes and to improving its treatment.

Other studies have been concerned with the question as to whether the small blood vessel disease characteristic of diabetes is an independent primary cause or an effect of long-term diabetes, and the possible role played by human growth hormone. In addition, there are a number of ongoing investigations of new approaches with a therapeutic potential, such as implantation of insulin-producing pancreatic beta cells, and various studies designed to understand better, and perhaps to forestall, development of the long-term complications of the disease.

## OBLIGATIONS FOR PROGRAMS IN DIABETES

	1970	1971	1972	1973 estimate	1974 estimate
National Institutes of Health: National Institute of Arthritis, Metabolism, and Digestive Diseases.....	\$8,052,000	\$7,856,000	\$8,182,000	\$7,416,000	\$7,100,000

NATIONAL INSTITUTES OF HEALTH, NATIONAL INSTITUTE OF ARTHRITIS,  
METABOLISM, AND DIGESTIVE DISEASES

A complicated disease, for which there is no known cure, diabetes ranks seventh on the list of diseases causing death in the United States. Diabetes has been known for some time to be a hereditary disorder. As a result of the body's inability to metabolize carbohydrates normally (which, in turn, is related to an impaired production or activity of the hormone insulin), the diabetic is unable to convert dietary carbohydrates properly into the stored form, glycogen, or to utilize them normally to produce the energy required for body functions. Thus, the carbohydrates, in the form of glucose, accumulate in the blood and, because of their high concentration, overflow into the urine. As the disease progresses, abnormal carbohydrate metabolism becomes associated with additional derangement in the metabolism of fats and proteins.

In its severe form, frequently called "juvenile type" diabetes because of its early onset in life, the untreated disease rapidly progresses to a grave metabolic state of imbalance, ketoacidosis, which may result in coma and death unless controlled by insulin administration and specific supportive therapy. Patients afflicted with its less severe form, the so-called "maturity-onset diabetes," may suffer from complications such as accelerated degeneration or "hardening" of the arteries, and thus may have a decreased life expectancy. Although the disease can be fatal unless properly treated, in most cases the more obvious clinical symptoms can be controlled. Despite apparent control of these symptoms, however, progressive changes occur in both juvenile and maturity-onset diabetes that may lead to a gradual deterioration of blood vessels, the kidneys, the nervous system and, particularly, the retina of the eye.

## CAUSATION

*Human Growth Hormone:* Diabetes, in essence, is an enigma. The modern investigator now recognizes that he is dealing with a complex, multifaceted disease, and not with a simple metabolic disturbance that can be successfully treated with insulin.

For example, plasma levels of human growth hormone (HGH) are known to be elevated in prediabetic and juvenile diabetic subjects. It is not known, how-

ever, whether these elevated HGH levels result from increased HGH release by the pituitary gland in the diabetic state, or from decreased clearance of the hormone from the blood.

The metabolic clearance rate of HGH in juvenile diabetic subjects is significantly lower than that of normal children. Data obtained by an Institute grantee, Dr. Daniel H. Mintz of the University of Miami (Fla.), has shown recently that the liver is responsible for over 90% of HGH clearance in man. This is consistent with the hypothesis that an as yet unknown defect in HGH clearance by the liver exists in diabetes.

*Infection:* Another scientist, at Pennsylvania State University, is conducting studies of diabetes in guinea pigs which seem to indicate that the disease may stem from an infectious process. Dr. Bryce L. Munger has found that if healthy guinea pigs are placed in a cage with diabetic animals, or injected with urine concentrate from diabetic animals, more than half become frankly diabetic within two to six weeks.

These acutely ill animals develop elevated blood glucose levels and glucose in the urine, react positively to glucose tolerance tests, and exhibit elevated blood cholesterol levels. Microscopic studies of the pancreas suggest features reminiscent of what was observed in juvenile diabetes in the 1920's, before the advent of insulin. Blood vessel changes characteristic of human diabetes were found in the animals' kidneys and striated muscle tissue.

Dr. Munger and his colleagues presently are conducting studies to determine if the disease can be passed from one species to another. Thus far, efforts to identify an infectious agent or its route of transmission have not been successful.

The hypothesis concerning a possible infectious cause also gains support from the fact that "epidemic" outcroppings of juvenile diabetes are reported periodically in certain areas. In addition, one study conducted in England has found that 85 percent of juvenile diabetes is preceded by an infection.

*Small Blood Vessel Disease:* Many investigators have demonstrated in recent years that, in general, capillary basement membranes are thicker in diabetics than in nondiabetics. Few investigators, however, have attempted to relate this phenomenon to the duration of known diabetes, to the degree of carbohydrate intolerance, or to the extent of insulin deficiency in the involved individuals. Such data are of utmost importance in establishing a possible causal relationship and in determining the orientation of research on the origins of the small blood vessel disease associated with diabetes.

Basement membranes form a delicate layer under the lining of the blood vessels. Dr. Joseph R. Williamson of Washington University, St. Louis, now has shown that in normal subjects and in diabetics significant thickening of these membranes is observed as an aging phenomenon. Significant age-related sex differences in basement membrane thickness are evident in normal subjects, but not in diabetics.

Observations on diabetics suggest that basement membrane thickness was probably normal in most subjects prior to the onset of carbohydrate intolerance, but that both the magnitude and incidence of basement membrane thickening increase with duration of carbohydrate intolerance. It is more common in diabetics over 50 years of age than in those under 50 years of age, and the incidence increases to 90% in diabetics with diseased retinas or kidneys, and to 93% in those who have had the disease for 20 years or more.

#### TREATMENT INNOVATIONS

*Transplantation of Insulin-Producing Cells:* In recent years an Institute-supported scientist has demonstrated the feasibility of transplanting a normally functioning pancreas into certain persons suffering from severe diabetes. At first the transplanted glands produced sufficient insulin to control the blood sugar levels of the recipients, but the grafted organs were eventually inactivated by the transplant rejection reaction of the patient's immune mechanisms.

More recently, Drs. Walter F. Ballinger and Paul M. Lacy of Washington University, St. Louis, have investigated the transplantation of insulin-producing pancreatic beta cells from normal to diabetic rats. Transplantation of such cells into pockets in the thigh muscles or into the peritoneal cavity resulted in significant reduction of blood and urine sugar levels and restoration of weight gain in the host animals. Although the disease was not cured, it was certainly modified and ameliorated. Microscopic studies subsequently revealed intact and functioning pancreatic cells in the transplanted rats, whose native pancreatic beta cells had been destroyed experimentally, indicating that the animals were utilizing the transplanted cells. This line of research ultimately may prove superior to transplantation of the entire pancreas.

**Conversion of Animal to Human Insulin:** The only practical source of insulin for treatment of diabetes has been insulin obtained from several different animal species. Unfortunately, immunologic intolerance to these nonhuman proteins develops in some diabetic patients.

Synthesis of insulin was first reported in 1963 by a NIAMDD grantee, Dr. Panayotis Katsoyannis of the University of Pittsburgh, who used sheep insulin as a model. His method, and others reported since (including one developed in China) are extremely expensive, time consuming, and do not, as yet, lend themselves to mass production of insulin.

It is now known, however, that human insulin differs from that obtained from pigs by a single amino acid. Using this fortuitous fact, another NIAMDD grantee, Dr. Michael A. Ruttenburg of the University of California, has developed a method whereby "human" insulin can be prepared simply and inexpensively through chemical manipulation on a large scale of readily available pig insulin. His method might permit the preparation of a pure, non-antigenic insulin molecule, or related man-made analogs which are therapeutically effective, as well as radioactively labeled or other modified insulins for research purposes.

The biological activity of the man-made "human" insulin, which was created by substituting one amino acid for another in the porcine insulin molecule, was found to be equal to that of pig insulin. The new insulin's immunologic innocuousness in man will have to be confirmed, however, before it can be used in human subjects. Research is now under way to test this.

**Drug Insulin Antagonism:** In a related finding, Dr. Peter H. Forsham of the University of California has shown that a drug used in the maintenance treatment of epilepsy also suppresses insulin secretion in normal healthy men. Although the effects of the drug—diphenylhydantoin—are of only moderate magnitude in non-diabetic individuals, implications for the large population with maturity-onset diabetes are apparent.

Many such diabetic patients are perpetually in precarious metabolic balance, and when their insulin secretion is further blunted by any stressful event, decompensation of their diabetes ensues. Dr. Forsham has warned that administration of diphenylhydantoin should be especially monitored in patients who have known hereditary risk factors for diabetes or are diabetics, or who are receiving other diabetes-inducing agents such as thiazide diuretics or corticosteroid drugs.

#### ORAL ANTI-DIABETIC DRUGS

**Mode of Action:** The ability of the oral antidiabetic drugs to lower blood sugar levels in patients with maturity-onset diabetes has been known for some 15 years. Their mode of action, however, still remains a matter of controversy. One recent study in the British journal, *The Lancet*, suggested that the sulfonylurea type drugs, such as tolbutamide and chlorpropamide, act by suppressing pancreatic secretion of the hormone glucagon, which, in turn, normally acts to increase blood sugar levels.

This finding has been challenged by Drs. Stefan S. Fajans and Jerome W. Conn of the University of Michigan, who have studied the effects of tolbutamide and chlorpropamide on plasma glucagon levels in healthy subjects. They have shown that neither acute nor prolonged administration of these agents depresses plasma glucagon levels in healthy men under normal conditions, nor even during periods of augmented release of glucagon induced by external stimuli.

#### COMPLICATIONS OF DIABETES

**Diabetic Retinopathy:** Progressive damage to the retina, or diabetic retinopathy, develops in many persons whose diabetes begins in childhood and who have been diabetic for 20 years or more. Several investigations have indirectly suggested a relationship between secretion of human growth hormone (HGH) and development of retinopathy.

Dr. Fajans now has shown that plasma levels of HGH are significantly higher in diabetic patients with retinopathy than in those without retinopathy. Although such an association does not establish a casual relationship, it would appear that diabetic retinopathy develops in a milieu which includes elevated plasma levels of HGH.

Dr. Fajans' data suggest that fasting HGH levels are elevated as a consequence of the diabetic state, and these levels are higher in diabetic patients than in healthy individuals, and higher in diabetic patients with retinopathy than in those without retinopathy.

*Measured vs Unmeasured Diet:* A measured restricted diet together with efficient use of insulin is the generally accepted method of managing juvenile diabetes. A 25-year study now has revealed, however, that the vascular changes characteristic of long-term diabetes develop relentlessly whether juvenile diabetics are maintained on a measured or unmeasured diet. Moreover, mortality rates also are essentially the same in the two groups of patients.

When Dr. Harvey C. Knowles, Jr. of the University of Cincinnati evaluated risk factors for degenerative changes in patients who had had diabetes for 20 to 30 years, no difference could be found between the two diet groups. As calculated by life table methods, after 30 years of known diabetes the risk of complications was: retinopathy 77%, blindness 34%, proteinuria 47%, azotemia 41%, and retinal neovascularization 45%. The risk of hardening of the arteries increased after 25 years of diabetes and that of retina and kidney disease leveled off.

Cumulative death rate in the study was 20% after 25 years of diabetes. This figure compares closely with that obtained in similar age groups treated with a more restricted diet in Boston (19%), and with a less restricted diet in Stockholm (22%).

Thus, if restrictive dietary regimens are more beneficial, it would appear that patients so treated either do not follow their regimens, or that the effects of such regimens are small in comparison to other unknown factors determining the course of diabetic complications.

*Kidney Transplantation:* At the University of Minnesota, Dr. John S. Najarian has been transplanting kidneys into juvenile-onset diabetics whose own kidneys have been ravaged by the vascular damage characteristic of long-standing diabetes. Previously, physicians have hesitated to perform such surgery in diabetics because of their surgical wound-healing problems, scarring and debilitated state.

It was also being assumed that the ongoing diabetic process in the graft recipient would result in the development of characteristic renal injury in the transplanted normal kidneys. Dr. Najarian reasoned, however, that the lesions would not necessarily return in the newly transplanted kidney and, even if they did, it would require five or ten years for them to do effective damage. Thus far, 21 diabetics have received new kidneys and 16 of them have survived longer than six months. Five of these 16 have survived for more than two years. The Minnesota surgeon has therefore concluded that a diabetic patient *can* have a kidney transplant and that the new organ may gain years of life for the recipient.

*Ketoacidosis:* In its severe, "brittle" form, untreated diabetics readily progress to a grave metabolic disorder, ketoacidosis, which may result in coma and death unless controlled by insulin administration and specific supportive therapy. Ketoacidosis is usually considered an indication of severe, acute failure of the insulin-producing cells of the pancreas, as serum insulin concentrations are practically non-measurable during such episodes. Insulin therapy is believed to be required indefinitely in such patients.

At the University of Chicago, Dr. Donald F. Steiner has developed a method of studying the secretory capacity of the insulin-producing ("beta") cells of the pancreas in patients who are receiving insulin therapy. He has found that patients suffering from ketoacidosis, despite very low serum insulin levels, do in fact have some insulin secretory activity. Subsequently, three of seven patients studied were managed on diet alone (without insulin), while the insulin dosage was substantially reduced in two others.

Dr. Steiner's observations are consistent with the idea that exhaustion of the insulin-producing cells, even when severe, is frequently partially reversible. He suggests that the need for continued insulin therapy in this group of patients be periodically reevaluated.

#### DIABETES AND THE PIMA INDIANS

Institute scientists revealed several years ago that the Pima Indians of Arizona are a unique population group in that their rate of diabetes is ten to fifteen times that of the general American population. Their studies have shown that almost half of the population aged thirty and over have abnormal glucose tolerance tests, and that many have eye and kidney disease and other problems related to diabetes.

The Institute's Southwest Field Studies Section is continuing its studies of the Pimas in order to determine the reasons for the increased incidence. By studying a population in this way it is possible to compare the characteristics of those

without diabetes or a particular complication, to those with it, and so deduce evidence of factors which are important in causing or aggravating the condition.

Test results now are available on about 5,000 Pima Indians, many of whom have gone through the same battery of examinations three or four times over a period of six years. The investigators now are able to assemble a large array of statistical information concerning the pattern of diabetes in Pima families. They expect, within a few years, to be able to postulate the mechanism determining the distribution among the Pimas.

#### DIABETES—ENDOCRINOLOGY CENTERS

The Institute has completed plans to permit support of a number of Diabetes-Endocrinology Research Centers throughout the United States, during the next year or two. Center grants will be limited to institutions where there is ongoing research in diabetes, and will be used to strengthen and to permit further development of these efforts. That is, these centers will provide core resources and services at an institution where a broad and substantial volume of excellent diabetes research already exists.

The centers are conceived as providing scientific personnel, administration, and central support services to accomplish research goals that would not otherwise be achievable. The grants are not intended to give direct support for ongoing research projects. Funds to initiate projects by new investigators and for exploratory or feasibility studies may also be furnished by this mechanism. Such funds may be requested each year of the center grant, but support of any particular new project will be limited to a three-year period, at which time the project should compete for a regular research grant.

#### OUTLOOK

Although diabetes is probably the most intensively studied of the metabolic diseases, it is hardly the best understood. Continued advances depend upon further knowledge of the disease and its complications, of genetic factors, and of insulin action. It is in these areas that research has made the greatest progress in recent years. The excellence of new research ideas and the level of quality of the scientists engaged in diabetes research is extremely high in this country. This fact alone presages further improvement in the diagnosis and treatment of diabetes, as well as its ultimate conquest.

#### DIABETES—NATIONAL INSTITUTE OF ARTHRITIS, METABOLISM, AND DIGESTIVE DISEASES

(Dollar amounts in thousands of dollars)

	Research grants		Fellowships		Training grants		Laboratory and clinical research	Research and development contracts	Biometry, epidemiology, and field studies	Total
	Number	Amount	Number	Amount	Number	Amount				
1967-----	153	\$4,728	22	\$301	15	\$633	\$744	\$69	\$200	\$6,675
1968-----	133	5,240	26	383	18	747	864	78	230	7,542
1969-----	174	6,213	40	554	21	906	1,096	72	199	9,040
1970-----	157	5,366	29	457	20	843	1,094	75	217	8,052
1971-----	121	4,982	34	484	18	828	1,244	79	239	7,856
1972-----	113	5,664	31	457	12	568	1,086	161	246	8,182
1973 <sup>1</sup> ---	107	5,581	25	387	9	443	1,124	74	250	7,859
1974 <sup>1</sup> ---	108	6,331	18	297	7	360	1,166	85	250	8,489

<sup>1</sup> Estimate.

Mr. BURTON. If I may address that, Mr. Chairman, as a matter of fact, most of the clear and promising things that are on the horizon are in the realm of those research grants that are funded by our institute.

Probably one of the most important things, the turning of a little corner, hopefully maybe a bigger corner, is this entering into efforts to transplant the special cells in the pancreas, so-called beta cells that produce insulin which have been done successfully in animals already.

They were transplanted in animals from normal animals into experimental animals which had been made experimentally diabetic and continued growing in these animals either in the abdomen or a pocket of the high muscle and supplied apparently enough insulin to keep the animals on a normal existence so they would not show major symptoms of experimentally induced diabetes.

From this, many of us take hope that one of these days we might be able to do this sort of thing also in human beings, because early transplantation efforts in human beings which involve transplanting of the entire organ of the pancreas are not too successful and only on a limited time basis because of the well-known rejection action.

One of the other fairly hopeful things on which work is being done involves what would be a supportive effort for the established diabetic, namely, a system of man made apparatuses which would see to it that he gets an almost automatic supply of the insulin he needs which is internally implanted and will supply this insulin which can be replenished every few months and so on.

There are other witnesses I am sure in the room that can address themselves to that in greater detail and they should because they are involved in the work directly.

Mr. ROGERS. Could I just ask you right there, what effect does this have on the blood vessel part of the disease? It is kind of a two-part disease, isn't it, one, the effect of the sugar, metabolism, and then the actual blood vessel?

Mr. BURTON. Right.

Mr. ROGERS. Would this have any effect on the blood vessel part of the disease?

Mr. BURTON. I would hate to make a categorical statement for the simple reason, Mr. Chairman, that we are confronted with two aspects of blood vessel disease. One is a specific aspect which is unique to diabetes itself and that is so-called microangiopathy, the impact of the disease on small, tiny blood vessels. This in turn will then damage an organ which depends on these vessels, for example the kidneys. Then there is the augmenting effect of the disease on the larger blood vessels in the body which is akin to atherosclerosis, hardening of the arteries such as in coronary heart disease. So we are dealing actually with two different things.

The second aspect I mentioned, the impact on large blood vessels in the body, is as enigmatic as the subject of atherosclerosis in general, which investigators who pursue cardiovascular disease are trying very hard to solve.

Mr. ROGERS. What would you say our budget is on the research, the actual research contract for these two aspects of the disease?

Dr. LAMONT-HAVERS. Research contracts? The only contracts I believe that NIH has on diabetes is in the National Eye Institute and that is a cooperative study with regard to retinopathy.

Mr. ROGERS. That is the only contract we have?

Dr. ZAPP. The rest is grants.

Mr. ROGERS. What about on grants?

Dr. LAMONT-HAVERS. We have approximately \$4 to \$5 million in grants.

Mr. ROGERS. How many overall projects would it cover in number, approximately?

Dr. LAMONT-HAVERS. It is about 100.

Mr. ROGERS. About 100?

Dr. LAMONT-HAVERS. Yes, projects.

Mr. ROGERS. You are going to give us a rundown on all of that.

Dr. LAMONT-HAVERS. Yes, sir. [See Diabetes, p. 36, this hearing.]

Mr. ROGERS. Let me ask this question quickly of one of my colleagues.

Why has the Secretary eliminated the Arthritis, Metabolic Diseases Program Project Committee, the Arthritis, Metabolic Diseases Research Career Program Committee, and Diabetes, Metabolism Training Grants Committee?

Dr. ZAPP. As you realize, Mr. Chairman, there was a press release last week which stated that some 119 of our nearly 400 advisory committees were abolished. That is, the nonstatutory ones, and it was for a variety of reasons. Some of them were overlapping and some were seldom used committees and others we felt were unnecessary. As to these three specific ones that you mentioned, I would have to defer on those to my colleagues.

Mr. ROGERS. Give us a comment on the record for that.

[The following information was received for the record:]

#### STATEMENT ON ELIMINATION OF SPECIFIC COMMITTEES

##### 1. *Arthritis Metabolic Diseases Program Project (AMP) Committee*

This initial review committee was established within the Division of Research Grants, primarily for the purpose of the initial scientific merit peer review of program project applications referred to the NIAMDD. There had been discussion regarding the future role of this committee between the Division of Research Grants and the NIAMDD for at least the past two years. It had been concluded that, considering the changing specific programmatic and scientific review requirements of the Institute, the types of applications which were being referred to the AMP Committee could be more effectively reviewed by special study sections or by utilizing existing study sections.

##### 2. *Arthritis Metabolic Diseases Research Career Program Committee and the Diabetes Metabolism Training Committee*

These committees were intimately involved in the review and evaluation of the Institute's extramural research training programs. In keeping with the evolving concepts in the support of training by the National Institutes of Health, these committees, in common with all other such committees at NIH, no longer had a function and were therefore dissolved.

Mr. ROGERS. Now, is there a need for coordination among the various Institutes at NIH that deal with diabetes research? Is there a need for coordinating?

Dr. ZAPP. There is a need and it is my understanding that such a mechanism exists.

Mr. ROGERS. What is that mechanism?

Dr. ZAPP. Well, I am talking about within the Institutes. I am not sure there is any specific advisory committee that sets across, within, in-house in NIH.

Mr. ROGERS. Just for the purpose of diabetes and I wonder if this varies.

Dr. ZAPP. Not a specific one, Mr. Chairman. I think the Director has a responsibility for coordinating these.

Mr. ROGERS. I understand, but he is only the director of one institute.

Dr. ZAPP. No, I am talking about the Director of the National Institutes of Health.

Mr. ROGERS. He directs everything but it gets to be rather an imposing task.

Dr. ZAPP. I agree, Mr. Chairman.

Mr. ROGERS. Suppose a person has diabetes, how does he receive information about the disease? Who should a person talk to about the disease? How does he receive information or how does he know? Is there any effort?

Mr. BURTON. If I may address myself to that, let us say a person has just recently been diagnosed as a diabetic and went to his physician or went to a public clinic, then at this point he will be given a line regimen by his physician. If he is a maturity-onset diabetic 50 or 60 years old, his physician will tell him what diet he should take and probably refer him to his dietitian. If there is no dietitian, and in many cases this is so, he will tell him where he can get the information from publicly available literature.

Mr. ROGERS. Who makes that literature available? Does the Government?

Mr. BURTON. In our Institute, our information office makes literature of this type available.

Mr. ROGERS. I am talking about in some towns, say Fort Pierce, Fla. Do you have the information available? How do they find out about it?

Mr. BURTON. You may mail a request to our Institute or you may ask for the very excellent brochures which the American Diabetes Association and the American Dietetic Association put out.

Mr. ROGERS. In other words, we rely more on the voluntary agencies to get it out than our own effort.

Mr. BURTON. Yes.

Mr. ROGERS. What is the budget for information on diabetes in the Institute?

Dr. LAMONT-HAVERS. Dr. Burton could answer it, but I imagine it would be impossible at this time to break our information budget down to specific categorized diseases.

Mr. ROGERS. Don't we know how many bulletins we put out?

Mr. BURTON. Yes, we will supply it for the record.

Mr. ROGERS. What do you think, very much, do you publish 10,000, 100,000 or 1 million?

Mr. BURTON. I would say in the order of magnitude of not more than 50,000 a year.

Mr. ROGERS. 50,000 a year.

[The following information was received for the record:]

#### 25,000 PIECES OF LITERATURE DISTRIBUTED BY NIAMDD EACH YEAR

The Information Office of the NIAMDD distributes a number of explanatory brochures related to diabetes and diets for diabetics upon request. This total is approximately 25,000 pieces of literature annually dealing directly with diabetes which are sent to patients, other members of the public, and various members of the health team.

Mr. ROGERS. How many are affected by diabetes?

Mr. BURTON. Known diagnosed diabetics, 2.8 million.

Mr. ROGERS. How many new ones a year do you think?

Mr. BURTON. We suspect about 325,000 more new cases each year. There are estimated to be about 4.2 or 4.5 million diabetics because many are undiagnosed and live in a borderline existence not knowing they have it.

Mr. ROGERS. Will you let use have those figures?

Mr. BURTON. We will supply those figures for the record.  
[The following information was received for the record:]

ESTIMATED 4½ MILLION AMERICANS HAVE DIABETES

According to the National Center for Health Statistics, an estimated 4½ million Americans have diabetes; of these, about 1.6 million are undiagnosed. In addition, another estimated 5 million Americans carry the hereditary predisposition for diabetes and will develop the disease later in life. There are about 325,000 new cases of diabetes each year, and 35,000 deaths are attributed to the disease annually. To this, one must add many thousands of deaths that are officially counted under the headings "heart disease" or "kidney disease" even though the real underlying cause was diabetes.

Mr. ROGERS. Is there any coordination of that information? What do we do to see that it is coordinated? How is it coordinated? Do you know that the information being put out by the voluntary area agencies are correct? Do you check and coordinate it with the Institute?

Mr. BURTON. Yes.

Mr. ROGERS. Who does it?

Mr. BURTON. We, for instance, refer people to specific booklets because there is a committee among three voluntary agencies, the American Heart Association, the Dietetic Association and the American Diabetes Association, which each few years updates these and they are excellent.

In this particular case, the Government does not duplicate them all over again the way we would not duplicate a textbook for medical schools as long as there is a good textbook available.

Mr. ROGERS. Suppose you have information but they are not ready to go to press, what do you do about it, anything?

Mr. BURTON. At this particular point, Mr. Chairman, there has not been any real radical changes in the diabetic diet for a long time except for things which again had been agreed upon over the last 5 years, that the emphasis should be properly more on losing weight in general and avoiding such things as carbohydrate food intake. They have done that nicely and our own scientists have had inputs into it and so have our grantees.

If I may make a point about coordination. The scientific community is a unique one in that respect that their lifeblood is communication with each other. The little phrase, "Publish or perish," among academicians, counts twice as much in the biomedical research community. "Publish or perish," or you will not get recognition as a researcher that you should have and will not get NIH grants either.

So there is naturally a compelling tendency all the time to let everybody else know what you are doing.

Mr. ROGERS. Of course, you don't get it published unless the editor of that particular journal decides it warrants publication, is that right?

Mr. BURTON. Most good publications have rather tough editorial committees.

Mr. ROGERS. That is right, and a lot of things don't get published.

Mr. BURTON. Yes, and the reason is for each good paper that stands the test of time, many more are written which would muddy the literature and mislead others, so one has to be careful.

At the same time, we try to take those that have been published by reputable journals and bring them to the attention of the research community in diabetes with a special effort which Dr. Zapp had mentioned, the Diabetes Literature Index.

Mr. ROGERS. Do you work with the National Library?

Mr. BURTON. The index is based on the computer tapes of the National Library. It comes out every month, and I think that it has one of the biggest impacts on bringing to the attention of researchers the latest research findings.

Mr. ROGERS. Good. I hope so. I hope we are getting it out. This committee would like to see what is done and would ask you to put a statement on the record on how you get it out, how it is coordinated, who updates it. Is there an automatic review, or is there not of the materials?

Dr. ZAPP. We will do that.

[The following information was received for the record :]

#### DIABETES LITERATURE INDEX

The Diabetes Literature Index is a regularly appearing monthly publication of the Institute which is disseminated broadly to all interested investigators in the field of diabetes. It is so-called "current awareness" publication—it supplies the reader with an up-to-date bibliographic citation of any research paper on the subject of diabetes or closely related to it—which has appeared recently in the world scientific literature regardless of country or language or origin.

It thus alerts the reader almost immediately to the existence of newly published scientific findings in the field of diabetes. It tends to lighten the workload of research workers in diabetes who would otherwise have to spend hours in the library keeping up with the literature, and it tends to obviate inadvertent duplications in research efforts since it alerts the investigator to the nature of various new research efforts carried out elsewhere. The contents of the Diabetes Literature Index are based on the computer tapes of the MEDLARS computerized storage and retrieval system of the National Library of Medicine. A unique process pioneered and supported by the Institute results in a selective retrieval from the MEDLARS tapes [which contain all biomedical research papers in the Index Medicus] of all of the items which are specifically related to diabetes. These are then screened by a specialist in diabetes before inclusion in the Diabetes Literature Index. Over 700 research workers in the field of diabetes regularly receive this publication and have given it much praise over the years.

Mr. ROGERS. I understand as the use of insulin continues over a long period, the incidence of diabetic retinopathy increases; is that phenomena being studied?

Dr. LAMONT-HAVERS. Yes.

Mr. ROGERS. Can you give us any clue as to why you know the inverse relationship exists?

Dr. LAMONT-HAVERS. This particular subject, diabetic retinopathy, is the particular concern of the National Eye Institute. It is obvious that the present treatment regimens for diabetes do not prevent the onset of complications. Thus, as individuals are living longer, one can expect the number of individuals with severe complications to increase.

One of the complications which indeed is a problem is retinopathy.

Mr. ROGERS. What are we doing about it, anything?

Dr. LAMONT-HAVERS. Well, the fundamental solution will be to understand why these complications occur, which will then lead to more effective methods of controlling them.

As far as retinopathy is concerned, the cooperative clinic study which is undertaken by the Eye Institute is for the present methods of treat-

ment or at least some of the modern methods of treatment, but it is not a preventative approach.

Mr. ROGERS. Let us have for the record what is being done in funding. How much Federal money goes for training support in diabetes? Will you give us a rough breakdown and then for the record supply the specifics? [See "Diabetes," p. 36, this hearing.]

Dr. LAMONT-HAVERS. Right, at the present time, during fiscal year 1974, the NIAMDD will support approximately \$290,000 in fellowships in diabetes and \$360,000 in training grants, and one should point out that many of the fellowships and training grants in endocrinology and metabolism are also related to this specific area.

We can give you specific breakdowns of the number of individuals involved.

Mr. ROGERS. Will it be more or less than in 1972?

Dr. LAMONT-HAVERS. It is less than 1972.

Mr. ROGERS. How much less would you say?

Dr. LAMONT-HAVERS. Well, in fiscal 1972, the expenditures in diabetes were approximately \$457,000 for fellowships and \$568,000 for training grants, approximately a 40-percent reduction.

Mr. ROGERS. Even a little more maybe.

Are these the funds that go to train researchers, teachers in this area?

Dr. LAMONT-HAVERS. Yes, sir.

Mr. ROGERS. You don't think we need an increase in training and researchers, people to find out the answers that we don't know?

Dr. LAMONT-HAVERS. No, I don't think that the problem is that we do not need more individuals in this area, the thought here being the fact that other mechanisms would be available to take care of this type of activity.

Mr. ROGERS. What mechanisms?

Dr. ZAPP. I think perhaps Mr. Chairman, that is an area for me as you realize I did testify before this subcommittee for the administration, at that time, on the proposal to terminate direct Federal support in the training grant fellowship area.

I also said at the conclusion of my statement that we felt that we were as much at a loss for good information on the need as the committee was and that as we begin to get an accumulation of evidence that we would then change our position and we have changed it.

Mr. ROGERS. Yes; you have come in and you have changed it some, which is encouraging to the committee. I must say the committee did not feel they were in the same degree of ignorance as the Department, however, in their training and fellowships. I think we felt we had enough experts.

Dr. ZAPP. I was not really trying to contaminate the committee in that direction, Mr. Chairman.

Mr. ROGERS. I must say the Department did not contaminate the committee because the committee acted and passed legislation out and, hopefully, the President will sign it. I believe he will.

Thank you very much.

Mr. Nelsen, any questions?

Mr. NELSEN. Thank you, Mr. Chairman.

I wonder about the various commissions we have. It seems to have become kind of a habit to come up with a new piece of legislation and set up a commission and then we think of a new area and set up another commission and this goes on and on and on.

I note you referred to how many commissions we have. Could we expand on that a little?

Dr. ZAPP. The advisory councils within the Department number nearly 400. They have been substantially reduced.

Mr. NELSEN. They are on a per diem, I presume, and on travel?

Dr. ZAPP. Yes.

Mr. NELSEN. Have you ever calculated what the costs of all of those various committees are?

Dr. ZAPP. I have not but the DHEW Office of Administration has. The committee realizes we were under mandate from Congress last year to go back and reevaluate all existing advisory committees and cut them back to those we felt were professionally necessary to operate our program.

Mr. NELSEN. Were you requested to do that?

Dr. ZAPP. Yes; by an act of Congress.

Mr. NELSEN. I see, in other words, we should not be severe on you because you did cut back because we asked you to do it?

Dr. ZAPP. That is correct. We may have disagreement on some of the selections made, but I think it would be an honest disagreement. I think we were carrying out the intent of Congress.

Mr. NELSEN. Have you any figures now? You indicate you have figures as to cost and travel and I would like those figures.

[The following information was received for the record:]

#### COST OF HEW ADVISORY COMMITTEES

The estimated cost of HEW advisory committees for Fiscal Year 1974 would be \$9.25 million (exclusive of staff costs). By reducing the number of advisory committees in the course of a review mandated by P.L. 92-463, it is estimated that approximately \$2.4 million (exclusive of staff costs) were saved, based on prior years cost experience with the groups terminated.

Actual cost of committees during calendar years 1972 was approximately \$10.4 million (exclusive of agency staff cost), and thus, although calendar year 1973 figures are not yet available they should be reduced by approximately the figure the eliminated committees abolition "saved," increased by the amount expended on groups since January 1973.

HEW does not have figures by category of cost, thus, we are unable to provide the cost by travel and per diem.

Mr. NELSEN. As to the information that goes out, with all of the various areas of research that are underway, have you any figures on how many pieces of information go out right across the board in the whole agency and the distribution of that information? I am just thinking of the tremendous task of getting that information out and how it can be done.

Certainly we want it out, but it does represent a tremendous effort, does it not?

Dr. ZAPP. It certainly does. As a matter of fact, this is another area where we are also undertaking initiative, to try to evaluate all of the publications in the Department to be sure the ones that are truly informational get out and look for better methods. If we have some which are simply self-serving we will cease publication of those.

Mr. NELSEN. Some of the testimony indicated that priority was given consistent with research opportunities available.

Is there some limitation as to how much you could profitably use in a research effort consistent with the help you have or the opportunities? Is that a factor?

Dr. ZAPP. Well, that is a factor. I think and I hope my statement reflected it, that coupled with the fact of research opportunities and funds available in relationship to other scientific priorities that exist within the National Institutes of Health, we felt from that sense of balance that diabetes was being treated fairly.

Mr. NELSEN. In another area, and I ask this question to try to gain some information as to whether or not we need to review it, there is an article on the cancer program either in the New York Times or one of our recent publications that indicated in our enthusiasm to do a job here we went overboard in how it is going to be spent and how research is going to be done. There is a possibility that we ought to examine that effort a little bit with the idea of better direction, better coordination, and I at sometime would like to visit with you about it because this is a subject our committee is very much interested in and I think played a very important role in the legislation that we did pass.

There are some changes that need to be made and I am sure we are amenable to make our dollars go as far as they can.

Now, in regard to the total dollars available to the Department, I believe that on projects we have instituted, for example, on medical schools the dollars seemingly are not there unless we raise taxes in order to increase the dollar income to the agency and to the Government. Therefore, I am wondering what your position is and is my appraisal right, that it is pretty much the dollar figure that is the real problem with the agency?

Dr. ZAPP. It is. HEW is a very unusual agency in a variety of ways and the size of its budget is nearing \$100 billion now. Because of recent changes or changes over the last decade in the mechanisms that Congress and the executive branch have chosen to use to assist the people who are in a sense in one way or another dependent on HEW, we have had more and more entitlement programs and are now to the point where 88 percent of dollars in HEW are what we would call uncontrollable expenditures. Of that remaining 12 percent that you may say is discretionary, some of that is questionable as to how much is entitlement and how much is not. Most of the areas in which we appear before this committee fall into that small percentage of the funds available to HEW where there is discretion. It means that, now, just as an example, the 5-percent social security increase is an additional \$2 billion of uncontrolled expenditures out of HEW.

Mr. NELSEN. That reduces your percentage of money available for various health programs?

Dr. ZAPP. That is correct, Mr. Nelsen.

Mr. NELSEN. I see. I believe I have no further questions. It is very easy for us to be critical of how many dollars the Department expended, how many people are working at a certain project and forgetting that the available funds, or the 12 percent, are getting smaller each time.

We have other programs and these are reduced unless we have dollars available to the agency itself. I thank you for your testimony.

Mr. ROGERS. Mr. Symington?

Mr. SYMINGTON. Thank you, Mr. Chairman.

First, with respect to the bill itself, Dr. Zapp, looking at the findings and declaration of purpose, section 2(a), there are 10 subsections there.

To save time could you tell us if you disagree with any of the findings and declarations?

Dr. ZAPP. Well, I think I would have to say that we would. I will make a quick analysis, although I hate to give that kind of official comment on a pending bill. I think there is some disagreement on the actual number of diabetics. I think there is another apparent disagreement because the information I have been given places diabetes in the position of the seventh leading cause of death based on a National Center for Health statistics chart, and the findings of the bill list it fifth. That again may be dependent on how many associated deaths from diseases such as heart or kidney disease are counted against it.

Mr. SYMINGTON. Is that the reason for that discrepancy, because I was going to ask you about that?

Dr. ZAPP. That would be my judgment from a quick look at it, Mr. Symington. If you assume there is 5 million that would differ from the count of confirmed diabetics. I think it would be including other deaths such as attributed to heart disease and the like.

Mr. SYMINGTON. Well, that is one specific qualification, but looking over the 10 aside from that, or the 9, do you find anything off hand that appears to be an exaggeration or inaccuracy of some kind? Since the bill rests on these findings and you have opposition to the bill, I want to be sure I know where it is.

Dr. ZAPP. I am going through, and right now I would only say maybe, this is more technical than anything else, Mr. Symington, that, in defining No. 9, because I think these are generally agreed upon things, the attainment of better methods of diagnosis and treatment of diabetes mellitus deserves highest priority.

We agree there, but it is highest as are other diseases within the institutes which are equally debillitating to people in this country.

Mr. SYMINGTON. How does NIH decide what portion of the budget to allocate money to a particular disease? I know they don't like or rather HEW, at least, does not solicit the Congress; does not always welcome them so it presumably makes up its own mind in some fashion. How do you do it?

Dr. ZAPP. It is a very complicated process that starts with recommendations early in the year from the various program people to their bureau chiefs and to their agency heads and ultimately in a case like NIH, to the Director of NIH, on through the balance of the Department and the Assistant Secretary for Health obviously having a prime responsibility in funds available and balancing priorities back and forth, to the Secretary, and ultimately to OMB and the President.

Mr. ROGERS. Excuse me, I note that our colleague, Congressman Steiger, is in the audience and won't you come join us up on the panel here? I apologize because I had not noticed you were back there.

Mr. STEIGER. Thank you.

Mr. SYMINGTON. As a cosponsor with Mr. Steiger on his bill, I certainly welcome him.

Dr. ZAPP. In that context, within the Department many times priorities are selected or surfaced from the agencies or in many cases—

for example, in the field of cancer—where a person has a very specific interest himself and which is well known to the committee.

Mr. SYMINGTON. Dr. Carter, as you know, has sponsored legislation to attempt to allocate research efforts proportionate to the disease's morbidity or mortality rate and so forth. Perhaps the cost effectiveness of keeping people alive and taxpayers and so forth. Is that a good idea, or do any of those inputs go into the decisions made?

Dr. ZAPP. I think to a degree, yes, Mr. Symington. On this basis it is difficult on the face of it to say those are not good ideas, but I think we realize it has to be based on a variety of other things including what the research opportunities are in those particular areas and the delivery systems that may be available. You know the time lost at work is a very difficult equation to lay on the top of the disease of mankind but it is an interesting one to grapple with.

Mr. SYMINGTON. But it is so difficult, really, that it calls for decisions that are in a sense perhaps societal, almost sometimes even political and not necessarily solely medical or budgetary. I suppose that is why we find ourselves willing to make suggestions from time to time, because we receive information from the national community about how people feel about efforts that are being made to fight diseases that affect their families or their friends in their communities. And you certainly don't object to that method?

Dr. ZAPP. No, I think it is a very understandable expression, and I think it is very logical that the people in the area that are particularly concerned or close to a particular disease would come to Congress for relief and assistance and attention.

I am sure you realize that a lot of our objection to this is entirely different from that and not at all related to specifics about the disease or the effort we feel should be made in the field of diabetes.

Mr. SYMINGTON. We have been told that the new emphasis, for example, on lung disease has perhaps been at the expense of heart disease funding.

Would that be an accurate statement?

Dr. ZAPP. I think I have seen the same information you have, Mr. Symington, and I would say it is possibly true. Here again we are responding to something. We say that maybe some diseases lost a little bit because of the response to other diseases by Congress last year. It may or may not be true but we have to realize in each case when we put a particular emphasis on something else the potential of it being at the expense of something else always exists.

We may not agree, you know, generally as to what money may be taken away from or where money may not be available for future increases in some area but we have to accept the fact that each time we do it in a particular area it is going to have an effect on some other area. That is why it is difficult and one of the reasons we have a strong feeling at this time for not getting statutorily locked into some of these areas.

I think we may not be able sometimes to respond to the scientific community when they come to us and say "We have really got something here." We find ourselves locked into 50 other diseases in such a manner that No. 51, which may offer the most promising things that any of us have seen in a long time, simply cannot compete.

Mr. ROGERS. Will the gentleman yield?

Of course, the obvious remedy for that is simply to come to the Congress if there is a problem and ask us to act. I am sure you will find the Congress most responsive.

Dr. ZAPP. To an additional categorical approach to it, Mr. Chairman?

Mr. ROGERS. To do anything to aid in funding research results in treating diseases. I think you would find the Congress most responsive.

Dr. ZAPP. I think the committee and the Congress as a whole have always been responsive in this area. We are concerned about statutory mechanisms that may not be leading us toward the end to which we both want to arrive.

Mr. SYMINGTON. This bill of course does not create an independent institute in those things. It merely tries to provide the context for an increased effort within the existing Institute.

Your testimony expressed a feeling that sufficient effort is going on today, both to coordinate and to fight this disease generally. So is your principal objection addressed to the additional moneys authorized or are you objecting to the organizational recommendations?

Dr. ZAPP. I think our principal objection, Mr. Symington, is one that we have voiced before the committee many other times. We have, you know, acted on this authority in various other ways that the Congress has already given the Department. We don't think, you know, what we consider to be rather narrow, that does not mean unimportant, categorical authority, necessarily improves the function or operation of the Department.

Mr. SYMINGTON. As for the additional authorizations, are they a source of discomfort to you?

Dr. ZAPP. I think they would be the source of probable disagreement with the bill; yes.

Mr. SYMINGTON. Is that because you consider them to be out of line with other diseases within that area that are covered by the Institute or just per se more than you can profitably handle?

Dr. ZAPP. Well, I don't think in the case of these we felt that that was something we necessarily had to have the funds to commit to. This is a different kind of thing that you are talking about there and I think if funds are available like Dr. Lamont-Havers mentioned a minute ago in fiscal 1974, even without a congressional mandate they are going to establish the first diabetics research institute outside of Washington. It may not be a large Federal effort, but it is part of a much larger effort. We happen to feel that with the funds we do have available, this small 12 percent, that this is a better way for us to approach the problem that we have, not just this problem but the problems in general across the Department.

Mr. SYMINGTON. The suggestion in the bill that there be 15 national research demonstration centers, do you reject that on the theory that enough research can be done in the existing facilities?

Dr. ZAPP. I think we would object to that from the standpoint of the funds that are available. There is enough, or there are sufficient outlets for qualified researchers to perform research in the field of diabetics, endocrinology, and metabolism, that mandated numbers of specific centers around the country are not needed to see that the funds that we have are adequately used. We think the review system within NIH and individual institutes is a good enough one and that good research is being conducted.

Mr. SYMINGTON. Of course, as a layman in this area, it does seem to me that with 5 million people suffering from this disease, and a discrepancy of 23 percent in the estimate that various experts have as to why people die who may have this disease, and third, the fact that the disease is in two parts, one, as it affects the pancreas, which I guess is fairly well understood and the other side of it is the blood vessels and deterioration of blood vessels and the fact it is happening all over the country, would seem to me to warrant a more widespread effort to focus on patients in different parts of the country, using different disciplines and different initiatives to search for answers.

I think that is the basis of the thinking.

Dr. ZAPP. I don't think what is in this bill is that much different from what is occurring with the funds they have now. I think we would simply say that it is not necessary by having some number that that is going to help the process that much more than the ones that are being established or than the research that they are funding now. This may not be necessarily through a recognized center but is directed to some very, very qualified researchers that may all be in one part of the country or may be in various parts of the country.

Mr. SYMINGTON. Just for the committee's information, is it clear whether the pancreas deteriorates and then the blood vessels go, or does it occur in the other direction or is there perhaps a third deficiency that causes one or both of those?

Mr. BURTON. The basic underlying defect probably is inherited to begin with. At that point, it is a matter of probably how much of an inherited charge of diabetes the individual has, whether it will emerge gradually toward the end of his life, the so-called maturity onset diabetes, or whether the lack of insulin activity in the body is in the beginning.

So we deal almost with two different diseases and again I would not address myself to that any further because there are at least 10 people in the room that probably know more about it than I do.

Mr. SYMINGTON. In that case I will withhold this line of questioning. Thank you, Mr. Chairman.

Mr. ROGERS. Thank you so much. We are grateful to you for your presence here today.

Dr. ZAPP. Thank you, Mr. Chairman.

Mr. ROGERS. Now we have two panels after the next witness and we will have to move along rather rapidly. So if witnesses could give their testimony as quickly as possible this would be helpful.

Our next witness is Dr. Heskell M. Haddad, Diabetes Research, Inc., New York, N.Y.

We welcome you and will be pleased to receive your statement and if you have a published statement it will be made part of the record at this point.

You may proceed.

**STATEMENT OF DR. HESKEL M. HADDAD, IN BEHALF OF DIABETES RESEARCH, INC.**

Dr. HADDAD. Mr. Chairman and members of the committee, my name is Heskell Haddad and I am clinical professor of ophthalmology at New York Medical College in New York.

The president of Diabetes Research, Inc., called me last Wednesday and asked me if I would be willing to testify before this committee. I had been interested in diabetes as an ophthalmologist and as a metabolic specialist, too.

I am a pediatrician as well as an ophthalmologist and diabetes has been a mystery to me as a physician and as a researcher. Fifty-two years ago when insulin was discovered, it was thought to be the cure for diabetes. Actually, all insulin did was prevent those patients who used to melt away with diabetes from dying earlier in their lives.

It increased the longevity of a diabetic and in doing so it brought along with longevity a museum or archive of diseases that are linked with diabetes, so we know that there are cardiovascular diseases, neurological diseases, ophthalmological diseases such as cataracts and retinopathy, and kidney diseases all associated with diabetes.

Unfortunately, the public did not recognize the basic elements of these diseases as diabetic in origin, so much so that when a great personality died afflicted with diabetes and crippled with it and blinded with it he was thought to have died with kidney failure and his colleagues at the U.N. came along and established a kidney fund for him and didn't recognize diabetes as the cause of his death.

This is ironic, because we know also, and I am sure you heard testimony and will hear testimony from my distinguished colleagues here, that research is being done on diabetes, but unfortunately all of the research we are doing is to catch up with what diabetes is causing in the body.

Diabetes is much more hidden, much more latent than we think. I give you an example.

When I was a practicing pediatrician, we discovered at that time that a newborn baby who would weigh more than 8 pounds, a so-called giant baby, could have a parent that was predisposed to diabetes, and this was proven to be true, that giant babies are born not necessarily to diabetic mothers, but to prediabetic mothers, and this week I had two patients, one at the age of 40 with blurred vision in one eye and a mild cataract and we did a test on him and found him diabetic, and we had another person with double vision because of sixth nerve paralysis, her eye turns in, and again she has unrecognized diabetes, which really brings me to the point of why I support your bill and, in fact, I would go further on your bill. I support this bill because I feel that two aspects are lacking on a very large scale. One aspect is the early detection of diabetes, not necessarily the treatment, but rather the early detection of diabetes.

We have to make efforts on the Federal and community levels, local level, or State level to improve detection. We have done detection, for example, for tuberculosis and I guess we can do detection also for diabetes. This will involve funds and effort, but it can be done.

Also, it requires some research to improve and expedite the tests that we are doing now.

Another thing is to have a nationwide, as you call it here, program, I would call it an agency really that will coordinate all efforts of research, not necessarily research that is being done to treat a certain manifestation of the disease, like diabetic retinopathy and using the laser beam—photocoagulation—but to find what is causing diabetic retinopathy.

This center will not do basic research in one area and locale but try to coordinate efforts all over the country and maybe with people abroad who are doing research on this, to try to find the mysteries of this disease.

That is actually the crux of my testimony and I thank you very much.

[Dr. Haddad's prepared statement follows:]

STATEMENT OF DR. HESKEL M. HADDAD, IN BEHALF OF DIABETES RESEARCH, INC.

Mr. Chairman and members of the Subcommittee on Public Health and Environment, diabetes should be a focus for legislative concern for four reasons:

1. It is a nation-wide health problem that is affecting or will affect 10,000,000 living Americans, and is increasing at the rate of nine per cent a year.
2. It is a crippling and killing disease, particularly among children.
3. It results in a two billion dollar loss to the economy each year, and untold larger sums in lowered productivity profits, and tax revenues.
4. It is a systemic disease the eradication of which would greatly reduce the incidence of blindness, heart attack, stroke, kidney failure, birth defects, and other major health problems.

Diabetes is the fifth cause of death by disease in the country, and a diabetic's life expectancy is 30 per cent less than the average person's.

Diabetes is now the major cause of blindness in the U.S. There are 154,700 blind now because of the disease, and by the year 2,000 an estimated 573,000 will be blind or have severely impaired vision.

Current studies estimate that 50 per cent of diabetics who have had diabetes for 20 years will develop retinopathy, a blood vessel disease of the eye's retina, as will 50 per cent who have had diabetes for 30 years. There is no cure for diabetic retinopathy, a disease classified into progressive stages, the last being blindness.

In order to combat diabetes, two major efforts should be made:

1. Nation-wide mechanisms should be provided for early detection.
2. Allocations of specific funds should be made on Federal, State, and community levels for research, and the proper management of diabetes.

I also suggest an independent agency, funded by the federal government, which would direct research and other related matters directly to the cause, cure, and treatment of diabetes.

We consider the \$4.1 million for diabetics in the fiscal year 1974 budget totally inadequate, and urge you to increase funds substantially for fiscal 1975, for humanitarian and economic reasons.

Thank you, Mr. Chairman.

Mr. ROGERS. Thank you for your excellent testimony and I am particularly pleased to know you are associated with the New York Medical College. I am very pleased to have an honorary degree from that fine institution, so I welcome you particularly.

Mr. Symington?

Mr. SYMINGTON. Thank you, Mr. Chairman.

Dr. Haddad, I was interested in your recommendations for a national or nationwide early detection program, because that is what I was about to ask the previous witnesses when they retired.

What would be the principal reasons and perhaps secondary reasons for that? Would it be early treatment or genetic counseling?

Dr. HADDAD. It is multifaceted, I would say. No. 1, even though some statistics show that diabetic retinopathy could develop in the eyes of patients who are prediabetic, we don't really know where the status of diabetes is in these patients. These are rather unusual cases and these are not the majority of cases that have diabetic retinopathy.

Most of them are the ones that have established diabetes and mostly renal failure patients and most of the patients that have kidney dis-

ease, or Kimmelsteel-Wilson's syndrome, are patients who have established diabetes, so the early detection of diabetes may prevent these manifestations of the disease.

Mr. SYMINGTON. Does the disease, since it is inherited, does it appear instantly in some form, or can it be hidden or latent and then appear in some form?

Dr. HADDAD. Certainly. Even children of diabetic mothers may not develop diabetes, so-called juvenile diabetes, but develop it late in their lives, so there is no real rule if a parent had diabetes, when the offspring will develop it.

Mr. SYMINGTON. So if a child is tested, there could conceivably be no sign of it?

Dr. HADDAD. That is right. I am not a geneticist to answer these questions properly, but I would only say that there are two things I could guess and one of them is, there could be a hidden diabetes or latent diabetes which is not detected by our current methods of diagnosis and the second is these patients are not developing diabetes immediately after birth but are developing it later, they may have the genes for it.

The third possibility is the genes. What kind of influence does the gene have on them? Are both or one parent diabetic and how they get to the heredity of diabetes.

Mr. SYMINGTON. Have there been studies made as to the likelihood of diabetes appearing in a child if both or one parent has it?

Dr. HADDAD. There have been studies I think by the Joslin Clinic on this.

Mr. SYMINGTON. What do they show? My colleague tells me they are going to tell us. Fine. I won't take their secret away from them.

In any event, it would seem quite important considering the widespread nature of this disease and the many facets in which it can make itself felt that there be early detection on a nationwide basis. Is it unlike sickle cell anemia? Does it affect all races equally?

Dr. HADDAD. Diabetes, as far as I know, is nondiscriminatory. Last November I held an international symposium on metabolic eye disease held for 4 days and 1 day was on diabetic retinopathy and we had speakers from Europe, Sweden in particular, and from Japan and the United States and Israel, and it seemed to me that in all of these countries, whichever race you study, whichever religion or nationality, the incidence of diabetes appeared more or less the same and the incidence of complications appeared more or less the same with a slight variation.

Mr. SYMINGTON. Thank you, and thank you, Mr. Chairman.

Mr. ROGERS. Thank you so much, doctor. We are grateful for your presence here today and your helpful testimony.

Mr. ROGERS. We now have a panel for the American Diabetes Association, Inc., New York, N.Y., and its executive director, Mr. J. Richard Connelly. We also have Dr. John K. Davidson of Atlanta, Ga., and if you gentlemen would like to come to take your place at the table, and Dr. Oscar B. Crofford of Nashville and Dr. Donnell D. Etwiler, Minneapolis, Minn., Dr. James B. Field of Pittsburgh, Pa., Dr. George P. Heffner of Fort Lauderdale, Fla.—and I am glad to see one of my fellow Floridians on the panel—and Mr. Myles H. Tanenbaum, Philadelphia, Pa.

We welcome all of you gentlemen and appreciate your taking time to come to give the committee the benefit of your advice.

We will be pleased to receive your statements.

**STATEMENTS OF A PANEL REPRESENTING THE AMERICAN DIABETES ASSOCIATION:**

- J. RICHARD CONNELLY, EXECUTIVE DIRECTOR, ADA;**  
**DR. JOHN K. DAVIDSON, CONSULTANT TO THE PUBLIC AFFAIRS COMMITTEE AND MEMBER, BOARD OF DIRECTORS, ADA;**  
**DR. GEORGE P. HEFFNER, MEMBER, BOARD OF DIRECTORS, ADA;**  
**DR. OSCAR B. CROFFORD, VICE CHAIRMAN, COMMITTEE ON RESEARCH, AND MEMBER, BOARD OF DIRECTORS, ADA;**  
**DR. JAMES B. FIELD, MEMBER, BOARD OF DIRECTORS, ADA;**  
**MYLES H. TANENBAUM, MEMBER, COMMITTEE ON PUBLIC AFFAIRS, ADA;**  
**DR. DONNELL D. ETZWILER, CHAIRMAN, COMMITTEE ON DIABETES IN YOUTH, AND MEMBER, BOARD OF DIRECTORS, ADA**

Mr. CONNELLY. Mr. Chairman, on behalf of the American Diabetes Association, I wish to express our appreciation to you and your committee for holding these hearings and also express our gratitude to you for the opportunity of being able to present our testimony.

If you wish, I would be glad to identify our witnesses and give their affiliations.

Mr. ROGERS. Yes.

Mr. CONNELLY. I will give them in the order of presentation of testimony. Dr. John Davidson is professor of medicine and director of the Diabetes Unit of the Emory University School of Medicine, member of the board of directors of the American Diabetes Association and the Association's Committee on Research. He is former chairman of our Committee on Public Affairs and presently a consultant to it.

Dr. George Heffner will testify next and he is associate clinical professor of medicine, Department of Endocrinology, University of Miami, past president of Florida Diabetes Association, and member of the Board of Directors of the National Association.

Dr. Oscar Crofford of Nashville is associate professor of medicine and head of the division of diabetes and metabolism, associate professor of physiology at Vanderbilt and chairman of the Metabolism Study Section of the National Institutes of Health. He is also a member of the board of directors of the American Diabetes Association and vice chairman of our Committee on Research.

Dr. James Field of Pittsburgh is professor of medicine and director of the clinical research unit, University of Pittsburgh School of Medicine, member of the board of directors of the national association, and served for a number of years on our Committee on Research.

Mr. Myles Tanenbaum of Philadelphia is an attorney, financial vice president of the Kravco Co., member of the board of directors and the executive committee of our affiliate in Philadelphia, Delaware Valley Diabetes Association, and a member of the National Association's Committee on Public Affairs.

Dr. Donnell Etwiler, Minneapolis, is clinical associate professor of pediatrics, University of Minnesota, pediatrics in St. Louis Park Medical Center, and director of the Diabetes Education Center. He is a member of the board of directors of the national association and chairman of our Committee on Diabetes in Youth.

With the permission of the committee, we will also submit additional testimony in writing by Mrs. Gail Patrick Jackson, chairman of our board of directors [see p. 83]; and Dr. Randall G. Sprague of Rochester, Minn. [see p. 80], a past president of this association. Dr. Sprague was to be with us today, but unfortunately, he is ill.

Mr. ROGERS. The committee will be pleased if the doctors will present their respective testimony.

#### STATEMENT OF DR. JOHN K. DAVIDSON

Dr. DAVIDSON. Mr. Chairman and members of the subcommittee, it is a pleasure for me to be here today, and I thank the chairman for the opportunity to appear before the subcommittee and to submit testimony approved by the board of directors of the American Diabetes Association concerning legislative proposals related to diabetes mellitus. There are a number of House bills, H.R. 4882, H.R. 6192, H.R. 6193, H.R. 6641, H.R. 7374, H.R. 7440, H.R. 7441, H.R. 8194, and possibly similar bills, all of which may be cited as "The National Diabetes Act of 1973."

In contrast to Dr. Zapp's testimony, it is the opinion of the American Diabetes Association that the needs of patients with diabetes in the United States are not being met at the present time.

In this connection, I might comment that the diet pamphlet which was referred to was published in 1952 as a joint effort of the U.S. Public Health Service, the American Diabetes Association, and the American Dietetic Association.

The section of the U.S. Public Health Service which was responsible not only for that effort but also for the effort which has given us the data on which we try to estimate the number of diabetics in the country at the present time, has since been phased out. That was Dr. McDonald's section.

I might also point out that the diet booklets that are available now are so badly out of date that they do not reflect, for instance, the fat content of milk. The fat content of whole milk is about 1 percent less than it was in 1952, and consequently this information needs to be updated.

I was not even aware until I heard this morning that these diet pamphlets are available from NIH. Certainly, they have not been distributed very broadly.

Mr. ROGERS. This is good for the committee to know, because, you know, we never know these things unless someone tells us. We hear the information before us given by the Department saying, "We are doing all of these things, but now we find out that action does not always follow the word. So I am delighted you brought it to our attention, and we will check into it and ask why not."

Dr. DAVIDSON. The needs of the diabetic population of this country are not being met at the present time. These needs cannot be met in the future unless the Federal Government expands its leadership role in this area and provides the financial support that is essential to implement effective legislation aimed at problems related to diabetes. The American Diabetes Association and other groups interested in diabetes can provide material assistance to the Federal Government in its efforts to cope effectively with these problems.

In that connection, I would just like to briefly state what the American Diabetes Association is. The American Diabetes Association is a voluntary health agency with a national professional membership of 3,000 members. An estimated 15,000 volunteers work with its affiliates, which serve 41 States. It was originally organized as a professional society in 1940 and became a voluntary health agency with professional and lay members a few years ago. It has published the journal *Diabetes* (circulation 6,500), which is the leading professional journal consisting entirely of papers devoted to diabetes research or clinical activities, for the last 21 years. It has published the *ADA Forecast* (circulation 85,000) for laymen for the last 25 years. It has published *The Affiliate Builder* which contains news of its national activities and of its affiliates for 15 years. It carries out a fourfold program of diabetes detection, patient education, professional education, and research on a continuing basis. Annually, it sponsors a general meeting, a professional education course, an allied health education course, and a research symposium. It also supports research into the nature and treatment of diabetes, and it supports the training of physicians preparing for a career in research or clinical practice related to diabetes. Despite the most diligent efforts of its professional and lay members, the limited financial resources of the ADA have restricted its services to a small fraction of the services that are needed by the diabetic population of the United States.

It is now apparent that diabetes mellitus is a major health problem in the United States, since the disease afflicts approximately 5 million Americans, and there are about 325,000 new cases of diabetes diagnosed each year. It is the fifth leading cause of death from disease, and 35,000 deaths are attributed to it annually.

As indicated by Senator Schweiker in his testimony, diabetes is the real underlying cause of many thousands of deaths that are officially counted under the heading of "heart disease," "stroke," and "kidney disease." It is the second leading cause of new cases of blindness, and it produces blindness almost 20 years earlier than the leading cause of blindness.

As indicated by Mr. Steiger, the complications of diabetes mellitus lead to many other serious health problems, including abnormalities of the skin, gastrointestinal tract, kidneys, eyes, nervous system, and blood vessels with resultant heart attacks, stroke, and gangrene of the extremities. Uncontrolled diabetes significantly shortens life expectancy. The severity of diabetes mellitus in children frequently involves greater problems in management than does diabetes mellitus in adults, although the present level of knowledge of therapy of diabetes mellitus has not provided solutions to many difficult problems in both children and adults. The magnitude of these problems is particularly obvious when one considers the delivery of health care to those who are either economically or educationally deprived. As was previously noted by Senator Schweiker, at the present time, premature death, disability, and sickness absenteeism due to diabetes, much of which could be prevented, cost the American economy at least \$2 billion annually. It is my understanding that these costs do not include the costs of medical care that are directly related to the consequences of diabetes.

It is the opinion of the American Diabetes Association that the citizens of the United States should have a full understanding of the nature of the impact of diabetes mellitus, and that the attainment of better methods of diagnosis and treatment of the disease deserves the highest priority. Specific attention should be directed toward the continued production of fundamental new knowledge which would form the basis of future advances in the understanding, prevention, control, treatment, and hopefully, eventually the cure of the disease.

The American Diabetes Association approves the intent of H.R. 4882 and all similar bills before this committee.

In H.R. 4882, the period of 9 months for development of the plan seems appropriate. The initially authorized number of centers for basic and clinical research demonstration centers would be at least 15, and an appropriate eventual number of centers could be determined by the Director of NIAMDD after the plan to develop the national diabetes program had been completed.

These National Research and Demonstration Centers for Diabetes would provide facilities geographically distributed according to population density so that satisfactory diabetes teaching for both professional and lay personnel would be available throughout the Nation. These centers would conduct basic and clinical research into, training in, and demonstration of advanced diagnostic, prevention, detection, and treatment methods for diabetes. H.R. 4882 and the similar bills provide for a comprehensive approach to research that must be done in the diabetes area if our understanding and treatment of the disease are to be improved. They also provide for the needs of basic research and the production of fundamental new knowledge which must form the basis of any techniques which may be developed to prevent or to cure the disease in the future.

Such centers, properly conceived and organized, could facilitate the rapid conversion of basic science information to clinical application. When basic knowledge is available concerning the cause, prevention and cure of diabetes mellitus and its complications, solution of the medical problems becomes the solution of the technical problems related to delivery of high-quality health care, including the acceptance by the public of the pertinent methods of therapy. It is essential that scientists and their organizations develop every possible method to educate the public and the Congress not only concerning the necessity of basic research, but also concerning the necessity of applying new research knowledge as rapidly as possible to the pressing clinical problems presented by diabetes mellitus and its complications.

Those of us who are scientists must admit that contemporary demands by the public and Congress for practical applications of basic research to pressing medical problems have not received as much attention from the scientific community as they deserve. Indeed, some individual scientists doing pure research have been known in the past to depreciate efforts by colleagues who have directed some of their research toward applied therapeutic goals. As a physician who has worked in basic science and in the clinic and who is now working in both areas, it is my belief that the national diabetes research and demonstration centers described in this bill will provide an ideal organizational structure for the effective interaction and collaboration of scientists, physicians and allied health personnel which will almost

certainly lead us to the solution of many of the unsolved problems now facing the diabetic population.

The American Diabetes Association applauds this manifestation of interest of the Congress in one of the most important chronic diseases that afflict mankind.

I wish to thank you, Mr. Chairman and members of this committee, for the opportunity to appear before you to testify on behalf of the American Diabetes Association on a subject that is of grave concern to the association and to many millions of people in this country.

Mr. ROGERS. Thank you very much, Dr. Davidson. We appreciate your testimony.

Your next witness is Dr. Heffner.

#### STATEMENT OF DR. GEORGE P. HEFFNER

DR. HEFFNER. Mr. Chairman and members of the subcommittee, thank you for the opportunity to appear here today and to share with you my views on the proposed legislation. What I have to say is certainly going to be repetitious of previous testimony, however, it is heartening to know that 100 members of the House of Representatives have recognized the seriousness of the diabetes problem by joining Representatives Vander Jagt and Steiger as cosponsors of H.R. 4882 or by sponsoring bills of their own which have the same objective: To bring the resources of the Federal Government to bear on what is rapidly becoming a national health crisis. No longer can the private sector alone fund the programs which are essential to combat diabetes successfully.

As a practicing physician with diabetic patients, I can assure you the very fact that this legislation has been introduced is a source of great comfort and hope to the millions of diabetics throughout the country who are afflicted with this disease.

Most of them can only look forward to tragic complications—blindness, amputation of limbs because of gangrene, and even kidney and heart failure. Studies that have been done indicate that 60 to 75 percent of individuals who have heart attacks under the age of 45 probably have diabetes. Before age 45, diabetes causes a fourfold increase in the incidence of coronary heart disease in males and a sixfold increase in incidence in females. Younger women seem to have a protection against heart attack unless they are diabetic when they apparently lose this protection.

Moreover, as serious as the problem is now there is every indication that it will become even more so in the years ahead. In the 15 years between 1950 and 1965, it has been estimated that the number of diabetics in this country very nearly doubled. The prevalence of diabetes is still increasing dramatically. Americans are living longer and those of us over 45 are particularly prone to diabetes. Another reason is that insulin therapy has prolonged the lives of juvenile diabetics into their reproductive years; since there is strong evidence that diabetes runs in families, there is a greater chance of its being transmitted to succeeding generations.

It is there, in my view, that we come to the crux of the problem—the necessity for finding what I have termed a genetic cure for diabetes. Environmental factors apart, diabetes can be caused by certain

genes of the chromosomes that carry the tendency toward the disease. Our research efforts must be concentrated on finding the way to prevent, control, or cure—eradicate, if you will—this inherited tendency for diabetes to develop. To mount a research project of this intricacy and magnitude requires funding far beyond the resources of the private sector to provide. For example, the American Diabetes Association, depending as it must on contributions, grants, bequests, and memorial gifts, has been able to devote only a little over \$1 million to its research programs.

In comparison, the National Institute of Arthritis, Metabolism, and Digestive Diseases of the National Institutes of Health in 1972 alone invested approximately \$8 million in diabetes research. While this investment is far greater than the American Diabetes Association's, it is still grossly inadequate in terms of the magnitude of the problem.

It is dismaying to note that based on a figure of 5 million known and unknown diabetics in the United States, this \$8 million appropriation amounts to an expenditure of only \$1.60 per diabetic American per year. As Senator Schweiker testified, that figure is now about \$1.25. This surely is not the extent of our concern.

It cannot be, for we must not overlook the hundreds of thousands of diabetics in this country who are suffering from complications such as those I have already mentioned. At the same time that we are channeling our efforts toward eradicating the roots of the problem, we must also be devoting our energies to preventing and/or treating those complications. The role of diabetes in producing heart disease, stroke, and peripheral vascular disease must be investigated and adequate resources must be provided to support this research.

I recognize that a cure for diabetes and its complications cannot be legislated. But I believe firmly that the bills under consideration establish a basis for effective programs to combat the disease and at the same time provide the financial support to carry them out. There are dramatic examples of diseases that have been virtually wiped out once Government support was enlisted in the attack on them. These bills, I believe, go a long way toward the eventual elimination of diabetes.

Mr. ROGERS. Thank you very much, Dr. Heffner, for your very helpful statement.

Dr. Crofford is our next witness. If you could highlight the points that you really think the committee needs to know, that is what we need to get at as quickly as we can.

#### STATEMENT OF DR. OSCAR B. CROFFORD

Dr. CROFFORD. I am Oscar Crofford from Nashville, Tenn., from the Vanderbilt Medical School. I would like to ask that the record be corrected on that point. Vanderbilt Medical School is in Nashville, not in Memphis. Nashville is in the Fifth Congressional District, and Hon. Richard Fulton is our Congressman. He has submitted H.R. 6441, which is an identical version of the bill under consideration today.

Mr. ROGERS. I had the pleasure of being in Nashville about a week ago and it is a great city, and a great university and you also have an interesting group there that are doing work in proprietary medicine.

Dr. CROFFORD. Yes, sir. I have a written testimony which I would like to incorporate into the record.

Mr. ROGERS. It will be made a part of the record, without objection [see p. 65.]

Dr. CROFFORD. And I would like to highlight my points.

Mr. ROGERS. It would be helpful.

Dr. CROFFORD. First, concerning a point raised by Senator Schweicker, indicating in the case of diabetes that many of the problems that face the patients are not short term problems, but are long term chronic problems. This gets into the area of research because the current policy of the NIH is to support short term projects by short term funding mechanisms. The usual research grant is of 3-year duration and it is subject to annual renewal. It is my judgment that you will never be successful in getting scientists to embark on a course of research involving long term problems taking 20 years to get the answer as long as the funding is of such short duration.

For this reason, I think that the kind of research and demonstration centers proposed in this legislation which will provide some continuity of funding, will make it easier for the physicians to embark on long term experiments that may lead to useful information in the field of the vascular complications of diabetes where we are certainly lacking in our knowledge.

The second point has to do with the question of whether there is in fact a large effort already in progress as suggested by Secretary Zapp. First, I would like to speak to the efforts of the American Diabetes Association. The total research budget of that organization this year is \$171,000. At the January meeting of the American Diabetes Association, we received and reviewed applications from 15 young scientists who applied for salary support to enable them to do research in the field of diabetes. Of these 15, 14 were recommended for funding, but our resources enabled only 7 of these to be awarded.

To me, this means there are seven young scientists who wanted to do research in the field of diabetes who will have to change their career goal unless additional sources of support are forthcoming.

This June, at the annual meeting of the American Diabetes Association, we reviewed 49 research grant applications. Of these, a majority—43—were deemed scientifically meritorious and were recommended for funding, but only 10 will be funded. This means 75 percent of the approved research grants that were submitted to the American Diabetes Association will go unfunded this year, because of the lack of resources that we have available.

As the American Diabetes Association progresses and matures as a voluntary health organization, we hope to be able to do better, but I think it unrealistic to think that the burden of support for research in diabetes will be borne by any agency other than the National Institutes of Health.

With respect to the effort of the National Institutes of Health, it is my understanding that 80 percent of the approved research grants at the present time will not be funded. The point is, of course, that the scientific community is not deficient in research ideas. However, if 80 percent of those approved projects do not get funded it is difficult to see that there is adequate effort that is already underway.

Mr. ROGERS. As I said, Congressman Symington and other members of the committee had a session with all of the directors of the Institute and what you say is true, that they are only funding 20 to 30 percent of approved projects which is rather shocking, I would agree.

Dr. CROFFORD. And I think 30 percent is optimistic in terms of what will happen in the current fiscal year. I think it is likely to be closer to 20 percent in fact.

The rest of my comments are directed to some questions you raised with respect to the center concept. There is a possibility of confusion here, in that these bills provide for the establishment of some national research and demonstration centers for diabetes. As you are aware, the National Institute of Arthritis, Metabolism, and Digestive Diseases embarked about a year ago on a program to try to establish some diabetes centers with funds already available to the Institute. It is my understanding that only one of those centers will be established and become operational in the immediate future. That one happens to be at Vanderbilt; and I am the principal investigator of that center and will be the director of that center. Therefore I am able to provide you with some of the facts and figures that you asked of the administration witness.

Vanderbilt Medical School is unusual in that one of the major research thrusts of the institution in the past 20 years has been in the area of research or hormone action, particularly in diabetes in the action of insulin. We had 70 members of our full time faculty—21 percent of the total faculty—who claimed that their main research interest was diabetes and wanted to participate in this center.

Our original budget estimate for the center was \$850,000. The budget we finally submitted was \$435,000 and it was indicated today by a previous witness that we are to anticipate funding of about \$250,000.

This \$435,000 budget would enable us to initiate 13 new projects which turns out to be an average of \$33,000 per new project. Now, I can assure you, from previous experience in the regular research grant mechanism, that this is a cost which is approximately half of what it would cost to set up 13 separate laboratories and set up these projects independently.

Part of this economy comes through the sharing of resources through the core laboratory about which you inquired. This core laboratory will cost \$145,000. That means if they are going to pay \$250,000 there will be \$100,000 left over for research. At \$33,000 per project, about three new projects can be initiated. That is 3 of the 13 we wanted to initiate and there are many, many other medical schools in the country who submitted applications that won't get any money at all. I agree that they are making a step in the right direction and I don't want to seem ungrateful because, certainly, we are better off than most places, but I cannot classify this as something which will enable us to make a quantum leap in our research productivity.

Mr. ROGERS. Not too much new initiative?

Dr. CROFFORD. There will be three new initiatives that will be fundable on the basis of the amount that they will provide.

Mr. ROGERS. What other fundings would the center have? Does it get funding from the university itself? From the American Diabetes Association, or what?

Dr. CROFFORD. We are a private medical school and get very little funding for research from the institution itself. I think that there will be one member of our faculty that will get his salary, which is \$15,000, from the American Diabetes Association to do research. The rest of the research is supported by independent research grants submitted by the investigator directly to the NIH. I think that is an important point, Mr. Chairman, because it is not our intent to support these bills with the understanding that by applying money to this purpose you take money out of some other worthy programs.

The intent is to provide additional money for research in diabetes in addition to that that NIH already has. I would hope that the Congress would look at the total Federal budget for some reallocation of funds so that this amount could be added to the amount already appropriated for the NIH and not take it out of one pocket and put it into another. This would not be a profitable thing to do, in my judgment.

Mr. ROGERS. Well, I think the committee shares that feeling and I think the Congress shares that feeling. However, within the realities of the day we have an Office of Management and Budget, and a Secretary of HEW who has just come from that Office so we have a rather difficult time in getting those points across, but we will try.

Dr. CROFFORD. I would cite two or three other advantages of the center concept. One is that centers create an environment that permits and encourages interdisciplinary collaboration, and centers facilitate the orderly progression of new knowledge from the laboratory to the patient's bedside. Unnecessary duplication of research could be minimized. Standards of excellence within the center could be established and quality could be thoroughly and thoughtfully monitored. Continuity of funding, as I already alluded, becomes a reality and long-term research objectives could be planned. Effective local administration reduces administrative costs and provides flexibility so that the time lapse between the research idea and the commencement of the project could be shortened.

On the basis of this experience, I would like to say that it is my judgment that 15 diabetes research and demonstration centers would be an appropriate number. I think that the annual operational budget should range from \$500,000 to \$1 million per year per center. Bear in mind that our center will be only a research center and when one gets into the demonstration aspects of it, the costs should be increased somewhat. I think a figure in that range, exclusive of construction costs, would be appropriate. I feel that new construction for these centers is a vital need at most medical schools and would encourage the committee not to delete section 437(b) of this bill which would provide for new construction in order to house the additional research and demonstration that could be done on the basis of these bills.

In concluding, Mr. Chairman, I am thankful to you for having provided me the opportunity of presenting this testimony. I feel that there are few bills where so many Americans stand to profit so much from such a modest expenditure of Federal dollars.

Mr. ROGERS. Thank you very much, Dr. Crofford. Do you do clinical research?

Dr. CROFFORD. Yes; I do clinical research.

Mr. ROGERS. Would you in the center?

Dr. CROFFORD. Yes, the center will do some clinical research but, truly, not a great deal. That is because clinical research is very expensive and we have been restricted in terms of the money that we will have available. It would be our hope that this could be expanded to include more clinical research. We feel strongly that it is not in the best interest of society to have discoveries made in the laboratory and have them stay in the laboratory. In our center we have tried to provide a mechanism for orderly progression of new knowledge from the laboratory up to clinical research.

Mr. ROGERS. Thank you.

[Dr. Crofford's prepared statement follows:]

STATEMENT OF OSCAR B. CROFFORD, M.D., VICE CHAIRMAN, COMMITTEE ON RESEARCH, AMERICAN DIABETES ASSOCIATION, MEMBER, BOARD OF DIRECTORS, AMERICAN DIABETES ASSOCIATION, CHAIRMAN, METABOLISM STUDY SECTION, A PUBLIC ADVISORY COMMITTEE TO THE NATIONAL INSTITUTES OF HEALTH, DIRECTOR, VANDERBILT UNIVERSITY DIABETES-ENDOCRINOLOGY CENTER, ASSOCIATE PROFESSOR OF MEDICINE AND HEAD OF THE DIVISION OF DIABETES AND METABOLISM, VANDERBILT UNIVERSITY SCHOOL OF MEDICINE, NASHVILLE, TENN.

Mr. Chairman and members of the subcommittee:

My comments today are intended to be representative of those that might be made by any one of a large number of physician-scientists who share with all of society the responsibility of providing in 1973 the best health care that is available for the 5,000,000 Americans afflicted with diabetes mellitus. In addition, medical research scientists have the special responsibility of developing new and better means of caring for the patients with diabetes today and of preventing the unremitting expansion of diabetes as a public health problem for future generations. I cannot appear before you and promise that an all-out attack on diabetes will produce in our life times a permanent cure or prevention of this disease. I am confident, however, that society cannot afford the loss of human resources and the health care costs for the ever increasing numbers of patients with diabetes if the presently available methods of treatment are simply continued and expanded. Thus, research, when defined in its broadest sense, is the logical means of making a significant reduction in the cost of health care for patients with diabetes and for alleviating the human suffering caused by this disease. Stated in another way, research in the field of diabetes is not expensive in comparison to the eventual consequences of inadequate research.

I cannot proceed to detail the inadequacies of our present research effort without acknowledging the historic accomplishments of our predecessors. Thus, the discovery of insulin has undoubtedly saved the lives of millions of diabetics. It is truly one of our first and most effective wonder drugs. In these days of rising health care costs insulin is a fantastic bargain. The cost to the average patient of a life-sustaining dose of insulin is about 10¢ a day. On the other hand, the discovery of insulin transformed the character of the disease, diabetes, from an acute condition leading to early death from diabetic coma to a chronic disease that far too often results in blindness, kidney failure, or in an acceleration of the blood vessel disease that leads to heart attack, stroke or gangrene. Thus, despite the great discoveries of the past, the fundamental cause of diabetes remains unknown, no permanent cure of diabetes has been achieved, and no means for the prevention of diabetes is yet available.

#### WHY IS THE PUBLIC SO UNAWARE OF THE SCOPE AND MAGNITUDE OF THE DIABETIC PROBLEM?

Given the statistics presented in previous testimony, why is the public so unaware of the scope and magnitude of the diabetic problem? Following the discovery of insulin virtually everyone believed that a cure for diabetes had been discovered and that diabetes had been eliminated as a significant medical problem. Indeed the physicians of the nineteen twenties were unaware that many of the patients whose lives were saved by insulin would develop the serious complications involving the eyes, kidneys, heart, nervous system, skin and blood vessels that we now recognize. The medical community adopted an unrealistically optimistic point of view. "Follow your diet and take your

insulin every day and you will lead a normal life." Even after the long-term complications of diabetes were recognized, and even today, there is a tendency to present an overly optimistic picture of the problems facing the patient with diabetes. Although this is understandable from the standpoint of the doctor relating to the individual patient, it has not moved diabetes into its proper place in the public eye in comparison to some of the more dramatic, though far less prevalent, diseases.

#### WHAT ARE THE RESEARCH NEEDS IN THE FIELD OF DIABETES?

Next, I would like to address the question: What are the research needs in the field of diabetes? Time will permit only a few examples. The first relates to research into better methods of caring for the millions of patients that already have diabetes. Many demonstration clinics are investigating the feasibility of the "team approach" to the management of diabetes. With this approach the patient is educated in the techniques of self care and he himself becomes a key member of his own health care team. Such a program involves the establishment of education centers for patients and their families and suitable training programs for nurse specialists, nutritionists, social workers and physicians—all members of the health care team. In theory such an approach amplifies the effectiveness of each physician. It utilizes the principles of preventive medicine to avoid unnecessary admissions to the hospital and provides better quality health care at lower cost. The effectiveness of such programs is as yet unproven and additional research into models of improved health care systems for patients with diabetes is urgently needed. This type of health care research—and it is research—is very difficult to fund through the regular research grant mechanisms of the National Institutes of Health. Several such programs were initiated through grants from various Regional Medical programs—an organization whose activities have been terminated. In my judgment, the types of Centers proposed in the legislation under consideration today would be an ideal means of providing the long-term support needed to evaluate these and other models of improved health care delivery systems.

Turning to the more traditional areas of research, I have suggested that the acute complications of diabetes (the example given previously was ketoacidosis or "diabetic coma") have been eliminated as significant medical problems. This is somewhat of an exaggeration. One single hospital, the Los Angeles County Hospital, continues to treat about 300 cases of ketoacidosis per year and about 11% of these die. Under the best of circumstances ketoacidosis carries a mortality of about 3%. Although it is true that ketoacidosis is a preventable disease, given ideal medical care, with a well informed patient taking the proper dose of insulin, many patients do not receive such ideal care and we must not lessen our efforts to develop more effective means of treating ketoacidosis in those instances where it is not prevented—particularly in children.

Other acute complications of diabetes require even more intense research. In the past few years we have come to recognize a complication of diabetes that goes by the extraordinary name of hyperosmolar nonketotic nonacidotic diabetic coma. In simpler terms, this is a type of unconsciousness or coma seen in diabetics—usually elderly diabetics—that is caused by an extremely high level of sugar in the blood. About 50% of the patients with this complication die and it is not a rare complication. One single hospital, again the Los Angeles County Hospital, treated about 100 cases of hyperosmolar coma last year. Yet the basic cause of this complication, though probably related to insulin insufficiency, is still not established.

Beyond these life threatening acute complications there are the numerous non-fatal complications that are less dramatic but that produce much suffering and many days of illness in the lives of diabetics. I am referring particularly to boils and other skin infections, bladder and kidney infections, vaginal infections in women and the many other acute complications that occur in diabetics with increased frequency but that require extensive research to develop more effective means of prevention and treatment.

As a final example of research needs let me mention the recent progress made in the area of pancreas transplantation and the artificial pancreas. Surely one of the most vital medical questions of our days deals with prevention of the long-term vascular complications of diabetes. The question is this: In patients with diabetes, can these complications be prevented or at least improved by good "metabolic control?" We use the expression metabolic control to include not only the elevated blood sugar but also the other biochemical derangements that are

associated with diabetes. I must confess that despite the importance of this question it cannot be answered with certainty today, and, furthermore, experiments are not yet in progress that are likely to answer this question. What this means is that millions of patients are being treated in an effort to control their blood sugar levels without absolute proof that even if the blood sugar level is controlled, the incidence or severity of the long-term vascular complications of their diabetes will be favorably affected. There are two principal reasons why this vital question cannot be answered. The first is that it is not yet possible to achieve "good metabolic control" in most cases of severe diabetes. The administration of our most modern insulin preparations once, twice or even three or more times daily, while it will prevent the acute complications of diabetes, will not achieve the almost perfect "metabolic control" that is produced by a normal pancreas that secretes exactly the right amount of insulin on a minute by minute basis. The goal of trying to achieve perfect metabolic control in diabetics has led several teams of investigators to attempt pancreatic transplantation in animals made diabetic with special drugs or in a few instances of human diabetes.

It appears that the transplanted pancreas survives and functions unless it is interrupted by the same type of immune rejection process that plagues other types of transplantation procedures. This is an exceptionally active and interesting field in diabetes research. A modification of this approach is to use an automated and fully artificial pancreas. Thus the blood sugar level in the patient would be monitored continuously by a tiny chemical sensor. The data would be fed into a miniature computer that would activate a pump to inject into the patient precisely the correct amount of insulin. Such an artificial pancreas is already under development in at least two laboratories and can probably be miniaturized to the size of a pocket watch and implanted beneath the skin of a patient. Although both of these approaches to the achievement of ideal metabolic control are still in the developmental stage, and may themselves not be the final answer, they are at least illustrative of the innovative type of research that must still be done before the question can be answered "Does good metabolic control prevent the long-term vascular manifestations of diabetes?"

A second obstacle to the answer of this question arises from the fact that these complications develop over the course of twenty or more years and the crucial experiments must be performed over a prolonged period of time. Support for long-term experiments cannot be obtained easily through the regular research grant mechanisms of the National Institutes of Health that are of three to five years duration. Few physician-scientists would embark on an experiment that would take twenty years to complete if his research support was only committed for three years. In my opinion the "National Research and Demonstration Centers for Diabetes" described in the legislative proposals being considered today would lead to the type of stable research support needed to carry out long-term studies pertaining to the vascular complications of diabetes.

#### RESEARCH SUPPORT FOR DIABETES

Research support for diabetes is derived largely from the federal government. In a recent survey at the Vanderbilt Medical School, 71% of the research support directed toward diabetes was derived from the National Institutes of Health, 13% from all other federal sources, and only 16% from all non-federal sources combined. Thus the National Institutes of Health provides the major share of research support for this disease at our medical school and I believe the same situation exists at other medical schools throughout the country. As the American Diabetes Association matures as a Voluntary Health Agency it will be able to provide more support for research in diabetes. At the present time, however, the efforts of this organization provide an annual research budget of only \$171,000—far less than needed to fund their own existing research programs. For example, at the January 1973 meeting of the Research Committee of the American Diabetes Association we reviewed the applications of 15 young physicians who were seeking one year of salary support that would enable them to pursue a research career in the field of diabetes. Of these 15 applications, 14 were determined by a peer review mechanism to be of high scientific quality and funding was recommended. Unfortunately, the budget permitted the funding of only seven of these applications. To me this means that there are seven highly trained young medical scientists who may of necessity turn away from their career goal of devoting their life to research in diabetes unless alternative salary support is somehow generated. I am saddened by such a potential loss of scientific talent at a time when so much research is needed.

At the June 1973 meeting of the Research Committee of the American Diabetes Association 49 research grants were reviewed. These are small grants, not to exceed \$5,000 each. Although 44 of these grants were approved on the basis of scientific excellence, only 11 will be funded. This means that 75% of the research recommended by the Committee will not be carried out unless alternate support is found. Although the American Diabetes Association is committed to a continuation of its efforts to support research in diabetes, it must compete with other voluntary health agencies for the "donation dollar" and it is unrealistic to think that the cost of the quantity of research needed in the field of diabetes can be borne by any agency other than the National Institutes of Health.

At the present time most NIH support in the field of diabetes is administered through the National Institute of Arthritis, Metabolism and Digestive Diseases (NIAMDD) via the regular research grant mechanism. I cannot overemphasize my enthusiasm for this method of supporting research. It is research support based on the scientific merit of the proposal as determined by the well established peer review system. I would not endorse the legislative proposals that we are considering today if it appeared that their funding was to be at the expense of the regular research grant mechanism. Regular research grants dealing with diabetes are already supported in inadequate and steadily decreasing numbers. At the present time approximately 80% of the research grants recommended for support will not get paid due to lack of money available to the NIAMDD. This classical means of support must be continued and should be funded at an increased level. I can assure you that the scientific community is not deficient in sound research ideas related to diabetes. The problem is that far too many of these research proposals are currently not being supported.

#### WHY DO WE NEED NEW PROGRAMS?

A natural question is "If regular research grants are so good, why do we need the new programs as described in H.R. 6641, H.R. 4882 and all similar and identical bills cited as the National Diabetes Act of 1973?" My answer is that regular research grants were not intended and are not flexible enough to accommodate the type of research needed to cope with major national health problems like diabetes. These bills have the potential of providing the stable, long-term research support that is vital to research in the area of chronic diseases like diabetes. Stated in another way, if the long-term vascular complications of diabetes evolve over the course of 20 years, then you will never get scientists to embark on a 20 year research program as long as their research support is subject to the uncertainties of yearly renewal. Scientists will continue to conduct short-term experiments and the problems of chronic disease will not be investigated.

The architects of these bills should be commended in that the bills provide flexibility in the design of the final plan for implementing the diabetes program and a means for obtaining up to date scientific input through the use of outside consultants. Today, more than ever, we are anxious that new health care programs be carefully designed at the outset so that once begun they can be carried through to fruition.

#### RECENT EXPERIENCE WITH A MINIATURE, PILOT-MODEL DIABETES CENTER

During the past 11 months I have had the opportunity to develop the plans and commence the establishment of a Diabetes-Endocrinology Center at Vanderbilt University Medical School in Nashville, Tennessee. To the best of my knowledge, this is the only such Center that will become operational in the near future due to lack of funds available to the National Institute of Arthritis, Metabolism and Digestive Diseases, the Institute that has authorized and is supporting the program in its entirety. Even our Center will be supported at a level far below that required for optimum research efficiency. Nevertheless, in so far as this Center can be considered as a miniature, pilot-model of the "National Research and Demonstration Centers for Diabetes" described in Sec. 437 of the bill under consideration, I can provide some of the advantages, potential disadvantages and cost estimates of such a program.

Vanderbilt Medical School is unusual in that research in Diabetes has been one of our major thrusts for the past 20 years. Our initial organizational meeting in October 1972 was attended by 78 of the 375 members of the full time faculty (21%), all maintaining that diabetes was one of their main research interests.

More were identified subsequently and some withdrew. In its completed form the Center will involve 70 professional investigators and numerous other support personnel. We have proposed 13 new research initiatives for the first year involving 38 professional scientists and physicians. By centralizing facilities and sharing equipment our first year budget was held to \$435,000 or approximately \$33,000 per project per year. From previous experience with the regular investigator-initiated research grant mechanism, I know this figure to be less than half of what would be required to set up 13 independent laboratories for the execution of an equivalent amount of research. Thus economy is one of the principal advantages of the Diabetes Center concept.

Other advantages will be mentioned by title only: Centers create an environment that permits and encourages interdisciplinary collaboration. Centers facilitate the orderly progression of new knowledge from the laboratory bench to the patient's bedside. Unnecessary duplication of research is minimized. Standards of excellence are established, and quality is thoroughly and thoughtfully monitored. Continuity of funding becomes a reality and long-term research objectives can be planned. Effective local administration reduces administrative costs and provides added flexibility. The time between the research idea and the commencement of the project can be shortened. Potential disadvantages include the danger that the funding of Centers might decrease the funds available for regular research grants. As stated previously, I would be strongly against such a course of action. There is the danger that research in diabetes could become localized to certain schools and regions to the exclusion of others. This can be prevented by careful attention to geographic considerations in the establishment of Centers and by the establishment of not one but an appropriate number of Centers. On balance I am convinced the advantages of the proposed "National Research and Demonstration Centers for Diabetes" far outweigh the potential disadvantages.

Based on this experience, it is my judgment that approximately 15 such Centers should be established and that an annual operational budget ranging from \$500,000 to \$1,000,000 per Center per year would be appropriate. These estimates do not include construction costs. New construction for "National Research and Demonstration Centers for Diabetes" is a vital need at virtually every medical school and provisions for this as described in Sec. 437(b) of this bill should not be deleted.

In conclusion, Mr. Chairman, I am pleased to have had the opportunity to provide testimony in support of the legislation under consideration today. I know of few instances where so many Americans, afflicted with such a serious disease, stand to benefit so much by such a modest expenditure of dollars. Thank you.

Mr. ROGERS. Our next witness is Dr. James B. Field, and his statement will be made a part of the record [see p. 72.]

#### STATEMENT OF DR. JAMES B. FIELD

Dr. FIELD. Thank you very much, Mr. Chairman. I will try to summarize.

I want to express my appreciation for the opportunity to testify before you concerning the important and fundamental role that research must and can play in helping the diabetic patient and to achieve the laudable goals of these legislative proposals such as H.R. 4882.

In the 1950's, the average life expectancy of a diabetic who developed the disease as a teenager was 22 years. Since that time, we have really only succeeded in extending his life expectancy 5 years.

Our lack of knowledge and our inability to prevent complications of diabetes or satisfactorily to treat those complications, once they existed, accounts for this lack of prolongation of life expectancy.

Mr. Chairman, you raised a question about the increased use of insulin and its inverse relationship to the increase in complications.

I would think one of the important if not fundamental questions which must be answered in diabetes research is the question of whether

strict control of the blood sugar or any other component in the blood by use of insulin and diet can in fact prevent or delay the complications of diabetes.

As Dr. Crofford emphasized, the need for long-term stable research support for this kind of project is of utmost importance. This kind of project, in order to provide meaningful information, would have to run at least 20 years, and I am sure you can appreciate the difficulty in trying to assess how well one is controlling the blood sugar in a diabetic patient.

This will take a long period of time, a large number of patients, and a tremendous commitment on the part of the investigators, but until we can answer this question of whether strict control of diabetes can prevent or delay the complications, we may be treating the diabetic somewhat in the dark. The answer to this question is of extreme importance and yet requires long-term stable research support which is not available under the present NIH system, as Dr. Crofford has emphasized.

There are devices and approaches which you will hear about from other witnesses, including transplantation of the pancreas or artificial devices which may be more successful in maintaining a normal blood sugar in the diabetic. In order to conserve time, I shall not go into greater detail, as others will cover this area.

These approaches are very important, but what can we do for the person with degenerative complications already? This raises another important need for research.

There are some existing data which suggests that one of the pathways by which glucose is metabolized in the body may be important in the changes which take place in blood vessels and which may provide a biochemical explanation for some of the degenerative changes in accelerated atherosclerosis which not only affects diabetics but may affect the population in general.

These kinds of study obviously need much more support than they are currently getting; they need to be expanded and extended.

I would like to cite one example of where I think the Federal Government's current policy may be somewhat shortsighted. This is the analogy between diabetes and polio. It has been estimated that since the introduction of polio vaccine, the savings to this country, in terms of the economic and health burden that the polio vaccine has obviated, represents approximately \$1 billion per year. This is the amount we would have to be spending each year if we didn't have the polio vaccine. If one looks at this savings compared to the amount of money expended to develop the polio vaccine in terms of all of the fundamental basic research and the clinical trials, this represents a tremendous investment and a tremendous return on a relatively small investment. I think by the same token that additional funds channeled into diabetic research could help reduce the \$2 billion figure we heard today, which is the annual cost of diabetes to the economy of this country.

I would certainly emphasize Dr. Crofford's statement, that additional funds for research should not be funds taken from one pocket and put into another, but that these should be additional funds to help reduce this tremendous drain that diabetes is taking of our economy.

There are several exciting areas in diabetes that I would just mention in passing in an attempt to save time. One is the experimental data in animals that certain viruses seem to be associated with changes in the islets of Langerhans of the pancreas, such that there may be a contribution of viral diseases to the etiology of diabetes.

You know and heard of the effects of genetics and obesity on diabetes, and yet we really don't understand very much about these factors.

It is obvious that more research is necessary to clarify these areas. There are certain drugs which are used in the treatment of high blood pressure and edema which can cause diabetes or exaggerate diabetes in patients that already have it.

These observations suggest there may be other toxic substances which we are not aware of which may have a deleterious influence and may be some of the factors grafted upon a genetic tendency toward diabetics which may actually make a person a clinical diabetic when he only had the tendency without these drugs.

I would like to emphasize again that although the Federal Government has played an important role in the past in supporting research, that this is a diminishing effort now rather than an expanding one. Although I know these figures are well known to you, I would like to summarize the support for research provided by the National Institute of Arthritis, Metabolism, and Digestive Diseases since 1968 specifically for diabetes research.

In 1968, \$7.54 million were spent for diabetes research. And \$5.24 million of this supported research grants and 82 percent of the 61 research grants which were approved by the NIAMDD were funded. Also \$0.38 million supported fellowships and \$0.75 million supported training grants training new investigators.

In 1969, support for diabetes research reached its maximum of \$9.04 million. However, because of limited funds, only 58 of the 94 approved grants—62 percent—were funded.

Funds for diabetes research declined in both 1970, 1971, and 1972. Also, \$7.85 million was spent in 1971, and research grant support fell to \$4.98 million, so that only 37 percent of the approved grants could be funded.

Funds for fellowships, \$0.48 million, and training grants, \$0.83 million, were less in 1971 than in 1969. Although there was some small increase in funds for diabetic research in 1972, \$8.41 million, because of inflation this does not really represent any increase in amount of knowledge which we will be able to obtain. Only 33 of the 57 approved grants were actually funded in 1972. As you and your committee well know, funds for training grants and for fellowships support which really represents an investment in research scientists in the future to make the necessary discoveries that we need, are now being phased out. I think your committee and you personally deserve a great deal of credit for having introduced a bill to restore this very important program.

Mr. ROGERS. I might say that the committee as a whole introduced the bill. The committee has moved along and is now awaiting action in the Senate. I hope the President will sign it.

Dr. FIELD. It has become increasingly clear that support for diabetes research is not commensurate with the needs of the diabetic patient and impact of this disease on our population and economy.

I am certain, as you have already stated, that you feel that the investment in diabetes research is not commensurate with the \$2 billion economic loss that we have per year.

I wish to thank you, Mr. Chairman, and the members of your committee, for the opportunity to convey to you the urgency and importance of expanded research support for diabetes and the potential benefit that such support can produce.

[Dr. Field's prepared statement follows:]

PREPARED STATEMENT OF JAMES B. FIELD, M.D., MEMBER, BOARD OF DIRECTORS, AMERICAN DIABETES ASSOCIATION, PROFESSOR OF MEDICINE, DIRECTOR OF THE CLINICAL RESEARCH UNIT, AND HEAD OF THE SECTION OF ENDOCRINOLOGY AND METABOLISM, UNIVERSITY OF PITTSBURGH SCHOOL OF MEDICINE

Mr. Chairman and members of the subcommittee, I want to express my appreciation for the opportunity to testify before you concerning the important and fundamental role that research must and can play in helping the diabetic patient and to achieve the laudable goals of these legislative proposals.

The momentous discovery of insulin by Drs. Banting and Best in 1921 raised expectations that the problem of diabetes mellitus would soon be solved. Insulin was life-saving for the juvenile diabetic patient whose life expectancy, before insulin was available, was approximately two years after the diagnosis was established. Furthermore, before insulin, diabetic coma caused about 50% of the deaths in diabetic patients, but now accounts for less than 5% of diabetic deaths.

In contrast to this impressive reduction in deaths due to diabetic coma, there has been a progressive increase in disability and deaths due to the vascular complications of diabetes. Today about 70% of diabetic patients die from the degenerative vascular complications which affect the blood vessels of the heart, brain, extremities, eyes, kidneys, and nerves. It is these changes which are responsible for the striking increased incidence of heart attacks, strokes, blindness, kidney failure, amputations and obstetrical mishaps in the diabetic. Before insulin, diabetic patients usually did not survive long enough to develop these vascular complications. In the 1950's the average life expectancy of a teenager who developed diabetes was about 22 years. Today we have extended life expectancy for this type of patient only 5 years. Our lack of knowledge and our inability to prevent or satisfactorily treat these degenerative complications of diabetes emphatically underscores the crucial importance for an expanded research program in and related to diabetes. Permit me to cite one example which is fundamental to our approach to these diabetic complications. We do not know today whether the vascular changes in the heart, kidneys, eyes and nerves of the diabetic are due to inadequate control of his blood sugar or whether they are a basic component of the disease and uninfluenced by rigid control of the blood sugar and fats in the blood. The medical literature contains reports on both sides of the issue, but for various reasons none of these have been definitive. We must undertake a long-term, well controlled study to determine whether a relationship exists between control of diabetes as exemplified by blood sugar and the degenerative complications. Because of our current inability to provide optimal blood sugar control and even evaluate whether we are doing this or not, such a project requires intensive and comprehensive study of a large number of diabetic patients over a 15-20 year period.

I am sure you are aware of the difficulty of obtaining daily blood sugar determinations on each of these diabetic patients, but even this might not be indicative of the control of the blood sugar during the rest of the day. Although we measure blood and urine sugar to evaluate diabetic control, measuring cholesterol, other lipids or other blood components might be more appropriate. Since the onset of diabetic degenerative complications is slow and insidious, the study must be long-term and certainly substantiates the importance of long-range, stable support of diabetes research as emphasized by Dr. Crofford. Our present ability to control the blood sugar in diabetics is far from optimal, and Dr. Crofford has clearly outlined to you some of the new, exciting and hopeful approaches in this area which necessitate greatly expanded research support which will facilitate better control of diabetes. It is imperative for the welfare of the diabetic patient that we know whether rigid control of diabetes will prevent the degenerative complications which account for

over 70% of diabetic deaths. To obtain this answer will be expensive and require 15-20 years.

Although this kind of study is fundamental in the long-range control of diabetes and its complications, it does little for the large number of diabetic patients who already have these complications or will develop them while the study is in progress.

For these patients there is an urgent need to markedly increase our knowledge concerning the cause of these degenerative complications and discover successful therapeutic approaches to diabetic retinopathy, diabetic involvement of the kidney and the blood vessels which account for the increased incidence of heart attacks, strokes and leg amputations. It is not as widely appreciated as it should be that undiagnosed diabetes may be an important and significant contributing cause to the heart attacks and strokes which occur in patients not known to have diabetes. It is obvious that knowledge concerning the cause and treatment of these complications in the diabetic will have important benefits for patients with arteriosclerosis and vascular disease, but who may not have diabetes. Evidence indicates that the basic underlying process leading to vascular changes in the heart, brain, kidney, eyes, nerves and extremities may be similar and therefore research effort to elucidate the underlying mechanism will produce maximum benefits although increased effort related to specific organs involved, such as the eyes and kidneys, should also be pursued.

One of the exciting and promising areas of current research indicates that the higher blood sugar levels in the diabetic cause alterations in one of the pathways by which sugar is metabolized. The consequences of this may cause biochemical changes in the cells of the blood vessels, retina, kidney and nerves which could be important in causing arteriosclerosis, blindness and kidney failure. If this relationship can be unequivocally established, it substantiates the concept that control of the blood sugar is important in preventing or delaying the degenerative complications of diabetes. We must extend, expand and accelerate this type of research as well as other promising approaches concerned with elucidating differences in essential tissue components in the diabetic and non-diabetic kidney. Although increased support for research does not guarantee answers to all the current problems facing the diabetic, it is manifestly clear that without such research support on a long-term, sound and dependable basis, we will not make much progress in providing the diabetic with a normal life expectancy and alleviating the suffering of himself and his family.

One can draw an analogy between diabetes and poliomyelitis. Without the support for fundamental research which made development of the polio vaccine possible, we might have better iron lungs and better hot packs, but we would still have the very large health, emotional and economic burdens associated with polio before the mid-1950's. It has been estimated that control of polio has saved over \$1 billion per year, representing a tremendous return on the research dollars expended. We have heard that diabetes costs the United States over \$2 billion per year, yet the National Institutes of Health spent less than \$10 million in 1972 in support of all aspects of research in diabetes. In addition to understanding the cause of the blood vessel, eye, kidney and nerve complications of diabetes, we must increase our research efforts toward successful treatment of these complications. Removal or destruction of the pituitary gland has benefitted some but not all patients with diabetic retinopathy. This approach has certain risks to the patient and creates certain additional medical problems. Such patients have diminished function of the glands controlled by the pituitary and must take hormone replacement medication. Laser beam photocoagulation is being used in treatment of diabetic retinopathy and carefully controlled, long-term studies are being initiated to assess its value. These studies require large numbers of patients and very specialized equipment and personnel. They cannot be done without some guarantee of long-term, stable research support. The diabetic's vascular disease in his heart and brain have markedly reduced his life expectancy and make him a poor candidate for kidney transplant or chronic hemodialysis as a solution to his kidney failure. Our inadequate knowledge and absence today of sufficiently promising approaches to the treatment of the kidney failure and the other degenerative complications of diabetes underscores the urgent need for expanded research support for diabetes.

The ultimate goal in the control of diabetes is its prevention. Because of past and current research we have extended our knowledge concerning the etiology of diabetes and some of the factors which are important, but the most important questions are still unanswered. The initial concept that diabetes is due to inade-

quate insulin secretion by the pancreas is an oversimplification. Insulin secretion still assumes a pivotal role in the development of diabetes, but the etiologic defect may be different in the childhood diabetic and the obese person who develops the disease in later life. We must know more about the way insulin is synthesized, released, and how it works at the cellular level, as defects in any of these could be responsible for inadequate sugar utilization by the diabetic. Recent animal experiments have suggested that certain virus infections of the pancreas may cause diabetes. These experiments must be vigorously pursued and applied to human diabetes. Patients with excess function of the pituitary and adrenal gland have a markedly increased incidence of diabetes indicating the importance of other hormones in the genesis of diabetes. We must unravel these relationships and their role in all diabetic patients. Thus, increased research into the broader area of endocrinology and metabolism will provide new information and insights which will directly benefit the diabetic. Heredity and obesity are two very important components in the development of diabetes, yet we don't understand the mechanisms nor can we satisfactorily mitigate their influence. Certain drugs, especially those used in the treatment of hypertension and excess fluid accumulation, exert a deleterious effect on diabetes. These are only examples of the unsolved problems in diabetes. Promising approaches are being made in these areas, but they will not be exploited unless there is adequate research support for them and scientists trained to pursue them.

The federal government has played an important role in supporting research in diabetes which has made possible our better understanding of the disease diabetes and its complications. However that support, instead of being expanded, is now being reduced. Although I am sure these figures are well known to you, I want to summarize for you the research support for diabetes provided through the NIAMDD since 1968. In that year \$7.54 million were spent. \$5.24 million supported research grants and 82% (50) of the 61 research grants approved by the NIAMDD council were funded. \$0.38 million supported fellowship and \$0.75 million were for training grants. \$1.17 million was for intramural research at NIH, field studies and contract research. In 1969, support for diabetes research reached its maximum at \$9.04 million. However, because of limited funds, only 58 of the 94 or 62% of research grants approved by the NIAMDD council were funded. \$6.21 million was spent for research grants and \$0.55 million for fellowship and \$0.91 million for training grants. \$1.37 million was spent for research at NIH, field studies and contracts. Funds for diabetes research declined in both 1970 and 1971. 7.85 million was spent in 1971. Research grant support fell to \$4.98 million so that only 37% (25) of the 67 grants approved by the NIAMDD council could be funded.

Funds for fellowship—\$0.48 million—and training grants—\$0.83 million—were less in 1971 than in 1969. Although funds for diabetic research increased to \$8.41 million in 1972, because of inflation, this did not really represent any real increase in the amount of research supported. \$5.6 million for research grants allowed funding of only 33 of the 57 grants approved by the NIAMDD council. Funds for fellowship were further reduced to \$0.45 million and those for training grants were unchanged at \$0.83 million. As you know, both the fellowship and training programs are to be discontinued. This action has serious long-term implications in terms of providing scientists to obtain new information needed to prevent and treat diabetes and its complications as well as those physicians to effectively apply this knowledge to the diabetic patient. It has become increasingly clear that support for diabetes research is not commensurate with the needs of the diabetic patient and the impact of this disease on our population and economy. I am certain that you will agree that an investment in diabetes research which would make significant inroads into the \$2 billion dollar annual economic loss due to this disease would be money well spent. Although it is important to detect **diabetes early and educate both the physician and the patient for the optimal care of his diabetes**, it is only as the consequence of expanded research in diabetes and related diseases that we can hope to avoid the ever-increasing economic and emotional toll which the diabetic and the nation are bearing.

I wish to thank you, Mr. Chairman, and the members of this Committee for the opportunity to convey to you the urgency and importance of expanded research support for diabetes and the potential benefits such support can produce.

Mr. ROGERS. Thank you, Dr. Field. I appreciate that.

Our next witness is Mr. Tanenbaum, and his statement will be made a part of the record.

## STATEMENT OF MYLES H. TANENBAUM

Mr. TANENBAUM. Thank you, Mr. Chairman. I will be brief.

Mr. Rogers and Mr. Symington, I sincerely appreciate the opportunity to appear before you today and to offer my views in regard to this matter and to that extent participate in the deliberations concerning how soon, if at all, our National Government is going to do something about improving the quality of life and perhaps the very existence of millions of Americans.

My qualifications for appearing here and offering my views are primarily as a parent of two children, each of whom became diabetic at age 7. The gist of my testimony will be pragmatic.

Why did my children develop diabetes? I don't know. Our doctors do not know. The research people do not know.

What health consequences will my children suffer by reason of their diabetes? I do not know. Our doctors do not know. The research people do not know.

There is simply too little known about this illness. You have heard this morning testimony of "maybes" and "possiblys" but no categorical probabilities. One thing we do know is that were it not for insulin, they would be dead today. Being diabetic, they take their insulin, they remain alive, and they follow the procedure that involves daily doses of insulin twice a day, as in the case of my daughter.

They must test the sugar content of their urine daily; their diet is carefully maintained; their exercise program and food intake must be carefully balanced; and they face the grim statistics of diabetes shortly becoming the leading cause of blindness in this country, it is still the fifth leading cause of death by disease, its side effects include arterial problems often leading to limb amputations, kidney ailments, and other serious health conditions, and a superb athlete such as Jackie Robinson can be reduced while still in his 50's to failing sight and ultimate death by a diabetes-induced ailment.

Life insurance either cannot be obtained or is issued on a rated basis. Certain forms of employment are barred to diabetics, and because of greater absenteeism for health reasons, employment problems are common.

Other of life's problems that inconvenience and affect the diabetic include the recent barring of cyclamates in prepared food items and a bill introduced in the House that would curtail the sale of hypodermic needles and syringes—intended for the control of addiction, but potentially having a serious effect upon the purchase of these needed items for diabetic treatment.

But unfortunately, the real tragedy occurs, as commonly would be the case, in regard to the disadvantaged people in this country. The poor and less educated are more the serious victims of this disease. Consider, if you will, the degree of comprehension required of a diabetic in order to care for himself. Not only is there the matter of the daily insulin doses as such, but the dosage must be adjusted daily to take into consideration the individual's daily sugar level, variations in physical activity, and changes in food intake.

Too much or too little insulin can have fairly immediate and often serious health consequences to which the individual or someone caring for him must promptly respond. Testing urine samples, and making

the related adjustment in the insulin dosage, is not a matter an uneducated person can readily comprehend. Recommended diets, with their attendant complicated food substitutes, challenges the mind of a more intelligent person. Who takes care of the less educated? How do the poor handle these costs? They can hardly afford a balanced diet. The answer is simple: They are the people who form the bulk of the unhappy statistics associated with diabetes.

The bill before you provides for the establishment of centers for the training, care, study, and research related to this ailment. It is a beginning, and frustratingly to the millions of diabetics and their families only a very modest beginning, in the struggle to understand the illness, to control its effects, to prevent its incidence, and perhaps even to cure its sufferers.

We hear so often these days talk concerning our quality of life. Such talk for the most part has been discussed in connection with our environment. Consider, if you will, the quality of life of a person suffering from diabetes: a child daily inserting a needle to maintain life, adjusting to employment problems, limiting activity level, and guarding always against reactions from too much or too little insulin. Does such a person raise a family, and if so, to what end? It is irresponsible and heartless to consider such a person as leading a normal life?

Normal for whom? It all resolves itself into a matter of priorities. Funds in the billions come into the U.S. Treasury annually.

We ask that you adopt an effective beginning program and then see to it it is so funded.

Inevitably, a number of this subcommittee or members of your families are diabetics. For those in such a circumstance, the implications of this illness are ever present and most striking. Their attention to the need for this bill requires no elaboration. It is to the others of this committee that I appeal. Please do something to curtail the spread of this illness and to assist in maintaining a reasonable quality of life for those who presently are afflicted with diabetes. Action is long overdue; delay will merely condemn that many more Americans to a level of life which can be avoided. Can we afford to take the risk of non-action and still consider ourselves responsible? Thank you.

Mr. ROGERS. Thank you, Mr. Tanenbaum, for a very personal statement which has great meaning to the committee.

The next witness is Dr. Donnell D. Etwiler. We will insert your statement in the record, Dr. Etwiler, and you may proceed as your wish.

#### STATEMENT OF DR. DONNELL D. ETZWILER

Dr. ETZWILER. Mr. Rogers and Mr. Symington, I, too, appreciate the opportunity to appear before you, since we have already submitted our written remarks, and I will make my statement very limited.

As chairman of the Committee on Diabetes in Youth of the American Diabetes Association, I would briefly like to discuss and perhaps extend on some of Mr. Tanenbaum's comments as regards the disease in children.

Diabetes occurs primarily in those over age 45, and it is estimated about 5 percent of diabetes occur in children. A recent study in the State of Michigan has demonstrated the incidence of diabetes to be about 1 in 600 children in a school-age grouping.

The nature of diabetes that occurs in these individuals is vastly different than the type we usually see in older adults.

Mr. Tanenbaum mentioned these children are insulin dependent; almost 100 percent of them require at least one daily insulin injections, and many times, two or three.

The onset of the disease in children is very different than we see in older individuals, also. Older diabetics may have signs or symptoms developing over many months or years. In children, it may appear in a matter of 2 or 3 days.

Diabetes frequently takes a very fulminating course in children, and rarely do we get a history over 3 or 4 weeks in duration. Thus, the likelihood of getting into very dangerous or life-threatening situations at the onset of the disease is very real.

The treatment of juvenile diabetes varies also. A study of the National Health Survey done a few years ago demonstrated that in older diabetics, about 25 percent could be controlled by diet alone, another 50 percent by diet and oral medication, and only 25 percent require insulin. As we mentioned, almost all of the children must have insulin, so that every day does start with an insulin injection.

I would oppose some of the statements made earlier this morning when representatives of the administration testified about control resulting in relatively normal life.

In 2 weeks from now, we will have the summer diabetes camp, and each morning there starts with all of the 115 campers doing urine tests, preparing and administering their insulin shots, eating a prescribed amount of food at a set time each day, and participating in a camp program which will accommodate the demands of their disease. This living pattern repeats itself day after day and is not part of a "normal life."

The long-term complications and social problems associated with this have also been already identified.

Diabetes, as it occurs in children, is frequently referred to as unstable diabetes or brittle in nature, so in a matter of minutes or days these children may develop what we call acute problems such as insulin reactions. These may occur at school, play, athletics. When a child's blood sugar gets too low, he feels shaky, tired, listless, rundown, perspiring, and becomes lethargic and unconscious. Convulsions may develop as a result of this sudden onset of problems associated with diabetes.

Another problem which may occur in a matter of a few hours or a few days is that of diabetic acidosis where the blood sugar gets too high. When this occurs in children, they are forced to go into hospitals, and mortality rates may run as high as 15 percent.

If the child is not threatened or has a minimum of the acute problems, he faces unique intermediary problems that may be identified over a few months or a few years. These are failures to grow and develop.

For instance, a short time ago we saw a patient in the office whose mother said, "My child is well controlled; he is just not growing."

He was the size of a 9½-year-old, and he was 15 years of age. He had the onset of diabetes at age 9. He was not controlled and was not growing or developing.

In the pregnant female young diabetic, complications during pregnancy are greatly increased, and chances of having a child with some kind of malformation are at least three times that of the nondiabetic.

The long-term complications you have already heard about. These allude to complications affecting the blood vessels, which in turn limit the life expectancy of such children to approximately 27 years after the onset. There are also many psychological problems associated with diabetes, and again Mr. Tanenbaum gave you excellent personal testimony as to these kind of problems.

These patients and their families do need to assume a maximal role in their own management. To properly care for a chronic disease like diabetes, we may have to turn the health care system around and say:

You, as a patient, are really responsible for 99 percent of your medical care, and it is you that gives insulin daily and watches your urine and tests and makes appropriate changes in your management and care.

When we do this, we now have to prepare, educate and support these people. This is part of the bill that we are supporting, which includes establishing educational centers for doing this. One of the questions that came up this morning was about the role and effectiveness of diet, and I would quote from some of the studies by Glen McDonald who was with the U.S. Public Health Service when they did a National Health Survey a few years ago and found that although 77 percent of all diabetics are given dietary prescriptions, less than 10 percent of the group had the knowledge to carry it out.

Life for these individuals with diabetes is considerably shortened, and they have many many problems and complications.

The reasons for the heretofore minimal support of diabetes are obvious; diabetes has been ignored because it is a subtle disease, it is not dramatic either in its final phases or its acute episodes. When death occurs, it is frequently related to other organ problems.

Here is a disease then that affects almost 5 million persons in the country, the fifth leading cause of death by disease and seventh leading cause of death.

This silent killer kills more than 35,000 individuals per year.

It seems imperative then that we direct more of our efforts toward finding its cause and cure. Our Nation's expenditures need to be reassessed and allocations or reallocations of funds directed toward diabetes.

[Dr. Etzwiler's prepared statement follows:]

STATEMENT OF DONNELL D. ETZWILER, M.D., DIRECTOR, DIABETES EDUCATION CENTER, MINNEAPOLIS, MINN.; PEDIATRICIAN, ST. LOUIS PARK MEDICAL CENTER, MINNEAPOLIS, MINN.; ASSOCIATE PROFESSOR, UNIVERSITY OF MINNESOTA, DEPARTMENT OF PEDIATRICS; MEMBER OF THE BOARD, AMERICAN DIABETES ASSOCIATION; CHAIRMAN, COMMITTEE ON DIABETES IN YOUTH, AMERICAN DIABETES ASSOCIATION

Mr. Chairman and members of the Subcommittee on Health and Environment, I appreciate this opportunity to appear today and present the following information concerning diabetes in youth.

It has already been stated that diabetes is the 5th leading cause of death by disease in the United States and affects almost 5,000,000 Americans. When this fearful disease strikes our youth, it does so with a severity seldom witnessed in older age groups. The incidence, onset, treatment, and course of the disease vary significantly in children.

For some time it has been stated that approximately 5% of all diabetes appears among those under 15 years of age and that the incidence of the disease is approximately 1 in 2,500. Recently, however, Dr. K. Gorwitz has obtained data from approximately 60% of the schools in Michigan serving children 5 to 18 years of age. The prevalent rate of juvenile diabetes from their study is almost 1 in 600! If this figure is verified in other parts of the country, there may be as many as

400,000-500,000 juveniles in the United States with overt diabetes! Early diabetes or chemical diabetes (here the child is without symptoms) is just now beginning to be investigated in depth. Dr. Richard Guthrie of Missouri has reported that this form of the disease occurs in 12-15% of the siblings of diabetics. Such abnormalities are suggestive of early disease and heretofore frequently have not been detected.

The abrupt onset of diabetes in children is not appreciated even by many health professionals. Symptoms seldom date back over 3 or 4 weeks and many times the disease appears in the fulminating form and presents a serious threat to life. Loss of 10 to 20 pounds in 2 or 3 days is not rare and histories of well children suddenly being overwhelmed by the condition are common. Initial treatment must be knowledgeable and vigorous as insulin becomes the difference between life and death. Prior to the discovery of insulin in 1921 by Banting & Best, the life expectancy of these youngsters was less than 2 years. Today, daily "shots" of insulin have become a way of life for thousands upon thousands of these children who inject themselves to stay alive. Even so, insulin is not the panacea it was once thought and today's young diabetics still face an abbreviated average life expectancy of 27 years after the onset of their disease!

These are not easy years; they are years of taking daily shots, regulating food intake, performing urine tests several times each day, observing activity patterns closely and adhering to the numerous demands of the disease. The acute problems of diabetic acidosis and insulin reactions are ever threatening. Diabetic acidosis is a serious complication with significant reactions may cause weakness, irritability, trembling, lethargy, unconsciousness, and seizures if not recognized and treated. Prolonged insulin reactions can lead to central nervous system damage and even death.

Poor control of diabetes results in diminished growth and failure to develop. The young female diabetic who marries and desires a family faces an increased risk to herself and to her babies, who may be stillborn or who exhibit deformities at 3 times the rate of infants of non-diabetic mothers.

Young diabetics seeking work find their employment barred by entire industries and are even refused employment under civil service. While employment restrictions are warranted in select cases, the wholesale barring of diabetics is demoralizing, destructive and does not adhere to the principles of equal employment opportunity.

The chronic problems which take their toll among these children are primarily vascular problems, such as stroke, early heart attacks, amputation, blindness and kidney failure. These complications shroud the future of the child with diabetes and are the daily silent fears borne by their parents.

In an attempt to identify and meet some of the needs of children with diabetes, the American Diabetes Association has recently established a committee on Diabetes in Youth which I chair. The objectives of this committee are:

1. To initiate and support research in the areas of cause, improved care and ultimate cure of diabetes mellitus as it pertains to youth.
2. To improve the health, health care and quality of life for those young individuals having diabetes mellitus.
3. To improve the knowledge, skills and objectives of individuals, both professional and nonprofessional, in meeting the physical, psychological and emotional needs of young diabetics.
4. To promote and encourage communication and activities and cooperation among interested professional and non-professional persons throughout the nation.

It is obvious that the momentous challenges faced by those with diabetes, are not and cannot be met by the American Diabetes Association and other interested groups and persons alone. The needs and demands of this disease, which annually results in 35,000 deaths in the United States, are monumental and are unmet as witnessed here today.

A cure for diabetes and its abolishment from mankind is the ultimate desire of each of us. This can be accomplished only through research. Currently diabetes research represents only 1/2% of the total National Institutes of Health's budget. Significantly more financial aid for such programs is mandatory!

The national government must also provide the leadership for stimulating the training and support of young research and clinical health professionals. The health care needs of the diabetic today are important and unmet. Interested and knowledgeable medical personnel can improve the diabetic's daily life and prolong his future, hopefully until such a time as when research efforts can provide the final answer. While research is promising for the future, we cannot

dey the needs of so many million Americans today and tomorrow. Leadership and financial aid in these areas must also be supported by the federal government.

Finally, I see the need and opportunity to stimulate, develop, and implement new systems of health care through efforts in the field of diabetes. Diabetes can and has served many of us in developing a team approach to medical services which includes the patient and members of his family as recognized members of the health care team. Systematic approaches to the treatment and support of chronic diseases can be modeled after efforts already being initiated and evaluated in the field of diabetes. Federal assistance in this area, however, is virtually nil and several of these young centers supported in the past by agencies such as the Regional Medical Program now face obliteration.

In summary, the pending legislation before Congress embodies the power and support necessary to initiate a powerful thrust toward alleviating the overwhelming burden borne by almost 5,000,000 Americans. Such legislation, leadership, and support by the Federal Government is long overdue.

Mr. ROGERS. Thank you very much, Dr. Etwiler, for an excellent statement. It is most helpful.

Mr. CONNELLY, I think it would be helpful to put into the record some of the literature that is passed out.

I think it would be well to have your information that is sent out, for instance, "How to recognize diabetes," "What do you do to take care of yourself?" and "What do you do on a diet?" If you have those, I think it would be helpful to have them for the record.

Mr. CONNELLY. Mr. ROGERS, we have a fourfold program of professional education for physicians and other scientists in the allied health professions; patient education—the diabetic and his family—public education and detection; and research. We have literature in all these educational areas, and we will be happy to supply it.

Mr. ROGERS. I think it will be helpful if you would supply the material for use by the committee.

Thank you very much, Mr. Tanenbaum, Dr. Heffner, Dr. Etwiler, Dr. Davidson, Dr. Crofford, and Dr. Field.

We thank you very much, and your testimony has been most helpful to the committee.

Also before you leave, will you let us know anything you have to say on the way this program is to be administered, particularly in the centers program.

[The following statement of Dr. Sprague and Mrs. Jackson were subsequently received for the record:]

STATEMENT OF RANDALL G. SPRAGUE, M.D., PH. D.; PAST PRESIDENT, AMERICAN DIABETES ASSOCIATION; SENIOR CONSULTANT IN MEDICINE AND ENDOCRINOLOGY (EMERITUS), MAYO CLINIC; PROFESSOR OF MEDICINE (EMERITUS), MAYO GRADUATE SCHOOL; CHIEF OF SERVICE, INTERNAL MEDICINE, ROCHESTER STATE HOSPITAL, ROCHESTER, MINN.

Mr. Chairman and members of the subcommittee, I appreciate the opportunity to present this statement to the committee which I believe will be helpful in the consideration of proposed legislation concerning diabetes mellitus.

With the discovery of insulin by Banting and Best at the University of Toronto in 1921, the serious health problems posed by uncontrolled diabetes mellitus appeared to be reaching solution. Injections of insulin provided what was lacking in the diabetic, and with careful use of this new hormone, plus diet, he could achieve normal health. Since then research on insulin has added immeasurably to the understanding of diabetes in the scientific sense, while in the human sense insulin has given literally millions of years of life to countless diabetics around the world.

Please permit me a short digression here to tell you that I have a special interest in these matters, for I have had diabetes for 52 years, ever since the summer of 1921 when Banting and Best were doing these historic experiments,

and I am able, thankfully, to appear before you now as a living example of what insulin can do. For me, insulin was life-saving and health-restoring, as it has been for many young diabetics whose days without insulin would have been numbered but who are alive and active today because of it. Up to the present time I have taken about 38,000 injections of insulin at the rate of two a day and with continued good health I will be pleased to take a few thousand more!

My real purpose in this personal digression is to emphasize the unfortunate fact that there are very few diabetics who have been as fortunate as I in terms of success in withstanding the disease for so many years. It is true that the ability of insulin to keep the diabetic individual metabolically healthy has resulted in a dramatic increase in the life expectancy of diabetics, particularly the young. Thus, the diabetic child of 10 years may expect 44 more years of life, representing about a 20-fold increase in duration of life with diabetes. With onset of diabetes after age 40, duration of life has increased two and one-half times. With insulin, diabetic keto-acidosis with coma has been changed from a very frequent cause of death to a very infrequent one. Insulin must be credited with most of this dramatic improvement in survival. But let me say again that there are very few diabetics who enjoy the long survival in vigorous health on insulin that have been my good fortune. The hard cold fact is that life expectancy of diabetics, regardless of attained age, is still only about two-thirds that of the general population.

Less than 20 years after the discovery of insulin it became evident that many patients with long-term diabetes were developing complications of the large and small blood vessels, with a variety of serious consequences and sooner or later a fatal termination. Thus, it has become painfully clear that insulin, at least as we have used it, does not prevent or solve all problems of the diabetic or insure normal survival.

The present state of knowledge of the vascular complications of diabetes can only be described as very inadequate. Involvement of the larger vessels takes the form of cerebral, coronary and peripheral arteriosclerosis leading to strokes, heart attacks and gangrene. In diabetics these changes occur at a much earlier age and in more severe degree than nondiabetics. Fully as important as such disease of the larger vessels is disease of the small vessels, or microangiopathy, which takes the vision and then the life of many young diabetics. This small vessel disease is specifically related to diabetes and eventually occurs in almost all the tissues of the body of virtually all diabetics if they live long enough. It manifests itself most destructively in the eyes and in the kidneys.

It is clear that much remains to be done. We do not yet know enough about diabetic vascular disease to apply scientific knowledge to its prevention and treatment. Acquisition of knowledge of biological phenomena, such as the blood vessel which shortens the life of so many diabetics, usually goes through three phases: first, discovery or recognition; second, description; and finally, precise definition of the mechanisms involved. In the case of the diabetic vascular complications medical science has tolled through the phases of recognition and description, but has made only a start on the difficult research task of defining the biochemical mechanisms by which these changes in the blood vessel walls come about. Research in this area, as well as in many other areas of diabetes, must be encouraged and supported if we are ever to have effective measures and treatment.

Diabetes is indeed a major health problem in our country. Its seriousness to the individual diabetic and to the nation is not yet widely appreciated, partly because it has relatively low visibility. Diabetes which is, in effect, "hidden" by being either undetected or well-controlled does not convey an impression of seriousness, which it truly should. In this country diabetes is the fifth leading cause of death by disease and the second leading cause of new cases of blindness. Heart attacks are at least two and one-half times more frequent in diabetics than in nondiabetics of the same age. The overall magnitude of diabetes and its complications can be better appreciated when one recognizes that there are close to 5 million diabetics in the United States, and survey data indicate that the prevalence of the disease is steadily increasing.

Certainly the establishment of a National Diabetes Program merits very high priority and is indeed urgent in view of the large number of people affected by diabetes, their need for care and instruction in self-care, and the overriding need for more research to enhance knowledge of the basic biological mechanisms of diabetes and its life-threatening complications.

STATEMENT OF MRS. GAIL PATRICK JACKSON, CHAIRMAN OF THE BOARD,  
AMERICAN DIABETES ASSOCIATION, INC.

Mr. Chairman and members of the subcommittee, I appreciate this opportunity to comment on the proposed diabetes legislation.

I can understand why all branches of the government in reevaluation processes are on the defensive, and I can readily see how the National Institutes of Health would be one of those to be on the defensive.

As a member of the NIAMDD I too might have a conflict of interest here. I am new on the committee, but I have not been impressed with the efforts that were directed toward the study of diabetes.

I might also say here parenthetically as a diabetic it is a good thing I am not a hypochondriac because after many of these meetings you go home almost as a basket case when you find out all the things that can happen and probably will happen to you.

I do not have a great deal of hope of taking advantage of new discoveries in the field of diabetic treatment in my lifetime, but I have a son who is a potential diabetic, and my main interest for years has been in the children who are affected with diabetes.

We do have to have more specialists in diabetes. The first doctor I went to—and it was when I was first in a coma—was a great doctor but apparently had lost touch. I was told the usual things, if you do not eat sugar, you will have no problem. I did not eat sugar, but it did not go away.

Fortunately for me when I again returned to coma I landed in the hands of Dr. Grishaw, who has taught me to adjust the disease to my life, and who has helped me to live a more productive life.

In my business, show business, many of us are seemingly flaunting the fact that we are victims who are learning to live with diabetes. I had the dubious honor of being diabetic of the year. Mary Tylor Moore, Dan Rowan, Jack Benny, and a number of people in our business, have come forward to be counted because we feel if one person might be motivated to be tested for diabetes, learn he is diabetic and receive the proper treatment, we might have helped to save a life.

In so doing we might motivate them to save another life, and this could become a chain of helping our fellow men and this is what it is all about.

The American Diabetes Association, of which I am fortunate enough to be the chairman of the board, has been in operation for 30 years. There have been great steps forward. They have accomplished many things.

We feel we can accomplish even more, but still we cannot do it alone. Many voluntary health organizations have functioned well, but have had to reach out a hand to the Government when their problems became bigger than they could handle, particularly the financial end of it.

This is happening to us. We feel if there is a way your bill can be enacted, and the number of people who will benefit from that can be helped, the \$2 billion figure might be lowered, and the money saved from that might be expended on other health services.

When we think of a figure like \$2 billion, which is hard for the average person to live with or understand, with all those zeros and the two in front, they seem to go on forever, but when I listened to the requests for grants in the NIAMDD committee, I must say that \$2 billion could go a very long way; in fact, it could restore so many people to constructive usefulness.

Our biggest problem today is taking advantage of human resources, and there seems to be a way that we can help that situation by a more thorough study of diabetes, more research on diabetes, more public education and more patient education, which is vitally important.

Too many of us have hidden behind the door with things of this sort. We are now coming out saying, gee, look at me. I, with hundreds of thousands of others, take shots—in my case two a day—and I have had some memorable experiences.

There was another woman in the motion picture business—for whom I was often mistaken—who was an alcoholic, and I can understand; our ages, and coloring were similar, but I saw people suddenly pointing to me, and I was saying, oh, no, it isn't I. Then if I were seen using a needle, people could say, not only is she an alcoholic; she is a hophead. So I have a dual purpose here.

But I do not look forward to having my son take shots. I must say after 20 years of taking shots, I am a little chicken about it, but I know that without it I would not be alive very long.

Some individuals say, I could never give myself a shot, but when you realize you will be dead in a short while without it, you are happy to take it.

But I do hope funds can be expended for research and education that will help us reach a point where our children of today and our children of the future will not have to take shots every day, and hopefully can be cured of this disease.

Mr. ROGERS. Our last panel today, and we appreciate the patience of those who have sat through our hearings, will be from the Joslin Diabetes Foundation, Boston, Mass., Dr. Priscilla White, chairman of the youth programs division, and I understand you will be accompanied by Messrs. Edward Ferguson, Freddy Sears, and James Mowbray; and Miss Barrie Orr, Miss Chris Wilson, and Mrs. Clifford P. Robertson, known to all of us as Dina Merrill, who happens to be a good Floridian also. We welcome Dr. Donna Younger, and Dr. William L. Chick, research associate, beta cell.

We are grateful to each of you for being here today and for your patience. I think it will be important to have as full a record as we can build, because people all over this Nation will read this record and know what the problem is. Perhaps we will be able to build some hope for the American people through our actions here.

So we are grateful to all of you for being here. You may proceed however you wish.

**STATEMENTS OF A PANEL REPRESENTING THE JOSLIN DIABETES FOUNDATION, INC.: DR. PRISCILLA WHITE, DIRECTOR, YOUTH PROGRAMS DIVISION; MISS BARRIE W. ORR; MISS CHRIS WILSON; EDWARD C. FERGUSON; JAMES H. MOWBRAY; FREDERICK F. SEARS; DR. DONNA YOUNGER; MRS. CLIFFORD P. ROBERTSON; DR. WILLIAM CHICK; AND JOHN MASON**

Dr. WHITE. Thank you, Mr. Chairman Rogers.

These five young people with me here today are active members of the Youth Committee of the Joslin Diabetes Foundation, Inc., and it is my privilege to be the director of the youth programs of Joslin Diabetes Foundation. All members of the Youth Committee developed their diabetes either in childhood or during adolescence. They are Frederick Sears, age 14, who returns by request, the youngest member of our committee.

Mr. ROGERS. We welcome you to the committee.

Mr. SEARS. Thank you.

Dr. WHITE. Christine Wilson who is assigned to perform a liaison service between the youth committee and the Elliott P. Joslin Research Laboratory, Barrie Orr, chairman of the youth committee, Edward Ferguson, cochairman, and James Mowbray, secretary-treasurer. Dr. William Chick, adviser, will address you separately describing his new and exciting experiments. The function of this youth committee is largely service to younger people with diabetes and to their families. You will also hear from the mother of a member of the youth committee. Mrs. Clifford P. Robertson, who in her public life is the talented and well-known film and television star, Miss Dina Merrill; also, my colleagues Dr. Donna Younger will speak briefly of diabetes in the mature and later years of life.

To this list has been added still another, John Mason, whom we thought was in a submarine off of Woods Hole, and he is an oceanographer and he will either make a 1-minute statement or answer questions.

Mr. ROGERS. We are glad he has surfaced and is here. As a matter of fact, Mr. Mason, I served on a committee on oceanography and I am very much aware of what you do.

Dr. WHITE. Why is diabetes in the young such a special problem that we have come to Washington? How does it differ from diabetes which develops in adult life? The adult with diabetes usually continues to produce life-sustaining insulin, but has difficulty in releasing the insulin from the beta cells of the pancreas; whereas the diabetic child in a period of some 5 years after onset loses the beta insulin producing cells from the islands of Langerhans of the pancreas. The insulin of the adult is trapped, that of the child is lacking.

What is the cause of diabetes? It is inherited but just what is inherited from and how diabetes is inherited are two unknown facts. New research suggests that precipitation of diabetes especially in the young follows infections which are probably largely viral in origin.

Since we have insulin available commercially why is its lack so crucial in youth? You and I who are without diabetes produce and release insulin on demand as the blood sugar rises after eating and we withhold insulin as the blood sugar falls before eating. Injected insulin lacks this automatic regulation. Therefore, the young with diabetes tend to have too little insulin when it is needed after eating and too much when it is not needed before eating. Without adequate insulin the young may fail to grow, develop, and to reproduce.

It is the belief of the physicians of the Joslin Clinic that this lack of insulin when needed leads to serious changes and complications in small and large blood vessels and in nerve tissue. Basic research and clinical experience support this belief. The changes which occur alter function in such structures as the retina—the seeing part of the eye—the glomerulus, which is the filter of the kidney, the structure and the circulation of the heart, and the blood vessels in the foot and leg.

When do these threatening changes occur in the young? When do they create disastrous results? The eye changes can be detected early in the midteenage period and threaten vision in the late teenage and early twenties. Impairment of kidney function can also be detected in the late teenage period and disastrous results are seen by age 30.

The signs of the involvement of the heart may be evident in the thirty's with heart attacks, severe ones in the forty's. Impairment of the circulation in the feet and legs may be evident in the late thirty's and forty's and disastrous results in the fifty's necessitating amputations. What despair ensues when these problems are recognized. At the present time, life expectancy in the young is some three quarters of the normal, but of course not all of this life is good life.

Few of us have families without diabetes. Dr. Elliott Joslin's interest in this disease arose from his mother's case, and one of these attractive, successful, and vital young people here is a close blood relative of mine. Only one of these young adults, and that of course excludes Freddy, is now free from the threatening changes which I have just described. New experimental ways of supplying the deficit of insulin on demand are being explored, but when will they be available? It could and should be now. These young people, beginning with Barrie, will tell you what it is to have developed diabetes in early childhood what it feels like to have this type of diabetes as a young adult.

Miss Merrill will tell the experiences of a mother and Dr. Chick the recent research advances.

Mr. ROGERS. Thank you so much.

## STATEMENT OF MISS BARRIE ORR

Miss ORR. Thank you, Dr. White, and thank you for letting us get a bite to eat.

Now, with a second wind. As you look at me, you may be saying to yourself "she looks like a healthy 24-year-old." This type of thinking certainly is not uncommon.

Today I would like to speak to you for a few minutes on the subject of diabetes and the future, not only for me, but also for the thousands of diabetics and prediabetics throughout the United States.

Diabetes is a metabolic imbalance and not only affects the normal functions of the pancreas, but also many other parts of the human body: Eyes, heart, kidneys, circulatory system, reproductive system, and so forth.

I would now like to state a case history of a 24-year-old white female who developed diabetes in 1954. She had the usual control problems during the age of 5 through 16. Migraine headaches were diagnosed at the age of 6. She also developed a urinary tract infection in 1969. Upon examination in 1970, eye hemorrhages were found and after many tests, it was decided that the laser beam should be used to stop the hemorrhaging. Subsequent laser beam treatments have been performed since 1970.

This eye problem, in turn, brought up several questions concerning pregnancy and diabetes. With eye damage already diagnosed, there is a good possibility of increased eye damage during pregnancy. There is also the chance of increased kidney failure, since this patient had a kidney infection in 1967. This young woman is concerned about any future pregnancy because of the possibility of increased eye damage and kidney failure. Should she jeopardize her health in order to bear a child, knowing other complications, such as blindness, heart failure, vascular problems, may occur? Would it be selfish to still want your own child knowing you may shorten your life? A diabetic's life span is 75 percent of a normal life span. This patient is concerned about endangering the child's life. Only 90 percent of births to diabetic women survive compared to 98 percent survival of births to nondiabetic women. This patient is also taking medication twice daily for elevated blood pressure. At present, this patient appears to be in good spirits and other than insulin and blood pressure medication twice daily is on no other medication.

With many thousands of diabetics already diagnosed and the many others who will become diabetics during their life time, I feel it is imperative that we band together for one common cause to find a cure for diabetes. It is easy for you to say they look and act like they lead normal lives, however, when you walk through a hospital, clinic, or doctor's office where physicians specialize in diabetes, you quickly realize that we are not all as healthy as we appear. Without our daily injections of insulin, we cannot survive. Many complications do not outwardly show, but slowly, through time, diabetes is destroying our bodies.

Research is the only answer. If we hope to find a cure, time and money is needed as I am sure you are aware. The future for the diabetic is, indeed a promising one. As Chairman of the Youth Committee of the Joslin Diabetes Foundation, Inc., I have had the opportunity

to talk and work with many diabetics. I have come to the conclusion that the public must be made more aware about diabetes so that they can better understand why we so desperately need funds to continue the research which is now going on.

Having had diabetes for 19 years, I am fully aware of the complications that can develop as I am the case history which I just referred to.

Mr. ROGERS. Thank you very much, Miss Orr, for an excellent statement.

#### STATEMENT OF MISS CHRIS WILSON

Miss WILSON. My name is Chris Wilson, I am a member of the Youth Committee of the Joslin Diabetes Foundation. I have had diabetes for 13 years and I am now 20 years old.

I think it is best to explain to you what has happened to me as a diabetic. My situation will show just how complex and potentially dangerous diabetes can be.

At the age of 6 I was losing weight, was very lethargic and showing typical symptoms, and was tested for many things but not for diabetes. On the verge of a diabetic coma it was discovered to be diabetes. At that point all I was told was to take insulin injections every day and stay away from obvious sweets. When I went for checkups my doctor never once—in 6 years, did a blood sugar test, which is the only real indication of how well the disease is being controlled. At 14 I was referred to a diabetic specialist. An example of his lack of knowledge about the importance of a balanced diet to control the disease was that he allowed me to go on a diet that consisted only of bananas. The implications of that are obvious, and I no longer went to see him.

At the age of 16 I developed diabetic retinopathy. This is caused by newly formed blood vessels in the retina which can eventually hemorrhage and result in blindness. At this point I was informed of a diabetic clinic where my eyes were treated with a laser. I also was involved in a teaching situation where I gained enough knowledge to put some control on my disease.

My point to all this is to hopefully enable you to see the importance of proper education and continuing research in this field. Because of my newly acquired understanding and the research into retinopathy I have my sight. This is not to say that eye research is completed, quite the opposite; there are many, many doors to be opened in every aspect of diabetes.

Thank you.

Mr. ROGERS. Thank you so much, Miss Wilson.

That was a very helpful statement.

#### STATEMENT OF EDWARD C. FERGUSON

Mr. FERGUSON. My name is Edward C. Ferguson. I am 25 years old, living in Malden, Mass. I was diagnosed as a diabetic at 13 years of age, and I am now taking insulin twice daily, totaling 54 units in all. I am a professional educator, teaching grades 5 and 6 in the public schools of Melrose, Mass. I am vice chairman of the youth committee of the Joslin Diabetes Foundation and have been working with diabetic children since I was 16 years old.

In February of this year I had the privilege of speaking before the Senate Subcommittee on Health, and at that time I discussed the urgent need for increased funds for the areas of research and education in diabetes. There are many stories which could be repeated here to illustrate the problems caused by diabetes and its complications. It is a frightening thing to watch a young adult as kidney problems develop, or as diabetic retinopathy unmercifully steals his vision. Yet, these things are happening, and not in isolated instances. Diabetes is the second leading cause of blindness in this country and the fifth leading cause of death, as you know.

These are truths that I and all diabetics must live with, but we cannot allow ourselves to be destroyed by this knowledge. The young diabetics I know are, in fact, very grateful to be alive, for we know what the outlook was for patients diagnosed before the discovery and availability of insulin in 1921 and 1922. The life expectancy of 2 years, while slowly starving to death, looks unbelievably black in comparison to the many healthy, productive diabetics of today.

Diabetics, even today, still face a very real challenge; namely, the complications which can arise due to our condition. The young diabetics I have talked with are very much aware of these complications. As Dr. White has expressed it, "The sword of Damocles is hanging over our heads." We understand the need for good control and how this may save us from the tragedy of blindness, kidney disorders, or heart problems. One fact that weighs heaviest on all of us is that even with the best control possible with present therapy, complications are still difficult to avoid.

The young people of our country have never been noted for their patience and understanding of what, to them, is an intolerable situation. Why is the treatment of diabetes essentially the same today as it was 50 years ago? I do not discount the modifications and improvements, but when the scientific capability exists to reduce and ultimately eliminate these complications we cannot be faulted for asking "Why?"

Federal funding of research programs is the means of reaching this goal. We can ask, even plead, for these funds, but it is up to the Government to provide them. The members of the Youth Committee have been giving of themselves in many service projects. We have developed educational material, organized discussion groups, and we have run special camping programs to help diabetic children prepare for the best possible future. It is, however, the scientific community which will take the necessary final steps in solving the problems we face.

I know the solutions will take time and money, and hopefully luck will be with me and other young diabetics until they do come to pass. Right now, I optimistically look forward to a long, normal life span. I hope to marry and raise a family, but I am forced to wonder if only luck will enable my children to avoid the complications I now face.

I cannot claim to speak for the 4½ million Americans with diabetes. I only feel that our goals and desires are similar to those of people everywhere. To repeat, our condition is the fifth leading cause of death, and heart attacks, strokes, and kidney failure frequently evolve from diabetes. Birth defects and still births are associated with it and it is the second leading cause of blindness.

These are the problems that we know about. We also know they can be solved. Now is the time to act.

I thank you.

Mr. ROGERS. Thank you, Mr. Ferguson, for all the activities in which you have participated in fighting diabetes.

#### STATEMENT OF JAMES H. MOWBRAY

Mr. MOWBRAY. I would like to start by saying that I am very pleased to have this opportunity to stand before you today and speak of my feelings regarding the diabetic condition. I think you can help. I hope that you will leave this hearing with an awareness of what the diabetic faces today and what possibilities lie ahead.

I am the parent of two redheaded children aged 5 and 4. I am a practicing engineer working in the field of biomedical engineering, and discovered my diabetic condition during the first semester of my freshman year of college.

I have personally lived with diabetes for 11 years now. During this time I have followed the progress in research with great interest and hope. My hope, of course, has always been that the diabetic condition will ultimately be truly and totally correctible.

I must, however, point out that during the first few months after discovering my diabetes I resigned myself to the fact that I had a chronic condition that I would always have to live with. At that point in time I was invited by Dr. Priscilla White to take part in the production of a film dealing with various aspects of the condition. Before the filming of the section that I was in, I remember discussing with Dr. White the possibility of finding a cure. I must admit that I expressed some skepticism. I remember vividly Dr. White's reply. She was most positive and confident that a cure will be found. That was in the spring of 1962. At that time it seemed unrealistic to even attempt to guess at a timeframe for accomplishing my goal. I went away from that conversation believing, but of course wondering "When?"

You might well ask why a real cure is so important. After all, insulin was discovered over 50 years ago, and good control is possible today, isn't it? I would first tell you some things which people often consider as the reasons why a cure is needed. For instance, my friends think that it would be marvelous if I did not have to take injections twice a day. And they are also sympathetic about my dietary restrictions. I would just say that the injections are certainly tolerable and I enjoy my meals probably more than the average person. If I felt assured that I faced a future free of physical complications, I would have no complaint with present therapy. But it is not as simple as that. I think that it is reasonable to anticipate progressing through life in an orderly growth fashion, and I would hope to enjoy each stage to its fullest. I fear that as a diabetic I may face more of a disintegration in the future rather than a growth. I do believe that "good control" will postpone or minimize potential complications, but I feel that only a cure will reduce the incidence among diabetics of vascular, renal, and retinal problems, as compared with the non-diabetic population.

I hope that what I have said thus far demonstrates to you that a cure is needed and that at the present moment diabetes is certainly not conquered. I think this is reason enough for you to consider supporting diabetic research. I think there is even more reason why, at the present moment, research must be vigorously pursued. That reason is that we are so close to finding new and better answers. I say this in large part based on the opportunities I have had in the last year to view the research being conducted in the Elliott P. Joslin Research Laboratory.

As a member of the Youth Committee of the Joslin Diabetes Foundation, Inc., I have met with members of the research staff and discussed their work with them. The message that I would carry from these meetings to you is that these research efforts are very near to paying off.

In February of this year hearings were held before the Senate Subcommittee on Health. Dr. George F. Cahill concluded his statement by saying: "Those of us in the field hope there will be no 'diabetes' for you to consider in the not-too-distant future, and your present investment is therefore crucial." Dr. Alexander Marble similarly stated: "I believe that the time for action is now and with great force." I hope by appearing before you today that I can underline the direction needed and indicated by these statements.

I did attend those hearings of February 26 of this year. Those testifying for research funding were unanimous in calling for increased funding. I was somewhat perplexed by the proposed reduction in funding. This just is not the time to consider such reductions. I would again convey to you my belief that we are very near a breakthrough and that this is not the time to deny funds. I would suggest to you that the future will judge us harshly if we do not pursue the achievable.

Thank you.

Mr. ROGERS. Thank you, Mr. Mowbray. Your statement is most helpful to the committee.

#### STATEMENT OF FREDERICK F. SEARS

Mr. SEARS. My name is Fred Sears. In September, I will have been a diabetic for 10 years. As you know, diabetes affects different parts of the body. It can, in time cause a person to lose his or her vision, harden the arteries, and make people lose their limbs because diabetics are more susceptible to gangrene than people who are not diabetic.

I remember that when I was just getting used to the idea of being a diabetic I had several problems. I would be invited to a friend's house for the night, and would not be able to go because I did not know how to prepare and fix my own shot. My parents could not go away for the weekend sometimes because even though there are nurses available to understand diabetes, they are hard to find. I was lucky. I found out about the Elliott P. Joslin Camp for Boys. There I learned how, with other diabetics my age, and some older and some younger, to give myself my own shot, and how to balance out my food intake with my diabetes.

Some diabetics who have not gone to Joslin do not even know that they have to take insulin regularly. Thousands of people are not aware

that they have this condition now. The word "diabetes" stands for the "wasting disease". This meant that people used to die of it because they did not have insulin which burns up the sugar you eat and enables you to live.

Some diabetics do not realize the importance of the foods they should have or not have. For example, if a diabetic does not have the foods he or she should have, such as milk or other proteins, they could go into a reaction.

If a diabetic goes out on Halloween and eats all the candy he can get, he can possibly go into a coma, which could result in death. A great deal of the success of my diabetes is due to Joslin and I think it would be terrible if research at Joslin could no longer move ahead because of lack of funds. There is also a Joslin camp run for girls, named after Nurse Clara Barton. These camps are pretty rare and it would be too bad if lack of funds were to be a negative factor for them in the future.

I would like to become a doctor. One of my reasons for this is that I owe something to the people who helped me with my diabetes. I remember the first time I went to the Joslin Clinic, and I was very scared. Dr. White gave me a stethoscope, which I still have. This also helped me get started. I would like to prove that, in spite of diabetes, I can become a good surgeon.

Diabetes research is the most important thing about diabetes right now. If a cure is invented or discovered, that would be great. Then there would be no need for diabetes camps. The fifth leading cause of death would be nonexistent. Some people would stop losing their limbs or eyesight.

To me, this would be the greatest possible thing that ever happened. I wouldn't have to watch my diet as carefully, or give myself injections. All of this would be great, but there have to be funds for research to make this possible.

Inflation has a terrible effect on diabetes research. When the prices go up, the same money buys less and, unfortunately, there was less fund-money last year, too. It is much more possible to find or invent a cure for diabetes with larger instead of smaller funds. While diabetes cannot be cured tomorrow, without proper funds it probably never will be.

It is possible that you, yourself, will become diabetic because in 20 years one out of five people will be affected by diabetes. With 5 billion people inhabiting the earth at that time, this means that approximately 1 billion people will be involved. These are the reasons why I think it is so important that funds be given to us for continuing research in the field of diabetes.

Thank you.

Mr. ROGERS. Thank you, Mr. Sears, for a most impressive statement. The committee will certainly consider your statement when we decide what future legislation to write.

#### STATEMENT OF DR. DONNA YOUNGER

Dr. YOUNGER. The tenor of my remarks is two points, really that the statistics you have been presented with over and over again do point to the need for responsible public approach I think to dealing with diabetes and yet it has been I think a stepchild in terms of private and public funding because of the nature of the disease and that and the

importance of a broad program, the interest here in finding a cure is extremely important, but I think one of the things I appreciate about the bill is that it is more than that approach to rehabilitation and treatment, which I think is important currently.

So in competing for the limited funds which are obviously going to be available from some of the remarks that came from the administration, people think it is important to realize that the end stage tragedy of diabetes truly is a dread disease that can compete with some of the other things that receive much publicity in that regard, as you have heard many times today, including blindness and gangrene and heart disease.

You see these healthy looking young people here today, but the people that couldn't come with us include a pharmacist that I left in the hospital today in his late fifties who had one leg amputated last year and lost his other leg last week because of blood vessel damage caused by diabetes.

Although a very determined and strong man it is unlikely that he will be able to be rehabilitated successfully to bilateral artificial limbs because the same blood vessel disease has also injured his heart to the point that it is questionable whether he will be able to tolerate the strenuous exertion needed for this kind of rehabilitation.

I left another young man of 28 who was dying of kidney failure due to diabetes until he received a kidney transplant 3 weeks ago. It is too early to say whether this will ultimately be successful for this young man or not.

Diabetes might be compared with an infectious disease that has a very long incubation period before the disabling symptoms become manifest. That's why the people who most people know have diabetes appear very well and therefore they don't reach the emotional state that some other diseases do. Not that this period of relative good health for the person with youth onset or insulin dependent diabetes is easy, as you have heard the young people say. I left another 5-year-old girl with diabetes for 1½ years whose mother called me earlier this week because her daughter had been unable to move her right arm or leg when she had tried to awaken her for the day. It was true that this was transient and gradually cleared over several hours after giving sugar, but can you imagine the anguish of finding your 5-year-old child paralyzed on one side and knowing that this could recur unexpectedly at any time or any place.

I have another patient, a very careful and intelligent civil engineer, who has limited motion in both shoulders, having broken one and dislocated the other in the violence of a convulsive hypoglycemic episode. This occurred in spite of very specific advice to allow sugars to run high. When he had attempted to do so, he lost weight, was weak, tired, and unable to function satisfactorily at work or with his family which includes five children. I am citing these examples because the bill states "that uncontrolled diabetes significantly decreases life expectancy." However, the best treatment of diabetes today achieves only variable degrees of control.

In our office, the nurses check every diabetic patient for whom the laboratory reports a blood sugar that, in any one else, would be considered normal, because if the insulin-requiring diabetic comes this close to being "normal" even transiently, he may well have trouble with severe hypoglycemia before leaving the office or on the way home.

Thus, the approach to preventing the end-stage tragedy of diabetes by so-called control of diabetes as currently known to medical science, is a goal that we aim for but cannot achieve. In fact, if we come close even transiently, we immediately insist that the patient take sugar to raise his blood sugar to abnormally high levels so that he can continue to function throughout the rest of the day.

Insulin by injection does not turn on and off in response to the body's needs the way one's own internally secreted insulin does. The dose that is selected is therefore deliberately inadequate to take care of meals required for daily good nutrition in order to avoid the low blood sugar problems of sudden weakness, inability to function as we illustrated, poor vision, and slowed reflexes with marked increase in susceptibility to accidents such as auto accidents with their inherent danger to others as well as the patient.

Because of the long number of years before the grossly disabling effects of diabetes take place, we all tend to think that this condition is not as vicious as some other dread diseases. When one sees a young person in their 20's, 30's, or 40's over a period of several years lose eyesight, feet, and kidneys in a course complicated by infections, heart attacks, and strokes, the fact that we know he had this condition for 10, 20, or more years prior to this end-stage tragedy does not make it less devastating than the death of a person with cancer, for instance, over a span of a few years. And blindness, heart attacks, strokes, and bilateral amputations are no less devastating in older people. In fact, the end-stage complications may be the first and dramatic presentation of the condition in adults.

I recently saw a chiropodist who had gone blind over a period of a few months, whose previous health had been excellent in all respects. The condition that accounted for his blindness was hemorrhaging within the eyes and tearing of the retinae for which there was no treatment. This is diabetic retinopathy. One may glibly talk about long-term careful treatment of diabetes to prevent disabling complications, but this is meaningless in patients such as this one whose first presence was an irreversible major disability. A common presentation is the middle-aged or older patient whose diabetes is first diagnosed when he faces amputation because an infected foot will not heal.

We know very little about what causes diabetes; or when it is present, how these devastating complications develop. We see a clustering in families that strongly suggest an inherited predisposition, and yet half of the youngsters have no relatives known to have diabetes at the time of onset. What can I say to the mother whose youngster needs injections every day, a restricted diet, and walks a tightrope between low blood sugars and diabetic coma, and still faces all of the end-stage problems we have been describing, when she looks at her other child and then turns to me and asks what can be done to prevent diabetes? Nothing.

This does not minimize the importance of treating each one of these many millions of people with diabetes, as best we know how. The mortality of diabetic acidosis can be minimized by treatment. The body's defense against infection is better with good treatment. The psychological devastation of struggling with this monster 365 days a year can be ameliorated. It is amazing what an intensive educational

program in such mundane matters as diabetic foot hygiene can do to minimize the frequency of major occupational and daily living disabilities. The entire program requires much more intensive and widespread education of medical and paramedical personnel.

Intensive programs for treatment and education must be readily accessible to all in their own language and cultural setting so that it can be applied meaningfully over a lifetime. We are all excited by the increasing hints that a cure of diabetes is now conceivable, if not actual. The possibility of cure or prevention of diabetes 5, 10, or more years from now means little to the man who was blinded with diabetes yesterday and needs rehabilitation today, the person losing his limb today who needs training to use a prosthesis tomorrow, or the patient dying of kidney disease who needs a transplant this month.

This is what the statistics of diabetes mean as they are manifest in individual human lives. This is the challenge of developing to its fullest the broad approach of the national diabetes program proposed in H.R. 4882.

Mr. ROGERS. Thank you, Doctor.

#### STATEMENT OF MRS. CLIFFORD P. ROBERTSON

Mrs. ROBERTSON. I am delighted to have this opportunity today to appear as a member of the delegation from the Joslin Diabetes Foundation. Diabetes is a very real problem to me, for I am the parent of a diabetic child.

You have already heard Dr. Priscilla White say that of the members of the Joslin Youth Committee here today, two are still free of complications arising from their diabetes. I am glad to say that my son, David, now in his mid-20's is also in this category; and naturally, like any parent of a diabetic child, I want to do everything I can to make sure that he remains healthy and can achieve the goals he has set for himself in his future life.

One of these, of course, is to become a parent and raise a family of his own. We know that the chances of David's children becoming diabetic are better than average, and if there should be any diabetes in the family of the girl he marries, there will be a greater increased chance of diabetes appearing among his children—one can even say that this would become a probability. Diabetes is perhaps a "family disease," and we who have experienced it in our children must bear in mind our grandchildren as well as we, ourselves, are candidates for this disease.

Dr. Elliott P. Joslin's interest in diabetes developed from the fact that his mother became diabetic late in life, and just last year his great-grandson developed diabetes at the age of 17. There is a gap of four generations between these two diabetics in the same family. This is a lesson for all of us to remember.

Therefore, I am particularly concerned that sufficient funds be made available from the Federal Government to carry the search for a means of prevention and care of diabetes to a successful conclusion. This must be done as quickly as possible. At this very moment, hundreds of thousands of our fellow Americans are threatened with severe and incapacitating, even fatal, complications arising from their diabetes.

One research project at the Joslin Diabetes Foundation comes to mind in this context, namely, the study of prediabetes which has been going on for many years. The physicians involved in this study are following several hundred prediabetic individuals—children of two diabetic parents and identical twins of a diabetic. They are observing all these people closely, as one by one they go on to develop true diabetes. The objective is to find a truly predictive test which could be applied in mass screening, so that the 5¼ million prediabetics now living in the United States can be easily identified. There is no way to identify them at the present time, other than through knowledge of heredity, and since you have to go back several generations this is almost an impossibility. Diabetes was very frequently not diagnosed in previous generations, nor was it shown on death certificates.

Thus, if a computerized profile of prediabetes could be found, and a quick, painless mass screening performed, we know that much can be done to delay the onset of diabetes and also perhaps to prevent the adverse changes in the body which cause the terrible complications you are hearing so much about today.

Wouldn't it be wonderful if all prediabetic and diabetic individuals could be identified, helped, and then—hopefully within a few years—cured of diabetes? Is this pipe-dream?

Five years ago, the answer would have been, yes, it is a dream. But now, we can truly say that only the limitation of adequate funding for diabetes research is holding back the dream from becoming reality.

In the Elliott P. Joslin Research Laboratory, there is an animal which has been cured of total diabetes. You will hear more about this from Dr. Chick in a few minutes. I am sure that David would be delighted if he could be the first human diabetic to be cured. Every parent of a diabetic child feels exactly as I do. We number in the millions, and I like to feel as I talk with you here today that I am saying what is in the hearts of all the fathers and mothers who could say to you, "Please save our children from blindness, early death, heart and kidney disease, and from mental and emotional anguish."

Thank you very much.

Mr. ROGERS. Thank you so much for your statement which is most helpful and makes all of us have a special feeling for this problem.

#### STATEMENT OF DR. WILLIAM L. CHICK

Dr. CHICK. Mr. Chairman, I don't know quite how to state this as far as this particular part of the session.

You are probably aware of the fact the most significant breakthroughs really in preventing or curing other costly diseases such as polio have been realized through basic research.

I am sure you are also aware of the fact that at present diabetes research both in our own laboratory at the Joslin and in other similar units is largely dependent upon NIH support. It is logical to assume that if progress toward finding a cure for diabetes is to continue then governmental support must also continue, and furthermore, that if progress is to accelerate, then support must also accelerate.

I am pained to say that in the case of my own research project, at a time when the need to expand our efforts is most pressing, funds are actually decreasing. I have been led to understand that next year present NIH support for our project will be reduced 10 percent as part

of an across-the-board reduction in existing grants. In addition I might also mention that phasing out of the training grant at our laboratory and also of fellowship support and the reduction in phasing out of general research support we estimate has cost the laboratory a quarter of a million dollars in support.

In addition, it is currently extremely difficult or totally impossible to obtain research support from private foundations. An example is the John A. Hartford Foundation in New York which has so generously helped to support a number of projects in the past, including our own. Because of financial difficulties involving A & P stock, they recently informed us that regardless of scientific merit, they would be unable to support any new proposals or requests for competitive renewal (including our own) for at least 1 year, or possibly longer.

Lack of vigorous support for diabetes research raises three serious questions:

First, since juvenile diabetics now survive through maturity and have children, the number of diabetics in the general population will continually increase. How will we deal with the problem of caring for larger and larger numbers of diabetic patients?

Second, there is concern as to whether commercial supplies of insulin will prove sufficient to meet demands over the next one or two decades. If not, how will we treat the one-half million patients in this country who currently require daily injections of insulin to remain alive?

Third, recent experiments in our laboratory have demonstrated that implantation of insulin-producing cells grown in tissue culture will cure severely diabetic laboratory rodents.

How can these findings be developed into a practical means for treating human diabetes without support for additional tissue culture and implantation studies both by our own and by other groups?

I might add that progress in accumulating a sufficiently large bank of insulin producing cells for our implantation work has recently been severely hampered by lack of funds for new personnel, for equipment, and for construction of additional tissue culture facilities.

Thank you.

I might also comment on a comment made by Dr. Field concerning the cure for polio. This is of great interest to me because Dr. John Anders, who, as you know, is one of the founders of virology and was instrumental in enabling a cure for polio to come about and is quite interested in our own work and we have collaborated with his group in some of our projects, but I might say this collaboration, however, has been seriously hurt by lack of funds to build additional facilities which would enable us to handle some of these potentially hazardous viruses.

Mr. ROGERS. May I ask you about the possible breakthrough where the animal has been cured? Could you tell us a little bit about that?

Mr. CHICK. Well, I would like to comment basically on two breakthroughs which I feel really are very significant and as to which I personally feel that a major amount of funding should be directed.

One is the project going on in a laboratory directed by Stewart Soeldner on an important beta cell.

Mr. ROGERS. What is his name?

Dr. CHICK. Dr. Stewart Soeldner, S-o-e-l-d-n-e-r.

Mr. ROGERS. Where is he located?

Dr. CHICK. He is located at the Joslin Laboratory.

Mr. ROGERS. Thank you.

Dr. CHICK. This is one area which really offers the potentiality for a so-called "cure for diabetes" in the foreseeable future.

The second is the possibility of being able to implant insulin producing cells into human diabetics whether these be freshly isolated cells or cells that have been maintained in tissue culture or actually in the test tube for variable periods of time.

Work involving implantation of the freshly isolated cells is going on at other laboratories in his country. As far as I know, work involving implantation of cells growing in a monolac culture is at this time only going on in our own laboratories at Joslin.

This work involves removing pancreas from new born rats. These cells in these pancreas are disassociated and they are essentially maintained in a sterile nutrient medium within an incubator within the laboratory for variable periods of time ranging up to several weeks, at which time they can be harvested and injected into animals which have been made diabetic with chemicals.

The results of our preliminary experiments appear exceedingly promising.

Mr. ROGERS. I think it would be well if you could let us have an outlined statement on these two particular research projects, the name of the investigator, and the funding that would be necessary, I would like to take it up with the committee when I receive it.

Dr. CHICK. I might mention that we have at this point not applied to the National Institutes of Health for supplemental funding for these projects, mainly because it takes immediately somewhere between 1 to 3 months of constant work to write up a grant.

Mr. ROGERS. You send it to me and we will see if we can't cut down on the time. Just give me a little summary.

Dr. CHICK. The only point I try to make here is this.

Mr. ROGERS. I understand.

Dr. CHICK. We hate to invest the time when we know that the chance of getting the grant funded are so low.

Mr. ROGERS. Well, I can understand that feeling. I hope we can change a little of that.

Dr. White?

Dr. WHITE. Thank you very much. I think it is evident we support the bill H.R. 4882.

Mr. ROGERS. I would like to say, on behalf of the committee, that the testimony has been most impressive and I hope many people all over the country will have the opportunity to read it. I think they will. Certainly, it will be brought to the attention of the Congress. I think you have made a real impact.

Dr. WHITE. Thank you.

May John speak a minute?

Mr. ROGERS. Yes.

#### STATEMENT OF JOHN MASON

Mr. MASON. I am John Mason and I am from Woods Hole as Dr. White mentioned in the beginning.

Unfortunately, I don't have a written statement prepared as I was just blown in from the sea by the fate of the winds and I can only say I hope the same winds which brought me the good fortune to be here do

the same for the ship of state and steer it in the direction to look favorably upon the bill we are considering here today.

I would just like to shortly mention one thing that I think has been a little bit passed over. I feel, as I say, very fortunate to be here today for three basic reasons. One is the Joslin Clinic which taught me everything I know about how to handle the disease.

The second is Dr. Priscilla White, whom I consider a sincere comrade and who has enabled me to handle the problem which I have, and the third is my parents whose love and devotion and help all through my life has enabled me to go through the past 15 years with diabetes.

I could be sitting here, as many people mentioned, with a white cane in my hand not being able to look at you, or possibly in a wheelchair without a foot or leg, but I am not because of these three things that have given me the ability to look at life and to deal with it to this point in time successfully.

But, as we all know, that is not the way it is intended to be forever and I think probably one of the reasons that we are all here is that we feel that diabetes is one of the least understood by the general public of the diseases.

We talk about it being the fifth killer or the seventh, depending on who is talking, but still it is a major killer and yet the general public is not aware of that.

Maybe that is not so hard to understand when a national agency claims that diabetes is one of the most widespread and important of their focuses, yet for fiscal 1974, it only delegates 5 percent of their budget to it.

I think I would make an analogy of the understanding, the general understanding of cancer, to the use by physicians of bloodletting versus the use of penicillin.

I think the analogy is not too far off base. But diabetes is not only a physical problem, but an emotional problem that Dr. Younger mentioned and I think that is a very serious problem because as young children we are very susceptible to our emotions.

It takes, obviously, money for research and things like that, but it also takes knowledge: it takes information of the general public to be able to handle a problem like this. I would just like to give two quick instances before I close of things that have come to my attention.

One was from a father, on the very vessel I just left, who just discovered that his daughter, 3 weeks overdue in pregnancy, had just been diagnosed as a diabetic.

Having seen me use a needle every morning on the boat, he was aware of my problem and came to me with one of the longest and saddest faces I have ever seen and asked me what was in store for his daughter and for his grandchild.

There was not much I could tell him except that under the good control that I have been able to maintain with the help of Dr. White and the Joslin Clinic there were great possibilities, but he didn't know, he was not aware, he was scared.

The second instance is a personal instance which, because of good family background, was only a minor catastrophe but, given another family, might have been a major catastrophe.

Picture, if you will, a 15-year-old child sitting on the backstairs of his house while his parents who have undergone the tension of this

disease for 2 years, due to a great deal of tension, in a discussion, say that they wished the child could have died rather than undergo the possibility which may be in store and the child hearing that statement from his own mother.

This could be a severe disaster in any family and believe me in many cases I am sure that it has occurred and caused many children to rebel. Perhaps even ending in their own death from rebellion.

I feel very fortunate to be here to have had these few seconds of your time. I only ask you to consider that you are in control of the possibility of 20 years from now, myself, being able to come back here in the same condition that I am in now and speak to you on the same subject.

Thank you, sir.

Mr. ROGERS. Thank you very much, Mr. Mason, for a very impressive statement. Hopefully this committee can take action that will enable you to visit us in 20 years and I am sure this committee will do what it can.

Before we adjourn I might say the committee would like to give each of these young people a book on the Capitol as a memento of their visit here.

We appreciate, Dr. White, your presence here today and the help you have given the committee.

Thanks to all of you, the session today has been most helpful.

The committee stands adjourned until Wednesday at 10 o'clock.

[Whereupon, at 1:40 p.m. the committee adjourned, to reconvene at 10 a.m., Wednesday, August 1, 1973.]

# NATIONAL DIABETES ACT OF 1973

WEDNESDAY, AUGUST 1, 1973

HOUSE OF REPRESENTATIVES,  
SUBCOMMITTEE ON PUBLIC HEALTH AND ENVIRONMENT,  
COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE,  
*Washington, D.C.*

The subcommittee met at 10 a.m., pursuant to notice, in room 2216, Rayburn House Office Building, Hon. Paul G. Rogers, chairman, presiding.

Mr. ROGERS. The subcommittee will come to order, please. We are continuing our hearings on proposed legislation to amend the Public Health Act to expand the authority of the National Institute of Arthritis, Metabolism, and Digestive Diseases in order to advance the national attack on diabetes.

Our first witness this morning is our distinguished colleague from Michigan who has been a driving force in the Congress for action on this legislation and is the author of a number of bills to focus in on this problem.

We welcome him, and will be pleased to have him come to the committee now, the Honorable Guy Vander Jagt.

## STATEMENT OF HON. GUY VANDER JAGT, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

Mr. VANDER JAGT. Thank you very much, Mr. Chairman, and members of the subcommittee. I am very, very grateful that this committee is holding hearings on this legislation, the National Diabetes Act of 1973. That appreciation is underscored by my own awareness of the almost awesome list of responsibilities before this committee, making it, I think, one of the busiest and hardest working subcommittees in the Congress.

And on the theory that actions speak louder than words, I would like to demonstrate that appreciation by giving only a very brief oral statement, submitting to you my formal statement for the record.

Mr. ROGERS. And without objection, your statement will be made a part of the record following your oral presentation.

Mr. VANDER JAGT. I feel secure in demonstrating my appreciation in this way, because I am aware of the outstanding medical testimony and case history that the committee received on Friday, and of the very excellent witnesses that are yet to appear.

I would like the thrust of my remarks to be directed to only one concern, and that is that the committee take the subject of diabetes from the bottom of the pile and put it on the top of that very immense

pile of concerns that the committee has; that diabetes be moved from the back burner to the committee's front burner.

I am convinced that if that is done, the great sensitivity, the intelligence and the commitment that this committee has demonstrated in formulating great health legislation in the past, will result in a strengthening of the Federal commitment to the attack on diabetes.

I am convinced that that would be the result because the need is so overwhelming. Diabetes is the fifth leading cause of death in the United States, the second leading cause of blindness, and a major cause of heart attack. One out of every 45 Americans at the instant that we sit here is suffering from diabetes. If you break that down into family groups, 1 out of every 10 Americans right now has his life directly affected by diabetes.

And I think a good indication of diabetes' prevalence is that 100 of our colleagues have cosponsored this legislation, many of them because they themselves or an immediate member of their family is suffering from this very dread disease.

I think it would be safe to say that there is no disease in America from which more Americans suffer, yet about which less is known, than diabetes. That is not too surprising, because right now diabetes is buried deep amid the many concerns of the National Institute of Arthritis, Metabolism, and Digestive Diseases.

One-half of 1 percent of the budget of NIH is devoted to the attack on this disease, which is the fifth leading cause of death in America, the disease that affects directly the lives of 1 out of every 10 Americans.

I think you will hear testimony—if you have not already heard it—that we are on the verge of some very significant medical breakthroughs in diabetes, but whether those breakthroughs come will depend on whether or not this committee and the Congress provides the impetus to push over the top on the breakthroughs.

In a representative study in Michigan covering 1 million school-children, it was discovered that 1 out of 600 children were suffering from diabetes. Our general assumption has been that diabetes occurs in 1 out of 2,500 persons. I think that shows the inadequacy of even our knowledge of incidence of this disease.

So this legislation, or some related means of strengthening the national attack on diabetes, can very literally give hope and help to millions of Americans today. For many of them, their lives depend on what this committee does.

I simply close by raising the poet's rhetorical question, "If not now, then when? If not you, then who?"

Thank you very much.

Mr. ROGERS. Thank you very much for an excellent statement. I am sure that the committee is anxious to try to do something in this area. We are having some problems this year in that field, but I am hopeful that the committee can design some legislation that will be helpful.

Mr. VANDER JAGT. Thank you very much.

[Mr. Vander Jagt's prepared statement follows:]

STATEMENT OF HON. GUY VANDER JAGT, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

Mr. Chairman, as the sponsor of H.R. 4882 and related bills I am deeply grateful that you and your subcommittee colleagues, despite an awesome legislative schedule, have convened hearings on the adequacy of Federal efforts to overcome the disease of diabetes. I am confident that these sessions will lead to an increased commitment of our resources to meet this expanding health problem.

Last Friday, the subcommittee heard extensive testimony on diabetes from the medical community, and also heard from a number of young people who are facing the future under this affliction. In recognition of your schedule and of the outstanding testimony that you already have heard and will hear later today, I will be very brief.

In his statement on Friday, Dr. John Zapp, Deputy Assistant Secretary for Legislation, Department of Health, Education and Welfare, said, "A major reason for the establishment in 1950 of the NIAMDD was to focus the national research effort on the problem of metabolic diseases, among which diabetes is the most widespread and important." I appreciate Dr. Zapp's description of diabetes' severity and significance, even if I do not share his conclusions as to the adequacy of current Federal support of research, training and demonstration programs in this field. I merely point to the level of funding for diabetes within the Institute and related agencies to illustrate that this disease is not receiving the emphasis in Federal health initiatives which its importance warrants.

Mr. Chairman, Friday's testimony should totally dispell any notion that diabetics who take the prescribed insulin shots live completely normal lives. Physically and emotionally, in their family life and in occupational roles, diabetics live with serious debilitation. Yet we too often dismiss this problem as if it has been eradicated by the availability of insulin. But events such as the recent death of Jackie Robinson jar us back to reality. We know so little about a disease that affects so many of our people, about a disease that is a leading cause of blindness and a major cause of heart attacks, strokes and blood vessel disorder, that sharply reduce life expectancy and causes millions of people to observe a strict regimen. It is a costly disease, not only in terms of national income lost by persons who are unable to work or severely restricted in their occupations, but also in terms of the expense which individuals and families who experience it must meet in order to sustain life.

A recent Michigan survey of more than 1 million school children revealed that 1 child out of every 587 has diabetes. This statistic contrasts sharply with the traditional national estimate of 1 in every 2500. The disparity in statistics itself expresses the inadequacy of our detection programs.

Mr. Chairman, the portion of H.R. 4882 that is identified as "Findings and Declaration of Purpose" speaks to the enormous need for expanded efforts at early detection of diabetes, at research into better means of treating the disease and at a means of preventing its onset. We need additional personnel who have the skills to apply improved treatment and to counsel those persons who become diabetic or who face its complications. You have heard that dramatic breakthroughs may be very close, yet can only be achieved with an acceleration of Federal support. In my view it is tragic that this nation is devoting only about \$1.25 per diabetic each year for research and related activities.

98 Members of the House, in joining Congressman Bill Steiger and myself as sponsors of H.R. 4882, urge this subcommittee to chart an expanded course, integrated with other health programs, that will give a higher priority to the health needs of 5 million diabetic Americans. We look at H.R. 4882 as a working paper, as a draft embodying basic components and a commitment which we hope this subcommittee, the architect of many outstanding health programs, will evaluate in its deliberations.

I appreciate this opportunity to appear before you, and to seek the enactment of legislation which will respond in an effective manner to the growing prevalence of diabetes among American children and adults.

Thank you very much, Mr. Chairman.

Mr. ROGERS. Thank you for your good work and your interest. Mr. Hastings?

Mr. HASTINGS. I have no questions, Mr. Chairman. I do want to add to what the chairman has said; certainly this subcommittee is more than willing to pursue the persistency of yourself, Mr. Vander Jagt.

I would hope that all of the people in the country who are close to the problems of diabetes will understand that it has been your persistence that has brought this matter as far as it has been brought, mainly because of your efforts, and we will obviously try to respond to the problem.

Thank you.

Mr. Vander JAGT. I thank my colleagues from New York.

Mr. ROGERS. Thank you for your presence today.

Without objection, the chair wishes to place in the record, as though read, statements submitted by Congressman William B. Widnall of New Jersey, Robert H. Mollohan of West Virginia, Jack Brinkley of Georgia, Edwin B. Forsythe of New Jersey, Robert H. Steele of Connecticut, and William S. Cohen of Maine.

**STATEMENT OF HON. WILLIAM B. WIDNALL, A REPRESENTATIVE  
IN CONGRESS FROM THE STATE OF NEW JERSEY**

MR. WIDNALL. Mr. Chairman, I appreciate the opportunity to express my views on H.R. 6192, the National Diabetes Act. I strongly support this legislation, which will provide a concerted effort to advance the national attack on diabetes.

The Federal Government is the largest sponsor of diabetes research in the United States. In fact, approximately 97 percent of all diabetes research is Government sponsored. Virtually all research is conducted under the National Institute of Arthritis, Metabolism, and Digestive Diseases.

H.R. 6192 mandates the director of the Institute to develop a program to expand, intensify and coordinate the Institute's activities respecting diabetes and related diseases. Both research and public education about the problem of diabetes will be expanded, and at least 15 centers for research and demonstration of clinical techniques will be established. An Interagency Technical Committee will coordinate those aspects of all Federal health programs and activities relating to diabetes. Finally, sufficient funding is provided by H.R. 6192 for this intensified attack on diabetes.

One must consider the devastating effects of diabetes to understand the importance of this legislation. Diabetes is the second or third leading cause of blindness, and the fifth to seventh leading cause of death in the United States. Almost 4 million Americans are diagnosed to have diabetes, and an additional 2 million persons are estimated to suffer from undiagnosed diabetes. An additional 5 million persons carry the potential to become diabetes, along with the almost 6 million presently afflicted. In the United States alone there are over 300,000 new cases annually, and it has been estimated that in 2 years 1 out of 25 Americans will fall prey to diabetes.

Diabetes is a complicated disease for which there is no permanent cure. It is considered a hereditary disorder, causing an inability to metabolize carbohydrates. Symptoms of diabetes include weakness, loss of weight, excessive hunger, and thirst, increased urination and occasionally arrested growth. Since the discovery of insulin 50 years ago, there have been no significant breakthroughs either in knowledge of the cause of diabetes or in scientific discoveries leading toward

its cure, nor are any significant breakthroughs anticipated in the near future.

Part of the reason for this failure has been a lack of concerted and high priority governmental efforts to find a cure for this disease. Diabetes' annual economic cost is estimated to be approximately \$2 billion, including medical costs, drugs and manpower loss. When one considers how the Nation's strength has been sapped because of diabetes, the importance of H.R. 6192 becomes clear. This bill will provide an effective mechanism and sufficient funding for a concerted attack on diabetes. Although expenditures on diabetes research and education will increase from previous levels, the end result of the National Diabetes Act's success will be savings to America in the long run. I strongly support this necessary, salutary and humane legislation.

**STATEMENT OF HON. ROBERT H. MOLLOHAN, A REPRESENTATIVE  
IN CONGRESS FROM THE STATE OF WEST VIRGINIA**

MR. MOLLOHAN. I am very pleased that the Subcommittee on Health and Environment has taken up consideration of H.R. 4882 and related bills designed to step up efforts to successfully deal with the problem of diabetes.

We know that diabetes is the fifth leading cause of death from disease in the United States. We also know that this disease is the second leading cause of new cases of blindness. We know that diabetes is a primary cause of circulatory ailments and thus contributes to heart attacks and amputations. But there are other things we do not know. For example, how many of our citizens actually suffer from diabetes? This we don't know because, at least from what officials in my State tell me, we do not have an effective reporting system. The cases that are diagnosed apparently represent only the "tip of the iceberg." The next question, then, is: How many of our citizens have diabetes but do not realize it? This is an important consideration because early detection is essential if this affliction is to be successfully treated before it causes physical damage. It is my hope that the legislation under consideration will provide for improved reporting and early detection systems so that health officials can do more, and do it more quickly, and thereby assist the afflicted before they suffer irreparable physical harm from diabetes.

There are many other unresolved questions that only research can answer. What causes diabetes? Is it hereditary? Can life-long dietary habits cause diabetes?

This disease, like many others, attack our elderly citizens much more prominently than persons in other age brackets. Yet, persons of all ages are susceptible to it, even the very young. Let me offer as a very poignant example a letter I received recently from a constituent:

My daughter has been a diabetic since age 6. Fortunately, her diabetes was diagnosed relatively soon after the symptoms developed so that, apparently, only a minimum of damage was done to body tissue by reason of high sugar level.

From my experience with my daughter and from study I have undertaken since her diabetes was first diagnosed, it is apparent to me that the symptoms of diabetes, particularly in children, are usually so subtle in developing and so close to the symptoms of other less significant childhood maladies that only

opport... r good medical examination and laboratory work can detect the  
 21- rly stages.

...f the disease pointedly emphasizes the need for greater research  
 21, by application of improved medical techniques, the disease can be  
 diagnosed at an earlier stage, many of the problems generally faced by diabetics  
 in their later years might be reduced or even eliminated. This probability alone  
 makes funding for research imperative. Consider, however, the possibility that  
 research can ultimately eliminate the need for insulin injection by finding a  
 suitable oral substitute for medication, or even can find a way to cure the  
 disease.

In three paragraphs this constituent has intelligently and concisely explained why diabetes legislation is so important. More research is badly needed so that this man's daughter and other youngsters do not have to live the rest of their lives facing the discomfort and inconvenience of daily insulin injections. Research is essential because it holds the key to a possible cure for this disease, a cure that, if found, would also spare from danger and impairment millions of Americans not yet born.

In the past several years, the Federal Government has made laudable efforts to improve research and treatment for heart attacks and cancer, two major killers. Diabetes is a serious problem, as well. Unfortunately, it has to this point been largely a "silent" disease with few large organizations or important individuals leading efforts to make us aware of how widespread and serious a problem diabetes is and what has to be done.

Only through expanded research can diabetes be successfully controlled and, hopefully, ultimately eradicated. This goal cannot be achieved without the Federal assistance envisioned in H.R. 4882 and related measures. It is my hope, therefore, that the members of this subcommittee will favorably report this legislation so that the entire Congress will have the opportunity to lend its support to the control and eradication of his dread affliction.

#### **STATEMENT OF HON. JACK BRINKLEY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF GEORGIA**

Mr. BRINKLEY. Mr. Chairman and members of the subcommittee, I am indeed happy to join with you in an effort to advance the national attack on diabetes. Since there is an alarming increase in the number of diabetes cases in our country, it is time that legislative action be taken to investigate the prevention and control of this incurable disease.

Diabetes has not only drawn the attention of this subcommittee, but has caused many concerned citizens throughout the United States to focus upon the widespread effects, symptoms, prevention, and therapy of diabetes; however, Mr. Chairman, there is a large number of the American people who are not familiar with any of the preventive and therapy methods used to treat this disease.

H.R. 6193 has adequate provisions to inform individuals of diagnostic, prevention, and treatment methods of diabetes. We must remember that the economically and educationally deprived person may not know about the establishment of federally funded programs to combat diabetes; also he may never inquire about such programs. Since they cannot reach us, we must contact them through well managed programs.

Another reason why I am pleased to cosponsor H.R. 6193 is the fact that there is an increasing measure of diabetes among our school-age children. First of all, Mr. Chairman, it is imperative that some steps be taken to promote good health in our Nation. Secondly, I think we should not allow our youth to be defeated by the effects of diabetes in their efforts to actualize potentials which are so vital to the success of our country.

A machine that needs repairing cannot function properly, if at all; conversely, a diseased body cannot produce efficiently. There is a simple solution for a malfunctioning machine and that is to manufacture new parts to replace old ones or even replace the machine. It is a great deal more complicated to keep a human machine producing, especially when it is highly susceptible to disease. If the simple solution of manufacturing parts for a machine were true with the human organism, all our problems would be solved. I am forced to believe that something can be done to reduce the diabetic's chances of being totally stricken by the many complications of diabetes.

In conclusion, Mr. Chairman, this is one of the most crucial stages of our decisionmaking process, especially when approximately 5 million Americans and their families will benefit from the enactment of this legislation. Advancements in this area will reduce our national diabetes statistics. Furthermore, enactment of H.R. 6193 will show the concern of Congress regarding one of this Nation's major health problems. Mr. Chairman, I strongly support this bill because it launches a national attack on diabetes. I am sure that many diabetics across the country will be highly appreciative of the concern of Congress in getting this legislation into effect.

We must not cease our efforts until this national attack on diabetes is a reality. Diabetes will not become inactive while we are making a decision, but will continue to take lives and drive diabetics into an invalid, physical state. Immediate congressional action is certainly warranted.

**STATEMENT OF HON. EDWIN B. FORSYTHE, A REPRESENTATIVE  
IN CONGRESS FROM THE STATE OF NEW JERSEY**

Mr. FORSYTHE. Mr. Chairman, first I would like to say that I am most grateful for the opportunity to testify in support of H.R. 4882, the "National Diabetes Act of 1973" and that I am very pleased your subcommittee is conducting hearings on this important legislation.

I am sure that the facts relating to diabetes are well known by members of this subcommittee, but I would like to summarize some of the most striking statistics on this disease. Clearly, diabetes is a major health problem in the United States. It afflicts approximately 5 million Americans. It is the fifth leading cause of death from disease, resulting in approximately 35,000 deaths annually. It is also the second leading cause of new cases of blindness in our country. Aside from the great human cost in suffering and loss of life, the annual cost to our economy of diabetes is estimated to be \$2 billion, including medical costs, drugs, and loss of manpower.

In addition, complications of diabetes may lead to many other serious health problems, such as deterioration of the blood vessels, the kidneys, the nervous system and, particularly, the retina of the eye.

Earlier this year, testimony before the Senate Select Committee on Nutrition and Human Needs indicated that mortality rates attributable to diabetes have increased steadily over the past 20 years. It was also revealed that, based on the widely held belief that susceptibility to diabetes is caused by a genetic defect, about 5 percent—some 10 million people—in the United States are genetically liable to the disease. While diabetes is probably the most common disease with a major genetic component as its cause, since the discovery of insulin to control the symptoms of diabetes some 50 years ago, there have been no significant breakthroughs in finding the cause of or cure for this disease. However, as one researcher stated during the Senate hearings, “genetically determined disease can be successfully treated, and diabetes is no exception. When we know the primary defect of this disease, a ‘cure’ will be found.”

Clearly, more research is needed. The report prepared by the National Institutes of Health for the HEW appropriations subcommittee this year confirms this need and indicates some of the many areas where further work on diabetes can and should be done. Some of the avenues to be explored include investigating the possibility of an infectious cause of diabetes, particularly in juvenile diabetes; further studies of the effects of nutrition on the incidence and treatment of diabetes; additional research on new methods of insulin synthesis and continued work on new developments in kidney transplants in juvenile diabetics.

Contrasted with this need is the fact that there has been a consistent decrease in Federal funds for diabetes programs since 1970. That is why legislation to expand the authority of the National Institute of Arthritis, Metabolism and Digestive Diseases to advance the national attack on diabetes is so important.

Under H.R. 4882, a national diabetes program would be established to expand and coordinate all NIH activities involving diabetes. Support would be provided for research into the causes, prevention, and control of the disease as well as for the training of specialized health personnel. This bill would also require the establishment of not less than 15 research and demonstration centers for diabetes throughout the Nation.

H.R. 4882 authorizes appropriations to carry out these programs at levels of \$25, \$35, and \$45 million for the next 3 fiscal years.

In closing, I would like to share with you portions of a very thoughtful and moving letter which I received recently from one of my constituents, Mrs. Rita Castro, of Cherry Hill, N.J. Mrs. Castro is the mother of a 9-year-old juvenile diabetic. I believe that her plea for a greater Federal commitment in the fight against diabetes speaks for itself.

Mrs. Castro writes:

Being the mother of a child, who was diagnosed diabetic at 8 years of age, I have had to learn to accept many painful facts of life for him. Not the least among them is having to administer two insulin shots a day to him, a highly restrictive diet for an active child, and difficulties in obtaining health insurance for him. I can accept these facts because they enable him to lead a relatively normal life and enable us to love and enjoy him.

There are, however, painful facts of life for him I can't accept. I can't accept the horrible complications of this disease that my good care and concern will not even prevent (diabetic blindness, stroke, and kidney failure).

There is, however, a way that we may be able to prevent these before the diseases of my son and other diabetics reach these stages, and that is with research. That, of course, takes Federal concern and Federal funds.

**STATEMENT OF HON. ROBERT H. STEELE, A REPRESENTATIVE IN  
CONGRESS FROM THE STATE OF CONNECTICUT**

Mr. STEELE. Mr. Chairman, members of the subcommittee, I appreciate this opportunity to present to the Subcommittee on Public Health and Environment testimony on behalf of the National Diabetes Act of 1973.

Let me first extend to you my most personal appreciation for holding these hearings. The subcommittee has done a great deal to familiarize the Congress with the heretofore little-understood and little-explored area of diabetes. The time is ripe for a well-coordinated national effort to control more effectively and perhaps to cure diabetes, and to provide an organized national format for diabetes education. These hearings on legislation now before this subcommittee represent a significant step toward that goal.

For many years, diabetes has been overlooked by Congress, by the executive agencies, and by the public in general. Whenever the question of Federal support for medical research has arisen, diabetes has received only low-priority funding.

Why has this been the case? The reason lies in the fact that diabetes does not have the dramatic character of cancer or polio or heart disease. Although it is the fifth leading killer disease in the country, it takes its toll in slow, subtle, and often invisible ways. It results in quiet, but lethal, degeneration of body organs. Its manner is sober and protracted, not instant or violent—and for this reason, the cruelty of diabetes often escapes public attention.

Moreover, diabetes is partially controllable through the use of insulin, and this has tended to diminish the sense of urgency about finding a cure which usually surrounds such dreaded diseases. With insulin, diabetes allows its victims to give the appearance of living a "normal" life, seemingly different from yours and mine only in requiring special medication and dietary caution. Since the diabetic under most circumstances does not look any different because of this disease, is not confined to permanent or long-term clinic treatment, and does not face death in the immediate future as a result of having diabetes, the Federal Government has closed its eyes to his desperate needs.

**CHANGES IN DIABETICS CONCEPTS**

Today, we are learning that this view is very much in error. We are learning that diabetes is among the most serious diseases affecting our population.

The statistics for diabetes are overwhelming. Conservative estimates are that more than 5 million Americans have been diagnosed as diabetic, and for each known diabetic as many as 3 other persons may carry an undetected genetic inheritance of diabetes. This means that 1 of every 10 Americans is a potential, if not actual, victim of the emotional, physical, and economic pain of diabetes.

Beyond the present diabetes population statistics, the outlook for the future is even more distressing. Because diabetes involves a genetic factor, and due to the life-prolonging use of insulin since 1921, the number of diabetics in the United States is growing at a rate that easily exceeds the growth rate of the general population. As more and more diabetics live to the age of marriage and begin to raise families,

more and more children with diabetic genetic traits are born. In fact, it is estimated that the diabetic population increases geometrically by 10 percent each year, and that by 1980 one of every five Americans will have diabetes or its genetic potential.

What do these millions of diabetics suffer? First, they must endure the daily rigor of regulating their blood sugar levels, always in fear of physical adversity ranging from minor pain to diabetic coma. While victims of the adult form of diabetes can control their disease with dietary restrictions and oral medication, the 1 million-plus victims of juvenile diabetics require daily or twice-daily injections of insulin to maintain fundamental body functions. In itself, this simple control of diabetes constitutes a significant national health hardship.

But the diabetic suffers more than the physical and emotional adversity of diabetes itself. He is also prey to the secondary complications that more often than not accompany diabetes. Although insulin treatment extends the life of the diabetic and avoids the early death that once was inevitable, it often results in the certain deterioration of the cardiovascular organs of the body. This may take the form of kidney failure, epidermal ulcers, and/or gangrenous extremities necessitating amputation. It may also take the form of diabetic retinopathy—destruction of the blood vessels in the eye leading to complete blindness. And often it means early death—the average diabetic can expect to live one-third less the time that you or I will live.

The dreadful significance of diabetes is clear. It is the fifth leading cause of death in the United States, and ranks higher when many deaths attributed to heart attack, neurological disintegration, kidney disease, and other causes that result directly from diabetes are included. It is the second leading cause of blindness. It limits life expectancy to 17 years after onset for adults and 28 years for children. It increases the chance of infant death in diabetic pregnancy. And—as if this massive human toll were not sufficient—its toll in economic terms is staggering: Including the impact of premature death, sickness, increased insurance rates, and medical diagnosis and treatment, diabetes costs over \$2 billion annually, with some estimates as high as \$4½ billion.

From these two statistics, two basic facts emerge: First, our present conceptual view of diabetes has been inadequate, and second, diabetes looms larger every year in the future of the health of the American people.

In respect to our diabetes concepts, we now know that diabetes is not a simple disease, easily treated with insulin injections. Rather, it is a complex disease system, which leads from simple insufficiencies in blood sugar levels to much more complex cardiovascular decay. And insulin is merely a control, able to prolong the life of the diabetic but not able to protect him from a myriad of other illnesses and afflictions. Insulin is a stopgap discovery; it is not a final cure.

Further, we now know that, beyond the present situation, the health problem represented by diabetes will worsen in the coming years. The percentage of the population of this country which either has in fact or is genetically inclined toward diabetes will grow; the number who suffer from diabetes-related ailments will grow; and the annual cost of diabetes will grow.

Obviously, diabetes presents a public health problem of alarming proportions. But what has been the reaction of the Federal Government thus far? Rather than mandating a full-scale national commitment to progress in diabetes control, it has done just the opposite. Whereas in fiscal year 1973 Federal diabetes research funds totaled \$8 million, for fiscal year 1974 HEW has proposed a 10-percent, \$1 million cutback. I can hardly see how this can be considered evidence of a firm Federal commitment to the Nation's diabetic population, although the Department has claimed otherwise before this subcommittee.

It is my belief that this commitment would best be provided by the diabetes legislation now before this subcommittee and the Appropriations Committee.

#### TWO-PRONGED APPROACH

The current state of diabetes research and treatment calls for a two-pronged attack—strengthening the long-term, institutional structures available to diabetes researchers and educators, and funneling an interim appropriation to diabetes research groups in order to maintain vital research programs that are threatened by projected money shortages. It is the former approach—strengthening the institutional means of dealing with diabetes—on which this subcommittee must act. The vehicle for that action, in my opinion, should be the National Diabetes Act of 1973 (H.R. 4882), of which I am a cosponsor.

Let me briefly comment on this important bill. If enacted, H.R. 4882 would move in two directions to bring us closer to a diabetes cure. In the first place, it specifies the development of a coordinated national diabetes program, under the authority of the National Institute of Arthritis, Metabolism, and Digestive Diseases. Presently, there is no such program. Diabetes research and education as they now exist are fragmented across the country, with no major coordinative body to assure cooperation and avoid duplication of efforts. This bill would provide the authority for that coordination. With an organized and streamlined system of research and information dissemination, and with improved means of public, professional, and patient education, we can bring both public awareness of diabetes and medical research for diabetes controls into sharp focus, thereby accelerating progress toward a cure.

Second, H.R. 4882, provides for brick and mortar, in the form of no less than 15 research, training, demonstration, and prevention centers. The importance of these centers, which would complement already operating private and public diabetes facilities, is self-evident. It has been projected before this subcommittee that only 20 percent of approved diabetes research grants will be funded this year—that means that the talents of 4 out of 5 research scientists who want to pursue diabetes studies will be lost. These centers will provide valuable opportunities for much of these wasted research abilities. Further, through their detection and prevention programs, the centers will contribute greatly to the direct alleviation of the sufferings of diabetic Americans. For the 5 million known diabetics, and for the 10 million more potential diabetics (those with diabetic genetic traits), the 15 or more centers will represent a firm beginning toward a strong net-

work of institutions designed specifically for combating diabetes. They will symbolize, in brick, equipment, and personnel, the intensified Federal commitment to a diabetes cure.

In order to finance this coordinated program and these centers, H.R. 4882 provides authorizations in the amounts of \$25 million for fiscal year 1974, \$35 million for fiscal year 1975, and \$45 million for fiscal year 1976.

Perhaps I can highlight the importance of this long-range fortification of diabetes institutional by outlining the second prong of my approach to diabetes in this congressional session. There is right now a desperate need in some research laboratories for emergency funding relief to keep vital diabetes projects alive. At least four prominent research groups across the country are near to a major breakthrough—the ability to implant cells in the pancreas which restore the insulin-secreting function lacking in diabetics. This discovery could mean the cure for the 5-million-plus diabetics in the United States. Yet, due to a lack of funds, these projects are about to close or to be drastically curtailed. Thus, while possibly on the eve of a monumental breakthrough, the lights in these laboratories could go out. And it is important to remember that cell implantation represents only one of many areas in which significant diabetes research is taking place.

To insure that these and other projects do not die, I have introduced a bill (H.R. 9304), now before the Appropriations Committee, which would appropriate \$20 million in emergency funding for diabetes research. It is my prayer that this one-time dollar boost, by keeping these projects going and by providing money for a number of presently unfunded projects, can push us through some of the major barriers now confronting researchers.

But this bill is only an interim measure. It makes emergency funds available for 1 year, but it does not change the fact that these—and indeed most—diabetes research groups must work on a month-to-month basis, never sure of continued funding for any length of time.

What is really needed, as has been pointed out repeatedly in these hearings, is a means of guaranteeing continued long-term support for diabetes research efforts. It is toward this goal that H.R. 4882 is directed. By establishing a well-coordinated national program for diabetes, falling within the permanent authority of the NIAMDD, and by providing for the opening of a large number of research and prevention centers, Congress will have signaled through concrete action its determination to minimize the sufferings of growing diabetic population as rapidly and completely as possible.

#### ECONOMIC PERSPECTIVE

Let me make one final point. Beyond its immense costs in human lives, suffering, and grief, diabetes inflicts huge economic adversity in the United States. Diabetes is more than a national health problem; it is an expensive one. Its raw economics prove the value of the congressional action proposed here. For example: H.R. 4882 authorizes for fiscal year 1974 \$25 million for the diabetes prevention and control program. Using the conservative 5 million diabetes population estimate, that is only \$5 per known diabetic. The average diabetic spends that much every week for medication and treatment. In 2 days,

diabetics spend more to care for their disease than the Federal Government spends in a year to cure it.

The rate of return for the investment under consideration is phenomenal—a \$2 billion yearly expense wiped out with a \$25 to \$45 million infusion of research funds. Clearly—and even without taking into account at all the physical and emotional hardships diabetes causes—an expanded Federal commitment to a diabetes cure represents legislating at its wisest.

In closing, I must emphasize to the subcommittee how essential this diabetes bill is. It will provide education and hope for millions of diabetics—hope that they will be cured, and hope that their descendants will not have to face the possibility of a diabetic life. But even more importantly, it will provide a sound, concrete program for the realization of those hopes, through national coordination of diabetes research and education and through the creation of physical plants for carrying out that research and education. And in making these provisions, H.R. 4882 authorizes only modest sums of money for probing what is now understood to be one of the Nation's most deadly diseases. Unarguably, it is a strong and reasonable piece of legislation.

It is my belief that the subcommittee shares this viewpoint, and that these hearings will come to be known as a major turning point in the conquest of diabetes mellitus.

I am eagerly looking forward to your favorable action on the National Diabetes Act of 1973.

Thank you very much for this opportunity to submit this testimony into the subcommittee hearing record.

**STATEMENT OF HON. WILLIAM S. COHEN, A REPRESENTATIVE IN  
CONGRESS FROM THE STATE OF MAINE**

Mr. COHEN. It is my privilege today to offer support for legislation introduced earlier this year by my colleagues, Congressmen Vander Jagt and Steiger, to initiate an attack on diabetes, one of the leading health problems in the Nation. This legislation, the National Diabetes Act of 1973 (H.R. 8882), would expand the authority of the National Institute of Arthritis, Metabolism, and Digestive Diseases to launch a long overdue national attack on the disease.

The need for this legislation is underscored by the fact that diabetes remains an extremely prevalent and complicated disease for which there is no cure. The national morbidity and mortality statistics for diabetes are difficult to assess because this hereditary disease not only affects the metabolism of carbohydrates—fats and proteins—but has long-term degenerative effects on the small blood vessels and the cardiovascular system. Thus, it is probable that many statistics listing the cause of death as "heart disease," "kidney disease," and "stroke" may actually be concealing the true magnitude of the effect of diabetes. But let us nonetheless examine those statistics as they are understood today.

It has been variously estimated by the National Center for Health Statistics, the American Diabetes Association, and the biomedical community at large that as many as 5 to 10 million people are afflicted with diabetes and that more than half this number are presently undiagnosed. The National Center for Health Statistics, for instance,

lists 3.8 million people as diagnosed diabetics in 1972 and 2 million undiagnosed cases for a total of 5.8 million people. It is estimated that there are 325,000 new cases of diabetes in the Nation each year and that from 35,000 to 38,000 die from the disease annually. The latter statistic does not include deaths from heart disease, stroke, and kidney disease.

Because diabetes has been identified as a hereditary (genetic) disease, it has been estimated that from 10 to 20 percent of the population carries the trait and that by 1980, one in five people will either be afflicted with the disease outright or carry it as a genetic trait to be passed on to their offspring. This statistic is particularly awesome when one considers that the reproductive capacity of the general diabetes population is not adversely affected enough to prevent the rapid proliferation of the disease. Thus it is further estimated that the incidence of diabetes will geometrically progress at a rate of 10 percent annually. Some experts have predicted a virtually total diabetic society within five generations if the disease is not checked soon.

To summarize these statistics, it is variously estimated that diabetes is the fifth to seventh leading cause of death and the second to third leading cause of blindness in the Nation. In terms of economic impact, the annual cost of diabetes is estimated to be approximately \$2 billion. Yet less than \$10 million annually is spent by the Federal Government for diabetes programs. This amounts to about \$1.60 per diabetic victim per year and this figure is threatened with a further reduction to \$1.25 in fiscal year 1974. Let us further examine these puzzling Federal funding figures for all aspects of diabetes research and control.

To begin with, the Federal Government is the largest sponsor of diabetes research in the Nation. Most funds for this research—71 percent—are administered by the National Institutes of Health, specifically by the National Institute of Arthritis, Metabolism, and Digestive Diseases and by the National Eye Institute. An additional 13 percent of all diabetes research money originates from other Federal sources. The remaining 16 percent originates from non-Federal, private foundations such as the American Diabetes Association. Thus the Federal Government is responsible for 84 percent of all funds spent for diabetes research.

In terms of actual Federal moneys spent for diabetes research, the largest budget is controlled by the National Institute of Arthritis, Metabolism, and Digestive Diseases. In fiscal year 1974, this budget is estimated to be \$7.1 million. An additional \$1.6 million is indicated for the National Eye Institute for research on diabetic retinopathy. If one excludes funds spent for basic endocrinological and metabolic research, the total Federal expenditure for diabetes, as mentioned earlier, is less than \$10 million. Juxtaposed against the 5 million or more people estimated to be afflicted with diabetes in one form or another at an annual cost to the U.S. economy of \$2 billion, this sum is inadequate to the point of ridicule. And, while the incidence of diabetes is shown to be increasing at the rate of 10 percent per year, the Federal commitment for diabetes research has steadily decreased, rather than increased, since 1969. For example, the principal NIH budget for diabetes programs has decreased from slightly more than \$9 million in fiscal year 1969 to slightly more than an estimated \$7 million in fiscal year 1974, a \$2 million decrease in 5 years. This

decrease is all the more significant when one considers the negative impact of inflation on the buying power of the research dollar during this period.

One clear answer to this extraordinary dilemma is that Federal funds for diabetes research must be increased substantially. The statistic of 2 million undiagnosed diabetics in this country provides a compelling argument for stronger Federal health delivery and research programs geared to diagnose, control the symptoms, and prevent long-term vascular degeneration caused by diabetes.

The National Diabetes Act of 1973 H.R. 4882 would be a major step toward solving some of these problems I have described. The bill would direct the establishment of a national diabetes program to expand, intensify, and coordinate the activities of the National Institute of Arthritis, Metabolism, and Digestive Diseases relative in its diabetes programs. It would provide for expanded research obligations, increased educational efforts, and professional programs associated with the disease. To carry out a successful program for diabetes prevention, control, and treatment, the act would authorize an appropriation of \$25 million in fiscal year 1973, \$35 million in fiscal year 1974, and \$45 million in fiscal year 1975.

The provisions of this act offer effective means for utilizing our enormous health resources to fight this increasingly prevalent and economically disastrous disease, not only at the Federal level, but at the local government and non-Federal levels. It would, for example, direct the National Institute of Arthritis, Metabolism, and Digestive Diseases to cooperate with other Federal health agencies, as well as State, local, regional, and nonprofit health facilities to prevent, diagnose, and control the disease, particularly in children.

In short, the act would be a first step in providing sufficient Federal funds to implement a truly meaningful national assault on diabetes. I strongly urge the adoption of H.R. 4882.

Mr. ROGERS. Our next witness is Mr. Robert Kronowitt, chairman of the board of directors, Juvenile Diabetes Foundation, Fort Lauderdale, Fla., accompanied by Gary Kleiman. We welcome you gentlemen, particularly being from Florida. I know of the good work you have done. The contact we have had has been most helpful in determining for me personally the problems involved in this disease and the necessity for greater emphasis in research.

We welcome you to the committee.

**STATEMENTS OF ROBERT KRONOWITT, CHAIRMAN, BOARD OF DIRECTORS, JUVENILE DIABETES FOUNDATION; AND GARY KLEIMAN, MIAMI BEACH, FLA.**

Mr. KRONOWITT. Thank you, sir. I am going to read a prepared statement, Mr. Rogers, and there is much more feeling than we can put in a prepared statement, but I think you all know how we do feel.

Gentlemen, we thank you for the opportunity to testify before your committee.

I am here as chairman of the board of the Juvenile Diabetes Foundation, formed less than 3 years ago by a group of parents of children with juvenile diabetes who were gravely concerned about the

appalling lack of information available about juvenile diabetes and the quality of the information that was available.

It quickly became apparent that the basic tenets of the foundation—namely, dissemination of information and education, family counseling, and funding of research—needed a priority rating. That priority has been given to the funding of research to find the answers that ultimately may save our children's lives.

To establish our credibility as spokesmen for a rapidly growing and extremely concerned group, the following facts are pertinent. The Juvenile Diabetes Foundation became a national organization just 5 months ago—there are now chapters forming in 17 States, representing thousands of families, with applications from many others. The reason for this explosive growth, in our view, has been that we have supplied a focal point for all those who do not understand why so little has been done in the past, for those who are disenchanted with the public information available.

I do not wish to belabor the statistics concerning diabetes in general and juvenile diabetes in particular. I will touch only briefly in this statement on a very few of the relevant figures—for ample, testimony has been heard before this committee from eminent physicians, investigators, and concerned individuals that diabetes is a devastatingly serious disease that has been shunted aside as the stepchild of major chronic diseases.

At the outset, I submit the testimony of Carl Stenzler, chairman of the Commonwealth of Pennsylvania Governor's Committee on Diabetes and Blindness given before the U.S. Senate Subcommittee on Health, February 26, 1973.<sup>1</sup>

I also submit the testimony given by Mrs. Edwin Ducat, president of the Juvenile Diabetes Foundation, at that same hearing.<sup>1</sup> Their testimony attests that juvenile diabetes kills, blinds, and maims our children in frighteningly increasing numbers every year.

To list quickly the figures:

There are 12 million diagnosed and undiagnosed diabetics in the United States.

There are 1 million juvenile (insulin-dependent) diabetics.

And 50 percent of all juvenile diabetics will suffer one or more of its devastating complications: Kidney failure; stroke; blindness; amputations; or death within 27 years of the onset of the disease.

But these are statistics, and all of us become inured to them. We tend to forget just what these statistics mean. Sitting with me is Gary Kleiman, 20 years old, a juvenile diabetic for 12 years. Gary, like a million others with juvenile diabetes, took his insulin shot daily, watched his diet, took care of himself under the finest medical supervision available. He was an amateur tennis champion, a talented art major. Fifteen months ago his eyes began to hemorrhage. He is now totally blind in one eye with 30 percent vision in the other and waiting daily for the final hemorrhaging that will mean total blindness.

We have many such case histories that we could read into this record. This is not an isolated case. It is but one of the 155,000 cases of retinopathy in this country that no amount of prior care can prevent.

But there is another aspect to the story of diabetes which is the basic purpose of this testimony.

<sup>1</sup> The text of the statements may be found in the printed hearings of the Committee on Labor and Public Welfare, Subcommittee on Health, U.S. Senate, held February 26, 1973, entitled "National Diabetes Research and Education Act, 1973."

That part of the story concerns the very real hope that the ultimate answer to those devastating complications is within the reach of researchers, not just within our lifetime, not just within a decade, but well within the next few years.

Existing research programs have already made diabetic rats non-diabetic. Researchers have already shown that insulin-producing cells can be reproduced in the laboratory and can serve as a transplant resource in smaller animals. Experimentation is now being done in this area on primates and is in urgent need of support. Other areas of investigation are concerned with the artificial pancreas, fundamental causes of the vascular disease in association with diabetes, to reverse and prevent vascular deterioration, but these are areas for the medical profession to discuss and identify.

Thus, major breakthroughs are possible although no one is in a position to project a timetable. The important point to be made is that these ongoing programs are on the verge of termination simply for lack of money. We will be pleased to identify those programs across the country—all previously approved, but not funded by the NIH—with specific details as to program funding needed, and the date it is anticipated that these programs will be terminated for lack of funds.

Mr. ROGERS. I think it would be very helpful to the committee to have this information if you will make it available.

Mr. KRONOWITT. We shall have it to you within a week, sir.

Mr. ROGERS. Thank you.

[The information requested was not available to the committee at the time of printing:]

Mr. KRONOWITT. If research funds are not available, people in diabetes research naturally will have to look for work in other fields, and may not be able to resume their work in diabetes since research can't be turned on and off with the flip of a switch. It may be too late and years of progress will be lost. In the meantime, the annual financial cost of diabetes to this Nation of \$4½ billion, and the horrendous cost in human life and suffering will go on, all for the lack of appropriate action in sufficient time.

We need bill H.R. 4882 to attack the underlying causes of diabetes, and we also need immediate emergency funding of existing research programs to prevent their imminent dismantling.

We place in your hands the lives of a million juvenile diabetics, 11 million more adult diabetics, and the concern of their families for a total of approximately 50 million persons—one-fourth of your entire constituency.

I submit an article from the New York Times dated Washington, July 26, 1973 [see p. 116], which stipulates that \$1.1 billion in health funds appropriated by Congress have not been spent by the health-related agencies of the Department of Health, Education, and Welfare.

To the average layman who looks to our Government and our elected representatives to act on our behalf, it is incomprehensible that a billion dollars should lie fallow while one one-hundredth of that amount would give 12 million citizens an excellent chance for avoiding death or slow destruction, organ by organ, from the ravages of diabetes.

The Juvenile Diabetes Foundation shall do everything within its power to support a viable research program in diabetes—thousands

upon thousands of parents of juvenile diabetics across the country are giving their support in the effort to maintain these research programs that hold the promise of an end to mankind's oldest recognized scourge. But help is needed now.

We are vitally concerned with the length of time needed to implement the allocation of money so desperately needed. We urge particular attention to existing programs. We believe the magnitude of the problem has been amply substantiated, and feel that while careful scrutinizing of viable programs is a necessity, delay in funding will prove that caution has resulted in the irretrievable loss of lives and time.

We ask that this committee find the means to fund now those recognized research programs—approved by the NIH—before these programs are dismantled and the years and lives are lost.

Control is not a cure. It keeps a diabetic alive.

Diabetes is a sentence of death for 50 percent of all its victims.

Those who point with pride at their longevity in living with diabetes do a disservice to that 50 percent with juvenile diabetes.

Thank you, sir.

[The article from the New York Times, referred to follows:]

[From the New York Times]

#### A BILLION IN HEALTH FUNDS FOUND UNSPENT BY HEW

(By Harold M. Schmeck, Jr.)

WASHINGTON, July 26.—During the last year, the Nixon Administration did not spend nearly \$1.1-billion in funds Congress had intended for major health programs, according to figures obtained by the House Commerce Committee.

The total withheld was more than one-fifth of the roughly \$4.759-billion allotted to the Health Services and Mental Health Administration and the National Institutes of Health, the two largest health-related agencies of the Department of Health, Education, and Welfare.

The discrepancies between funds available for spending and funds spent were found in the mass of data sent to Congress by the Department.

This led to an exchange of letters between the Commerce Committee chairman, Representative Harley O. Staggers, Democrat of West Virginia, and Caspar W. Weinberger, Secretary of Health, Education, and Welfare.

"I am dismayed that you have felt it appropriate to impound the billion dollars your letter describes," Mr. Staggers said in the latest letter, which he made public. "I am not convinced that this is legal, necessary, or in the best interests of the people of our nation."

He asked the Secretary for program-by-program justification for not spending the money that was allocated in the continuing Congressional resolution under which the department's spending was authorized during the 1973 fiscal year.

The funds authorized by the resolution were, in effect, appropriations. They were handled through the resolution mechanism because of the President's veto of the health appropriation bill for 1973.

In a letter to Mr. Staggers, Secretary Weinberger defended the withholding of the funds as legal, but a spokesman for the Commerce Committee said there had not yet been a reply to the request for a program-by-program analysis.

A detailed breakdown of the unspent funds showed that even some of the programs given special public emphasis by the President were affected. For example, the National Cancer Institute left \$58,859,000 unspent in a total budget authority of \$492,205,000.

The National Heart and Lung Institute left unspent \$44,217,000 from its permissible spending level of \$300-million.

Most severely hit were Federal mental health programs of \$743,723,000 available, \$199,209,000 was unspent.

The Administration's decision not to spend such large sums that had in effect, been appropriated was criticized sharply today by Representative Paul G. Rogers, chairman of the Commerce Committee's Health and Environment subcommittee.

Mr. Rogers, Democrat of Florida, said the Administration was not carrying out the laws passed by the Congress and was thus distorting the constitutional premise of the separation of powers.

Saying he considered it a "very serious situation," Mr. Rogers suggested it might be necessary to hold hearings on the subject and even to call for the resignations of officials who refuse to carry out the laws involved.

In his letter to Secretary Weinberger, Mr. Staggers said the programs in question had been created to meet specific needs, such as protection from disease, health manpower, biomedical research and improved health services of many kinds.

"Unless these needs in fact do not exist, or have been met, or are being met by alternative superior programs, then these impoundments must be considered a sad failure of our Government's commitment to serve its people," the letter said.

A spokesman for the Department of Health, Education, and Welfare said there would be no comment until Mr. Weinberger had replied to Mr. Staggers' latest letter.

Mr. ROGERS. Thank you very much, Mr. Kronowitt, for an excellent statement the concern that you and your foundation have, has provided the impetus which will allow us to try to do something with this problem.

Mr. Preyer?

Mr. PREYER. Thank you, Mr. Chairman. And I also want to thank you for a very powerful statement. It's good to have Gary here. We wish him luck.

I was particularly interested in your suggestion that major breakthroughs are possible, and I think we will want to go into the nature of those, but perhaps some of the medical professors that will be here later will give us the opportunity to do that.

You have given us a very good framework for discussing this bill. I appreciate your testimony.

Mr. KRONOWITT. Mr. Chairman, can Mr. Kleiman say a few words?

Mr. ROGERS. Yes; I thought I would call on Gary, but let's see if any of the members have any questions of you first.

Mr. CARTER. Thank you, Mr. Chairman. Let me congratulate you on your interest in diabetes, Mr. Kronowitt. It causes much more difficulty throughout our country than the proportionate support which has been given to it. It's really a dread disease.

I notice that you figure that approximately 5 percent of our youngsters—a little more than 5 percent—of our people throughout the country—are affected by diabetes.

Along with that, our young people who have diabetes are unable to take the oral medication, is that not correct?

Mr. KRONOWITT. That is correct, sir.

Mr. CARTER. As in most cases of juvenile diabetes, patients are unable to take oral medicines, which make it very difficult.

Have you had an opportunity to check the genetic factors in relation to diabetes?

Mr. KRONOWITT. Mr. Carter, I have read all the testimony given on Friday, and it's the same kind of thing that we have checked into at some length. There is a great deal of evidence that one of the causes of diabetes is hereditary, a genetic defect.

There is also some evidence to the fact that it may be caused in some cases by a virus. There is so much work to be done on the basics of this, that there really isn't any complete agreement as to a single cause. It may be several diseases in one.

Mr. CARTER. And it is closely related to arteriosclerosis?

Mr. KRONOWITT. Very closely, sir.

The oral medication you spoke of is a chemical which stimulates the pancreas to produce insulin. In a juvenile diabetic, no amount of oral medication would be effective. The pancreas simply does not produce insulin, and it must be taken by injection.

Mr. CARTER. I have been very much interested in this disease, and I never thought it had the support which it should have. Personally, I will support it, and try to give it the support which it so rightly deserves. It's one of the dread diseases afflicting a large proportion of our population.

I want to thank you for your presentation.

Mr. KRONOWITT. Thank you, sir.

Mr. ROGERS. Mr. Hastings?

Mr. HASTINGS. Thank you, Mr. Chairman. I have no questions. I would just like to make a comment, doctor, that I, along with my colleagues, certainly am most interested, and we will do our utmost to try to be of some assistance.

I am particularly interested in the project that the chairman has asked you to identify. That will be extremely helpful if you provide that list of research projects that you say are scheduled to be terminated.

Thank you very much for your testimony.

Mr. KRONOWITT. Thank you, sir.

Mr. ROGERS. Mr. Nelsen? Mr. Heinz?

Mr. HEINZ. Thank you, Mr. Chairman.

I'd like to thank Mr. Kronowitt and Mr. Kleiman for being with us. I was particularly interested in, as expressed earlier by the members of the committee, the possibilities of making some real progress in this area. And I was previously aware, of course, of the impoundment of funds, whose impoundment had been made public, I believe, on July 26 just last month.

I would just like to take this opportunity to express how much the revelation of that information underscores to me the need for the Congress to enact good and responsible antiimpoundment legislation.

That should go hand in hand, I feel, for the benefit of all our people, with a workable spending ceiling proposal. We did, I think, manage to start with an approach just last week on antiimpoundment that I feel Congress will adopt and which we will send it to the President and we will get it through somehow, because I think there are areas of human need that we are inclined to neglect, and this is certainly one of them.

So I thank you very much. I have no questions, however. I am pleased that you are with the committee.

Mr. ROGERS. Thank you. Gary, we'd be delighted to have a statement from you. I had the pleasure of getting to meet you before, and I am delighted to see you.

#### STATEMENT OF GARY KLEIMAN

Mr. KLEIMAN. I am sorry to say I have no outline, because I wouldn't be able to read it anyway. But I'd like to thank you on behalf of the diabetic population, to get a chance to speak. If I stammer or stutter

a little bit, it's just because I am getting my thoughts together a little bit.

Mr. ROGERS. That's all right. You take your time. This committee is anxious to hear what you have to say.

Mr. KLEIMAN. I will speak just about my life and about what I have learned in the last year and a half.

Thirteen years ago, in April 1960, I became a statistic, a diabetic. And at the time, the doctors felt, "Look around, Gary, it's great to have diabetes, it's controllable. You can lead a perfectly normal life."

So I went about with that attitude for the first 12 years. No problems. Never went into shock, never went into coma. I went away to a camp—not a diabetic camp, just a regular camp. I went away to college.

I became the first freshman ever to play on the varsity team at Syracuse University. And if that's not control, what is? Who could possibly do all that I have mentioned if they weren't under control?

Then in one day, February 1972, a year and a half ago. I had a checkup at Syracuse and the doctor noticed I had severe problems with my eyes. And that's when it all started.

I learned more about diabetes in the last 15 months than I ever knew existed. I have total blindness in my right eye, and I had laser beam treatment in my left eye to try to save some central vision, which it did, but it's destroyed so much of the other vision, I can just about get around.

It's hard to express the kind of education—the lack of education—that went through our family and millions of others. The idea, the myth that diabetes is controllable. The symptoms might be controllable for a period of time, but the disease is not controllable.

So I became another statistic after 1960. In 1972, I became a statistic with complications, the retinopathy, and kidney disease, and renal failure, for the most part.

So it added on another statistic. For 9 months, the only chance I had was to be a patient at Duke University and try the famous rice diet to help for the kidney and vascular deterioration. For 14 months, all I have been eating is rice and fruit. And it's helped my kidneys a little bit, but my eyesight can still go at any time now, not to mention the amputation of limbs, further complications with vascular deterioration.

During the 9 months at Duke, I met people from all ages, all walks of life, color, creed, anything. Black people, young people—a 17-year-old girl, completely blind from the disease—under perfect control her whole life.

And myself, under perfect control. So I am now another statistic, as I said, with complications.

And I have one other statistic that I am headed for—one of two—and with your help, I am hopeful that the second will shine through. I can either die of diabetes within the next 10 years, or, with your help, with immediate funding, I could be one of the new statistics with a cure.

That's what I am hoping for. Thank you.

Mr. ROGERS. Thank you very much, Gary, for relating to us how this affects a person and a family. Your testimony is most impressive. And I am very hopeful that this committee can do something that will improve the situation. Dr. Carter?

MR. CARTER. Mr. Chairman. Gary, certainly you get close to me. I have a son hardly as old as you are who has—not diabetes—but a condition which is equally dangerous.

I have always been thankful since I have served on this committee that I have never voted against anything which would be helpful in the health field.

I want to promise you that I will not break faith with you, as one member of this committee, and I feel that all members feel the same way.

I will continue to do everything in my power to help youngsters such as you and to prevent the last complication you mentioned.

MR. KLEIMAN. Thank you.

MR. ROGERS. Mr. Preyer?

MR. PREYER. Thank you, Mr. Chairman. Gary, I join Dr. Carter. I think you have made a very moving statement.

But what thrilled me in these statistics, and I am sure we all want to do all we can to help. You have done a lot for others like you who can't be here to speak for themselves.

MR. ROGERS. Mr. Nelsen?

MR. NELSEN. No comment, other than just a thank you to the young man, and to the witnesses before us today. Thank you very much.

MR. ROGERS. Mr. Hastings.

MR. HASTINGS. I can only reiterate what my colleagues have said, that certainly I will participate as much as possible to try to be of some assistance to you and the many, many people like you in the country. Thank you.

MR. ROGERS. Mr. Heinz?

MR. HEINZ. Gary, thanks. You do a particular service that Congressman Preyer touched on, and that is, you do make us aware, when we see the numbers that we see, that those numbers represent living, breathing, very much alive, very real and wonderful human beings.

I wish in a sense there were many more people who were as dedicated to being a turned on, active human being as you, and the reason for that is that I wish that all the people who work in the health area—I don't mean the members and staff of this or the Senate committee—could have more experiences in meeting and talking with people who are the victims of the disease that you are a victim of, and I think if more people at HEW and more people at NIH, more people down at 1600 Pennsylvania Avenue had more direct person-to-person experience of this kind, that they would get a different slant on things, too.

I don't say this to be critical of any individual at all, or any group of individuals. But the fact of the matter is that any bureaucracy, regardless of where it's located, tends to become insensitive—insensitive to people and to people's needs. It's almost inevitable.

But the kind of effort you have made here today I think is the kind of effort that can crack down those barriers and that can bring hope to you and to other people who have the same kind of problems that you have. Thank you very much.

MR. KLEIMAN. Thank you. Mr. Heinz, let me say just one thing. It's very true that it takes people such as myself who are afflicted with diabetes, because no one can argue with a walking person who has the problems.

But knowing myself and our family—who is for the most part above average intelligence, overall—we did not stop asking, questioning, fighting, even those 12 years that I was under control—so-called.

But the truth is, if someone came up to me with the same problems that I had and told me, while I was playing tennis, while I was doing my art work, that these complications could happen, I would probably have told them they were out of their mind.

So for that reason, for someone like me to go around, it's the least I can do personally. Because now I know. It's always going to happen to the other guy, not to me. And I believed that, I think more than anybody in the world.

I was used as a case study. Whenever anyone in our community got diabetes, or whatever complications, they would call me to say, "Hey, what's the story, how do you have diabetes and play tennis? How do you go away, what happens?" I'd say, "No problem, you take your shot, proper diet, and you'll be fine."

I met a lady one day on the street. She knew I was a diabetic and her son just became a diabetic. And I said to her just what I previously said, and I walked away. Six months later was the time I found out about my eyes.

So it's not as easy as it seems to move people to believe. I believe all too well right now, and it scares me to believe what can probably happen within the next few years.

So it takes more than just one person saying it. It takes a lot of backing.

Mr. HEINZ. It does, but it's still, nonetheless, through the effects of just one person, often, that many people are moved. Thank you.

Mr. KLEIMAN. Thank you.

Mr. ROGERS. Gary, let me ask you this. Did your family have any difficulty getting information? Where did they have to go to? Was this a problem?

Mr. KLEIMAN. Yes, sir. Well, for the most part, for the first few years, my mother was told, "Be thankful it's only diabetes." That's the first she was told.

Second, they are not looking for a cure; insulin was the control—which it's not. Diabetes is not controllable. The symptoms are controllable, but the deterioration of up and down of the blood sugar level all day long, this is not told.

The problem the physicians have is whether, for the well-being of the patient, should they tell them in 10 or 12 years you are going to be blind, have renal failure, amputation. Or do they tell them you can lead a perfectly normal life. What do they tell them?

They have to stop worrying about what they can tell them and get on the bandwagon of curing the disease, which they are on the threshold of curing.

Mr. ROGERS. Well, we are very anxious to do something. We hope we can give impetus to increased research. And I am sure this committee is very favorably impressed with your testimony. We thank you for being here Mr. Kronowitz, to represent the organization. We also thank Gary's father.

Also, I am very proud of the work that your foundation has done. I think it's excellent to get chapters in other parts of the country to bring to the attention of the American people the needs in his field. Then I think we can get action. This committee will try to participate.

Mr. HEINZ. Mr. Chairman, just to follow that, it just occurred to me, in reviewing the testimony, that there was one thing that Mr. Kronowitt said that perhaps bears just a little further explanation on his part, because it is quite important.

That is, he mentioned when he was talking about the financial research need, that one-hundredth of \$1.1 billion would have gone a long way in funding the research requirements, and I don't think I heard anyone ask him why \$11 million—if I am still able to divide by a hundred—is a number that makes some sense.

Mr. KRONOWITT. Mr. Heinz, the figure is taken from the discussions that we have had over the past year, and from I don't know how many phone calls in the past few days, since we heard we were going to testify, with eminent investigators across the country, Seattle, Boston, St. Louis, New York, et cetera.

I asked them specifically, "What are your problems?" These incidentally, are investigators, where names were given to me as each having previously been approved for funding by the NIH.

I asked each one, "How much money do you need? How long will the money you have on hand last? When will you run out?"

It was practically unanimous; they are running out by November and January—November of this year, and January of next year. They will be out of money. They will stop. And some of these programs—and I am going to try to state it in a way that one one will be offended—these are very dedicated people, most of them are on salary at universities. They are not in a position to come here and tell you that they need the money now, that they are in a position of a breakthrough. They are not in a position to say to you: If we stop now, we have to let this tissue culturist go, we have to let that gentleman go, and he will have to go into something else, and we can't ask him a year from now to come back. He's going to be gone, finished.

But I added them all up, Mr. Heinz, and they came to a good deal less than \$11 million for the next 12 months.

Mr. HEINZ. Well, you did state earlier that you would give us an indication of what those needs were.

Mr. KRONOWITT. I shall.

Mr. HEINZ. And I think we'd be most appreciative of that, as the chairman has already stated. Thank you.

Mr. KRONOWITT. I shall, indeed, sir.

Mr. HEINZ. And I thank the chairman for yielding.

Mr. ROGERS. I might mention, in the testimony of the first hearing just the other day, the Joslin Clinic people testified that they were having to reduce their research as a result of funds being cut off.

Hopefully, this committee can take action. I have asked for specifics on the research projects, particularly, as you mention, with the animals where they can become diabetes free.

So this is most encouraging, and this committee wants to see that that research is accelerated, not reduced.

Mr. KRONOWITT. Yes, sir.

Mr. ROGERS. Thank you for your presence. It's most helpful.

Mr. KRONOWITT. Thank you very much, sir. We appreciate it.

Mr. ROGERS. Our next witness is Mr. John F. Nagle from the National Federation of the Blind, Washington, D.C. Mr. Nagle, this committee welcomes you to our meeting, and we will be delighted to receive your testimony.

**STATEMENT OF JOHN F. NAGLE, CHIEF OF THE WASHINGTON OFFICE, NATIONAL FEDERATION OF THE BLIND**

Mr. NAGLE. Thank you very much, Mr. Chairman. Mr. Chairman and members of the committee, my name is John F. Nagle. I am chief of the Washington office of the National Federation of the Blind. My address is 1346 Connecticut Avenue, NW., Washington, D.C. 20036.

Mr. Chairman, we are appearing here, today, to express the full and unqualified support of the National Federation of the Blind for H.R. 4882, the National Diabetes Act of 1973.

Mr. Chairman, the National Federation of the Blind is a nationwide organization with a membership primarily of blind men and women.

Representative of every background, activity, and area in the Nation, the members of the National Federation of the Blind are rank-and-file Americans, sharing with our sighted fellow citizens the same goals and ambitions, the same talents and abilities.

By our organized efforts, by our individual example, we seek to translate hopes and objectives held in common into improved conditions and equalized opportunities for all blind people.

We as blind people know that, today, blindness does not have to be a disaster in a person's life.

But we also know that, far too often, it is a disaster because of no help or training at all, or because of inadequate or incompetent help or training necessary for adjusting to the changed circumstances resulting from loss of sight.

We as blind people believe that the economic and social consequences of blindness upon the individual, his family, and society generally are so great and grave as to justify and demand a substantial governmentally managed and financed effort to ascertain the causes and to control the consequences of diabetes in order that blindness attributable to this disease may be eradicated from the lives and experience of the men, women, and children of this Nation and throughout the entire world.

Mr. Chairman, members of the committee, I have endeavored to obtain statistics to support the crucial need for enactment of H.R. 4882, but though I have found figures aplenty, they vary to such an extent I will not cite them.

But I did learn this from my search for statistics:

Diabetes is a major disease in the Nation, affecting the lives of millions of Americans, both adults and children.

I also learned that diabetes is one of the major causes of diminished or destroyed vision in America.

And as a major disease in the Nation, as a major cause of blindness in the Nation, the dollar cost:

For health care facilities and personnel;

For rehabilitation and vocational rehabilitation facilities and personnel;

For lost earnings and welfare costs;

For vanished taxes and curtailed or terminated productivity;

And for the irreparable harm and devastating damage to the lives and livelihoods of a great number of our people—

All these are harmful to the Nation's strength and detrimental to the Nation's well-being, and demand resolution by a nationally

directed attack upon the dread disease, diabetes, that all may be freed from its ravages, that the Nation may be relieved of its cost and burden.

H.R. 4882, the National Diabetes Act of 1973, would mount just such an attack.

As American citizens with a proud concern for this Nation, we urge you to give your prompt and favorable approval to this proposed most ameliorative legislation.

As blind people, as persons who know of the consequences of diabetes in our own lives, for many of us are without sight because of diabetes, we ask and urge that you act quickly and affirmatively on H.R. 4882 that its benefits may the sooner be reflected in the lives of Americans living today, in the lives of generations of Americans who will come after us.

It is our hope that the program of research and education contained in H.R. 4882 will prove so far-reaching and so effective that in but a few years the disease diabetes will be unknown in our society, and the word "diabetes" will retain only a slight measure of interest and curiosity for the medical students and medical historians of tomorrow.

I thank you very much, Mr. Chairman, for this opportunity to appear and present these views.

Mr. ROGERS. Thank you, Mr. Nagle, for an excellent statement, and for the information you have given us in this concern on diabetes. And also for the great work that you are doing for the blind.

Mr. Nelsen?

Mr. NELSEN. Just to again emphasize the appreciation our chairman has so graciously expressed, I know those of us here appreciate the effort that you expend and the handicap that you suffer, and in spite of it all you are in there pitching, and I think you deserve our thanks and our appreciation.

Thank you very much.

Mr. ROGERS. Mr. Preyer?

Mr. PREYER. Thank you, Mr. Chairman. I have no questions. But I, too, want to thank you, Mr. Nagle, for your very impressive testimony, and for your appearance today.

Mr. ROGERS. Mr. Hastings?

Mr. HASTINGS. I have no questions, Mr. Chairman.

Mr. ROGERS. Mr. Nagle, thank you, and we are grateful to you for being here today.

Mr. NAGLE. Thank you very much, Mr. Chairman and members.

Mr. ROGERS. Thanks so much.

Our next witnesses are witnesses for the Committee on Diabetes and Blindness, Commonwealth of Pennsylvania. Mr. Carl Stenzler, chairman of the Committee on Diabetes and Blindness, and Dr. Arnall Patz and Dr. Richard H. Schwarz.

We have a most distinguished member on this committee from Pennsylvania who has been doing outstanding work in the health field, and his contribution to the work of this committee has been most beneficial to the committee. And I am sure to the people of this Nation.

It's a pleasure to call on your colleague, John Heinz, to welcome these good Pennsylvanians and give them the introduction.

Mr. HEINZ. Thank you very much, Mr. Chairman, and it's indeed a pleasure to welcome Mr. Carl Stenzler, who is the chairman of the

Committee on Diabetes and Blindness in the Commonwealth of Pennsylvania. I think a little bit of background on the committee Mr. Stenzler chairs is in order before I say a few words about Mr. Stenzler, who himself is a remarkable and unique gentleman.

The committee that he chairs is the creation of our Governor of Pennsylvania, who in 1972 created the committee, organized for the public interest and for the benefit of the people of the Commonwealth of Pennsylvania, with the following four tasks:

First, it was charged with representing the 300,000 known diabetics in Pennsylvania, and, by extension, the diabetic population of the United States.

Second, it was charged with effecting the proper identification of the disease and of its progressive debilitating nature, and to educate the public as to its findings.

Third, it was charged with developing recommendations as to needed therapeutic and research action, and to determine how funds might best be allocated.

And finally, it was mandated to lobby its recommendations to the national officials, and, of course, the Congress, in order that legislation appropriating funds for therapy and research might be obtained.

And to my knowledge, Mr. Chairman, what the Governor of our State, Governor Shapp, has done is not only unique in Pennsylvania, in the health area, but it is unique in any State that I am aware of. It is nationally unique that any Governor has created such a committee with, really, such national impact, and such great national importance.

The committee, I think, is also doubly unique in that Mr. Stenzler chairs the committee, and I'd like to tell you just a few things about Mr. Stenzler, because he is not only a unique individual, he is also statistically unique.

Mr. Stenzler became diabetic at the age of 11, in 1924. Insulin was discovered in 1922. Probably less than 1 percent of the people who have had 50 years of experience with diabetes are alive to tell about it.

Not only, therefore, does Mr. Stenzler approach the subject, therefore, with a personal experience and individual knowledge, but he has a family that also shares with him that knowledge. He has two daughters. One is a diabetic and is legally blind from it.

His other daughter, Miss Terry Stenzler, works in Washington, D.C., and on her own time, I understand, helps her father lobby for diabetes legislation.

And when I was talking with them out in the anteroom previously, I want you to know that she keeps him on the straight and narrow, and wasn't going to let him make any mistakes in talking with a member of the committee before he gave his formal testimony.

It is indeed a pleasure to introduce Mr. Stenzler, as chairman of the committee, of course along with the other two gentlemen who are here representing the committee, and who have done, as I understand it, a great deal of work with Mr. Stenzler.

Mr. Stenzler, on behalf of the State of Pennsylvania and all the people, I am personally delighted to have this opportunity to welcome you to our subcommittee. Thank you so much.

Mr. STENZLER. Thank you very much.

Mr. ROGERS. Mr. Stenzler, we welcome you and your colleagues. And if you would introduce them for the committee, that would be fine.

**STATEMENTS OF CARL STENZLER, CHAIRMAN, COMMITTEE ON DIABETES AND BLINDNESS, COMMONWEALTH OF PENNSYLVANIA; DR. ARNALL PATZ, PROFESSOR OF OPHTHALMOLOGY, DIRECTOR, DIABETIC RETINOPATHY CENTER, WILMER INSTITUTE, THE JOHNS HOPKINS HOSPITAL, AND MEMBER, BOARD OF DIRECTORS, NATIONAL SOCIETY FOR THE PREVENTION OF BLINDNESS; AND DR. RICHARD H. SCHWARZ, PROFESSOR OF OBSTETRICS AND GYNECOLOGY, UNIVERSITY OF PENNSYLVANIA SCHOOL OF MEDICINE, DIRECTOR, THE JERROLD R. GOLDING DIVISION OF FETAL MEDICINE, AND MEMBER, COMMONWEALTH OF PENNSYLVANIA COMMITTEE ON DIABETES AND BLINDNESS**

Mr. STENZLER. On my right is Dr. Arnall Patz. He is professor of ophthalmology, director of the Wilmer Ophthalmological Institute of the Johns Hopkins Hospital and Medical School.

Dr. Patz is one of the country's most respected authorities in diabetic retinopathy, there is no one that exceeds him.

On my left is Dr. Richard Schwarz. Dr. Schwarz is a professor of obstetrics gynecology at the University of Pennsylvania. Also he is director of the Jerrold R. Golding Division of Fetal Research. I think you will be surprised by my bringing a doctor here representing maternity. This is one of the facets of diabetes that have been divulged.

I regret Dr. Robert Bradley, director of Joslin Clinic is held up in Boston. The airport was closed because of the accident yesterday.

Dr. William Litkoff, professor of medicine in the Hahnemann Medical College and director of the Cardiovascular Institute, called me yesterday to say there was an emergency. I brought his statement with me plus a paper that he has written for the committee.

Mr. ROGERS. We will be glad to receive them in the record. We welcome you, Dr. Patz and Dr. Schwarz, to the committee.

[See statement of Dr. Bradley, p. 134, and Dr. Likoff, p. 136.]

Mr. STENZLER. My name is Carl Stenzler, I am a concerned layman, a diabetic, and chairman of the Committee of the Commonwealth of Pennsylvania on Diabetes.

I have a longstanding interest in developing important legislation that will initiate meaningful, urgently needed diabetes and blindness research and education.

As such, I am grateful for the opportunity to develop Commonwealth committee judgments, fears, and suggestions relevant to H.R. 4882, the National Diabetes Act of 1973.

In April—the correct year is 1972—this committee is a little over a year old; Gov. Milton Shapp, responding to lay requests for organized public interest in diabetes, created the Commonwealth of Pennsylvania Committee on Diabetes and Blindness. Governor Shapp asked me to develop and chair the committee.

A review of several hundred medical papers and medical publications, reporting on the years 1950-70—75 percent were funded with USPH money—and many consultations with medical authorities revealed an unusual unanimity of concern.

Every research conclusion identified an extraordinary number of complex, little understood, frightening complications specific to or interrelated with diabetes.

The overwhelming weight of the evidence identified vascular deterioration as the locus of concern. In time, for reasons unknown, all diabetics are subject to the relentless, progressive degeneration of the large and small blood vessels.

The average time for deterioration of clinically detectible angiopathy is 10 to 15 years after onset. Control does not prevent, at best it might retard, the degree of severity, ranges from mild to severe.

Always, the vascular destruction is potentially malignant. The circulation is broadcasting catastrophe to virtually every part of the body—eyes, heart, kidneys, brain, lower extremities, nervous, and vascular systems, teeth and gums, male and female sex competence, maternity, childbearing capabilities of diabetic mothers, and, finally, to the children of diabetic mothers who too frequently are borne malformed or with brain damage.

For the entire syndrome of major health indignities, there are no preventive, remedial, or clinically dependable arrest therapies.

The Commonwealth committee was structured to represent and make visible every important problem that is diabetes.

The composition of the Commonwealth committee—15 physicians whose judgment and authority is respected nationally and internationally, and whose areas of expertise are most impacted by diabetes.

I offer into the record a position paper that identifies the origin, purpose, and membership of the Commonwealth committee. Each member is preparing a critical summarization of his discipline. These papers will be issued by the Commonwealth of Pennsylvania in a report of findings later this year. Twelve chapters discussing diabetes, manifest in the heart, kidney, vascular degeneration, neuropathy, anesthesiology, maternity, genetics, juvenile diabetics, podiatry, and the eyes, are ready. These I offer into the record.

Mr. ROGERS. Without objection, the statement and the 12 chapters of the report will be printed as an appendix to this hearing. [See pp. 169-213.] We are grateful for the good work you have done in bringing them to the committee's attention.

Mr. STENZLER. Thank you.

"In short, diabetes is disease. It affects every part of the body. We don't know what to do." That is the way Dr. Henry Simmons, Deputy Secretary of Health, the Department of Health, Education, and Welfare, defined the diabetes problem.

Because of the mysterious origin, uncontrolled impact on all body systems, lack of preventative, remedial, and arrest therapy, and the limitation of life potential beginning with birth, terminating with premature death, indeed spilling its frightening genes onto future generations, the Commonwealth committee believes H.R. 4882 is inadequate, that as it is presently structured, it cannot cope with diabetes as we know it today.

The authors of the bill omitted a proper definition of diabetes. A statement of some consequences is inadequate. The Congress and all the people it represents should know what they are fighting. They should know and understand the monumental scope of destruction capability inherent in this disease.

If you will follow with me on the bill, I made some comments about each section under "Analysis of Findings and Declaration of Purpose."

The findings are understated or omitted. The purpose does not answer the needs projected by diabetes as it is now understood.

Section 2(1), the American Diabetes Association projects 10 million diagnosed, undiagnosed, and potential diabetics. Most doctors concur. Many believe this is an understatement. Among them is the Director of the NIAMDD, Dr. Donald Whedon. The bill identifies 5 million diabetics. The reasonable figure generally is assumed higher and tragically we really don't know how many people are afflicted. I will say this to you, I defy the man to tell me that in his vision either self or family or friends or acquaintances he doesn't see diabetes. That is an extraordinary prevalence.

Section 2, in 1949, an arbitrary reclassification of the causes of death reduced diabetes as a cause of death by 43 percent and increased cardiorenalvascular diseases as a cause of death by the same sum.

The fact that onset and onslaught are 15 or 20 years apart does not erase the prime cause. Statistics developed by Dr. Tokuhata, Commonwealth of Pennsylvania epidemiologist, placed diabetes as possibly the "third" cause of death. Senator Schweiker talked about the death certificate saying cause of death was heart disease or brain damage, or hypertension when the underlying cause is diabetes. The model reporting area for blindness, proceedings of the 1968 conference, published by HEW identified diabetes as the first cause of adult blindness affecting those between 40 and 60 years old. Public Health Service Bulletin 1000, series 10, No. 49, October 1967, identified diabetes as a major cause of limited vision. It reported 389,000 diabetics with impaired vision; 151,000 were without useful vision in either eye. This is 1964 and 1965. And, incidentally, "without useful vision in either eye is not to be equated with legal blindness." The Harvard School of Public Health Report prepared for the Retina Foundation projects 574,000 partially or totally blind diabetics by the year 2000. That's only 27 years away.

No. 3, diabetes is a systematic disease that evolves many serious health problems. The complications are not secondary.

Four, diabetes, controlled or uncontrolled, decreases life expectancy by one-third. The average duration of life after onset is 19.1 years. A juvenile or adolescent onset diabetic is expected to live an average of 30 years after diagnosis.

No. 5, H.R. 4882 does not establish an agency that would be responsible for the transmission of public information to the people. As a matter of fact, up to this present time, the NIAMDD in reports to the respective House and Senate Appropriation Committees identifies diabetes as a disease which when under control allows the diabetic to live a full, normal life. I have here several letters of rebuttal which I wish to enter into the record [see p. 136] because it is extraordinary to have the highest authority in this country, the Director of the NIAMDD, misrepresent in fact subvert, the cumulative scientific knowledge that has been developed with NIAMDD money and at the

same time contradict every U.S. health publication issued since 1950. I have 10 here.<sup>1</sup> Read them. They are awesome and frightening in what they tell you is happening, and I just don't understand Dr. Whedon saying this is a "no-sweat" disease.

No. 7, there is adequate therapy for overt diabetes. There is no therapy for duration-related stages of diabetes. The statement is ambiguous. By all the content around it it appears as though they are talking about overt diabetes that area which Dr. Whedon has given impetus for research. Acute diabetes is serious; there is no question about it; but the big problem is vascular degeneration and there H.R. 4882 omits comment.

Juvenile-type diabetes. affects almost all children, most juveniles, and some adults, is brittle, labile, unstable, projects problems in management—that's true. Coma, a serious problem of juvenile diabetes, has been reduced to 1 percent as a cause of death. Other problems can be coped with. Diabetes affects every age; it doesn't discriminate. While a mature diabetic or a mature onset is presumed to be stable, easily controlled, at diagnosis 4 percent have less than 20/100 vision; 31 percent are identified with hypertension; and about 17 percent show abnormal electrocardiograms.

The importance of where you research now. We have no money. We have very little research. From my discussions with doctors around the country there is very little on the horizon at this moment that offers much hope, and I hope the previous witness is correct but I find the term "research" is as broad as the blue sky. I would like to know what they are talking about. I find that a doctor says we are very successful if he extends the sight of a person with retinopathy from 5 years to 7 years or if a person with a transplant lives 9 months beyond the point of where death might have occurred, this is success.

These are not successful in terms of the living or those afflicted. They are a moment of something in history.

No. 9, does this statement mean early diagnosis and treatment—surely diagnosis is not a problem nor is the treatment of overt diabetes. The problem is to detect duration-related vascular degeneration early. Sight could be preserved for an indeterminant period of time

<sup>1</sup> References:

- (1) Health statistics: Diabetes reported in Interviews, United States, July 1957 to June 1959. U.S. Department of Health, Education, and Welfare. Public Health Service, series B, No. 21.
- (2) Characteristics of Persons With Diabetes, United States, July 1964 to June 1965. National Center for Health Statistics. U.S. Department of Health, Education, and Welfare. Public Health Service, series 10, No. 40.
- (3) Characteristics of Visually Impaired Persons, United States, July 1963 to June 1964. National Center for Health Statistics. U.S. Department of Health, Education, and Welfare. Public Health Service, series 10, No. 46.
- (4) Diabetes Source Book, Division of Health Services and Mental Health. U.S. Department of Health, Education, and Welfare. Public Health Service, publication No. 1168. Revised 1968.
- (5) Diabetes Control/A Public Health Guide. Public Health Service, publication No. 506. Revised 1969.
- (6) Diabetes and You. Public Health Service, publication No. 567. Revised 1968.
- (7) Diabetes Guide for Nurses. PHS Bulletin No. 861. Revised 1969.
- (8) The Model Reporting Area for Blindness. Proceedings of the 1968 conference.
- (9) Public Health Service, publication No. 1000. Series 10, No. 40, October 1967. Characteristics of Persons With Diabetes.
- (10) Diabetes Fact Book. Public Health Service Bulletin, 1962.

or the loss of sight could be retarded. There is a possibility. The young man who preceded us, if a competent ophthalmologist had seen him early? Had there been fluorosine studies which allow doctors to examine the—correct me, Dr. Patz, if I'm wrong—the fluorosine studies that allows the doctor to look into the eyes and see what the blood vessels are doing and with early laser properly administered, this boy might have been spared or given a grant of additional time. One doesn't know, but certainly early detection in terms of the angiopathy might help, whereas early detection of diabetes does not help retard or prevent vascular degeneration. It does not eliminate the major problem and I might be very blunt to say that the diabetes detection and education programs as they have existed amount to—with the knowledge we know now—nothing more than patient recruiting programs.

The problem is to detect duration-related vascular degeneration early. I spoke at great length with Dr. Likoff. Some patients, if they are caught early, the hypertension or the other problems of vascular degeneration, related to the heart, you could preserve or enlarge or extend their lifespan.

What does deserve the highest priority is the development of a therapy that will arrest the relentless progression of the deterioration of the blood vessel system. This could mean the difference between life and death. From this perspective, from talking to doctors usually of the highest authority, it appears that the research should be addressed first to seeking a therapy that will arrest blood vessel destruction. There are 10 million diabetics and if you can address research that will merely stop the relentless progression—forget remedy, forget prevention, cure is so far removed at this point that nobody really knows where to begin—just stop it; and this young man will live if you stop the relentless progression of the vascularization in his kidney and his eyes—just stop it.

Then you look for remedial therapy and then you seek preventive-type therapy and then you seek the cure.

Now I have raised the question of cure with many, many eminent men and I have gotten this answer: "We don't know where to begin." I compared it with the atomic bomb and said, "Why don't we set up an organization and bring the best brains from all over the world." The answer came back: "With the atom bomb they knew the physical laws. All they needed was the men and the money to translate them into fact."

"We don't have enough knowledge of the basic laws to even begin proper research," and that's a frightening definition.

No. 10, the existing mechanisms in NIH make it virtually impossible for a director of an institute to direct, coordinate or correlate broad-based, comprehensive research in all institutes. Dr. Whedon has not been able to establish or develop broad-based research in the NIAMDD where he directs research pertinent to diabetes; endocrinology, kidney disease, nutrition and diabetes. All four are as much a part of diabetes as is diabetes itself. There is little cooperative work within that institute. There is only meager cooperation between the other institutes, meaning the National Eye Institute and possibly the National Heart and Lung Institute. Other institutes ignore diabetes.

If you read the institute reports presented to the respective appropriations committee, the Institute of General Medical Sciences, which researches genetics, and that is the big monster in this, the proliferation potential, they don't so much as mention diabetes. If you read the reports from the Institute of Neurology and Stroke, they don't mention diabetes. And yet diabetes, because of neuropathy which destroys the sex competence of both male and female of at least half of the diabetic population, is probably one of the greatest causes of family breakup. This is not discussed.

The National Heart and Lung Institute doesn't mention diabetes, and yet each year it is estimated on good authority there are about 250,000 diabetics who die from diabetes caused heart disease.

The history of NIH and the NIAMDD is marked by indifference to diabetes and lack of understanding of the problems inherent in the disease. The bill which was to some extent influenced by Dr. Whedon, completely ignores vascular degeneration. That doesn't appear anywhere in the bill. This is the most critical challenge presented by diabetes for it equates life blindness and death.

Dr. Whedon's annual representation of diabetes as a "no sweat" disease reduced congressional interest to minimal, is distortion and contradiction of scientific findings. His projection of hopes never were fulfilled and were without foundation.

I seriously question the capability of NIAMDD performing what it is not interested in doing, what it could have done but didn't. The term in this instance means meaningful diabetes research and management.

I have criticized a great deal and I thought it essential. I hope I am not considered either picayune—I thought it was necessary to break that statement into what it means.

Analysis of the diabetes programs, the national diabetes program. Can the Director of the NIAMDD develop a comprehensive broad-based inter-institute diabetes program—and after what I have said, I wonder. He hasn't coordinated within his own institute. Is the National Advisory Council capable of offering valid suggestions to the director, for the composition of the National Advisory Council does not represent diabetes.

The problem is complex and merits the highest level of authority in each of many disciplines that makeup the diabetes syndrome.

Diabetes prevention and control programs: (1) Diabetes cannot be prevented. In all the U.S. Public Health publications there is one remark dedicated to prevention. It says "reduce." That's pretty meager, to set up a whole program on it. Diabetes cannot be controlled. This has been the point of my whole statement: The relentless degeneration of the vascular system.

Now, how are you going to spend money on preventing and controlling what you don't know or understand? National research and demonstration centers. Why not assess and strengthen the number of existing research centers in the United States that have competent personnel and need work? There are hundreds and hundreds of very good ones. Why create additional cost new buildings which are not needed, when you desperately need money for research? This section is a confusion of ideas, some valid and some invalid, and some a duplication of effort.

I recommend, because diabetes is a systemic disease that is a major contributor to the disciplines of each institute, this committee develop enabling legislation that will block out of existing national institute funds or add to them \$65 million for comprehensive, broad-based, cooperative diabetes research to be performed singularly and collectively by the respective concerned institutes. [See "Proposed budget"; p. 158, this hearing.]

The National Eye Institute, \$5 million for research; \$1 million to develop a laboratory animal that represents the retinopathy in the human eye. Until this time, including now, every person who goes under laser or suppression of pituitary function is a guinea pig. The number who have been blinded in seeking to preserve sight is substantial. I suggest \$1 million to develop this animal. It's a lot of money for a laboratory animal, but does preservation of your eyesight from destruction by the first cause of blindness make this a valid expenditure? I think so.

For the National Institute of Arthritis, Metabolism and Digestive Diseases, I recommend \$4 million for diabetes. This is a reduction of \$4 million from the current budget. They are working on about \$8 million. For kidney research in diabetes, \$7 million; for the research in endocrinology, \$6 million; for the research in nutrition, \$3 million. Incidentally, the endocrinology is that area of the body governed by the respective glands. There is no question that the pituitary gland has great impact on diabetes but nobody knows why.

Nutrition—there is immense evidence, not in the United States, by doctors in Jerusalem, South Africa, and England—the money in Jerusalem, the research was funded by U.S. Public Health funds. The weight of evidence and the impact of nutrition on diabetes is tremendously great.

The National Institute of Neurologic Diseases and Stroke should get \$10 million. The number of diabetics affected by neuropathy most doctors say ranges from 50 to 95 percent in 10 to 25 years. How it affects diabetics varies from sex impotence to painful neuritis, skin sores, and finally to death by stroke.

The National Institute of General Medical Sciences conducts genetics research, this is the mysterious force that separates diabetes from all other diseases. It proliferates in geometric proportion. There were only a handful of diabetics 50 years ago. There are 10 million today and probably more. It is increasing at the rate of 10 percent a year. Two years ago it was 9 percent. It will continue to increase geometrically because we don't know what is being inherited. We don't know how it is inherited, but we do know one thing; that it runs in families and not only does one child get it but possibly two. Not only are they diabetics, but they will bear children who in turn will again increase the diabetic population. So it is reasonable to assume that in three or four lifetimes at the present rate of increase, we are going to have a diabetic, cardiac, blind society and I haven't found one man who denied that thesis, as awful as it sounds. The usual response is, "it can't happen," but it is happening.

I requested \$2.5 million for the training of doctors. How does a doctor talk to a patient; how do you inform a patient as to the full impact of this problem? This young man raised it—how can you tell

a person that 10 or 15 years from now they possibly could be blind or have heart disease or in 15 or 20 years be dead? That's being God.

Somewhere, there must be a way of informing a diabetic so they know what to do with their lives. I believe Mr. Schwarz is going to raise a point, the problem of mothers. It is possible, even probable, that in 10 to 20 years after she gives birth there isn't going to be a mother. They don't know.

Patient education? Patients must be educated to understand their problem. This is not easy because you're working with the most important part of your function, just being alive and living.

There must be \$2.5 million set aside for the establishing of health care and health delivery programs, developing patterns that would be utilized by the States. I know that in the Commonwealth there is the general feeling that health care and health delivery are State functions, whereas research is not; and it is within the State responsibility—podiatry, for example, diabetes is the major cause, if not the first cause, of amputations. Many limbs could be saved if some of the less fortunate people had a place to go to and have their feet tended to—just as simple as that—or those could have their eyes examined or their blood pressure taken. Early detection could possibly extend sight, reduce the number of amputations, and retard angiopathy.

My second recommendation: Because diabetes is complex, diverse, and affecting virtually every part of the body, placing in jeopardy the life potential of unborn children and grandchildren to whom we owe a responsibility, because the existing mechanisms within NIH are unable to cope with the systemic problem of monumental proportions, I recommend the Director of NIH and/or the Under Secretary of Health of the Department of HEW, working within the existing legislation—legislative prerogatives—granted the executive branch of Government: (1) initiate within 30 days a National Diabetes Commission.

This National Diabetes Commission would represent the major threats inherent in the syndrome—eyes, heart, diabetology, endocrinology, nutrition, neuropathy, vascular degeneration, and genetics. In addition, there should be two concerned lay people with comprehensive knowledge of the disease and its problems. Two chairmen should be designated by the President, one to be drawn from doctors, the other from lay representatives.

The Commission will function as a planning body working with involved directors of the Institutes. They will design a blueprint for effective, cooperative, broad-based action by the Institutes. Responsibility for the coordination will be assumed by the Commission which will report to the Director of the NIH and the Under Secretary of HEW, and also to the general public, whether its findings are good or bad.

Such plans should be complete at the end of 6 months or in time for the 1975 budget considerations. Funding for the Commission should be derived from existing agencies administering comprehensive public health from funds for comprehensive health planning.

I talked an awful lot. I hope I didn't overtalk. I want to thank you very much and if there are any questions I will certainly try to answer them.

[Testimony resumes on p. 148.]

[The attachments to Mr. Stenzler's prepared statement follow:]

STATEMENT OF ROBERT F. BRADLEY, M.D., MEDICAL DIRECTOR OF JOSLIN CLINIC,  
BOSTON, MASS.

I am Robert F. Bradley licensed to practice medicine in the State of Massachusetts. I was graduated from Yale University School of Medicine in 1943, and am a Board Certified Specialist in Internal Medicine, being a Fellow of the American College of Physicians. I have worked with diabetic patients, their families and their problems for 25 years, and have been Medical Director of the Joslin Clinic for 5 years. I am also currently a Member of the Governor's Committee concerned with Diabetes and Blindness, Commonwealth of Pennsylvania.

A great deal has already been written and said concerning the role of diabetes mellitus as a major health problem in the United States. Rather than to regale with repetition of data and emotion-laden anecdotes, I would like to mention briefly some of the covert ways in which diabetes affects so many of our people. In the appended statement concerning the "Degenerative Vascular Disease"<sup>1</sup> produced or accelerated by diabetes the comment is made that with one or two exceptions "diabetes mellitus affects more years of human living than any other single disease or condition". Disorders effectively competing for this dubious distinction are unexpected, as they include conditions such as mental illness and degenerative arthritis rather than cancer or heart disease. The reasons for this large, as yet incompletely unmasked role of diabetes are two fold: (1) Like hypertension and certain other cardiovascular risk factors, diabetes often is associated with no symptoms until a disabling or life-threatening complication makes its appearance; (2) Those individuals who know they have diabetes are or should be faced with the need to deal with it day in and day out. A specific diet must be followed, the urine tested for sugar and frequently acetone at least once each day, and in many instances insulin must be taken by injection once, twice, or even more often daily. Despite early diagnosis and maintenance of such day in and day out rigorous treatment, rarely does the diabetic manage to maneuver indefinitely through daily life without severe insulin reactions, diabetic coma, or bad infection. Furthermore, premature blood vessel disease or a crippling neuropathy inevitably take their toll during the most productive years.

The manifestations of diabetes mellitus are now known to be so protean, that its pervasive damage to so many parts of the human body has replaced syphilis and tuberculosis as the scourge of a great many individuals and their families.

Diabetes is now the great imitator. In its early stages it greatly enhances the chances of becoming obese, increases fetal loss late in pregnancy, and may cause insidious fatigue and behavior changes before the more characteristic overt symptoms appear. Insulin requiring diabetics may be able to avoid dying of diabetic coma in childhood or early adulthood, but they are daily at risk of requiring help from a member of the family or hospitalization because of either too much or too little insulin. This "critical balance" between insulin, diet, exercise, and the stresses of daily living enhances the anxiety and emotional problems of all but the most stable, poses a significant socioeconomic burden, threatens the diabetic with loss of employment, particularly afflicts the uneducated or poorly trained, greatly increases the chances of epileptiform type seizures, decreases the chance of successful pregnancy even in the face of expensive and assiduous medical care, and at any time may impair the physical or intellectual performance of the individual.

Having faced all of the above problems and many more, and having done his best to handle them in such a way as to lead a normal life, it is only the occasional individual with diabetes whose living is not disabled or shortened sooner or later. The coronary heart disease and stroke produced by diabetes are intertwined in this huge total problem as it currently afflicts all Americans. The costly and disabling effects of gangrene are in some way peculiarly related to the effects of diabetes. The numbers of people affected and the estimated costs are surprisingly large, as indicated in the appended testimony presented before the Subcommittee on Health of the U.S. Senate Committee on Labor and Public Welfare, February 26, 1973. Unfortunately, these problems are not limited just to older people in the sixth, seventh or eighth decades, but occur in the young diabetic in the third, fourth and fifth decades of life.

<sup>1</sup> See "Diabetes Mellitus and Degenerative Vascular Disease," printed on pp. 182-185, this hearing.

Through its effects upon the small blood vessels, especially capillaries, the diabetes role runs neck and neck with senile macular degeneration as a cause of new blindness, because of its effects upon these small blood vessels in the retina. It also contributes to the development of senile macular degeneration, some forms of glaucoma, and the formation of cataracts.

Its effects upon small blood vessels in the kidney account for the fact that kidney failure and uremia produce approximately one-half the deaths of young people with diabetes. At present the artificial kidney and transplantation of kidneys is far less successful and associated with a great deal more misery and expense, than is true of similar treatments for kidney failure due to other causes.

The single most common manifestation of the effects of diabetes is that upon peripheral nerves, which sooner or later are involved to a slight or significant extent in nearly 100 per cent of individuals with diabetes. Manifestations are those of pain, complete loss of sensation, loss of muscle power and coordination, collapse of certain bones and joints, a variety of gastrointestinal problems, loss of sexual function in the male, loss of normal bladder function with vulnerability to urinary tract infection, and a whole host of other occasionally occurring neurologic problems that may or may not be reversible.

In short, diabetes partially or totally wrecks lives. The psychologic and socio-economic effect upon the families is incalculable.

#### RECOMMENDATIONS CONCERNING DIABETES LEGISLATION (H.R. 4882)

The Bill H.R. 4882 to amend the Public Health Service Act to expand the authority of the National Institute of Arthritis, Metabolism and Digestive Diseases in order to advance the national attack on diabetes rightly provides for a much greater effort and resources to help overcome this national health problem. However, the provisions of this bill provide a thrust which in some areas fails to recognize the extent to which diabetes involves the whole human body, and in other areas provides for rigidly structured programs that may waste a considerable portion of the resources which H.R. 4882 is attempting to provide. The following comments and suggestions are intended as a constructive outline for improvement in the bill in its present form:

1. While expansion of the authority of the National Institute of Arthritis, Metabolism, and Digestive Diseases is a logical vehicle to handle an increased effort concerning the biochemical and metabolic aspects of diabetes mellitus, it is unlikely that even an expanded institute would have the breadth of knowledge and interest to provide the best effort towards solving the most serious clinical diabetes problems, namely degenerative vascular disease, neurologic involvement, blindness, and kidney disease. I suggest that the additional support for diabetes as it relates to these specific problems should be so identified either through a separate institute, or through existing institutes, such as the National Heart and Lung Institute, National Eye Institute, etc.

2. Whoever is the Director of the National Diabetes Program should be instructed that the "council" or equivalent body of national advisors must include some representation of those physicians who are regularly caring for diabetic patients and experienced in the broad spectrum of problems besetting them. This will be the only certain way in which the research efforts pursued under the National Diabetes Program are relevant to existing health problems of the diabetic and are continually correlated on a national basis.

3. Under H.R. 4882 the provision for the development of not less than 15 centers for basic and clinical research as provided under Section 437 is too restrictive, in that fewer than 15 may turn out to be more desirable, or a great many more may be needed. As presently provided the breadth of the effort and support for the centers risks the expenditure of excessive sums for construction, detection, and education, such that centers might be developed with a view to utilizing available funds rather than being committed on a long-term basis to helping the diabetic.

Just as centers should not be established in arbitrarily designated numbers, support should not be limited to an arbitrary interval of 5 years. Rather, such support should be on an indefinite basis, with the obvious proviso that the council advising the National Diabetes Program is satisfied that a given center is utilizing support for the purposes of the program, and that alternate funding has not become available in the meantime. Only by a commitment on the part of the National Diabetes Program will the numbers of qualified personnel necessary to make the program truly effective be willing to commit themselves, on a career basis, to its objectives.

STATEMENT OF DR. WILLIAM LIKOFF, PROFESSOR OF MEDICINE, HAHNEMANN MEDICAL COLLEGE AND HOSPITAL, DIRECTOR, CARDIOVASCULAR INSTITUTE, PHILADELPHIA, PA.

I appreciate the privilege of having a statement regarding the interrelationship of diabetes mellitus and heart disease placed into the record.

Regrettably, the bill under consideration fails to accomplish all that it might in the interest of eliminating diabetes mellitus as an important health problem in this country. Fundamentally, it does not provide a grand strategy for an attack upon the issue including basic and clinical investigation, professional and lay education, and the delivery of adequate health care to those already afflicted. The absence of such a strategy is recognized by a fixed, administrative structure responsible for allocated funds, and inadequacy of funding.

The Committee is once again reminded that diabetes mellitus is a most serious disorder unquestionably involved in the pathogenesis of systemic vascular disease involving every major organ of the body. Present statistics fail to recognize the consequences, morbidity and mortality because so many victims are statistics under the categories of heart disease, renal and eye disorders.

A proper grand strategy would give the highest priority to research aimed at understanding the basic mechanisms of diabetes mellitus. National programs should call for an adequate mix of basic and clinical research. It should provide for a balance between individual research projects financed by grants and large scale targeted research efforts funded by contracts.

Funds to support education should be clearly indicated. Not only the lay public requires instruction in the recognition and the treatment of diabetes mellitus, but Professional education is far from satisfactory and in some instances entirely prefatory.

The bill should take into consideration that skilled manpower in medicine in general is lacking and that facilities for ambulatory care particularly in urban centers are insufficient and inadequate. Funding to develop these centers is essential if a well balanced program against diabetes is to be initiated.

It is difficult to envision in our present state of knowledge that a public bill designed to support a significant effort in the health field could ignore or fail to fund preventative projects. So is the case in the present bill.

Finally, it is reasonable to hope that national interests could be assisted by the development of a special council of experts in diabetes mellitus with a clear avenue of input into the National Institutes of Health.

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LETTERS OF REBUTTAL TO THE REPORT ON DIABETES PREPARED BY THE NATIONAL INSTITUTE OF ARTHRITIS, METABOLISM, AND DIGESTIVE DISEASES

JOSLIN CLINIC,  
Boston, Mass., May 9, 1973.

MR. CARL STENZLER,  
*Chairman of the Governor's Committee, Concerned with Diabetes, Commonwealth of Pennsylvania, Office of the Governor, Harrisburg, Pa.*

DEAR MR. STENZLER: AS I was about to dictate this letter I found the April 5, 1973, letter from Benjamin T. Burton, Ph. D. to you and the statement regarding diabetes prepared by the National Institutes of Health, which was presented to the House Appropriation Hearings on April 5, 1973. My thoughts are as follows:

Review of the report concerning diabetes mellitus by the National Institute of Arthritis, Metabolism and Digestive Diseases, NIH, as presented recently reveals an extraordinary lack of interest by those preparing this report in those people who have diabetes, as compared to statements showing a keen interest in only the acute chemical changes characteristic of the acute diabetic syndrome. Thus, in one paragraph it is stated by the NIAMDD as follows: "In a severe form, frequently called "juvenile type" diabetes because of its early onset in life, the untreated disease rapidly progresses to a grave metabolic state of imbalance, ketoacidosis, which may result in coma and death unless controlled by insulin administration and specific supportive therapy". In the same paragraph it is stated "Today, with proper treatment, most diabetics can lead a normal life". Herein lies the extraordinary lack of understanding as to what the diabetic must do day in and day out to attain this "proper treatment", and the statement itself acknowledges this problem in a weak manner by stating "can lead a normal life".

The fact is that even with most intelligent, educated and consistent effort, many of these individuals find it extremely difficult to lead a normal life and face an average duration of life after onset of diabetes in adolescence or childhood of only 30 years.

The failure of NIAMDD spokesmen to acknowledge the problems of the diabetic is indicated in the same paragraph referred to above in which it is stated, "Despite good control of clinical symptoms, however, and despite our ability to hold in check the abnormal blood sugar level, the long-term complications of diabetes, primarily those affecting blood vessels, peripheral nerves, kidneys and the eyes, develop relentlessly in too many cases".

What this sentence from our National Institutes of Health is saying quite simply is that because we are not that interested, or more importantly because we do not have the money, these diabetic problems, which are the crux of the issue, are too much for them and they might as well forget them. Why should these changes go on "relentlessly?" Why does the metabolic arm of the National Institutes of Health hide behind a dollar sign the importance of these truly serious complications which sooner or later affect each and every diabetic? Is it because these problems are primarily "vascular" and the NIAMDD by its very name deals only with the "metabolic"?

In its statement the NIAMDD mentions the "long-term complications of diabetes", as indicated above, implying these are the only long-term effects of diabetes. The role of diabetes in accelerating vascular disease causing heart attacks, stroke, and gangrene has been thus virtually ignored. The investigative programs of the National Heart and Lung Institute regarding "heart" also pay little attention to the role of diabetes because, it is felt diabetes is taken care of through another institute. Presumably this would be the NIAMDD. Where does this leave diabetes mellitus and its adverse effects upon blood vessels in virtually every organ in the body?

The pervasive effect of diabetes in accelerating vascular disease, with resultant heart disease, stroke, and gangrene, has been briefly outlined in a report entitled, "Diabetes Mellitus and Degenerative Vascular Disease" submitted to Senator Schweiker and other members of the Subcommittee on Health Legislation of the Senate on February 26, 1973. In the report from the NIAMDD the statement is made "Patients afflicted with its less severe form the so-called maturity onset diabetes, may suffer from complications such as accelerated degeneration or "hardening" of the arteries, and thus may have a decreased life expectancy. Although the disease can be fatal unless properly treated, in most cases it can be well controlled". This statement is at best debatable, and at least incorrect. Diabetes is as readily controlled as a high cholesterol level in some individuals, but in many is less so. If one applied the NIH reasoning to the effect of cholesterol and fat upon heart disease, etc., then a similar statement could be made concerning the need or more money to handle the problem of heart disease, because the same conclusion could be reached "the disease can be fatal unless properly treated, in most cases it can be well controlled". With such reasoning the major ongoing research programs of the National Heart and Lung Institute could be dismantled, thus saving taxpayers hundreds of millions of dollars.

A number of other thoughts do come to mind as one begins to pull apart the reasoning, but I think the above is the major portion of my thoughts at this moment.

Sincerely yours,

ROBERT F. BRADLEY, M.D.

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JEFFERSON MEDICAL COLLEGE OF THOMAS JEFFERSON UNIVERSITY,  
DEPARTMENT OF OPHTHALMOLOGY,  
Philadelphia, Pa., May 11, 1973.

MR. CARL STENZLER,  
*Chairman, Governor's Committee, Concerned With Diabetes and Blindness,  
Elkins Park, Pa.*

DEAR MR. STENZLER: Thank you for bringing to my attention the report on diabetes prepared by the National Institute of Arthritis, Metabolism, and Digestive Diseases. I hope that my reactions to this document may be of interest to you.

It represents, in my opinion, a dangerous reshuffling of data. The key, underlined statement in the first page "Today, most diabetics can keep their disease

under control, enjoy a normal home and family life, and can work with only minor complications.", seems to be a misrepresentation of the fate of a significant portion of diabetics. In all honesty, in defense of this statement the previous statement should be considered, "Prior to the discovery of insulin and diagnosis of diabetes in the early years of life was equivalent to a death warrant." This is only partially true as the discovery of diabetes at any stage usually was equivalent to a death warrant but underlines the role of insulin: the chemical aspect of diabetes can be kept under control. The rest of the picture is actually characterized well in the second page of the report, first line of the second sub-heading, "Diabetes, in essence, is an enigma." We know today how to make a handful of curious facts, this report giving a succinct report of some of the latest.

However, using the figures contained on the very report which are not that different from the other statistics: 34% of the diabetics were blind after thirty years, 47% had proteinuria, 41% had azotemia, and 20% were dead. The report does not provide the statistics or in general even mentions neuropathy, skin infections, sexual problems. Nor is the misery of hyper- and hypoglycemia, a common fate of the younger diabetic who is "brittle", mentioned. I feel, however, that even the facts published in the report contradict the opening statement "today most diabetics, etc. 20% death and 34% blindness, not to speak of other little unpleasant facts, seem hardly the enjoyment of normal home and family life nor can they in any man's book validly be called minor complications.

The report has another curious inconsistency. It seems to equate severe diabetes with the juvenile type and the less severe diabetes with maturity onset. While it is true the juvenile type is usually more severe, anybody that thinks that the maturity onset is free of problems should either spend some time in any diabetic treatment center or read any of the standard text. As a matter of fact, most of the literature reports more problems with the maturity onset than with the juvenile type, a fallacy probably based on the low rate of survival of the juvenile of rather recent years.

I hope that the above may be of some assistance in your efforts of obtaining mature legislation to fight diabetes on a nationwide level. I would like to restate my conviction that diabetes is *the number one* public health problem facing the Western civilization and the road toward a solution is difficult as so little is actually known and there are no animal models.

Sincerely yours,

THOMAS BEHRENDT, M.D.,  
Professor of Ophthalmology.

SCHEIE EYE INSTITUTE,  
Philadelphia, Pa., May 11, 1973.

MR. CARL STENZLER,  
Chairman, the Commonwealth of Pennsylvania, Committee on Diabetes and Blindness, Office of the Governor, Harrisburg, Pa.

DEAR MR. STENZLER: The NIAMMD special 1973 report on diabetes was presented to the House Appropriations. "Today, most diabetics can keep their disease under control, enjoy a normal home and family life, and to work with only minor complications".

The statement "with only minor complications" is incredible. Every U.S. Public Health publication is in contradiction. In front of me is the Model Reporting Area for Blindness Proceedings of the 1968 Conference, published by the U.S. Department of Health, Education and Welfare, Public Health Service, U.S. Department of H.E.W. Spelled out without equivocation are these facts:

- (1) Diabetes is the first cause of blindness for the 40 to 60 years age group.
- (2) Diabetes is the second cause of blindness for the 20 to 40 year age group.
- (3) Diabetes is the fourth cause of legal blindness for the over 60 year age group.

The appalling number of blind in the 20 to 40 year age group for the most part represent juvenile diabetics who have had the disease for ten to fifteen to twenty years. Surely these are not minor complications.

In addition, diabetes source book 1969 published by the Department of H.E.W. identifies 151 thousand diabetics without useful vision in either eye—"not to be equated with legal blindness" and 238 thousand diabetics with impaired vision. It must be noted diabetics with impaired vision always brink blindness because diabetic retinopathy is malignant.

For this disaster to so many people there is no known cause nor is there remedial therapy. The best that we can offer is "palliative" or "stop-gap" assistance.

I urge you when testifying before the House Appropriations Committee that you plead for needed research funds and proper understanding of the disease.

Sincerely yours,

HAROLD G. SCHEIE, M.D.,  
Chairman and Director.

HOSPITAL OF THE UNIVERSITY OF PENNSYLVANIA,  
Philadelphia, Pa., May 17, 1973.

Mr. CARL STENZLER,  
Chairman of Governor's Commonwealth Committee on Diabetes and Blindness,  
Office of the Governor, Harrisburg, Pa.

DEAR MR. STENZLER: As an obstetrician long interested in the care of the pregnant diabetic and in the welfare of her offspring, I would like to add my voice to the protest of inadequate funding of research in all facets of diabetes mellitus. Although insulin has made it possible for the juvenile diabetic to survive long enough to reach a point of reproductive capability, it falls far short of making it possible for that same individual to lead a normal, uncomplicated, unencumbered life. The interplay between diabetes and pregnancy is multifaceted. First, there are concerns regarding the diabetic mother herself. Pregnancy is diabetogenic and certainly at least transiently worsens diabetes as evidenced by markedly increasing insulin requirements and a greater tendency to the development of ketoacidosis. Although it seems that the insulin requirements, as a measure of the severity of the diabetes reverses itself after pregnancy, there is essentially no evidence regarding the state of the cardiovascular renal system of the patient and whether or not the microangiopathy and indeed even the large vessels undergo progressive degenerative change as the result of pregnancy. Certainly we know that with the increased frequency of urinary tract infection during pregnancy the occurrence of such infections may well accelerate degeneration of the renal status of the diabetic. Then, too, there are numerous concerns regarding the offspring of the diabetic patient. Since diabetes has as one of its primary targets the vascular system, it can and does, indeed, in pregnancy attack the vasculature in the placenta and in some instances thereby can be responsible for the stillbirth of the infant. It may also produce an infant which suffers hypoxic damage and is not stillborn but liveborn with brain damage responsible for long term problems which may, in fact, have even greater impact on the family unit than the stillbirth of a child. Above and beyond these deficits in the diabetic patient's ability to sustain in a healthy fashion her fetus in utero, there is a two to three-fold increase in the incidence of congenital malformations in the offspring of diabetics. Certainly in this time of emphasis on population and limited reproduction, one must turn concentrated attention not only to the absolutes of children or no children, but to the quality of life in these children and to minimization of children born with serious birth defects.

Yet, another question is related to the occurrence of diabetes in the offspring of the diabetic patient. There is, perhaps, no disease which is less well understood from the genetic standpoint than is diabetes mellitus. The only thing that seems clear at this point is that there are those families in which diabetes is a hereditary disease. Simplistically, investigators in the past have felt that this disease followed simple patterns of recessive autosomal inheritance, however, it is perfectly obvious from studies in twins and in other family studies that this is indeed not the case. It would seem apparent also that there may be several forms of inheritance or perhaps as concerns the genetic aspect several types of diabetes. Much need be done in clarifying this broad area.

Finally, as an obstetrician and gynecologist, I am concerned with the total health of the woman whom I care for during the course of pregnancy. When I see the longstanding juvenile diabetic through a pregnancy and assist her in the birth of a child, I cannot help but have grave concerns not only for all those problems I have outlined regarding the health of the mother and the projected health of the newborn, but I must also feel great concern for the family unit in which this child may well be motherless within 10 to 20 years as the result of the rapidly progressive cardiovascular renal complications of diabetes mellitus. As an obstetrician and gynecologist, but basically as a physician dealing with patients with diabetes mellitus, I would implore support not only at the existent level but of markedly expanded programs for the investigation of all aspects of diabetes mellitus not just those related to reproduction. It must also be obvious to anyone looking into the problems of diabetes mellitus that the penetrating

study of a disease with such extensive vascular implications might well shed light not only on diabetes but on a great many other degenerative vascular diseases. George Cahill, who is an illustrious diabetologist, has described diabetes as a syndrome composed as a sequence of events about which there is considerable knowledge in the middle and a gross lack of knowledge at either end. The ends obviously are the cause and at the other end the detailed knowledge of the total impact. It is apparent to me that we must get on about the clarification of these details and that to do so will be a costly business but one in which the rewards are immeasurable.

Respectfully submitted,

RICHARD H. SCHWARZ, M.D.,  
*Professor of Obstetrics and Gynecology.*

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UNIVERSITY OF MARYLAND,  
SCHOOL OF MEDICINE,  
DEPARTMENT OF SOCIAL AND PREVENTIVE MEDICINE,  
DIVISION OF CLINICAL INVESTIGATION,  
*Baltimore, Md., May 9, 1973.*

Mr. CARL STENZLER,  
*Chairman, Commonwealth of Pennsylvania, Committee on Diabetes and Blindness, Governor's Office, Harrisburg, Pa.*

DEAR MR. STENZLER: The following statement was presented by the NIAMDD representative to the House Appropriations Committee in April of this year: "The year 1972 marked the 50th anniversary of the discovery of insulin, the hormone that means life for many diabetic individuals. Prior to the discovery of insulin a diagnosis of diabetes in the early years of life was equivalent to a death warrant. Today, most diabetics can keep their disease under control, enjoy a normal home and family life, and can work with only minor complications."

The last sentence of this introductory statement in particular must be challenged. While the acute complications of diabetes, in particularly ketoacidosis, are controllable by insulin, the long-term vascular complications of diabetes continue to resist treatment. Diabetics have a large excess of cardiovascular conditions such as myocardial infarctions, strokes, blindness, kidney disease, and amputation of limbs which distinguish them from the normal contemporary. Quantitatively from a public health point of view diabetes is also a much larger problem than meets the eye. Four million Americans are known to be diabetic, and many more millions have not been diagnosed. Even if one looks only at maturity-onset newly diagnosed diabetics, the enclosed monograph shows that among these maturity-onset noninsulin-dependent recently diagnosed diabetics four percent already had a visual acuity of less than 20/100 in at least one of their eyes; 10 percent had significant ECG abnormalities; and 31 percent suffered from hypertension. This is far in excess of what you would expect in people of the same age and sex class who were not diabetic.

In sum, I would therefore support your efforts to obtain funding for a concerted effort in researching the cause of diabetes and adequate therapeutic means to control the complications.

With best personal regards,

Cordially yours,

CHRISTIAN R. KLIMT, M.D., Dr. P.H.,  
*Professor and Director.*

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JOHNS HOPKINS UNIVERSITY,  
SCHOOL OF MEDICINE,  
*Baltimore, Md., May 8, 1973.*

Hon. RICHARD S. SCHWEIKER,  
*U.S. Senate Office Building,  
Washington, D.C.*

DEAR SENATOR SCHWEIKER: The American public has been lulled into a sense of false security with the assumption that insulin, which, indeed, does control the abnormal sugar metabolism, has eliminated the serious aspects of diabetes. Nothing could be further from the true state of the medical facts today. Insulin

has simply permitted these patients to live long enough to develop vascular complications of diabetes in the major organs throughout the body. These changes occur in the kidneys, the heart, brain, and in the eye. Taking the eye, for example, diabetic retinopathy, the blood vessel complication in the eye, has become the largest cause of new blindness in patients between the ages of 20 and 60. This represents the gainful occupational period with its socio-economic hardships combined with the emotional burden for the patient and his family.

In the Diabetic Retinopathy Center at the Johns Hopkins Hospital, we are receiving new patients with diabetic retinopathy at an alarming increase in frequency. In questioning a series of new patients on a random basis, I was impressed with the significant number who have serious visual impairment, but who have in no way reported their visual handicap to either Internal Revenue for tax benefits or other agencies. I mention this finding because I am convinced that the present figure of approximately 60,000 citizens in the United States who are legally blind from diabetes is probably underestimated. With the annual cost of approximately \$5,000 per year to maintain each diabetic blind individual, and assuming the rock bottom number of 60,000 legally blind from diabetes, we are faced with the staggering yearly cost of \$300,000,000 to support these citizens. The National Eye Institute of NIH is to be commended for its judicious use of the approximately two million dollars available to it for research on diabetic retinopathy. But the 150 to 1 ratio of patient costs to amount spent on diabetic eye research by NIH is a sad commentary on the state of Federal support for a condition that has become the largest cause of new adult blindness in this country.

As a member of a sixteen hospital National Cooperative Study on the problem of diabetic retinopathy, I can assure you that my experience at The Johns Hopkins Hospital is shared by the investigators at each of these institutions. Furthermore, I am aware that, in many Centers that are not participating in the study, the same situation exists. I recognize that other major diseases, such as heart disease, cancer, and sickle cell anemia, have been given special priority in recent appropriations. I fully agree that these important diseases should receive proper funding for medical research. Yet, when one looks closely at the causes of death from patients listed with heart disease or kidney disease as a primary cause, we see in a very significant number that diabetes was, indeed, the basic cause of their demise.

I urge your support of legislation for increased appropriations to support diabetic research, training of personnel and facilities for patient care. I make this request both as a physician responsible for the care of patients with diabetic retinopathy, and on behalf of the five million known diabetics in the U.S. who are potential candidates for this serious complication of their disease.

Respectfully yours,

ARNALL PATZ, M.D.,  
*Professor of Ophthalmology.*

#### VITAL STATISTICS ON DIABETES

AVERAGE PREVALENCE OF KNOWN DIABETES AND RATE PER 1,000 POPULATION BY AGE AND SEX, UNITED STATES, JULY 1957-JUNE 1959

Age	Male	Female	Age	Male	Female
Average number (in thousands):			Rate per 1,000 population:		
All ages	660	871	All ages	8.0	10.0
Under 25	40	27	Under 25	1.1	.7
25 to 44	106	93	25 to 44	4.9	3.9
45 to 54	108	139	45 to 54	11.2	13.7
55 to 64	181	244	55 to 64	25.2	31.5
65 to 74	156	260	65 to 74	34.4	50.3
75 and over	68	109	75 and over	31.5	38.8

Source: U.S. National Health Survey. Diabetes reported in interviews, United States, July 1957-June 1959; Public Health Service Publication No. 584-821, Washington, U.S. Government Printing Office, 1960.

ESTIMATED PREVALENCE OF KNOWN AND UNSUSPECTED DIABETES AND RATE PER 1,000 POPULATION BY AGE,  
UNITED STATES, 1959

Age	Known cases <sup>1</sup>	Unsuspected cases <sup>2</sup>	Total	Age	Known cases <sup>1</sup>	Unsuspected cases <sup>2</sup>	Total
Estimated number of cases (in thousands):				Rate per 1,000 population (in thousands):			
All ages.....	1,530	1,400	2,930	All ages.....	9.0	8.1	17.1
Under 25.....	67	51	118	Under 25.....	.9	.7	1.6
25 to 44.....	199	240	439	25 to 44.....	4.4	5.2	9.6
45 to 54.....	246	360	606	45 to 54.....	12.4	17.9	30.3
55 to 64.....	424	366	790	55 to 64.....	28.4	24.2	52.6
65 to 74.....	416	258	674	65 to 74.....	42.9	26.2	69.1
75 and over.....	177	126	303	75 and over.....	35.6	24.5	60.1

<sup>1</sup> U.S. National Health Survey: Diabetes reported in interviews, United States, July 1957-June 1959; Public Health Service Publication No. 584-521, Washington, U.S. Government Printing Office, 1960.

<sup>2</sup> Unknown cases defined as diabetes unsuspected by the patient or physician. Estimate prepared on basis of studies and surveys by the Diabetes and Arthritis Branch, Division of Chronic Diseases.

ESTIMATED PREVALENCE RATES OF DIABETES MELLITUS BY AGE, UNITED STATES, 1963

Age group (years)	Rate per 1,000		Ratio to population (approximate)	
	Known	Total known and unknown	Known	Total known and unknown
Under 25.....	1.1	1.8	1:900	1:550
25 to 44.....	5.1	10.3	1:200	1:100
45 to 64.....	24.4	45.0	1:40	1:22
65 and over.....	47.5	70.0	1:20	1:14

Sources: Known diabetes: unpublished data from National Health Survey; Unknown: surveys and studies by Diabetes and Arthritis Program, Division of Chronic Diseases.

UNDIAGNOSED AND DIAGNOSED DIABETES, BY AGE, UNITED STATES, JULY 1959-JUNE 1961

Age	Total	Undiagnosed diabetes <sup>1</sup>	Diagnosed diabetes <sup>2</sup>		
			Total	Male	Female
NUMBER (IN THOUSANDS)					
All ages.....	3,156	1,426	1,730	790	941
0 to 24.....	139	56	83	39	44
25 to 44.....	464	236	228	109	119
45 to 54.....	680	368	312	160	152
55 to 64.....	857	373	484	232	251
65 to 74.....	688	263	425	171	254
75 plus.....	329	130	199	78	121
RATE PER 1,000 POPULATION					
All ages.....	17.9	8.1	9.8	9.2	10.4
0 to 24.....	1.7	.7	1.0	1.0	1.1
25 to 44.....	10.2	5.2	5.0	5.0	5.0
45 to 54.....	33.1	17.9	15.2	16.0	14.3
55 to 64.....	55.6	24.2	31.4	31.5	31.2
65 to 74.....	68.6	26.2	42.4	36.9	47.0
75 plus.....	62.0	24.5	37.5	34.4	39.8

<sup>1</sup> Estimates of undiagnosed diabetes prepared on basis of studies and surveys by Diabetes and Arthritis Program, Division of Chronic Diseases, U.S. Public Health Service. (Civilian noninstitutional population used, same as in source 2.)

<sup>2</sup> Diabetes reported in interviews, July 1959-June 1961. Estimated annual average. Unpublished data. Division of Health Interview Statistics, National Center for Health Statistics, U.S. Public Health Service. (Civilian noninstitutional population.)

ESTIMATED NUMBER OF LEGALLY BLIND PERSONS,<sup>1</sup> BY CAUSE, UNITED STATES, 1962

Cause	Legally blind persons	
	Number	Percent
All causes.....	399,300	100.0
Infectious diseases.....	20,950	5.2
Diphtheria neonatorum.....	1,200	.3
Syphilis.....	8,400	2.1
Other.....	11,350	2.8
Injuries.....	11,700	2.9
Poisonings.....	13,800	3.5
Retrolental fibroplasia.....	12,710	3.2
Other.....	1,090	.3
Neoplasms.....	5,730	1.4
General diseases.....	81,300	20.4
Diabetes.....	44,860	11.2
Vascular.....	30,250	7.6
Other.....	6,390	1.6
Prenatal influence.....	66,510	16.7
Unknown to science.....	151,850	38.0
Glaucoma.....	54,020	13.5
Senile cataract.....	62,310	15.6
Myopia.....	17,290	4.3
Other.....	18,230	4.6
Undetermined and not specified.....	47,460	11.9

<sup>1</sup> "Visual acuity for distant vision of 20/200 or less in the better eye, with best correction; or visual acuity of more than 20/200 if the widest diameter of field of vision subtends an angle no greater than 20°."

Source: Estimated statistics on blindness and vision problems. NSPB Fact Book, 1966. The National Society for the Prevention of Blindness, Inc., New York.

## OTHER CONDITIONS AMONG PERSONS WITH DIABETES, UNITED STATES, JULY 1964-JUNE 1965

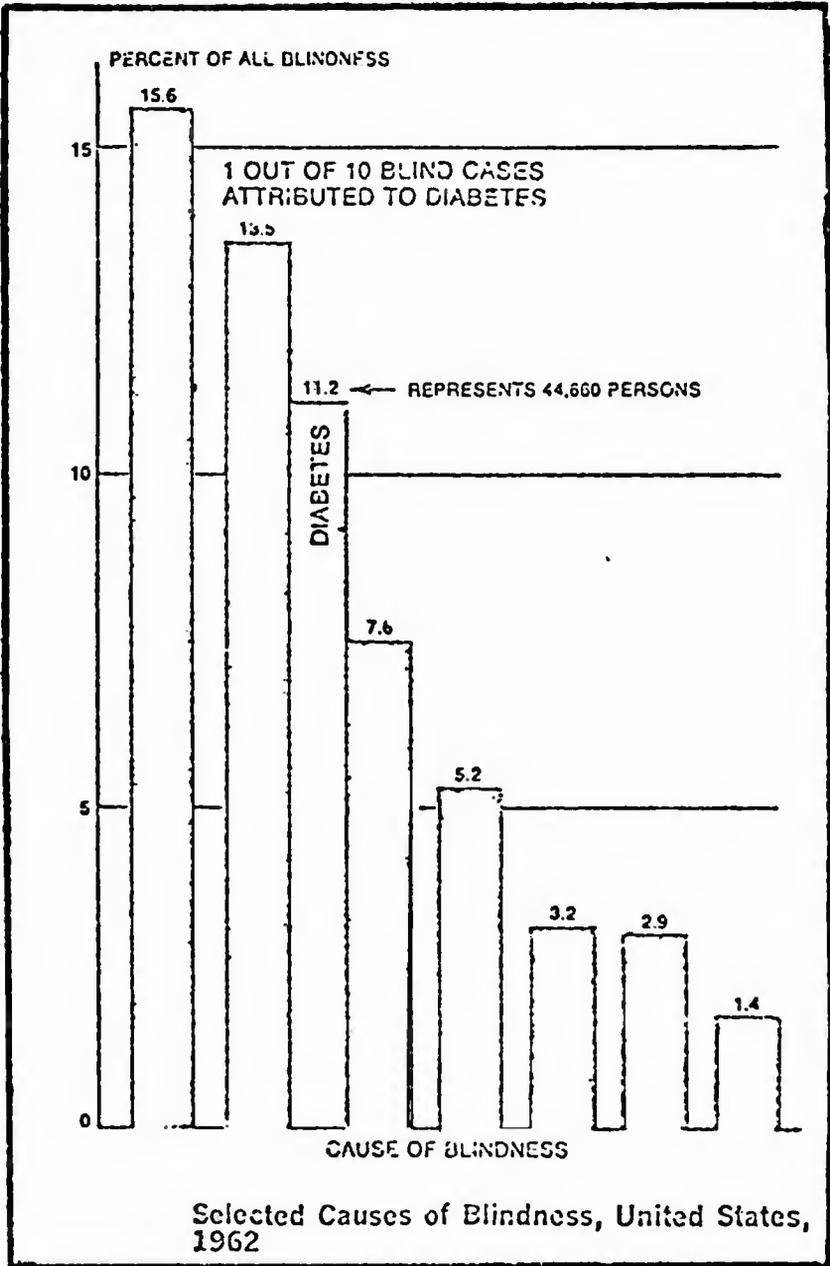
Selected conditions in addition to diabetes	Persons with diabetes	
	Number <sup>1</sup> (in thousands)	Percent of total
Heart condition.....	485	21.1
Hypertension without heart involvement.....	387	16.8
Vascular lesions, CNS.....	76	3.3
Impaired vision, total.....	389	16.9
Impaired vision.....	238	10.3
Blind, both eyes <sup>2</sup> .....	151	6.6
Cataracts.....	93	4.0
Glaucoma.....	36	1.6
Genitourinary disorder.....	190	8.3
Gallbladder.....	84	3.7
Skin disorder.....	75	3.3
Goiter and thyroid conditions.....	71	3.1
Paralysis, complete or partial.....	50	2.2
Gout, tuberculosis, or senility.....	35	1.5
Absence of:		
Fingers, toes.....	51	2.2
Major extremities.....	33	1.4

<sup>1</sup> Many persons have more than 1 condition.

<sup>2</sup> "Inability to read ordinary newspaper print with glasses and impairment indicating no useful vision in either eye." Not to be equated with legal blindness.

Note: Neither visual impairment nor any other condition in this table is to be interpreted as caused by diabetes.

Source: Characteristics of persons with diabetes, United States, July 1964-June 1965. U.S. Department of Health, Education, and Welfare, Public Health Service Publication No. 1000-Series 10-No. 40, October 1967. Washington: U.S. Government Printing Office.



## PREDICTED NUMBER OF DIABETICS

[Using prevalence rates of July 1965 to June 1966]

Age	Prevalence rate used/1,000	(In thousands)			
		1970	1980	1990	2000
<b>Both sexes:</b>					
40 to 44.....	20.0	239	230	347	419
45 to 54.....	20.0	468	447	496	713
55 to 64.....	43.7	809	926	888	993
65 to 74.....	64.4	782	941	1,087	1,050
75+.....	57.9	444	514	619	726
All ages 40+.....		2,742	3,058	3,437	3,901
<b>Male:</b>					
40 to 44.....	29.6	173	167	254	308
45 to 54.....	29.6	334	319	357	517
55 to 64.....	29.6	259	290	279	316
65 to 74.....	51.6	286	326	371	361
75+.....	50.9	154	169	200	231
All ages 40+.....		1,206	1,271	1,461	1,733
<b>Female:</b>					
40 to 44.....	31.0	189	182	271	327
45 to 54.....	31.0	375	359	386	563
55 to 64.....	31.0	303	352	338	374
65 to 74.....	74.9	508	621	725	697
75+.....	62.9	291	350	426	365
All ages 40+.....		1,666	1,864	2,157	2,326

## PREDICTED NUMBERS AND PREVALENCE RATES OF DIABETICS (USING 9 PERCENT YEARLY INCREASE IN ABSOLUTE NUMBER WITH DISEASE)

[Prevalence in thousands]

Age	1970		1980		1990		2000	
	Number	Prevalence rate per 1,000						
<b>Both sexes:</b>								
40 to 44.....	239	20.0	454	39.4	669	38.5	884	42.1
45 to 54.....	468	20.0	889	39.7	1,310	52.7	1,731	48.5
55 to 64.....	809	43.7	1,537	72.6	2,266	111.5	2,994	131.7
65 to 74.....	782	64.4	1,485	101.6	2,188	129.6	2,892	177.4
75 plus.....	444	57.9	843	94.8	1,242	116.2	1,642	130.9
All ages, 40 plus.....	2,742	43.6	5,208	66.3	7,675	85.8	10,143	93.8
<b>Male:</b>								
40 to 44.....	173	29.6	328	58.2	484	56.2	639	61.3
45 to 54.....	334	29.6	635	58.8	935	77.6	1,236	70.7
55 to 64.....	259	29.6	492	50.1	725	76.9	958	89.9
65 to 74.....	286	51.6	543	85.9	800	111.3	1,057	151.2
75 plus.....	154	50.9	293	88.4	432	110.1	571	125.8
All ages, 40 plus.....	1,206	35.2	2,291	63.9	3,376	82.2	4,461	89.1
<b>Female:</b>								
40 to 44.....	189	31.0	359	61.2	530	60.6	701	66.3
45 to 54.....	375	31.0	713	61.6	1,051	82.3	1,389	76.4
55 to 64.....	303	31.0	575	50.6	848	77.8	1,120	92.8
65 to 74.....	508	74.9	964	116.3	1,421	146.7	1,878	201.8
75 plus.....	291	62.9	554	99.5	815	120.5	1,077	135.2
All ages, 40 plus.....	1,666	42.3	3,165	74.2	4,665	95.5	6,165	106.2

## ESTIMATED PREVALENCE OF LEGAL BLINONESS BY CAUSE UNITED STATES, SELECTED YEARS, 1940-62

Etiology	1940	1950	1957	1960	1962
Infectious diseases.....	48,800	41,900	32,900	20,170	20,950
Ophthalmia neonatorum.....	9,800	4,900	1,800	1,150	1,200
Syphilis.....	18,200	17,400	12,800	8,080	8,400
Trachoma.....	6,700	6,000	1,600	350	360
Dther.....	14,100	13,600	16,700	10,590	10,990
Injuries.....	20,300	21,400	16,700	11,280	11,700
Poisonings.....	1,100	4,100	9,000	13,660	13,800
Retrolental fibroplasia.....	200	2,900	8,100	12,610	12,710
Dther.....	900	1,200	900	1,050	1,090
Neoplasms.....	1,500	2,700	4,200	5,520	5,730
General diseases.....	11,800	28,400	53,700	78,280	81,300
Diabetes.....	3,200	12,600	28,400	42,990	44,660
Vascular.....	4,900	9,700	22,000	29,130	30,250
Dther.....	3,700	6,100	3,300	6,160	6,390
Prenatal influence.....	21,900	33,700	45,700	64,200	66,510
Hereditary.....	7,400	12,000	15,200	NA	NA
Not specified.....	14,500	21,700	30,500	NA	NA
Unknown to science.....	78,800	119,600	129,300	146,180	151,850
Glaucoma.....	27,700	38,000	45,700	52,010	54,020
Senile cataract.....	38,000	65,200	60,000	59,980	62,310
Myopia.....	NA	NA	15,700	16,640	17,290
Dther.....	13,100	16,400	7,900	17,550	18,230
Undetermined and not specified.....	46,100	45,600	47,500	45,710	47,460
Total.....	230,300	297,400	339,000	385,000	399,300

## 10 LEADING CAUSES OF DEATH—DEATH RATES PER 100,000 POPULATION, UNITED STATES, 1960

Cause of death	Death rate
All causes.....	951.3
1. Diseases of heart.....	367.9
2. Malignant neoplasms, including neoplasms of lymphatic and hematopoietic tissues.....	146.9
3. Vascular lesions affecting central nervous system.....	110.1
4. Accidents.....	52.3
5. Certain diseases of early infancy.....	39.8
6. Influenza and pneumonia, except pneumonia of newborn.....	33.2
7. General arteriosclerosis.....	19.9
8. Diabetes mellitus.....	15.9
9. Congenital malformations.....	12.4
10. Cirrhosis of liver.....	10.8

Source: U.S. National Office of Vital Statistics. Vital Statistics—Special Reports, vol. 52, No. 7.

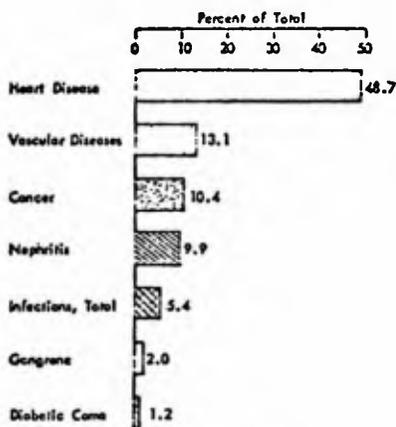
## ESTIMATED NUMBER OF DIABETICS BLIND FROM RETINOPATHY

	1970	1980	1990	2000
A. Aged 40 and over (in thousands):				
Assuming current prevalence rates.....	144.1	165.6	190.1	207.0
Assuming 9 percent annual increase in prevalence.....	144.1	273.8	403.5	533.4
B. All ages <sup>1</sup> (in thousands):				
Using current prevalence rates.....	154.7	178.1	204.4	222.6
Using 9 percent annual increase in prevalence.....	154.7	294.4	433.9	573.5

<sup>1</sup> Those aged 40 and over account for about 93 percent of all blind diabetics. Multiply numbers in pt. A by 100/93 to get estimate of total number of blind diabetics.

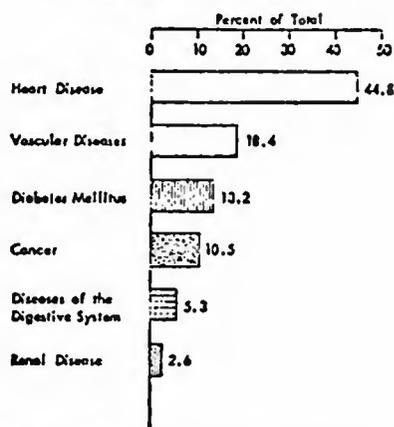
## SELECTED CAUSES OF DEATH AMONG DIABETIC PATIENTS IN TWO STUDIES

Experience of Joslin Clinic, Boston, Mass., 1950-56\*



\*Deaths reported through September 11, 1956

Source: Stat. Bull. 30:3, March 1957

Experience in a Community Epidemiologic Study  
Oxford, Massachusetts, 1947-1957\*\*

\*\*Source: Wilkerson, M. L. C.; Kroll, L. P.; and Butler, F. K. Diabetes in a New England Town. IV-A 12-year progress report on the 70 diabetics found in the original Oxford, Mass. study. To be published.

## MEMBERSHIP LIST, THE GOVERNOR'S COMMITTEE ON DIABETES AND BLINDNESS

Cari Stenzler, Chairman.

## EYES

Harold G. Scheie, M.D., Professor and Chairman Department of Ophthalmology, University of Pennsylvania.

Charles Schepens, M.D., President, Retina Foundation, Boston, Massachusetts; Associate Professor of Ophthalmology, Harvard Medical School.

Irving H. Leopold, M.D., Professor and Chairman Department of Ophthalmology, Mt. Sinai School of Medicine, New York.

## SMALL BLOOD VESSEL DEGENERATION

Richard A. Field, M.D., Senior Scientist, Retina Foundation, Boston, Massachusetts; Associate Professor of Medicine, Harvard Medical School.

## LARGE BLOOD VESSEL DEGENERATION

Robert F. Bradley, M.D., Medical Director, Joslin Clinic, Boston, Massachusetts.

## KIDNEYS

Arnold S. Reiman, M.D., Chief of Medical Services, Hospital of the University of Pennsylvania; Professor of Medicine, University of Pennsylvania.

## HEART

William Likoff, M.D., Professor of Medicine, Hahnemann Medical College.

## TEETH AND GUMS

Merwin A. Landay, M.D., Professor of Dentistry, Temple University School of Dentistry.

## JUVENILE DIABETES

Robert Kay, M.D., Professor of Pediatrics, University of Pennsylvania.

## MATERNITY

Charles R. Schuman, M.D., Professor of Medicine, Temple University College of Medicine.

## GENETICS

Arthur G. Steinberg, Ph.D., Professor Biology, Professor of Human Genetics, Western Reserve University, Cleveland, Ohio.

## EPIDEMIOLOGY AND RESOURCE INFORMATION

George K. Tokuhata, Dr. P.H., Ph.D., Director, Division of Research and Biostatistics, Pennsylvania Department of Health, Harrisburg, Pennsylvania; Professor of Biostatistics, University of Pittsburgh Graduate School of Public Health; Associate Professor of Community Medicine-Epidemiology, Temple University College of Medicine.

## ANESTHESIOLOGY

Stephen J. Galla, M.D., Associate Professor of Anesthesiology, University of Pittsburgh School of Medicine.

## NEUROPATHY

Richard Chambers, M.D., Professor of Neurology, Thomas Jefferson Medical College.

Hon. Robert Rovner, Esq., State Senator, Commonwealth of Pennsylvania.

Robert Dechert, Esq., Senior Partner, Dechert, Price and Rhoades.

Christian R. Kilmt, M.D., Professor & Director, Div. Clinical Investigation, University of Maryland Medical School, Baltimore, Maryland.

Mr. ROGERS. Thank you very much, Mr. Stenzler, for a very comprehensive statement. Excellent. I think before we will start questioning, however, if it will suit the committee, we will go ahead and receive the statements from your colleagues, and then we will question at that time.

Dr. Patz.

## STATEMENT OF DR. ARNALL PATZ

Dr. PATZ. Mr. Chairman, I want to thank you for the privilege to appear before this subcommittee. My remarks stem from my experience as director of the Diabetic Retinopathy Center at Johns Hopkins and as a member of the board of directors of the National Society for the Prevention of Blindness.

The public at large, and even some members of the medical profession, have been lulled into a sense of false security on the assumption that the administration of insulin to regulate the blood sugar level of the diabetic patients controls all of his problems.

Although insulin regulates the blood sugar level damage to small blood vessels throughout the body continues insidiously throughout the lifetime of a diabetic individual. For example, in the eye, damage to blood vessels in the retina affects 75 percent of diabetic patients after 20 years' duration of diabetes. Fortunately, all of these individuals do not become blind, but enough diabetics sustain severe retinal damage that diabetic retinopathy has become the largest cause of blindness in the United States between the ages of 20 and 60.

According to the National Society for the Prevention of Blindness, there are now 53,000 legally blind diabetic individuals in this country, and I would like to emphasize that this is a rock bottom figure, in my opinion, based on our experience in the Diabetic Retinopathy Center at Johns Hopkins and I illustrate this—with this young gentleman, Gary, here this morning—following the hearings for Senator

Schweiker's bill in January—we analyzed the new patients who were referred in with diabetic retinopathy of the type of this young man and it was rather revealing to us that about one-half of these people had not formulated any way to see that there were some statistics insofar as reporting their visual handicap. They were not getting special tax benefits. They were not listed on any particular blind rehabilitative program at their admission to our program.

So emphasizing this figure, which I accept as a rock bottom figure, I would like to continue to state that with an average annual cost of approximately \$3,000 to \$5,000 to maintain each blind person annually, we have this staggering amount of \$150 to \$250 million per year for support of these individuals. Contrast this \$200 million average figure with the approximately \$2 million available to the National Eye Institute of NIH for its entire research programs concerning diabetic retinopathy, a ration of \$100 to maintain the diabetic blind for each \$1 spent on research.

The National Eye Institute is to be commended for its judicious use of the limited funds available. Recognizing the high priority of diabetic retinopathy, a 16-hospital cooperative study has been sponsored to test photocoagulation treatment. Photocoagulation is that technique of coagulating or welding abnormal blood vessels in the retina by focusing a light or laser beam on these vessels. And I would like to emphasize, in view of Mr. Stenzler's remark about maybe early treatment with a laser might have prevented this man's visual demise, even if this treatment proves definitely beneficial, we already know that many stages of retinopathy cannot be treated by photocoagulation.

As a member of this cooperative study and of the executive committee that supervises this 16-hospital program, I recognize its importance as it represents the principal therapy now available. But in actuality, this approach is a stopgap one and comparable to putting a finger in the dike. What is required in addition is a major increase in basic research support to determine the fundamental cause of retinopathy and to develop methods of prevention of this dreaded complication of the disease.

In reference to the NIH budget insofar as the Eye Institute is concerned the cooperative study just mentioned utilizes approximately one-half of the \$2 million available to the Eye Institute for diabetic retinopathy programs. With only \$1 million remaining approximately to support all other research studies on diabetic retinopathy, it is quite obvious why several important basic research grant applications during the past 2 years have been endorsed and approved by its Scientific Advisory Council, but yet could not be funded by this agency.

In closing, I would like to strongly recommend legislation in the field of diabetes to provide increased appropriations for multidiscipline and coordinated research, training of research scientists, and the improvement of facilities for patient care; and I make this request as a physician responsible for the care of patients now afflicted with diabetic retinopathy and on behalf of the 5 million or more known diabetics in the United States who are potential candidates for this serious complication of their disease.

Mr. Rogers. Thank you very much, Dr. Patz, for a very helpful and excellent statement.

## STATEMENT OF DR. RICHARD H. SCHWARZ

Dr. SCHWARZ. Thank you, Mr. Chairman.

I, too, have submitted a more detailed statement and I will also simply highlight a few points in my particular area of concern.

Before I do that, I would like to underscore, however, some of the remarks of Mr. Stenzler concerning the broad-based nature of diabetes and the fact that it does cross the lines of almost all the Institutes in the NIH, and I think to attempt to localize the authorities specifically under one institute might well be to the sacrifice of expertise in some of the other areas.

I would suggest also that we contend with this complexity by the creation of a National Commission on Diabetes which could be indeed made up of some of the most expert workers available in all aspects of this problem; and then I believe that such a group could coordinate the investigative efforts both basic and clinical on a nationwide basis providing the best chance for solving some of these fundamental problems in diabetes.

For just a few specific points, you might wonder why an obstetrician gynecologist is included as a member of a committee on diabetes and blindness. Notably absent in the proposed bill was any specific reference to pregnancy, to perinatal wastage, to congenital malformations and only the most limited reference to genetics as concerns diabetes.

Many diabetic women are unaware that their reproductive capabilities are impaired and many undertake pregnancy with no more concern than their nondiabetic peers. Nothing could be farther from the truth. The diabetic woman has a 1-in-5 chance of having a still-born or a neonatal death when she finally gets past the threat of early miscarriage. In the very best of circumstances, in the very best institutions, this risk might be reduced to 10 to 15 percent. Even that is twice the normal rate for perinatal deaths. The nondiabetic risk is approximately 6 percent.

If the patient does conclude successfully the pregnancy there's a threefold increase in the possibility that the child will have a significant congenital malformation. The across-the-board background risk is about 2 to 2.5 percent. The diabetic has a 6-percent chance of having a child with congenital malformations and indeed the chances of a lethal malformation are increased sixfold in the diabetic.

Mr. Stenzler already alluded to diabetes in the offspring. As of 1973, the genetics of diabetes is not understood. We did think a few years back that the disease could be categorized and we knew precisely what the risk might be. It becomes increasingly clear that diabetes may be several diseases genetically. There are those families in which diabetes is strictly a sporadic occurrence. There are other families in whom there's a strong familial tendency. We must develop an understanding of the genetics, the mode of inheritance of diabetes, so that patients can be counseled about the chance of diabetes in their offspring before they conceive, before they undertake a pregnancy. Children born to diabetic mothers may not have a live mother by the time they reach maturity. How does one make this clear to the young couple when the wife is already pregnant at the time they come for care?

Does pregnancy cause progression or deterioration in juvenile diabetes? Current opinion says no, unless there are major complications

during the pregnancy. However, there remains considerable lack of knowledge in this particular area.

As an obstetrician, I hope that I have pointed to just a few of the major areas of concern as regards diabetes and the reproductive process, areas which require investigative clarification.

I should also point out that the study of a problem such as the vascular insufficiency which leads to the stillborn infant might well shed light on diabetic vasculopathy in general. Just as the blood vessels course through all the organs and organ systems in the body, so is the pathology of diabetes protein. We owe it to the nearly 10 million diabetics in this country to direct ourselves effectively to the problem with adequate funding and a good coordinating effort. I feel that this can be done and I would therefore urge the distinguished members of this committee to consider this more broad-based approach to a major medical problem.

Thank you.

[Dr. Schwarz's prepared statement follows:]

STATEMENT OF DR. RICHARD H. SCHWARZ, PROFESSOR OF OBSTETRICS AND GYNECOLOGY OF THE UNIVERSITY OF PENNSYLVANIA SCHOOL OF MEDICINE AND DIRECTOR OF THE JERROLD R. GOLDING DIVISION OF FETAL MEDICINE AND A MEMBER OF THE COMMONWEALTH OF PENNSYLVANIA COMMITTEE ON DIABETES AND BLINDNESS

Prior to the discovery of insulin by Banting & Best in 1921, the combination of diabetes and pregnancy was not a problem, simply because the diabetic either died before she reached the child bearing period or was infertile as a result of having an uncontrolled disease. When upon rare occasion a pregnancy did occur in a diabetic in the pre-insulin era the maternity mortality rate was 25% and the perinatal loss was 50%.

Some have implied that insulin has completely eliminated the problems and the diabetic woman can undertake a pregnancy with no more concern than the non-diabetic. Nothing could be farther from the truth. Although the chances that a diabetic can successfully conclude a pregnancy have been improved immensely, she still faces many more problems than a non-diabetic, many of which may not even be known to her.

The first concern is the worsening, at least transiently, of the diabetes which occurs with pregnancy. Insulin requirements increase and the risks that diabetes may go out of control (diabetic coma) is also increased. Because the insulin requirements return to normal after the pregnancy stress has passed, it is assumed, although clearly not proved, that this does nothing to the life expectancy of the mother. Only more extensive investigation will answer that question. The pregnant diabetic is also more prone to certain complications, particularly urinary tract infection and preemclampsia which might well worsen the overall health status of the mother. It is a saddening experience to see a long-standing diabetic go through a pregnancy, when one knows that the patient will probably be blind or even dead before her child reaches maturity. In the latent diabetic, i.e., the patient with the genetic predisposition but without overt evidence of the disease, pregnancy may bring out diabetes for the first time. Although there is a general understanding of these processes, it is imprecise. Knowledge of how this occurs would shed increased light on diabetes in general.

The second concern lies with establishment and successful conclusion of a pregnancy. Infertility is not a great problem if the diabetes is well controlled, however, given poor control, failure of ovulation or conception with early miscarriage are increased in frequency. Once the pregnancy is established and beyond the likelihood of miscarriage, the concerns are not past. Indeed the perinatal mortality rate (which includes stillbirths plus neonatal deaths) is markedly increased, averaging 12-15%. This figure is at least 3 times that for the non-diabetic. The reason for the problem is that diabetes in all patients has a profound effect on blood vessels. In the case of pregnancy the blood vessels in the placenta are affected making it unable to support the life functions of the fetus in utero. To compensate for this problem diabetics are often delivered early, commonly by cesarean section but then there are the problems of prematurity to contend with. Such information has been gleaned in recent years, concerning

the evaluation of the well-being of the fetus and the timing of delivery but much more must be learned. Even with all the latest developments and the best efforts of the very best hospitals in this country, the perinatal mortality has not been reduced below 10%. If the diabetic delivers a live baby and the baby survives the complications of the newborn period, what is this in the outlook? The baby has a threefold increased chance of having a congenital malformation and a sixfold increased risk of having a lethal malformation. The frequency of malformations in the general population is 2-2.5% and 6-6.5% for diabetes and of lethal malformations 0.3% as opposed to 2.1-2.9%. Not only do a great many patients not know of this risk but the precise genesis of the malformations is not really understood either.

Finally as concerns the children, there is the potential that they may develop diabetes. The genetics of diabetes is not really as clear as once thought. Indeed it is possible that diabetes may behave differently in different families as concerns inheritance patterns. Regardless of the pattern, however, it is generally true that there is an increased chance of developing diabetes in the offspring of a diabetic and a marked increase if both parents have the disease. The risks are greater if there is diabetes in other members of the family.

Thus pregnancy is not something the diabetic should undertake lightly, even though her disease is apparently well controlled at the time. She and her husband should be made aware of the problems both for her and the child and this should be done prior to conception. Beyond the medical concerns there is also the economic burden of the larger number of physician visits, extra laboratory studies and even prolonged hospitalization. The latter, i.e., separation from the family unit, has a social and economical impact as well as the economic one.

In a disease with such protein manifestations as diabetes it is not surprising that there is a significant interplay with pregnancy. It is also not shocking to find that with the large gaps in the basic understanding of diabetes, in general, there are even larger gaps in knowledge regarding its interplay with pregnancy. The needs for research in this area are vast. How is the increase in congenital malformations brought about? What are the genetics of diabetes? How is the dysfunction of the placenta in the diabetic pregnancy brought about? The answer to the latter question might well shed light on the vascular problems of diabetes in general. Does pregnancy alter the life expectancy of the diabetic? How can the perinatal mortality rate be reduced to approximately that in non-diabetics, or in fact, can it? In this day of great attention to the quantitative aspects of human reproduction we must focus increased attention on the qualitative aspects as well. If fewer children are conceived we must do everything possible to assure the health of those children while guarding the health of the mother as well. This concept presents very special problems for the diabetic.

Although as an obstetrician-gynecologist, I speak to a rather sharply defined area of diabetes, as a physician and as a citizen, I urge the distinguished members of this subcommittee to give higher priority to the many areas of diabetes research and also to consider the establishment of a national scientific advisory commission to coordinate these efforts because of their diverse nature.

Mr. ROGERS. Thank you very much, Dr. Schwarz, for an excellent statement. Although we are fortunate in having two doctors on our committee who are aware of the medical problems you have addressed so vividly, I am sure the committee has learned a lot of facts from the testimony of this panel of which we were not previously aware.

Dr. SCHWARZ. Thank you, Mr. Chairman.

Mr. STENZLER. Congressman Rogers, may I read Dr. Bradley's paper? [See p. 134.]

Mr. ROGERS. I would like to have it read. Our only difficulty, Mr. Stenzler, is that the call to the floor has come. We have to be there in 5 minutes. But the committee will read that and we will also have our staff read it. Your testimony has been most helpful.

Dr. CARTER?

Mr. CARTER. I certainly have enjoyed the presentations of all the distinguished gentlemen here today and I think it's been exceedingly helpful to point out particularly that diabetes is not just a disease of the pancreas but is a systemic disease which most of us—many

of us have realized that for many, many years and the significance of this disease is causing so many other ill effects than coma or shock. We see so many deaths resulting directly from diabetes and many times they are not always attributed to diabetes.

I believe recently we thought that diabetes began as a—and I guess that still is a belief—as a degeneration of the islets of Langerhans in the pancreas, and probably this is true. We do see this degeneration of the islets of Langerhans and we observe the effects of pituitary, particularly in acromegalics. Most of them have diabetes.

Don't you think really that the effect on the vascular system is perhaps somewhat similar in the eye and the kidney and heart, the same pathology which causes a retinal hemorrhage will perhaps later cause obstruction of an artery on the surface of the heart or in a limb? Do you think so?

Dr. PATZ. If I may answer that, sir, I think this is probably one of the major reasons for a coordinated basic research effort, because I would certainly assume that there is an interrelationship, at least in terms of the appearance of the pathology in the kidney and the eye. There are many similarities and people who have kidney disease—there is a very close correlation with the complication of retinopathy. So I would certainly subscribe to that general concept.

Mr. CARTER. And that genetic factor, of course, that is not understood, but we do notice that when a diabetic marries a diabetic, oftentimes all of their children or most of their children are diabetic. I don't know that that really follows the Mendelian law as some diseases do, such as sickle cell anemia, but there is a tendency.

Anyways, I think this committee will certainly consider what you gentlemen have had to say and I know that I want to support a strong bill in this committee.

Thank you, Mr. Chairman.

Mr. ROGERS. Thank you, Dr. Carter.

Mr. KYROS?

Mr. KYROS. Just one question. Turning your attention to H.R. 4882, which would expand the authority of the National Institute to include diabetes, I understand one of the doctors testified that the multidiscipline approach toward diabetes is better and that perhaps it would not be best to mount a research attack on this disease by categorizing and compartmentalizing it within an institute of its own.

Now, what are the other doctors' feelings about that? Do you all agree on that or do you agree with the bill, H.R. 4882, as it is written?

Mr. STENZLER. Diabetes is a disease without precedent. We have never had a disease with such monumental proportions affecting literally every part of the body, and we really don't know how to handle it.

Now, we suggested, one, that overall Diabetes Commission, which incidentally would function independent of being afraid of what the legislative adviser told them to say. This is a problem with your directors. They are told—

Mr. KYROS. What directors?

Mr. STENZLER. Directors of the National Institutes.

Mr. KYROS. You think they are told by the Congress?

Mr. STENZLER. No. I think they are told what to say by—

Mr. KYROS. You mean by the executive?

Mr. STENZLER. Right. However, the appointment of a commission that is independent of that fear and representing the highest level of authority—

Mr. KYROS. You mean without the NIH?

Mr. STENZLER. No, no—working with NIH. This group would work with the five or six NIH Directors. They are not disturbing NIH. They develop a plan together and it is then thrown right into NIH for transmission to the respective units, but there is a new direction and a new vigor.

At this moment, the most that has ever been spent for diabetes research is about \$8 million a year, which is fantastically small. There has never been drive within the NIH, an overt recognition—in private there are lots of conversations—but you must create a force that is capable of moving what is now cumbersome, and there is no director who can really oversee other directors. They are autonomous to a great extent and if they feel that other things ought to be done, the probabilities are that's what they are going to do.

Mr. KYROS. Thank you very much. Thank you, Mr. Chairman.

Mr. ROGERS. Mr. Heinz?

Mr. HEINZ. I would be happy to yield to the gentleman from Indiana.

Mr. HUDNUT. Mr. Heinz, I thank you. Mr. Chairman, I have to leave for a noon appointment, like yourself, and Mr. Heinz has several questions and I only have one, so he said he would yield to me.

I would like to express my deep appreciation for the testimony this morning which has been most helpful. I am personally involved in this whole question because we have a 20-year-old daughter who has had diabetes for 6 years and has been a brittle diabetic and while I am not familiar with the technical language that you gentlemen have used this morning, I am familiar with some of its manifestations.

She has had diabetic neuritis and severe pain and last year we had her in five different hospitals around the country, including the Mayo Clinic and the Joslin Clinic. She has had problems with depression as a result of this pain and now she is facing an operation on her eyes 2 weeks from today for what I would call cataracts, but I guess that's not the right word.

But anyway, our family has been personally involved in this and I am deeply committed to doing what we can to develop a strong bill here and augment and enrich the program at the national level to advance the national attack on diabetes.

The one question I would have is this, Mr. Stenzler: You indicated that you didn't like that portion of the bill that has to do with the 15 new centers because you thought that actually the money could be better spent on research in existing centers rather than putting money into bricks and mortars for new centers.

I wonder if you could expand on this a little bit.

Mr. STENZLER. Yes. I have made as strong a statement as I could that the first priority in developing meaningful research—we have no money at all to begin with today and that—the point of the centers is that there ought to be an assessment of what is in existence. If you look at that—and I don't question the need—but there are centers. There are competent institutions around the country. Now, if we would strengthen them we would do better. They are all crying for support.

Mr. HUDNUT. How many centers are there? Did you say 150?

MR. STENZLER. No, I didn't. I said there are at this moment none—there are many centers—Joslin is a center; the institute out at the University of Minneapolis has a marvelous diabetic teaching unit. There are centers in Chicago, in Dallas, in Los Angeles, and I really can't answer specifically because this question has never come up; but I know there are a considerable number of institutions around the country with competent people and competent personnel who need some degree of funding, rather than putting money into new bricks and mortar. I can understand your thinking. This thing hits and you will go anywhere, any place that offers a degree of hope. Dr. Patz' center, the Retinopathy Center at Johns Hopkins. There are other parts of Johns Hopkins that are equally devoted to the dissemination of information as well as research. The University of Maryland. There are marvelous centers for research depending upon what you are looking for.

MR. HUDNUT. So you're saying take the money that we have authorized or are projecting to authorize in this bill and rather than put it into new centers, put it into existing centers to enrich their program in research and therapy.

MR. STENZLER. Right. But what I am saying, with what money we don't have—and we really don't have money now—we should support the most urgent need. The neuropathy your daughter has, stop it—just stop it. Don't cure it; just stop it; and that would be the most marvelous gift that you would ever get. Just stop it. Just stop that thing that nobody can stop, that relentless progression. That is where the neuropathy is one and the retinopathy—these are almost inevitable consequences that happen to most diabetics in a mild or severe degree, and nobody knows how severe it will get or how quickly it will go. This is what you want.

MR. HUDNUT. In your itemizing of the categories of where we need to put this help, whether its cardiovascular research or ophthalmology or something else, I didn't hear you mention the whole question of tension and hypertension and the input from the psychiatric realm. The reason I have suggested this, I have talked to several psychiatrists and doctors and it's hard for me to get an answer—maybe there isn't an answer—as to whether or not juvenile diabetes is a stress disease; but I felt on the basis of my own personal experience that there is a correlation between tension and a tendency toward diabetes.

MR. STENZLER. I think you are absolutely right. I tried to set in motion a transition period. The institutes up to this time, for whatever reasons you want to give them, have virtually ignored diabetes—all of them. They have never—read their statements to the appropriations committees and you would think that diabetes is nothing to concern ourselves with. Read where they have put their emphasis. The National Eye Institute—now \$2 million, and I think their budget is \$38 to \$40 million. It's not much when you are talking about what is now the first cause of blindness and which is accelerating at a rate that is frightening. It's geometric. Now, something is wrong.

So I suggested, one, let's mandate \$5 million or \$6 million. This is transition. We don't really know where to put our research money. There isn't that much known. I can identify one. We talked of metabolism. Diabetes is historically a metabolic problem. There are, today, researches which turned up chemical diabetics. Merely the examina-

tion of large heart patient groups—there are no symptoms, but substantial numbers come up with abnormal glucose tolerances. This is chemical diabetes which usually leads to overt diabetes.

Dr. Chambers, who is a member of this committee and whose paper I hope you will read, has expressed a theory that diabetes is caused by a neuropathy and he can substantiate that, but that's why there should be a commission where these men can talk to—let gods talk to gods, because they are the only ones that know.

There is another research now in Dallas, Tex., by a Dr. Sapperstein. He's been examining the children of diabetic parents and doing research on the—measuring the thickening of the lower membrane in the large arteries in the thigh, and these young people show a thickening of the membrane which is definitely indicative of the breakdown of the blood vessel. They show no symptoms of anything.

Now, does the vascular cause the metabolic? Does the metabolic cause the vascular? Does the neurologic cause the endocrine? Nobody really knows, and the point is, at this point, it can be caused in all four areas. It can be a multitude of diseases with a common core.

I forget which one of the doctors mentioned—I guess it was the Congressman—a few years ago there was a theory that a simple recessive gene was the genetic factor that carried this disease from parent to child to grandchildren right down the line. Today, that is not questioned, but it is supplemented; that it is not only possibly a simple recessive gene but it could be a polygene and there could be many different genes and they spawn this disease called diabetes in different methods and different manners.

Why does the disease take an average of 40 years after birth to mature? The average diagnosis of diabetes is after 40. That's when about 80 percent of the diabetics are identified. Why? And it is agreed that the genetic factor is there when they are born. What is there? We don't know. What we have learned in all research can be summed up in four words: What we don't know. There hasn't been, in the entire history of NIAMDD, one clinically acceptable therapy developed for any single phase of diabetes. As a matter of fact, there hasn't been a therapy developed anywhere in the world that can stop, that can—I use that word—I would be very happy just to stop it, and then search for a remedy and then prevention and the cause—that cure that is so far beyond the comprehension of most doctors today that it is almost unrealistic to discuss it.

I mean—correct me, Dr. Patz, on that.

Dr. PATZ. I would certainly agree.

Mr. STENZLER. We have talked of cure in there. That's nonsense. That's talking words. Cure is just so remote.

Mr. HEINZ. Dr. Stenzler, may I ask a few questions? Do you have any more questions?

Mr. HUDNUT. I yield the balance of my time back to the distinguished gentleman from Pennsylvania, who was so gracious to let me ask my questions.

Mr. STENZLER. Congressman Heinz. I love being made an instant doctor, but I'm just a former businessman.

Mr. HEINZ. Well, you're doing pretty well, very well indeed.

Mr. STENZLER. A worried father.

Mr. HEINZ. I've really got quite a list of questions. I don't know how much time we are going to have because we may get a quorum call at any instant. We have taken testimony in the committee that the medical cost of diabetes was in the area of \$2 billion. Do you have any belief whether that figure is a high number or a low number, an understatement or an overstatement?

Mr. STENZLER. I have a confirming figure of that if I can find it in these papers.

Mr. HEINZ. Well, if that's in the ballpark—

Mr. STENZLER. He uses a low figure of \$2,328 million and a high figure of \$2,505 million.

Mr. HEINZ. Who are you quoting?

Mr. STENZLER. Dr. Tokuhata; he is the Commonwealth epidemiologist. Incidentally, I would be glad to offer it into the record. He has done quite a lot of research for us and he is also a member of the Commonwealth Committee. He says: "Note: Does not include annual expenditures for construction or programs of research, case finding, rehabilitation; (2) Estimated cost of diabetes in the United State economy"—now his reference is Diabetes Source Book, U.S. Public Health Service 1968—"was increased on the basis of available information to obtain estimates for 1973."

Mr. HEINZ. Based on the testimony you and your associates have given today, you have indicated, for instance, that there are 250,000 cases of heart disease that may have been caused by diabetes. Therefore, it is possible that that \$2 billion to \$2.6 billion number is really an understatement.

Mr. STENZLER. That's quite possible.

Mr. HEINZ. In that vein, you are proposing, as I understand it, a \$61 million research and development proposal. I don't believe I'm clear on whether you were thinking of an annual expenditure of \$61 million, a first-year expenditure of \$61 million, or—what time period does that \$61 million cover?

Mr. STENZLER. This is a transitional figure. They are all tiny sums. Nobody really knows where you are going to find that hope. No one knows.

Mr. HEINZ. We face the same problem, as you're probably aware, in cancer research today. There has been a formation of a Cancer Institute, yet we have had many people testify before us that the chances of actually finding the cure for cancer in the Cancer Institute is pretty slim. It could easily be found by somebody doing genetic research or some other allied areas. So I appreciate the validity of your proposal in principle.

Let me ask you this: In the numbers that you gave us, I added them up and I only got up to around \$40 million and I have a feeling you might want to submit for the record of the committee—and I am only proceeding this way because time is short—a list of the \$61 million.

Mr. STENZLER. I will. I will submit this. I have a list.

[The following proposed budget was received for the record:]

*Proposed budget for diabetes research*

<i>Agency</i>	<i>Requested funding</i>
National Eye Institute.....	\$5,000,000
Develop animal or animals for laboratory use <sup>1</sup> .....	1,000,000
<b>Total</b> .....	<b>6,000,000</b>
<b>National Institute of Arthritis Metabolism and Digestive Diseases:</b>	
(a) Diabetes.....	4,000,000
(b) Kidney.....	7,000,000
(c) Endocrine.....	6,000,000
(d) Nutrition.....	3,000,000
<b>Total</b> .....	<b>20,000,000</b>
National Institute of Neurological Diseases and Stroke.....	10,000,000
National Heart and Lung Institute.....	15,000,000
National Institute of General Medical Sciences.....	5,000,000
National Institute for Child Health Development.....	3,000,000
Dental Research.....	1,000,000
Education:	
Improved doctor/patient communication.....	1,250,000
Patient education/A diabetic must understand his disease and know how to live with it.....	1,250,000
Planning: Health care model health delivery at the State plan for: and community level.....	2,500,000
<b>Immediate enabling needs for diabetes research and education</b> .....	<b>65,000,000</b>

<sup>1</sup> Virtually all diabetic eye patients receiving available therapy are guinea pigs. The number blinded while receiving therapy is considerable.

Mr. STENZLER. But I want to get clear that that is a transition. It is a transition prior to the development of plans by a National Diabetes Commission because what I am saying is that there is immense competence in every institute. It isn't being utilized in this direction. I want to create a direction, a mandated direction. This is the importance of the request for this kind of legislation. It's quick. It moves the ball off dead center.

Mr. HEINZ. Well, I will get to that in a minute. There are a couple other things I would like to have the benefit of your thinking on first.

When Senator Schweiker testified earlier, he came up with a number of about \$1.25 per diabetic per year as the amount of research expended. Recent revelations, both last week and today, indicates that that's probably a high number. We don't spend that much on diabetic research.

Mr. STENZLER. I don't think we do.

Mr. HEINZ. If, in fact, there are 10 or 11 million diabetics, as both you and the previous witness have testified, and if HEW is only spending \$8 million a year, as seems to be the case, we are talking about an expenditure of 55 cents per diabetic per year on all phases of research.

You have proposed to us an expenditure at the transitional level that you have indicated at about \$6 per diabetic per year, assuming 10 to 11 million diabetics.

Let me ask you: Do you have any evidence or statistics to show how that level of expenditure that you propose—and I really have no numbers myself at this point—compares to the efforts made on cancer or stroke or other diseases that we seem to be concentrating on? I would suspect that it's low myself, but I don't have the numbers.

Mr. STENZLER. I would be guessing. These are figures that you

talk about and I have never really—I know that the heart and lung bill created very substantial sums of money. I hear the heart men complaining they are not getting it. I mean, you know, here's a billion dollars and we're complaining because much of it has been impounded or frozen by Executive decree, and they are not getting what they want.

The cancer bill, which again is a major bill that was passed by Congress—there's fact and there's fiction—I don't know, but I suspect they far, far exceed the request for diabetes; and what I am suggesting here is minimal.

Mr. HEINZ. I couldn't agree more, because the expenditure, just taking the conservative figure of \$2 billion a year, amounts to about \$200 per person afflicted with diabetes per year. What you are proposing is equal to \$6 per diabetic per year or 3 percent, while there's scarcely a business firm in the entire United States that doesn't spend 3 percent of its entire sales dollar on research and development. Those that don't are in declining and troubled industries and those that are being successful spend substantially more.

Mr. STENZLER. I think the figure of \$2 billion is low.

Mr. HEINZ. I think you're right. It's probably low.

Mr. STENZLER. Dr. Patz gave you some figures, I am going to add to them. The center for the blind, which is in Philadelphia, told me that they are paid \$3,000 per patient for a 12-week basic training course. This basic training course teaches one how to just simply be alive, go to the bathroom, go up stairs and go down stairs and that's it. That's 12 weeks.

The number of blind, if it amounts to within Pennsylvania of, say, 6 percent of our diabetic population, which is about the figure for those blind by diabetes—am I correct, Dr. Patz?

Dr. PATZ. That's right.

Mr. STENZLER. You come up with, within the State of Pennsylvania—and I don't know where the money is coming from, whether it comes from the State or through the Federal Government—it's one of those major bills that usually moves on because they are very human—I think your figure is going to be far in excess when you talk of rehabilitation, and that's only 12 weeks.

I also found another interesting thing at the Blind Center. The rate of increase in blindness caused by diabetes has moved from 2 percent to 25 percent. Now, whether that's a true figure or not, it certainly is more than a straw in the wind.

Mr. HEINZ. We have an expert witness here. What would you attribute that to, Dr. Patz?

Dr. PATZ. Well, I think it's clearly recognized that just during the past three decades that depending upon what set of statistics are used there's been a three- to four-fold increase in blindness from diabetes, and it's just that insulin came along approximately 50 years ago and the diabetic is now living long enough to develop these late complications of the blood vessel disease which unfortunately the retina is prone to; and as I mentioned, 75 percent of the diabetics who had diabetes for 20 years have some degree of diabetic retinopathy.

Mr. HEINZ. Is this also a question of diagnosis?

Dr. PATZ. I do not feel it's diagnosis because the blind person doesn't require sophisticated diagnosis to find out he is incapacitated.

Mr. HEINZ. I mean from diabetes.

Dr. PATZ. No. I think the recognition of the changes have been in terms of the ophthalmic specialty have been clearly documented even before the discovery of insulin. I don't think it's case finding. I think it's a true increased incidence of this particular complication.

Mr. STENZLER. I think I can add to that figure with fairly decent expertise. In 1923, prior to the discovery of insulin, retinopathy was a rare unique disease. By 1942, roughly 20 years after the discovery of insulin, the National Society for the Prevention of Blindness recorded 3,300 legally blind. By 1960, the National Society for the Prevention of Blindness recorded 45,000, an increase of 1,300 percent. At the same time, glaucoma and senile cataract remained at almost a constant level.

Now, there is a little hook in there because although there were 44 or 45,000 declared legally blind in 1962, the Federal survey in their U.S. health publication No. 1,000, indicated that by 1965 there were 151,000 diabetics without useful vision and then—not to be equated with legal blindness. Now, legal blindness is a legal definition of less than 20/100 visual acuity. That's very legal, but when you have no useful vision in either eye, how blind do you have to be to be blind?

Now, my feeling is when you have no useful vision in either eye, you are blind and should be recognized as such so that you have got an almost 75 percent difference between what is reported as legal blindness, what the Government reported as with no useful vision. On top of that, in the same report—

Mr. HEINZ. It's an important point.

Mr. STENZLER. It lists 238,000 with limited vision. Now, in retinopathy one is on the brink of blindness at any given moment and there's nothing they can do about it. Incidentally, once blindness is identified, death is anticipated in 5 to 10 years from kidney disease, heart disease, or brain damage. So that blindness is literally a terminal marker.

Mr. HEINZ. May I, in the short time remaining to us, turn to what I would call the implementation recommendations that you gave us. You proposed a National Diabetes Commission as a means of getting a program off the ground quickly, as a means of reporting, as a means of planning, as a means of monitoring. In the Senate bill S. 17 that Senator Schweiker, who testified before our committee on Friday, introduced, he proposed a National Task Force on Diabetes.

Are you sufficiently familiar with his proposal to comment on what the difference is between his national task force and your National Diabetes Commission?

Mr. STENZLER. Senator Schweiker is projecting a national task force which will take 18 months to identify the problem. I think it is very evident that you don't need a task force to identify what almost every interested doctor knows; and 18 months is 18 months of time lost.

The Commonwealth of Pennsylvania Committee is a body—and I dare say it has expertise—nationally and internationally famous expertise—and I dare say that if we were asked to prepare a plan we would have one within 6 months or a lot less.

Now, coordinating a group that's part in Boston and part in Cleveland and part in Baltimore is a little difficult, particularly when they have great responsibilities on their own particular hospital or work,

but this could be done. You could put a couple Ph. D.'s down and have them review all the papers that have come through as the result of NIH grants and they will come up with a report in 3 or 4 weeks. You don't need 18 months.

Mr. HEINZ. Let me ask this: In terms of the differences in the responsibilities and the powers of the commission, as opposed to the task force, and apart from the difference in time frame that you have just mentioned, what other differences would you characterize?

Mr. STENZLER. As I remember, the task force is primarily advisory. It is to tell NIH what it thinks is necessary. And with the history of NIH, it is mechanically incompetent to handle this kind of an inter-related program. Now, there must be someone who is responsible for what they do. You used the term "monitor." That's marvelous. There must be some respected group. And incidentally, I again repeat, the quality of these men should be such that they are immune to administration requests to change the content of what they say in order to justify a reduced budget; and I think that's rather pathetic, which is what they have done.

Mr. HEINZ. As you may be interested in knowing, we have taken some steps to make sure that that doesn't happen because a lot of the reports tend to get submitted to OMB before they get submitted to us, and we have made some statutory recommendations for change in that regard.

Mr. STENZLER. Well, I have a letter from Dr. Whedon in which he says, "I see eye-to-eye with you." Well, you have heard me sound off. You have also heard Dr. Whedon. And if you have read his testimony as expressed to both Appropriations Committees, there is a big difference between intent and what he said. "I had to do."

Mr. HEINZ. Mr. Chairman, I am not aware, by the way, that Dr. Whedon's testimony has been available to the members of the subcommittee. It might be advisable if we could send that testimony to the members of the subcommittee.

Mr. KYROS [presiding]. Do we have a copy of it?

Mr. HEINZ. Apparently it was submitted to the Appropriations Committee—the House Appropriations Committee?

Mr. STENZLER. The House Appropriations Committee, which would be Mr. Flood, and the Senate Appropriations Committee, which would be Senator Magnuson.

Dare I read his comments?

Mr. HEINZ. No. The chairman is acting with great patience. He should have gaveled me down 10 minutes ago.

Mr. Chairman, I am most appreciative and I have one last question. With respect to your National Diabetes Commission—and I am very sympathetic to the objectives that you are trying to accomplish there is one problem that comes to my mind, and that is that it's difficult to serve two masters. All of us in Congress know what it's like to serve half a million of them. It's a little easier to serve half a million than it is two. It strikes me that there might be a dichotomy of control between the Commission and the Director of NIH; that the money we have talked about is in part going to be run by the Director of NIH and/or in part by the National Diabetes Commission. And I recognize that some of the things the Commission, as you recommended, would be enabled to do would be outside of

NIH, but with respect to those things that have to do with within NIH, do you see a problem of the subdirectors in NIH having to serve two masters?

Mr. STENZLER. Not really, because the Director of NIH is part of the Commission. He functions there. The five directors work with the Commission in preparing the planning. There must be a unanimity of where do we go, like any general staff.

Mr. HEINZ. So, in a sense, the Director of the NIH would be responsible to the Commission?

Mr. STENZLER. That's right, but the five directors being on the next lower echelon are responsible to the Director, and by indirection to the Commission.

Mr. HEINZ. What would be the relationship between the Commission and the Assistant Secretary for Health to whom at the present time the Director of NIH reports?

Mr. STENZLER. It would be advisory.

Mr. HEINZ. All right. Thank you. Mr. Chairman, I have no further questions except I would like to commend, once again, Mr. Stenzler here and Dr. Patz and Dr. Schwarz for being with the committee. I think you have made a major contribution to the legislative recommendations that we have received. I personally have found your testimony extremely valuable. I think I speak for the committee when I say that we all look forward to not having this just a one-shot deal but working with you to develop a piece of legislation that will not only move quickly and stand a chance of passage and get signed into law, but will be a good and effective and workable and timely piece of legislation, and I thank you sincerely.

Mr. STENZLER. May I offer the services of this committee to you to your committee at almost any time, because this group has only one interest. We represent only people, and this group here, which is totally unpaid, has been working to the hilt; and at any time within reason, I think you can call on almost any man to make himself present to advise or counsel or suggest.

Mr. HEINZ. Well, thank you very much.

Mr. STENZLER. And this is a tremendously broad group.

Mr. KYROS. Thank you very much, and that is a very, very generous offer, and we appreciated your testimony, and the committee is now adjourned.

[The following statements and letter were received for the record:]

STATEMENT OF PROFESSOR ROBERT M. BLIZZARD, PAST CHAIRMAN, PUBLIC AFFAIRS COMMITTEE, THE ENDOCRINE SOCIETY; ACTING CHAIRMAN, DEPARTMENT OF PEDIATRICS, JOHNS HOPKINS UNIVERSITY SCHOOL OF MEDICINE; AND PROFESSOR DAVID R. CHALLONER, CHAIRMAN, PUBLIC AFFAIRS COMMITTEE, THE ENDOCRINE SOCIETY; ASSISTANT CHAIRMAN, DEPARTMENT OF MEDICINE, INDIANA UNIVERSITY SCHOOL OF MEDICINE

Mr. Chairman, the organization which we represent is the Endocrine Society, a society of 2500 North American physicians, chemists, physiologists and investigators who do research in and care for patients who have diabetes and related endocrine (glandular) diseases. We are concerned about the over 4,000,000 individuals in the United States and over 26,000,000 world wide who have diabetes. This represents one in 50 people.

The assignments I gave myself after being requested to testify before this committee are as follows:

(a) To bring to the attention of the members of this committee and their colleagues the potential significance of the act which they are proposing, and to urge

that the content of this bill maximally benefit the constituencies of each of you—specifically, the constituency of the world numbering over 26,000,000 people born, and millions more to be born, who have either what we term “diabetes mellitus” or a related glandular disease.

(b) To bring to your attention that the way this constituency can best be helped is not by setting up centers that are created primarily for treatment.

(c) To bring to your attention that the way this constituency can best be helped is in two ways: *first*, by answering through research and multiple questions about the causes of endocrine diseases including diabetes, the genetics of these diseases, the complications of diabetes, and the prevention of the multiple types of diabetes and related glandular disorders. These questions can, and must, be answered through research carried out in the centers that are being proposed. The *second* way you can best help this constituency of over 26,000,000 people is by supporting training; to support primarily the training of research scientists so they can continue, even ten years from now, to pursue solutions to the questions that must be answered, but also to support the training of nurses, nurse practitioners, and paramedical personnel so that those who have or may develop diabetes or diabetes related entities and/or complications can be detected and preventive measures instituted.

This is not to say that patients and patient care are not important considerations in our goals. This is to say that we *cannot* realistically treat a significant proportion of the 4,000,000 plus diabetic patients in the United States by creating bills of this type and in centers of the type being considered. In such centers financial support for patient care should be limited to those patients participating in research and training projects. Again, therefore, my assignment today is to provide you with the information and data that will encourage you to write and support the National Diabetic Act in the way our constituency will be helped most.

#### BACKGROUND INFORMATION REGARDING DIABETES AND RELATED GLANDULAR (ENDOCRINE) DISORDERS

Diabetes mellitus, or “sugar” diabetes, is not one entity, just as cancer is not one entity and heart disease is not one entity. Most people are unaware of this fact. Although most individuals who have sugar in their urine and high blood sugar levels are called diabetics, the causes, the genetics, the treatment, and the complications will vary in accord with the type of diabetics that an individual has. We are not even aware of all the types of diabetes mellitus that exist or of their causes. The 4,000,000 plus people in this country who are stated to have diabetes mellitus actually have different types of diabetes. For example, there is an entity called juvenile diabetes mellitus in which the individual produces little insulin and the treatment usually must be given by injection of insulin. Also there is diabetes which usually develops in people over the age of 40 and which is called “adult onset diabetes.” In this entity individuals often make excessive insulin in contrast to what one would expect. Many individuals in this group can be treated with oral “hypoglycemic” agents and do not require insulin injections. There also is a type of diabetes which occurs in newborns and is poorly understood. Even within the first two groups mentioned in this paragraph there are probably multiple causes, and, as cancer and heart disease are general terms, diabetes is also a general term as exemplified by the previous statements.

Through research, which is being markedly curtailed at the instruction of our national administration, we have begun to answer a few of the questions and develop some techniques which permit us to begin to understand some of the variants of diabetes. We have recently learned that insulin occurs in more than one form in the blood and there is a “big” insulin in addition to the usual “small” insulin. We do not know what the significance of the “big” insulin is and how this may relate to some cases of so-called diabetes mellitus. In addition, we have recently learned there are hormones not previously known which contribute to the secretion of insulin. We have learned, and I personally have published, about the probability that some individuals develop diabetes because they develop an allergy to their own cells which secrete insulin. We also have learned that certain patients with diabetes develop an allergy to their thyroid tissue and other tissues and actually destroy themselves organ by organ, but we have not learned why, and, therefore, how to prevent this form of the disease.

We have learned that the younger patients who develop diabetes are those who are most apt to develop complications of the kidneys and the eyes. In the latter instance the patient with diabetes often proceeds to complete kidney

failure and will die at an early age if transplant is not possible. In respect to complications of the eye, many patients with diabetes with an onset in childhood will end up blind. However, we have not learned how to prevent these complications. Recently it has been determined that some of these patients can be treated by taking out the pituitary or master gland of the body and that treatment also can be directed at the eye itself using laser beams.

These are only a few of the facets learned by research sponsored through this committee and directed by the National Institute of Arthritis, Metabolism, and Digestive Diseases over the past few years. Although better methods of treatment have been found, through research we have only begun to answer the problems that will clarify the types of diabetes and related glandular diseases and their causes, genetics, and treatment. A few of the research problems that need immediate attention are listed subsequently.

#### RESEARCH PROBLEMS THAT NEED IMMEDIATE ATTENTION

Studies by cell biologists, biochemists, immunologists, and basic science investigators are essential. The role of both types of insulin, the role of glucagon which is an insulin antagonist secreted by the pancreas, the role of growth hormone secreted by the pituitary, and the role of many enzymes found only within the cells themselves need to be elucidated. Attention to the action and interaction of insulin and all of these hormones, along with others at the cell level, is essential not only to understanding how best to treat, but how to avoid complications that we see in many patients with diabetes mellitus.

Genetic studies must be done utilizing each sub-category of diabetes mellitus. We now know essentially nothing about the genetics of diabetes because we have not been able to identify the sub-categories until relatively recently and still are not able to identify all. Genetic studies will have to be carried out as the sub-categories are further elucidated.

The actual amount of insulin produced over a 24-hour period in relation to the amount of glucagon, growth hormone, and other hormones must be measured. The technique for measuring the 24-hour production of such hormones has only been established in the last two years. Elucidation of the interrelationship of production rates of these various hormones will undoubtedly tremendously advance our understanding of the causes of glandular diseases, and indicate better forms of therapy than those currently available.

These are a few of the problems that deserve and require immediate attention. Doctor James Field has submitted testimony concerning other problems.

#### THE TRAINING THAT NEEDS TO BE ACCOMPLISHED

Training must be directed toward research fellows whose goals and interests are to pursue research and who have made a commitment to basic investigation for at least five years. These research scientists may be either Ph. D.'s, M.D.'s, or both. The history of trainees in research is that they contribute significantly in the thought processes and in the accomplishments of their perceivers, while developing the full qualifications for performing independent research investigation. Exemplary are the 20 scientists who have become independent investigators in my laboratory while spending three years in training. Research productivity would have been cut at least 50 percent if these individuals had not participated in obtaining the answers we were seeking.

There also needs to be training of medical and nursing teachers. Such training programs require much less investment of time than that required of individuals in research training. Such teachers should be trained not only in diabetes but in the related fields of endocrinology. Because of the monetary considerations—i.e., that individuals so trained would increase their ultimate wages through this system as partial support—a partial loan system could be utilized to accomplish their training.

The training of paramedical personnel is essential also. This includes nurse practitioners, technicians, etc. The training of such individuals could, in general, be accomplished in a year, and one year fellowships should or could be given.

#### GOAL OF PATIENT PARTICIPATION

In the opinion of those whom I represent and for whom I am speaking today, patient participation should be voluntary. The programs proposed should use patients and encourage their participation primarily as individuals willing to

participate in research and training projects. The establishment of diabetic centers *should not be primarily directed toward treatment*. Patient care should be a by-product of the investigation carried out. It is the opinion of those that I represent that funds can be much better utilized to help the constituency of diabetics and potential diabetics by elucidating the causes, and payment for treatment should be through other mechanisms such as private third party payment, National Health Insurance, Medicare or Medicaid. We urge that in writing such legislation emphasis be placed on the support of research and training and not on treatment per se although we do realize that patients will be treated as part of the research.

#### EVIDENCE THAT THE GOALS CANNOT BE OBTAINED AT THE CURRENT LEVEL OF FUNDING

The National Institute of Arthritis, Metabolism, and Digestive Diseases is the Institute through which funds for most research in endocrine and metabolic disease have been directed. The budget for research in this Institute in 1969 was \$2.3 million dollars. Approximately 40 percent of these funds were directed toward research to solve the problems related to diabetes, glandular, and metabolic diseases. The proposed research budget by the administration for fiscal year 1974 is 88.7 million dollars with the same percentage for research. Research inflation during the past four years has been 8-10%, and, therefore, only 32-40% (4x8-10%) of the funds available in 1969 are proposed to solve these problems.

The total number of research scientists sponsored by NIAMDD in 1969 was 459—only 180 will be sponsored in 1974. The average training period is five years and, therefore, at this rate only 36 per year complete this training. Training grants sponsored by NIAMDD in universities throughout the country in 1969 numbered 302. By 1975 they are projected to be less than 100 and nearly completely phased out the subsequent year. For competing research grants themselves, 33.4 million dollars was available in 1969, but only 20 million dollars is proposed for 1974. Considering inflation, we immediately realize that only 1/3 of the funds available for this purpose in 1969 will be available in 1974. The following table clearly demonstrates how funds for NIAMDD and, consequently, for training and basic research have decreased and why additional appropriations are essential to support the research and training in diabetes and endocrine diseases.

NIAMDD	1969	1970	1971	1972	1973	1974
(1) Total budget.....	130.8	122.6	129.0	145.0	139.0	133.0
(2) Total for research.....	82.3	77.1	80.7	93.6	91.3	88.7
(3) For competing research.....	33.4	21.7	19.3	31.0	19.2	20.0
(4) Percent diabetic and endocrine related.....	(1)				38.5	40.1
(5) Number of fellowships in NIAMDD.....	459					180
(6) Number of training grants.....	302					159

1 40 percent of (2).

Obviously any funds made available to the NIAMDD to establish diabetic centers *must be in addition to those currently budgeted and not a reallocation of funds within that budget*.

#### SPECIFIC PROPOSALS REGARDING PROPOSED BILLS

Even this bill does not adequately emphasize that the constituency of diabetics, and those interested in diabetes, will be best served by assuring that at least 50% of all funds designated must be used for basic and clinical investigation and/or training of research scientists.

I reemphasize that all funds appropriated and authorized for the establishment of diabetic centers *must be beyond* those that would otherwise be appropriated for NIAMDD. Reallocation of funds would be to the detriment of not only the scientific community but to the diabetic constituency. The more than 4,000,000 diabetics cannot possibly benefit from the \$40,000,000 allocation per year for treatment. These 4,000,000 diabetics, plus those unborn, *will* benefit significantly from \$40,000,000 per year allocated for research and training.

We urge that the National Institute of Arthritis, Metabolism, and Digestive Diseases be the administrative unit through which the development of centers occurs; this organization has the experience to carry out the goals of this leg-

isiation. We believe it would be a mistake for any organization other than the NIAMDD to be responsible for the administration of this legislation. We also believe that close tie-in should be devised to whatever extent is necessary with other institutes, and, especially the Eye Institute.

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STATEMENT OF FRANCES E. PENTLARGE, WORCESTER, MASS.

My daughter has had diabetes since she was four. It has always been so bad that they could not control it in the hospital. She has had kidney trouble and high blood pressure for two to five years. Her life expectancy is 10 years, more or less, with some years of dialysis treatment, possibly blindness, perhaps a kidney transplant, (her doctor says I am not too old to donate a kidney, it really depends on whose kidney matches best). But really, perhaps God will be merciful and spare her all the troubles.

She has just finished her first year at college, very successfully; although a great part of each day is taken up with care of her physical health. She has to take two kinds of insulin twice a day, and more some days. She is supposed to test her urine 4 times a day and sometimes every half hour. She is supposed to weigh and or measure all her food, three meals and three snacks each day. She tests her blood sugar frequently. She measures her blood pressure daily. She adjusts her insulin doses, and her seventeen daily pills according to the results of the various tests. She always has to have sugar with her in case of an insulin-reaction. Fruit is best, but it does not pack well and does not keep well, so she carries life savers instead, which she must never eat unless she is having an insulin reaction. She carried raisins for years, but is so sick of them that I think the sight of them tends to make her nauseated. She averages one insulin reaction per day (low blood sugar). The symptoms and signs include just about every unpleasant feeling and condition there is, dizzy, cold sweat, everything including convulsion.

Few people at college knew that she had diabetes, none knew what her prognosis is, or what her daily life included. It has been like this since she was four; of course it used to be that her father and I took care of her. Who else could be expected to learn all that? It includes a precise knowledge of the composition of all the foods she eats, and their rates of digestion.

The thing I always found the hardest was to remember to take fruit or candy with us if we went for a spur of the moment walk, or swim.

This "cure" for diabetes can not undo the damage that has been done to every cell in her body, but it might stop the continual deterioration that continues every day.

I want it to stop as soon as possible.

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SILVER INDUSTRIES, INC.,

July 27, 1973.

HON. PAUL C. ROGERS,

*Congress of the United States, House of Representatives, Committee on Interstate and Foreign Commerce, Rayburn House Office Building, Washington, D.C.*

DEAR CONGRESSMAN ROGERS: I was delighted to learn from Dr. Dowling of the Joslin Clinic that you have called the House Sub-Committee on Health to hold hearings on the diabetes legislation, Bill HR 4882 on Friday, July 27th, and Wednesday, August 1st.

I urge in the strongest possible terms that this sub-committee recommend favorably for adequate funding.

I am attaching to this letter a brief outline reciting the problem of the diabetic and the current position of research in this field. As you can see, time is of the essence. A breakthrough in research is imminent, but could be sacrificed easily to inadequate funding. Once set aside, this critical research could be resumed only with great difficulty, with loss of time and effort already expended, and with needless loss of many lives.

Your support and comments will be greatly appreciated. Five million diabetics now living in the United States under a sentence of slow death, blindness and crippling await your action with hope and prayers.

Very truly yours,

JULES SILVER, V.M.D., *President.*

Enclosure.

## DIABETES—A SUMMARY

1. *Scope of the problem.*—There are today approximately 5 million diabetics in the United States. Appallingly, an additional 5 million or more now living will become diabetics. Even worse, since diabetes is a disease with clearly established hereditary factors, the annual increase in the number of new victims exceeds the general growth in population.

2. *Cost of diabetes.*—For diagnosis and treatment as well as care of those made indigent by the ravages of diabetes, the current yearly cost in the United States is approximately 4½ billion dollars—and the cost goes higher every year.

3. *History of treatment.*—Insulin, originally thought to be the solution to the diabetes problem with no more than the inconvenience of one or more daily injections, has been available for about 50 years. Tablets taken by mouth have been available for about 15 years and were believed to offer effective control to at least some diabetics without even the inconvenience of daily injections, but the tablets could never be given to victims of juvenile diabetes. And yet, diabetes today is the most frequent cause of blindness in the United States, and the 5th leading cause of death.

In truth, insulin and the oral antidiabetics have succeeded only in a very limited sense. They have spared the victims of diabetes from a swift and merciful death which occurred before these became available. However, the life of the diabetic has been prolonged at a terrible cost: now, he faces, inevitably, a lingering and far less merciful death. His disease, apparently under control, progressively destroys his blood vessels—leading to kidney failure, blindness and amputation of extremities made necessary by irreversibly poor circulation.

4. *Current research.*—Seldom in the history of medical research has it been possible to state with such certainty that mankind is on the verge of a significant breakthrough.

Researchers have not succeeded in growing, in the laboratory, pancreatic beta cells, the cells which produce insulin only. These laboratory-grown beta cells when transplanted into animals as high as monkeys are not rejected and continue to function, secreting insulin as does the normal pancreas.

This cell transplant is less than a year from being ready for use in man.

Adding greater importance, the transplantation of specific, functioning cells which continue to function as would a whole organ leads to exciting possibilities for the treatment of a wide variety of other diseases now inadequately controlled.

In addition, Dr. Soeldner at the Joslin Clinic has developed and is ready to test in humans "artificial pancreas" which will be implanted in the body and will keep continuous track of blood sugar levels, mechanically metering out insulin as needed. This is a second direction of greater importance.

5. *Immediate financial need.*—Key researchers in diabetes are now working on a month-to-month basis. One has funds only until November. Teams might have to be disbanded, perhaps never to be brought together again. Funding is needed now so that work in progress is not stopped midstream with resulting lost time if it ever can be started again. After a time lapse, one research team can not pick up where another left off because animals under observation would have been slaughtered. The work would have to be started again, with as much as a year lost.

It is needed *now* so that the 5 million diabetics and the 5 million pre-diabetics in this country will no longer face lifespans shortened by 15 to 20 years as an inevitable, cruel death.

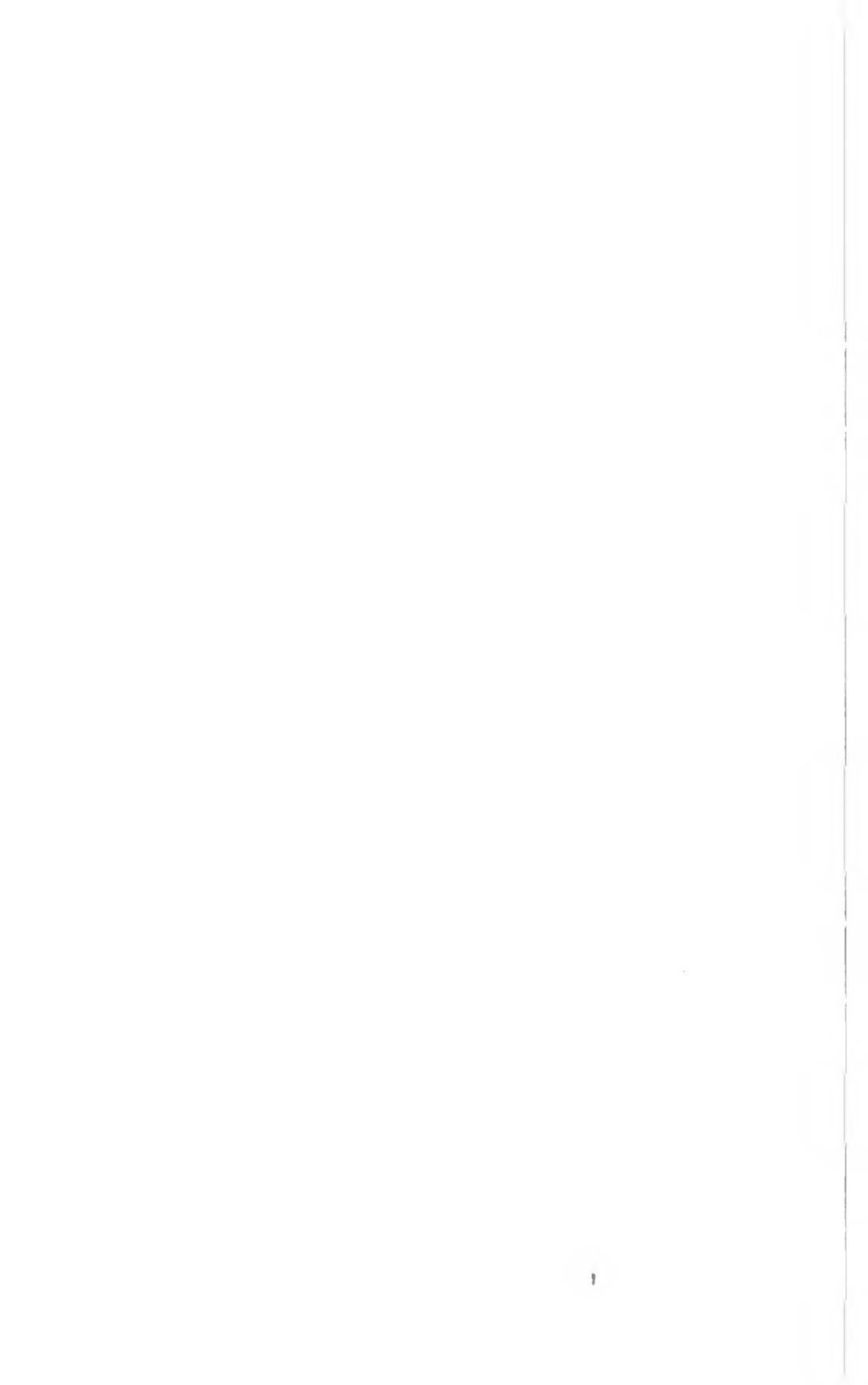
It is significant to note that the 20 million dollars needed amounts to less than a dime per person in the United States. Every person today living has about 1 chance in 8 of becoming diabetic.

6. *Need for Federal funds.*—Only Federal funding can save this benefit for all of us, and in time.

Because of the progress already made in research and the acute shortage of funds now threatening that research with extinction, the need is immediate. Truly an emergency exists, an emergency which can be met only with an emergency funding bill.

We can not forget, either, what a gift it would be to the world and how much more goodwill it would buy for the U.S. than all of our foreign aid programs combined.

[Whereupon, at 12:25 p.m., the hearing was adjourned.]



## APPENDIX

### POSITION STATEMENT—THE COMMONWEALTH OF PENNSYLVANIA COMMITTEE ON DIABETES AND BLINDNESS

#### PROBLEM STATEMENT

Diabetes mellitus (short form: diabetes) begins as the commonly known "sugar sickness" and matures into a progressive vascular disease causing blindness (retinopathy), heart failure (myocardial infarction), kidney failure (nephropathy), and lesioned nerve endings (neuropathy).

Diabetes occurs when sugar excess in the blood and sugar wastage in the urine are present. Discovery of insulin enabled persons formerly condemned to premature death to survive, have families, and maintain relatively normal lives. Prior to this discovery in 1922, almost two-thirds of all persons with diabetes dies in coma within five years of onset.

The increased lifespan made possible by insulin therapy has simultaneously allowed the mature, systemic nature of the disease to surface. Within ten to thirty years from onset, an estimated 95 percent of all diabetics experience major complications in one or more primary body functions.

In 1935, 500,000 diabetics were recorded in the United States. In 1959, an estimated 2,930,000 persons were diagnosed or undiagnosed diabetics. By 1968, the number of diagnosed diabetics alone had increased to 4.2 million persons; and by 1970, to 5 million. In 1972, the American Diabetes Association estimated that one out of every twenty Americans was a diagnosed or potential diabetic.

One out of every four Americans—50 million persons—or 25 percent of the population, carries the recessive gene that transmits the disease to children or grandchildren in his genetic make-up. The diabetic population is expected to increase by one million persons every three years. By the year 2000, an additional 10 million persons may become diabetic.

#### THE IMPACT OF DIABETES MELLITUS

*Diabetes is the first cause of adult blindness, and the second cause of all blindness in the United States.*

In 1940, diabetic retinopathy accounted for 1.4 percent of all blindness. By 1962, this proportion increased to 11.2 percent, an increase of 1300 percent. During the same period, the prevalence of legal blindness (20/200 visual acuity in each eye) due to glaucoma and cataract remained fairly constant.

The Harvard School of Public Health predicts an estimated 573,000 persons will be blinded or experience severe visual impairment from diabetes in the next three decades. This figure represents more persons than the number blinded from all causes today.

*Diabetes is a major cause of cardio-vascular and renal impairment.*

The Joslin Clinic found that 52 percent of all diabetics die prematurely from heart disease; that almost half the patients with disease onset under age fifteen die of kidney disease; and that 50 percent of all diabetics blinded by retinopathy will die from heart, kidney or brain disease within five to ten years from onset of blindness. Approximately 72 percent of the diabetic population succumbs to diabetes-caused premature death from cardio-vascular and renal problems.

*Diabetes is the first cause of male impotence, and a serious cause of female sexual incompetence.*

*Diabetes is the first cause of pregnancy loss.*

Diabetic mothers bear 15 to 20 more fetal waste, and three times as many malformed children than their non-diabetic counterparts. Brain damage among children of diabetics is frequent.

*The life expectancy of a diabetic is only two-thirds that of the general population.*

A diabetic child at age 10 years can expect to live only 44 more years as compared with the 62 years for a non-diabetic child of the same age. At age 30, the diabetic's remaining life may only 30 years, while a non-diabetic can anticipate another 42 years.

Mortality among diabetics is higher at every age. Death rates are from five to ten times greater for the general population among children, and at least double in later life.

*Diabetes is now the fifth cause of death in the United States.*

In 1969, diabetes was the eighth cause of death. And, Dr. George Tokuhata, Director of Research and Biostatistics for the Pennsylvania Department of Health, has determined that many recent deaths accorded to heart or kidney failure were, in fact, the result of mature diabetes, a fact that went unrecorded on the death certificate. Applying the Pennsylvania statistics of unreported cases of diabetic deaths, nearly 304,000 instead of 38,000 persons are expected to die annually with diabetes in the United States. If all these deaths, including underlying and contributing causes and unreported cases, were considered together, diabetes could become the third leading cause of death.

#### WHAT IS NEEDED

There is neither prevention nor cure for the disease. The cause is unknown, although unquestionably, diabetes represents a genetic defect. The progressive lethal impact of the syndrome on all body functions can be partially retarded with therapy, but not stopped. Experts even disagree as to the proper direction for palliative therapy, treatment and control.

The disease must be properly identified, its cause and cure sought.

Arrest and preventive therapy must be developed and made available.

Physicians must be trained in the most effective methods for teaching diabetics how to best live with the disease.

Funds for continued research into all aspects of the disease—symptomatic, genetic, environmental and therapeutic—must be made available. Comprehensive research efforts into the interrelationship between diabetes and other body disorders must be initiated.

#### PUBLIC AND PRIVATE INTEREST

Since 1945, medical journals have documented the negative impact of diabetes on major body functions. The National Institutes of Health (NIH) have prepared numerous studies and publications that discount the benign image of the disease generally projected to the public. However, these conclusions have not been well publicized. And, although diabetes is a documented cause of, and bears direct relation to, many of the problems which NIH is charged to explore, the disease has received but minimal recognition and research effort.

Private interest in diabetes has concentrated on detection and public education programs. Little attempt has been made to lobby Congress for increased funding levels or for recognition of the potential impact by diabetes on the nation's population. Individual organizations jealously compete for limited public funds and attention.

The American Diabetes Association (ADA) and the National Association for the Prevention of Blindness (NAPB) are the most notable of the private interest groups. The ADA was created by the medical profession, and represents the interests of physicians with diabetic patients. The NAPB represents the welfare of, and provides education and counsel for, all blind persons. Both organizations effect strong public education programs directed toward blindness prevention. However, until recently, neither released data concerned with the deleterious impact of the diabetes syndrome and its relation to blindness.

The Joslin Clinic and the Retina Foundation specializing in research and treatment; the former, in diabetes, and the latter, in problems of the retina. Although their work is primarily supported by Federal Appropriations, these organizations have lobbied Congress for only minimal sums. Attempts to coordinate their research efforts and limited funds have failed.

The Juvenile Diabetes Association (JDA) is more militant. Established as a non-profit corporation in 1970 by parents of juvenile diabetics in Pennsylvania, the organization has begun to actively press for additional research funds and recognition for the special needs of the 10,000 juvenile diabetics and their parents in the state.

## LEGISLATION

Prior to 1972, the Congress neither approved nor introduced legislation bearing direct relation to the problems of diabetes.

More than one billion dollars is authorized and spent annually for education and rehabilitation of the blind. Yet, a total of only \$37 million has been appropriated for all research into the cause and cure of blindness. In FY 72, only \$1.4 million was allocated for the study of diabetic retinopathy.

Dr. Harold Schel, Professor and Chairman of the Department of Ophthalmic Research of the University of Pennsylvania, contends the private sector spends as much money yearly for eye wash as for eye research, and an even greater sum for eye cosmetics.

The ADA estimates an annual revenue loss of more than \$2 billion in uncollected taxes, lost earnings and non-productivity on the part of diabetics. It projects a yearly national cost of an additional \$2 billion for the treatment and rehabilitation of diabetics.

Yet, the current annual Federal expenditure per diabetic is only \$1.60.

Major health legislation has passed both Houses of Congress without hearing testimony from either the public or private sectors that more than casually identified the needs of diabetics. Equally significant, no funds have been authorized for exploratory research into the relationship between diabetes and other major diseases despite wide documentation of their interaction.

*In 1972*

Senator Richard S. Schweiker (R., Pa.) introduced (S. 3880) to amend the Public Health Service Act for FY 73. The bill provides for education with regard to, and detection of, diabetes. It authorized grants for public and non-profit screening, counseling, and treatment programs through the Department of Health, Education and Welfare, and for establishment of similar programs within the Public Health Service and Regional Medical Program. The bill established a task force to conduct a comprehensive study to determine the magnitude of diabetes, to evaluate its economic and social consequences, and to formulate a long-range plan to combat the disease.

S. 3880 was not reviewed.

In July, Senator Schweiker introduced a \$4 million add-on amendment to the HEW appropriations bill. Congress appropriated \$2.5 million and 22 additional positions to the National Eye Institute "for an accelerated research program . . . to allow NEI to develop a(n) . . . integrated approach for diabetic retinopathy and closely related vascular diseases of the eye.

President Nixon vetoed the Public Health Service Act.

*In 1973*

Senator Schweiker has reintroduced legislation (S. 17) to amend the Public Health Service Act. This bill is an expanded version of (S. 3880).

Senator Gale McGee (D., Wyo.) has introduced an amendment (S. 648) to the Public Health Service Act that would expand authority of the National Institute of Arthritis, Metabolism and Digestive Diseases. The Institute would develop and present to Congress a National Diabetes Program expanding and coordinating all NIH activities respecting diabetes. It authorized diabetes prevention and control programs through various health agencies at levels of \$25, \$35 and \$45 million for the next three fiscal years, and requires establishment of training centers concerned with diagnostic, prevention and treatment methods.

Senate Sub-committee hearings have been held on (S. 17) and (S. 648); a revised version of the two bills is being prepared.

Congressmen William Stelger (R., Wisc.) and Guy Vander Jagt (D., Mich.) have co-sponsored a companion bill, (H.R. 4882) to (S. 648) that is cosigned by 51 additional Members of Congress. Sub-committee hearings have not yet been scheduled.

The Administration has expressed no interest in these bills, recommending a phase-out of the Regional Medical program and consolidation of its functions with existing endocrine research programs. It also recommends legislation that substantively reduces the number of fellowships and training grants available and that discontinues research into specialized diseases.

## THE COMMONWEALTH OF PENNSYLVANIA COMMITTEE ON DIABETES AND BLINDNESS

In 1970, Governor Shapp of Pennsylvania, responding to lay request for organized public interest in diabetes, created the Commonwealth Committee on Diabetes and Blindness. The Committee was charged with four tasks:

- (1) To represent the 300,000 known diabetics in Pennsylvania and, by extension, the diabetic population of the United States.
- (2) To effect proper identification of the disease and of its progressive, dehabilitative nature; and to educate the public as to its findings.
- (3) To develop recommendations as to needed therapeutic and research action; and to determine how funds might best be allocated.
- (4) To lobby its recommendations to national officials in order that legislation appropriating funds for therapy and research might be obtained.

Chaired by Carl Stenzler, a concerned layman, the Committee is composed of leading physicians whose functional areas are most impacted by diabetes—heart, eyes, kidneys, brain and the nervous system. Defined as a “loose coalition” of special interests, its primary function is that of a catalyst for Congressional interest and appropriations. No member is asked to relinquish separate identity, area of expertise or capacity to obtain funds. The Committee hopes to effect strong, organized representation where, previously, competition for limited funds and attention resulted in unmet need and duplication of effort. In its fullest sense, the Committee is a “medical body with political overlay.” Committee membership is being expanded to include representatives of the youth, the elderly, organized labor pension fund, insurance funds and other health lobbies bearing relation to diabetes.

Each member is now preparing a critical summation of the impact of diabetes on his functional area. These papers will be issued in a report of findings and recommendations later this year. In addition, members respond to public requests for information; a panel of members recently testified as hearings on (S. 17) and (S. 648). Testimony is currently being prepared for additional hearings in both Houses.

The Committee recommends:

- (1) *Creation of a National Health Commission on Diabetes; to be charged with exploration of problems and/or promise of therapy, prevention techniques and cure of diabetes.*

Through a structured membership representative of those functional areas of the body most affected by mature diabetes—heart, eyes, kidneys, brain and nervous system—the Commission would recognize diabetes as a syndrome with impact on all body systems. Its chairman, appointed by the President; its members would be politically independent, and thus, more able to focus on medical problems. Two laymen would also be included in the committee membership. Within one month of its creation, the Commission would present recommendations concerning therapy and specific research directions to its chairman. These would be forwarded to existing institutions, possibly the NIH, already charged with research and/or therapeutic responsibility. Within one year and for each year thereafter, the Commission would submit a report to NIH testifying to accomplishments or breakthroughs or the lack thereof. It would also prepare summaries of major recommendations for release to the general public.

- (2) *Appropriation of \$50 million in Federal Funds earmarked for research and education, and allocated over a three year period at the discretion of Congress.*

Such funding would permit development and provision of arrest and preventive therapy. It would enable young new brains to enter research, and provide physician training as to how to best educate patients to live with the disease. Training centers similar to those now operated by the Joslin Clinic could be established. The money would also be used to educate the public about the pro-

gressive, debilitating nature of diabetes. Lastly, these funds would be seed money for research into the systemic nature of diabetes, and to coordinate this research with that ongoing for other diseases.

The Commonwealth Committee believes the above recommendations to be but a stop-gap solution to a long-range problem. Additional, continued research funding that supersedes traditional, annual Congressional review is essential to extensive, long-term research into the cause and cure of diabetes, and its relationship to other body functions. The Committee feels it is imperative that this inter-relationship be explored, if permanent solutions are to be achieved.

From a policy standpoint, the Committee believes these recommendations to be consistent with the Administration's position on block grants for comprehensive research, and on stimulation of local initiative through state participation in a fair-share program.

#### APPENDIX A—THE COMMONWEALTH COMMITTEE ON DIABETES AND BLINDNESS

*Chairman.*—Carl Stenzler, concerned layman.

*Eyes.*—Harold G. Schei, M.D., Professor and Chairman, Department on Ophthalmology, University of Pennsylvania; Charles Schepens, M.D., President, Retina Foundation, Boston, Mass.; Associate Professor of Ophthalmology, Harvard Medical School; Irving H. Leopold, M.D., Professor and Chairman, Department of Ophthalmology, Mt. Sinai School of Medicine.

*Small blood vessel degeneration.*—Richard A. Field, M.D., Senior Scientist, Retina Foundation, Boston, Mass.; Associate Professor of Medicine, Harvard Medical School.

*Large blood vessel degeneration.*—Robert F. Bradley, M.D., Medical Director, Joslin Clinic, Boston, Mass.

*Kidneys.*—Arnold S. Reiman, M.D., Chief of Medical Services, Hospital of the University of Pennsylvania; Professor of Medicine, University of Pennsylvania.

*Heart.*—William Likoff, M.D., Professor of Medicine, Hahneman Medical College.

*Teeth and gums.*—Merwin A. Lauday, M.D., Professor of Dentistry, Temple University School of Dentistry.

*Juvenile diabetes.*—Robert Kay, M.D., Professor of Pediatrics, University of Pennsylvania.

*Maternity.*—Charles R. Scbuman, M.D., Professor of Medicine, Temple University College of Medicine.

*Genetics.*—Arthur G. Steinberg, Ph. D., Professor of Biology and of Human Genetics, Western Reserve University.

*Resource information.*—George K. Tokuhata, Dr. P.H., Ph. D., Director, Division of Research and Biostatistics, Pennsylvania Department of Health; Professor of Biostatistics, University of Pittsburgh Graduate School of Public Health; Associate Professor of Community Medicine, Temple University College of Medicine.

*Anesthesiology.*—Stephen J. Gallia, M.D., Associate Professor of Anesthesiology, University of Pittsburgh School of Medicine.

*Neuropathy.*—Richard Chambers, M.D., Professor of Neurology, Thomas Jefferson Medical College.

*Epidemiology.*—Christian R. Klmt, M.D., Professor and Director, Division of Clinical Investigation, University of Maryland Medical School.

*Concerned laymen.*—Hon. Robert Rovner, State Senator, Commonwealth of Pennsylvania; Robert Dechert, Esq., Senior Partner, Dechert, Price and Rhoades.

## DIABETES AND THE EYES

(By Peter H. Morse, M.D., Assistant Professor of Ophthalmology, University of Pennsylvania School of Medicine, Presbyterian-University of Pennsylvania Medical Center; Harold G. Schele, M.D., Director, Schele Eye Institute; William F. Norris and George E. DeSchweinitz, Professor of Ophthalmology, Dept. of Ophthalmology, University of Pennsylvania School of Medicine, Presbyterian-University of Pennsylvania Medical Center)

Diabetes mellitus may affect the eyes in many ways, the most serious of which is known as diabetic retinopathy. For some reason, still incompletely understood, the normal blood vessels may be altered in the eyes of diabetics, resulting in a leaking of plasma into the retina. This fluid, which is incompletely reabsorbed, leaves the retina in a swollen (edematous) condition which seriously interferes with vision because of the predilection for this to occur in the central part of the retina near the macula. The macula is  $\frac{3}{10}$  mm in size and it is here that all the fine central and color vision reside. Larger defects in the normal blood vessels may lead to hemorrhage of various sizes which may also interfere with vision.

There are small dilatations of the blood vessels in the posterior part of the eye near the macula which we call microaneurysms. Some of these may leak plasma, further compounding the patient's difficulty.

The other major alteration in the retina in diabetes involves the formation of new blood vessels which are never as strong as normal blood vessels. These new blood vessel leak plasma but more particularly, are prone to massive hemorrhage. Associated with this new blood vessel formation, there is a variable amount of fibrous tissue which in combination with the new blood vessels is known as proliferative retinopathy. This fibrous tissue, in many cases, undergoes contraction and may secondarily detach the retina in the eyes of diabetics.

The tragic fact is that often, both the changes of chronic leaking vessels and new blood vessel formation are so insidious that the patient is not aware of these changes until they are often beyond effective or satisfactory treatment. The longer the retina in an eye with markedly reduced vision remains edematous or swollen, the less likely is the prospect of restoring vision with what limited treatment is available today. Once the new blood vessels and fibrous tissue progress to a certain extent, there is already so much damage that available therapy can be of little benefit to the patient. In some of those patients with extensive neovascularization or new blood vessel formation, large hemorrhages in the eye may clear but unhappily, in a large number, once this has occurred, there is no restoration of vision because of failure of resorption of blood and further hemorrhage.

It has been noted that the problem of diabetic retinopathy and blindness has been compounded by medical advances in the treatment of patients with diabetes mellitus. The longer the duration of diabetes, the greater the chance for development of retinopathy and severe visual impairment in any given patient. Fifty percent of diabetics with disease for twenty years duration will develop retinopathy of 95% of patients with diabetes for thirty years will develop retinopathy. (1) This figure is made even more staggering by the fact that there has been an increase of 1300% in blindness caused by diabetes since 1940. (2)

It is estimated that one in twenty people is a potential diabetic and  $\frac{1}{3}$  of the population are carriers with a 50% chance of passing the trait for diabetes mellitus on to their children. (3)

Currently, diabetes is responsible for 11.2% of blindness in the United States and diabetes is ranked as the second leading cause of blindness. (2, 4) However, it must be remembered that the two other leading causes, cataract and glaucoma, are largely curable or controllable with early diagnosis and medical or surgical treatment. One particularly alarming fact is that among juvenile diabetics, severe hemorrhage and visual impairment often occurs in the third decade of life.

Since diabetic retinopathy is not a reportable cause of blindness, it is rather difficult to obtain accurate projections and statistics. Because of the increased longevity of diabetics and the fact that many do not develop the disease until they have borne children, coupled with increasing detection of diabetes in screening programs and more adequate medical facilities, it is estimated that there is

a 9% annual increase in the number of diabetics. The Harvard School of Public Health estimates that there are currently 154,700 people blind from diabetic retinopathy and by the year 2000, 573,500 people in the United States will be blind from diabetic retinopathy. From published figures of the Harvard School of Public Health in January of 1964, there were 2,311,000 diabetics, 120,000 of whom were blind and 341,000 of whom were visually impaired. Therefore, 35.2% of all diabetics visually impaired were blind. In 1965, 38.8% of all visually impaired diabetics were blind. (5)

In 1967, figures from the American Diabetes Association projected an actual and potential diabetic population in the United States of 9,800,000 people. Because of the fact that currently, about 7% of all diabetics are destined to go blind, this calculates out to an enormous number of 686,000 people in the United States destined for blindness due to diabetic retinopathy. (6)

In the Commonwealth of Pennsylvania, the Center for the Blind, from January 1963 to April 1972, noted that 42 of 402 trainees were blind due to diabetic retinopathy (10.4%). (7)

Unfortunately, today very few people consider the protean manifestations of diabetes mellitus and especially the retinopathy. The potential blindness is often glossed over and the importance of regular eye examination minimized. Despite the fact that our present methods of treatment could best be described as stop-gap, there are certainly a number of patients who are benefited by these treatments and useful visual acuity may be either restored or prolonged for an indefinite period of time. As stated before, because of the frequently insidious nature of diabetic retinopathy, many patients are unaware of their difficulty until it is beyond the stage of even the most advanced treatment available today. Commonly, patients will say, "If I had only known!" Probably the best method of treatment currently available is that of photocoagulation or laser treatment to seal off or "spot weld" leaking blood vessels in the eye, as well as new blood vessel formation at a reasonably early stage before either have led to severe visual impairment or irreversible secondary change with severe hemorrhage and contraction of fibrous tissue.

Unfortunately, this method of treatment is not curative and there are countless numbers of diabetics for whom this is not feasible. The long-term results of this form of therapy are currently under study. There is no question that diabetes and diabetic retinopathy are a rapidly growing problem in the United States and the Commonwealth of Pennsylvania, to say nothing of the world. It is urgent that something be commenced at the present time because it is going to take some lengthy period before the answer is found. The objectives should be three-fold. 1) We must evaluate and refine the present methods of treatment and diagnosis. It must be remembered, however, that while this approach along with a widespread public education program might be of benefit to some individuals, it does not attack the basic underlying cause of this dreadful disease. 2) The real answer will come from intensive metabolic and biochemical studies of tissue and cell constituents, as well as enzymes, hormones, and their interaction at a very basic level which underlies the manifestations of diabetes mellitus. 3) One must invest in an entirely new approach to determine the specific cause or chemical mechanism which leads to this crippling disease. Therefore, the urgency in this matter lies not only in making available information and present methods of therapy, but also intensive investigation to determine what can be done to prevent the disastrous complications of this disease. All that one can do is cope with the already present damage and disabilities in an inadequate way, but we desperately need to find a means of prevention for a rapidly growing and severely disabling disease process.

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## DIABETES MELLITUS AND HEART DISEASE

(By William Likoff, M.D., Professor of Medicine and Director, Cardiovascular Institute, Hahnemann Medical College and Hospital, Philadelphia, Pa.)

The fundamental importance of diabetes mellitus in heart disease essentially depends upon the frequency with which the metabolic disorder is accompanied by coronary atherosclerosis and its complications. Both the morbidity and mortality rates from coronary atherosclerosis have increased materially over the years, despite the fact that insulin, all antidiabetic agents and dietary measures have contributed to the better control of carbohydrate metabolism.

Morbid studies clearly document the greater incidents of coronary atherosclerosis in individuals with diabetes mellitus. Clinical evidence is equally imposing. Angina pectoris and myocardial infarction are observed with much greater frequency among diabetics than among non-diabetic individuals. The predisposing effect of diabetes on the development of atherosclerosis is witnessed by the fact that women who menstruate normally are uniquely protected from coronary vascular disease, unless they suffer from diabetes mellitus. Furthermore, the metabolic disorder also appears to hasten the time coronary vascular disease appears in either sex. Finally, pre-clinical or clinical diabetes has been found to be more prevalent in patients with coronary heart disease than in the general population.

Coronary arteriography, the technique by which the internal caliber of the coronary arteries is visualized radiographically, has provided considerable evidence supporting the view that diabetes mellitus is responsible for precocious and more malignant forms of coronary atherosclerosis. Indeed the pathologic lesions often are observed to be widely distributed throughout the vascular channels and to involve the lesser vessels in the coronary circulation. Serial arteriographic studies indicate that the evolution of coronary atherosclerosis is more closely related to the presence of diabetes mellitus than to any other of the purported risk factors, such as hypertension, stress, cigarette smoking and hyperlipidemia.

Over one-half of the patients with diabetes mellitus, who suffer an acute myocardial infarction for the first time fail to survive. Less than 40% recover from a second attack. These statistics are more unfavorable than those encountered in patients who do not suffer from diabetes. The annual attrition rate for survivors likewise is much more unfavorable for diabetic than non-diabetic individuals.

The premature onset, severity and rapid evolution of coronary atherosclerosis in patients with diabetes mellitus, and the fact that in coronary heart disease fully 65% of cases show abnormalities of carbohydrate metabolism suggests a possible common denominator in the etiology of these diseases. This is supported in part by the observation that abnormalities in small arteries and capillaries precede the appearance of carbohydrate disturbances in diabetic patients. However, at least to this point, investigation has not established the fact that a common denominator exists, let alone its exact nature.

In addition to coronary atherosclerosis, hypertension is common among diabetics. The exact relationship between the two problems is uncertain. There are a number of disease syndromes which feature hypertension and diabetes. Most prominent among them is acromegaly or hyperfunction of the anterior pituitary gland. Cushing syndrome or hyperfunction of the adrenal cortex, and myxedema or severe hypothyroidism. In addition, intercapillary glomerular sclerosis, a severe progressive structural affliction of the kidney, is also associated with diabetes mellitus and hypertension, as well as severe albuminuria and peripheral edema.

The combination of diabetes mellitus, coronary atherosclerosis and hypertension often terminates in the development of an acute myocardial infarction and immediately or later, in the clinical manifestations of congestive heart failure.

It is reasonable to suspect that a metabolic deficiency secondary to the diabetic state may serve as contributory factors in the development of the heart failure.

The statistical and clinical links between diabetes mellitus and coronary

atherosclerosis appear to be all the more reasonable when examined in the light of current theories regarding the pathogenesis of atherosclerosis. The most widely held of these theories relates the origin of atherosclerosis to a disturbance in fat metabolism, and more specifically in the metabolism of cholesterol. The detailed evidence for this theory is based chiefly on the cholesterol content of human atherosclerotic lesions and the development of hypercholesterolemia and atherosclerosis in many experimental animals following cholesterol feeding. Diabetic individuals tend to exhibit identical abnormalities of cholesterol metabolism thoroughly and prior to the development of overt manifestations of atherosclerosis.

Another of the substantial concepts in the pathogenesis of atherosclerosis is that the vascular lesions evolve from conglutination of platelets along the endoperitoneal lining of the vascular channels. Platelet conglutination is believed to take place as a result of obstructional deformities for increase in the adhesiveness of those blood elements. Although variations in the structure and biochemical function of the platelets is extremely difficult to demonstrate, evidence is accumulating that they are observed frequently in diabetic patients as in non-diabetic patients who suffer from advanced atherosclerosis.

The suggestion that diabetes mellitus and coronary atherosclerosis share a common pathogenesis is a unique challenge in basic and clinical investigation. There remains, however, the current problem of the common occurrences of these clinical problems and the difficulties which arise as a result in diagnosis and therapy. It is immediately obvious that the presence of one of these clinical diseases emphasizes the need to inquire about the possibility that the other likewise exists. The gain from a diagnostic viewpoint alone, the acute coronary accident is sometimes associated with hyperglycemia, glycosuria and ketonuria, as well as shock, nausea and vomiting. These findings may be so dramatic and the laboratory abnormalities so marked that the diagnosis of diabetic coma may be reached while that of the acute myocardial infarction may be ignored. Conversely, diabetic coma may actually occur with or be precipitated by an acute coronary occlusion and may be overlooked in favor of the cardiac trouble.

It is well recognized that the association of an acute myocardial infarction with diabetic coma requires special caution and treatment in order to avoid iatrogenic hypoglycemia or too vigorous administration of fluids, either of which could induce serious cardiac problems such as coronary insufficiency, electrical dysfunction, or congestive heart failure. In the treatment of all cases of chronic diabetes mellitus, particularly adults in the sixth and seventh decades, it should be assumed that pronounced coronary atherosclerosis is probably present. The vascular condition can indicate sharp reductions in blood sugar which tend to cause troublesome coronary insufficiency and dysrhythmia.

Here from the perspective of current knowledge, the following statements regarding diabetes mellitus and cardiovascular system appear reasonable:

1. Severe and premature atherosclerosis is encountered with unusual frequency in patients with diabetes mellitus.
2. Diabetes mellitus accelerates coronary atherosclerosis with a more pronounced effect in the female than in the male.
3. A diabetic patient older than 40 in either sex can be assumed to have significant coronary atherosclerosis, particularly if the diabetes is of long duration or associated with hypertension.
4. The morbidity and mortality rates in diabetic patients with coronary atherosclerosis is much greater than in non-diabetic individuals.
5. Hypertension, particularly that secondary to kidney lesions, is frequently encountered among diabetic patients, particularly with disease of long duration.
6. Contained within the lipid metabolic and platelet conglutination series regarding the pathogenesis of atherosclerosis are number of observations which suggest that a common denominator links the cause of atherosclerosis with that of diabetes mellitus.
7. In the present state of our knowledge, the concurrent diabetes mellitus with coronary atherosclerosis adds to the burdens of therapy, and often leads to inadvertent misadventures.

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## KIDNEY DISEASE IN DIABETES

(By Arnold S. Relman, M.D., Chairman, Department of Medicine, University of Pennsylvania)

Patients with diabetes nowadays rarely die of diabetic coma. The use of insulin and various types of oral agents has made it possible to control the blood sugar level in the vast majority of patients and thereby to prevent the development of ketosis. Nevertheless, diabetes continues to exact a great toll in death and disability. The death rates among diabetics have been reported to be anywhere from one and a half to three or four times higher than those in the general population, and a diabetic child has a life expectancy that is about fifteen or twenty years less than that of his non-diabetic contemporaries.

The reason is mainly that diabetics are more prone to develop disease of their blood vessels and this in turn leads to serious and often fatal damage to the heart, brain or kidneys. At the present time, about three-quarters of all diabetic deaths are due to cardiovascular or renal damage. The specific role of the kidney in this mischief cannot be accurately assessed, but we know that it must be great. Kidney failure is the commonest cause of death among diabetics under the age of 20, whereas it accounts for only five to ten percent of deaths among diabetics of all ages. On the other hand, significant disease of the kidney is found at autopsy in half to two-thirds of all diabetic deaths, and kidney disease in turn often causes high blood pressure. High blood pressure is more than twice as common among diabetics as among non-diabetics, and it is known to be an important predisposing factor in the development of arteriosclerosis. Inasmuch as arteriosclerosis of coronary arteries is by far the commonest cause of death among diabetics over the age of 50. It follows from what has been said that renal disease with its attendant high blood pressure must play a significant contributory role in the causation of a very high percentage of all diabetic deaths, not just in young diabetics but in older patients as well.

What kind of kidney damage occurs in diabetic patients? Among those who develop diabetes under the age of twenty, the most common type of damage is a peculiar disease of the small blood vessels called *intercapillary glomerulosclerosis*. This condition appears to be a degeneration of the walls of the capillary vessels in the glomeruli of the kidney. It is rarely found in patients without diabetes, it usually develops after diabetes has been present for at least 5 or 10 years, and it almost always is associated with a similar type of damage to the small blood vessels of the eye. Intercapillary glomerulosclerosis causes albuminuria, swelling of the tissues with edema fluid, and high blood pressure. Functional impairment of the kidney may develop slowly and insidiously, but once it is well established, progression of uremia is usually inexorable. Patients with uremia due to this form of kidney disease are very difficult to manage. They usually do not get along very well with hemodialysis (use of an artificial kidney) and they do not respond well to kidney transplantation either.

Another very common type of kidney disease, found mainly in middle-aged and elderly diabetics, is called *arteriolar nephrosclerosis*. This condition, which occurs frequently in non-diabetic patients as well as diabetics, is characterized by a thickening of the walls of the smallest arteries in the kidney. The result is a reduction in the supply of blood to many parts of the kidney, and a consequent atrophy and scarring of the organ. Arteriolar nephrosclerosis rarely leads to extensive or progressive kidney failure but, like intercapillary glomerulosclerosis, it is usually associated with high blood pressure. It also tends to make the kidney more susceptible to the third and very common form of kidney disease called *pyelonephritis*.

Pyelonephritis is caused by a bacterial infection, which usually reaches the kidney by spreading up the ureters from the bladder and lower parts of the urinary tract. Bladder infections are extremely common in non-diabetic patients as well, particularly in young women in their teens and twenties, and in the elderly of both sexes. But for some reason that is not yet entirely clear, such in-

fections are several times more common in diabetes. Probably 15 to 20 percent of all diabetic women have bladder infections, the number increasing with age. Elderly diabetic men also show a very high incidence of urinary infection. In most cases the infection is asymptomatic, but occasionally it causes clinically overt attacks of cystitis. If the infection spreads up the ureters to one or both kidneys, pyelonephritis will develop. This condition, like infectious of the bladder, is often symptomless and can be detected only by culture and examination of the urine; and by other special tests. Sometimes, however, acute flare-ups of the pyelonephritis cause fever, pain in the flank, and pain on urination. At any rate, whether the disease is symptomatic or not, evidence of pyelonephritis can be found at autopsy in at least a quarter or a third of all patients with diabetes of long standing. In most cases the disease is not severe enough by itself to cause kidney failure, but it is often a contributing factor to the renal failure associated with intercapillary glomerulosclerosis, and it may well be responsible for the occurrence of high blood pressure in a significant fraction of diabetic patients.

These three conditions, *intercapillary glomerulosclerosis*, *arteriolar nephrosclerosis*, and *pyelonephritis* account for the great majority of the kidney disease in diabetics. Diabetic patients are of course also susceptible to all the other forms of kidney disease, but without any notably increased frequency.

What can be said about the cause of these kidney diseases? *Intercapillary glomerulosclerosis*, as already stated, is peculiar to diabetics, so it must either be a result of the metabolic disturbances characteristic of diabetes, or else be determined genetically in the same way that the metabolic disturbances are. This problem has not yet been resolved, there being evidence to support both alternatives. However, it is especially interesting to note that changes closely resembling intercapillary glomerulosclerosis have been found in the kidneys of patients who became diabetic as the result of surgical removal or extensive disease of their pancreas, so that the role of inheritance seems to be of minor importance at least in those instances.

The cause of *arteriolar nephrosclerosis* seems to be related to arteriosclerosis and high blood pressure. Whatever leads to the thickening of the walls of arteries elsewhere in the body, and the deposition of fat and calcium in the inner lining of their vessels, apparently also causes thickening of the walls of renal vessels. High blood pressure can *result* from this change in the kidney blood vessels, but it can also be a *cause* of the thickening as well.

*Pyelonephritis* is usually due to bacterial invasion of the kidneys, the risk being from the bladder directly up the ureters. Sometimes the infection is inadvertently implanted in the bladder through the use of catheters or other instruments, but the frequency and persistence of urinary tract infections in diabetics cannot be explained by this means alone. There is, in fact, very suggestive evidence to indicate that the resistance to infection of the diabetic urinary tract is less than normal. Some investigators believe this is due to reduced bacteria-killing activity of the white blood cells of diabetics, but this will need further investigation.

*What about treatment and prevention?* There is nothing much that can be done to change the natural history of intercapillary glomerulosclerosis once it is established. Whether good control of diabetes can prevent the development of intercapillary glomerulosclerosis or retinopathy (both of which seem to result from the same kind of small vessel disease) is still a hotly-debated but unresolved issue. A recent report on a prospective long-term follow up of a large group of patients who developed diabetes before the age of 16 reveals that nearly 80 percent of all patients develop retinopathy by the end of 30 years of disease, nearly half have proteinuria and 40 percent have some degree of kidney

failure. There was no suggestion from this study that strictness of dietary control of the blood sugar had any marked effect on these results. In three widely separated diabetic clinics, each with a different philosophy of treatment, the mortality in juvenile diabetes after 25 years of disease was remarkably similar—about 20 percent—and most of the deaths were due to renal disease. There is little reason at this point to believe that stricter control of diabetes, by the means presently available, could do much to change this picture. On the other hand, it remains to be determined whether some totally new approach to treatment could be devised which would result in normalization of blood glucose levels throughout the day over a long period of time and would have a significant effect on the development of renal disease and retinopathy. This is a problem which is urgently in need of intensive investigation.

Similar considerations apply to the question of the prevention of the arteriosclerotic changes in the arteries, which are responsible for *nephrosclerosis*. There is no doubt that the presence of diabetes is associated with the premature development of arteriosclerosis in many patients, and with accelerated progression of the disease, resulting in early and progressive nephrosclerotic damage to the kidneys. What we simply do not know at this point is how much of this vascular damage is determined genetically, and how much results from metabolic and biochemical abnormalities which conceivably could be modified by more effective forms of treatment. This problem is closely related to the whole issue of arteriosclerosis—one of the most urgent and important of all public health issues. Arteriosclerosis of the coronary arteries (as well as of arteries in the brain, kidney and elsewhere in the body) is the largest single cause of death and disability in the country today. The effect of diabetes on arteriosclerosis is a lead that demands further and more extensive investigation.

*Pyelonephritis* and bacterial infections of the urinary tract offer more hope of immediate approaches to prevention and treatment. The key seems to consist of a more vigorous program of detection in the diabetic population, aggressive treatment and continuous follow up of patients. These goals require more physician and patient education, and better support and organization of ambulatory services for diabetics. In many parts of this country, these services are simply unavailable to large numbers of diabetics, either because of costs, or limitations of facilities and personnel.

In the last analysis, however, future progress in the prevention and treatment of diabetic renal disease must await the development of new basic knowledge. We do not know enough about the cause of blood vessel disease in diabetes to be able to offer our patients effective therapy or prevention. *Research* is the greatest need in this area, and this is where the greatest public support must be directed.

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## DIABETES MELLITUS AND DEGENERATIVE VASCULAR DISEASE

(By Robert F. Bradley, M.D., Medical Director, Joslin Clinic, Boston, Mass.)

I am Robert F. Bradley, licensed to practice medicine in the State of Massachusetts. I was graduated from Yale University School of Medicine in 1943, certified by the American Board of Internal Medicine in 1952 and for the past five years have been Medical Director of the Joslin Clinic Division, Joslin Diabetes Foundation, Incorporated. I am in the practice of internal medicine with special reference to diabetes mellitus. I am also currently a Member of the Governor's Committee concerned with Diabetes and Blindness, Commonwealth of Pennsylvania.

Diabetes greatly increases the prevalence and accelerates the progression of hardening of the arteries (atherosclerosis or arteriosclerosis). (1) All blood vessels in the body are affected, some more rapidly than others. The process is one by which the walls of blood vessels, particularly the inner wall or intima, are thickened. Narrowing of the channel (lumen) interferes with circulation to various portions of the body. Involvement of the coronary arteries to the heart, cerebral blood vessels to the brain, and peripheral blood vessels to the lower legs and feet produce the devastating mortality and morbidity which accounts for two-thirds or more of death among diabetics (2) and a huge cost to the U.S. citizen. (3)

### HEART DISEASE

Cardiovascular disease of this arteriosclerotic and degenerative type is by far the most common cause of death among all persons in the United States, producing 34 per cent of the mortality or more than 625,850 deaths for the year 1967. (4) These numbers are obviously now higher. Coronary artery disease is easily the predominant factor. For comparison nearly 70 per cent of the diabetic population has been dying of arteriosclerotic and degenerative cardiovascular disease. Coronary heart disease alone produces more than 54 per cent of all deaths. (1, 2) Deaths due to cancer were 16.8 per cent in all of the United States, compared to 12 per cent amongst diabetics. All other causes of death including accidents totaled 29.1 per cent for all people in the United States, 12.8 per cent in a representative diabetic population.

At present the American Diabetes Association estimates the prevalence of diabetes mellitus conservatively at 5 per cent in the United States, (5) or in excess of ten million people. Each year more than 31,000 deaths among the 625,850 due to arteriosclerotic and degenerative heart disease are at least in part produced or hastened by the presence of diabetes. The true role of diabetes is probably much greater, because the elevated blood sugar by which it is characterized often produces no symptoms, particularly in the adult, so that its undetected presence contributes to a great many more heart deaths than is apparent from death certificates.

Although the estimates of the prevalence of diabetes have only recently been revised upward to the above mentioned ten million or more persons in the United States, prevalences amongst adults, particularly those over the age of 50, range as high as 78 per cent. (1, 6, 7) Obviously, it is premature to predict that such a high prevalence of diabetes in older people is the only or major factor in the more than 650,000 coronary and degenerative heart disease deaths occurring each year in the United States, or even to attribute one-half of these deaths to diabetes. On the other hand, it is safe to predict that prospective epidemiologic studies will soon show diabetes as playing at least a causative contributory role in somewhere between the 5 per cent based upon current conservative prevalence data and 50 per cent. This would mean that diabetes is playing a causative contributory role in cardiovascular disease deaths in the United States which might be as high as 325,000 individuals per year.

The tendency has been to attribute the effects of diabetes as operating through metabolic pathways which produce increased blood fats (lipids) or through its contributory role in producing or accelerating hypertension, but its inherent effects

in producing coronary disease are illustrated in the fate of children with diabetes, who after 15-40 years almost invariably develop significant coronary artery disease, frequently in the absence of abnormal blood fats, high blood pressure, or other currently known risk factors. The frequency of symptomatic coronary heart disease and even fatal coronary attacks in both young women and young men in their 20's and 30's is a dramatic expression of the effects of diabetes per se. It is well known that the presence of diabetes mellitus plays such a significant role in the development of coronary heart disease in the female, that both symptomatic and fatal heart disease occur with greater frequency than in diabetic men. (1)

#### STROKE

Cerebral vascular diseases or stroke as a cause of death occurs with twice the frequency in both the diabetic male and female in the United States population at large. (1) Although the extent to which deaths due to stroke amongst diabetics contribute to the overall 200,000 or more of such deaths each year in the United States, (4) it may also be conservatively estimated that 10,000 or more are in part produced or significantly hastened by the presence of diabetes. Diabetes may well play a significant role in 5 to 10 times this number depending upon its true prevalence in an aging population. It is safe to invoke a much greater role for the effects of diabetes based upon the known higher prevalences of high blood sugar levels amongst adults age 50 and over.

Not only is diabetes an insidious risk factor in the known abhorrent cardiovascular mortality in the United States, but it contributes greatly to *disability* from cardiovascular disease of the coronary and arteriosclerotic or degenerative type. Cardiovascular disease and stroke are overwhelmingly the greatest sources of disability among adults in the United States. Diabetes contributes as well to this disability not only by accelerating the hardening of the artery process, but by producing an as yet ill-defined disease of smaller arteries, such that many individuals who may not die of a coronary attack or stroke nonetheless are permanently disabled by inadequate function of the muscle (myocardium) of the heart, or portions of the brain.

In Table I are estimated the yearly direct and indirect costs of morbidity to all people in the United States of cardiovascular and central nervous system arteriosclerosis. Even if diabetes contributed significantly to only a fourth or less of these costs, the dollars and man-hours of work lost are staggering.

#### PERIPHERAL VASCULAR DISEASE

A third and often overlooked site of degenerative vascular disease in the diabetic is in the peripheral arteries, namely those to the lower legs and feet. Although no longer contributing in major degree to mortality, peripheral arterial disease in diabetics has created an extraordinary morbidity due to gangrene and amputation of one or both legs, and an insidiously great cost in terms of employment loss and dollars. Based upon a study in one hospital (Table II) it has been estimated that five million days per year may be used on a national basis for the handling of peripheral vascular disease in diabetics at a cost of several hundred million dollars. (8)

Gangrene is 50 to 70 times more common in diabetics than in non-diabetics (Table II). (9) Gangrene in a woman is currently almost 100 times more likely to occur in a diabetic as compared to the non-diabetic. In a report by the National Heart and Lung Institute panel on Peripheral Vascular Disease, (10) the lack of interest in peripheral vascular disease and research into its origin is evident in the following statement from one of the conclusions of the panel, " \* \* \* there is little research interest in peripheral vascular disease. Clinical interest has also waned because of the lack of imaginative and innovative approaches to peripheral vascular disease". In a specific recommendation it was stated, "In order to stimulate interest in this field, research in peripheral vascular disease should be identified as a national goal. The methods that the NHLI has used successfully for stimulating research in heart and lung disease should be extended to peripheral vascular disease". (10) Clearly, any approach to solving this problem must investigate the origin of the blood vessel changes which produce circulatory insufficiency rather than merely looking for means of dealing with the problem of amputated lower extremities once the disease has already progressed. To this end it would be naive not to discover the mechanism by which diabetes plays such a prominent role in peripheral vascular disease and indeed into the origins of diabetes itself.

The successful identification of one or more of the factors in the development of degenerative vascular disease, and the means to prevent and/or treat this

arteriosclerotic process, would so substantially solve the mortality and morbidity problems of the United States citizen, that such an advance would be unparalleled in medical history. Because of the limited extent to which diabetes mellitus has been identified and emphasized as an underlying factor, the total research effort directed toward solving the diabetes contribution to the problem has been disgracefully miniscule. No research directed toward reducing heart disease, stroke and peripheral vascular disease can be considered comprehensive until the role of diabetes in producing such diseases also receives adequate attention in terms of study and monetary support. An increased circulating blood sugar, or diabetes, may turn out to have greater significance as a risk factor in the production of arteriosclerotic or degenerative vascular disease than any others currently receiving so much attention, such as cholesterol, blood pressure, and smoking.

"Diabetes mellitus affects more years of human living than any other single disease." (11) The only serious competitor for this dubious distinction would be the process of aging itself or mental disorders. "Before age 45 diabetes causes a fourfold increase in the incidence of coronary heart disease in males and a sixfold increase in incidence in females". (12) These individuals are primarily those who have suffered from and died of coronary heart disease, frequently accompanied by stroke and/or gangrene, despite ten to forty years of struggling with daily attention to the self-administration of insulin, urine testing, restricted diet, and a greatly increased frequency of acute illness and hospitalization related to the acute metabolic emergencies characteristic of diabetes mellitus.

TABLE 1.—NUMBER OF DEATHS BY CAUSE OF DEATH UNITED STATES, 1967<sup>1</sup>

Cause of death	All ages	Percent	Direct cost (in millions)	Indirect cost (in millions)
All causes .....	1,851,323	100	.....	.....
Arteriosclerotic and degenerative heart diseases (420-422) .....	625,850	34	2,072	13,103
Vascular lesions effecting central nervous system (330-334) .....	202,184	11	971	3,399
Total vascular and degenerative lesions of heart and central nervous system, excluding hypertension and other diseases of arteries .....	828,034	45	3,043	16,504

<sup>1</sup> As compiled from data appearing in reference Nos. 3, 4.

TABLE 2.—THE HIGH COST OF FOOT LESIONS—NEW ENGLAND DEACONESS HOSPITAL, BOSTON, MASS., DIABETIC FOOT ADMISSIONS 1969

Condition	Number of cases	Patient days
Gangrene .....	142	4,719
Infection .....	32	724
Ulcer .....	159	3,391
Chercot's .....	6	64
Abscesses; cellulitis .....	33	580
Osteomyelitis .....	45	1,264
Total .....	417	10,742

Note: Total hospital admissions equaled 10,321 (including diabetes). These used total patient days equaled 119,870, while 417 diabetic foot cases used 10,742 patient days. Average total cost per hospital day equaled \$101.08. Therefore, more than \$1,000,000 yearly is the hospital cost (not including medical fees) for care of patients with severe foot lesions and complications in this 1 hospital alone.

TABLE 3.—ATHEROSCLEROTIC GANGRENE—AUTOPSIES<sup>1</sup>

Age	Nondiabetic (59733) (percent)		Diabetic (2130) (percent)		Role of frequency (diabetic/non- diabetic)
	Male	Female	Male	Female	
20 to 40.....	0	0	3.4	0	All ages > 40.
40 to 60.....	0.1	0.08	14.7	14.0	Male 53:1.
60 to 80.....	0.45	0.46	24.3	24.6	Female 71:1.

<sup>1</sup> From Bell, E.T., *Amer. J. Clin. Path.* 28:27, 1957.

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## DIABETIC NEUROPATHY

Report to Governor's Committee Concerned with Diabetes, by Richard A Chambers, M.D., Professor and Chairman, Department of Neurology, Jefferson Medical College and Hospital, Philadelphia, Pa.

Diabetic Neuropathy is the term given to disorders of the peripheral nervous system due to Diabetes Mellitus. Its incidence is related to the incidence of Diabetes Mellitus which has not been estimated. Estimates vary from about two million persons up to about twelve million persons with Diabetes Mellitus in the U.S.A. The incidence of neuropathy among patients with Diabetes Mellitus has, in previous years, been disputed and figures varying from three per cent to seventy-five per cent of diabetics have been given.

In a Diabetic Clinic about fifty per cent of the patients can be shown by a skilled examiner to have clinical evidence of disorder of the peripheral nervous system. (1, 2, 3). If to this is added the evidence that may be obtained from electrical study of the peripheral nervous system and of the muscles, the incidence of neuropathy will in some clinics become as high as 75% of patients. These figures need qualifying in three respects. The first is that they are approximations. The second is that the evidence of diabetic neuropathy increases with the duration of diabetes (1) and, thirdly, a great majority of such patients have no symptoms related to involvement of the peripheral nervous system. Only about 20% of diabetic patients in whom a peripheral neuropathy is detectable have symptoms attributable to disorder of the nerves. These figures then would give a total number of patients with diabetic neuropathy which might vary from 1.5 to nine million patients and a figure for those who have symptoms due to it varying from 0.3 million to 1.8 million persons in the U.S.A. There is no difference between sexes in the incidence of diabetic neuropathy nor any known genetic predisposition to it. The incidence of the neuropathy is related to age in that it increases with the duration of the diabetes.

The difference between estimates of two and of twelve million patients with diabetes is extreme and the author's opinion is that the numbers of diabetics in the United States probably approximate to the higher rather than to the lower figure. The reason for this opinion is that a large number of cases of Diabetes Mellitus present to their physicians with one or other of its complications and the diabetes, itself, is an illness of unknown duration revealed by its late manifestations.

As far as is known at present, two types of disorder due to diabetes affect the peripheral nerves. The first is the occurrence of single or multiple areas of infarction of peripheral nerve (4). In such a lesion, for example of the third cranial nerve or of the lumbar plexus, there is a focus of necrosis of the nerve bundle. Distal to it the affected nerve fibers degenerate. The focus is swollen and infiltrated by inflammatory cells. In the later stages the swelling subsides and regeneration of the damaged fibers starts and proceeds with varying degrees of completeness.

The second disorder is a change in the cells covering the nerve fiber (5). A nerve consists of a cell out of which a process, the axon, emerges. This axon is sheathed down its length by a series of cells known as Schwann cells—the whole looks, therefore, like a cable with an insulating layer. The "insulating" layer is known as the myelin sheath. Nerve fibers are divided into two classes—myelinated fibers in which the insulating layer encloses only one nerve fiber and unmyelinated fibers in which the insulating layer encloses many fibers. The myelinated fibers are larger and conduct nervous impulses more rapidly than do the unmyelinated fibers.

In diabetic neuropathy the changes seen in the Schwann cell (myelin sheath) by light microscopy consist of a shrinkage of the cells so that the axon is bared over a greater or lesser length. The ultrastructural examination of such nerves (6) shows that there is a hyperplasia of the basement membrane of the Schwann cell as well as changes within the cell. In the unmyelinated fibers

it is not uncommon to find inclusion material and in the myelinated fiber there are changes in the endoplasmic reticulum which becomes vacuolated and swollen. There are multimembranous bodies and a number of electron dense granules dispersed throughout the cytoplasm of the cell. It seems that these particles correspond to glycogen beta particles.

In the initial stages of diabetic neuropathy there are few changes in the axon. As the process extends, some of the axons die and the changes of Wallerian degeneration are then apparent in that fiber.

The most striking findings that have so far been described in the peripheral nerves of diabetic patients concern the large myelinated fibers. This is probably because these are easier structures to work with rather than because the lesions of these structures are the most important. A consideration of the clinical features of diabetic neuropathy would suggest, however, that the lesions of the unmyelinated fibers are likely to prove important.

These two types of disorder of the peripheral nerves in diabetes are related to two main clinical pictures of diabetic neuropathy. The first type, the infarct of nerve, gives rise to disorders of single nerves—that is to say, the disturbance of function is localized and asymmetrical. The lesion of the myelin sheath of the nerves, on the other hand, gives rise to a symmetrical and peripherally distributed disorder. It involves the longer nerve fibers earliest and, therefore, makes itself felt first in the feet, subsequently in the fingers and hands and only in the later stages does it involve the trunk.

Related to the neuropathy of Diabetes Mellitus there occur changes in other tissues. Many of these changes are classified under the heading of "trophic" changes. They consist of ulcers in the skin of the parts from which sensation is deranged, cellulitis, osteolytic lesions, osteomyelitis and destructive arthropathies. Neurogenic atrophy of muscle, dilatation of the bladder and, in some cases, of the ureters are also seen.

Most of these changes are due to loss of the normal ability to feel pain from the affected parts. A special case of this is seen in the bones of the spine in the neck. A destructive arthropathy here is common in Diabetes Mellitus and may lead to damage to the spinal cord or spinal roots.

These two main types of diabetic neuropathy have been described separately. They may, however, co-exist in the same patient and certain variations may occur. One variation, which is rare, is a subacute and extensive neuropathy that occurs when an untreated diabetic is first treated with insulin or oral agents. Another rare cause of neuropathy related to diabetes is a neuropathy due to sensitivity to one or other brand of insulin. This sensitivity is usually related to a sensitivity to the proteins of the animal species from which the insulin has been prepared.

The clinical picture of the distal symmetrical neuropathy of diabetes is seldom dramatic. In most cases there are no symptoms and the neuropathy is discovered in the course of a clinical examination. In such cases the usual findings are wasting of intrinsic muscles of the feet and minor changes in cutaneous sensitivity of the feet extending, perhaps, for an inch or two above the ankle. These changes usually concern the ability to feel pain the affected areas and to judge differences in temperature. Sometimes there may be excessive discomfort rather than loss of sensation to pin pricks and sometimes there will be a diminution of the ability to detect a vibrating tuning fork applied to the foot. Often the ankle reflexes are absent or depressed.

Recently it has been shown (7) that asymptomatic abnormalities of sensory function—tactile, visual, auditory and gustatory—may be demonstrated very early in the course of Diabetes Mellitus.

It is worth noting that these minor or asymptomatic abnormalities of sensory function can be a cause of disability, sometimes considerable. For example, in the event that a diabetic patient suffering from a relatively minor degree of neuropathy becomes blind, the sensory impairment—minor though it seems to be—may be sufficiently serious to prevent the patient's learning to read Braille.

Another way in which minor sensory defects may be of importance is in the production of dizziness which is so common a complaint in middle aged and elderly patients. In many cases this symptom is due to minor impairment of multiple sensory pathways. For example, in the patient who has a retinopathy and early cataracts, whose vestibular system is suffering from the effects of advancing age, who suffers from spondylosis as well as from a peripheral neuropathy almost all of the afferent systems concerned with the orientation of that patient in space are to some degree interfered with. It is believed that

this combination of defects, and it may be noted that all of them may be the consequence of diabetes mellitus, underlies the symptom of dizziness which is often so disabling in these patients.

In some 20% of cases of diabetes the patient will complain of symptoms due to a neuropathy. In a series of 150 cases the symptoms were pain in 13%, numbness of the extremities in 11%, cramps in 5.5%, ulcers of the feet in 5.5%, diarrhea in 3.3%, weakness, excessive sweating, constipation, retention of urine, ataxia and postural hypotension occurred in a few cases each. Out of this group of cases the major disability was due to the neuropathy in twenty-one. (8)

An additional symptom is the reported occurrence of impotence in 50% of men with diabetes. (9) This symptom may have many causes and, as well as neuropathy, the following are common causes—psychological disturbances, vascular disease of the brain, damage to the spinal cord, uncontrolled diabetes and illness unrelated to Diabetes Mellitus. In general, impotence, secondary failure of women to achieve orgasm, disorders of the gastrointestinal and of the urinary tracts are common in diabetic patients, particularly in those with neuropathy. Nevertheless, the attribution of these symptoms to neuropathy does not rest upon a secure foundation of morbid anatomy.

Diabetic neuropathy then can present in a variety of ways and in patients who are not known diabetics. In the diabetic the longer the duration of the illness, the greater the likelihood of the occurrence of a neuropathy. (1)

There is reasonably good evidence that control of that aspect of diabetes reflected by increases in the blood sugar level helps to prevent the occurrence of a symptomatic neuropathy (1) and to reduce to some extent the severity of its manifestations when they occur. (10-11) Clearly such a symptomatic neuropathy is usually a late event in the natural history of diabetes and reversal of this, as of any advanced pathological process, is unlikely to be complete.

The occurrence, manifestations and natural history of diabetic neuropathy are now quite well known. Important new clinical knowledge is now likely to come from prospective studies of newly diagnosed diabetic patients or from a study of the children of diabetics to identify the genetic and environmental factors which may determine the occurrence of neuropathy, the extent to which neurological symptoms are manifest, to study the structural and functional changes and their progression in relation to these factors and to treatment. Parallel studies in experimental diabetes are urgently required for the more precise examination of hypotheses.

Immediate clinical measures are screening programs, educational programs with special reference to diet and genetics, and the provision of podiatric facilities.

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**CURRENT STATUS OF JUVENILE DIABETES**

**A Report Prepared for the Commonwealth of Pennsylvania Committee on Diabetes and Blindness, by Robert Kaye, M.D., Professor and Chairman, Department of Pediatrics, Hahnemann Medical College and Hospital, Philadelphia, Pa.**

The discovery of insulin and its clinical use resulted in a dramatic increase in the life expectancy of children with diabetes. Prior to the use of insulin, the child with diabetes was doomed to die in one to two years. In spite of this change, the outlook for life expectancy of the 150,000 diabetic children in our country is still disheartening as it remains approximately two-thirds of the general population. (1) A child who becomes diabetic at the age of ten may expect only 44 more years of life in contrast to the 62 years anticipated by his non-diabetic peers. It is discouraging to note that survival for juvenile diabetics has shown no improvement based on a comparison of data for the periods of 1960-1966 with those of 1956-1959. (1) This indicates that unless there is developed some major advance in methods of treatment no further improvement in survival of diabetic children will occur.

Diabetes is ranked as the 8th leading cause of death in the U.S. and the proportion of the population dying from this cause is increasing. (2)

In 1966, 38,000 deaths were certified as due to diabetes and in 35,000 the disease was listed as a contributory cause. An additional 37,000 deaths were estimated to be the result of this disease as deaths in patients with cardio-vascular-renal disease may fail to note the contributory role of diabetes. (1)

Deaths from ketoacidosis and infection have decreased in diabetes with an increase in mortality from cardio-vascular-renal disease. (3) These angio-pathic deaths occur mainly in subjects with a duration of diabetes of 15-25 years (4) following which there is some improvement in survival. The mortality from vascular disease has risen from 46.8% in 1922-1929 to 76.6% in 1956-1962. (5) During this interval coronary artery disease as a cause of death has increased four-fold and renal disease threefold.

Even more disturbing than mortality statistics are morbidity and disability data attributable to long term complications. Data from Sweden indicate that 20% of long term survivors of juvenile diabetes are wholly or partially disabled. (4)

Priscilla White of the Joslin Clinic has reported the status of 478 juvenile diabetics surviving 30 years after onset. (6)

- 48% had peripheral neuropathy
- 26% had urinary tract infections
- 90% had retinopathy
- 30% had proliferating retinopathy
- 8% were blind
- 34% had kidney disease
- 37% had hypertension
- 50% had peripheral vascular disease

The incidence of vascular disease increases with the age of the patient and the duration of diabetes.

<i>Incidence of vascular disease (percent)</i>	<i>Duration of diabetes (years)</i>
1	5
2.5	10
20	15
60	20
90	30

By age 30 63% of juvenile diabetics have vascular disease. (3)

Diabetes is the third leading cause of blindness in our population. The 44,660 blind diabetics constitute 11.2% of the blind of this country. Blindness in diabetics is 13 times as frequent as in the population as a whole. (1)

According to the National Health Interview Survey, diabetes disables more than 562,000 persons. Among diabetics, there is three times the rate of sickness and absenteeism of the general population. (1) Hope for the future may come from transplantation of pancreatic tissue or from the development of an artificial pancreas.

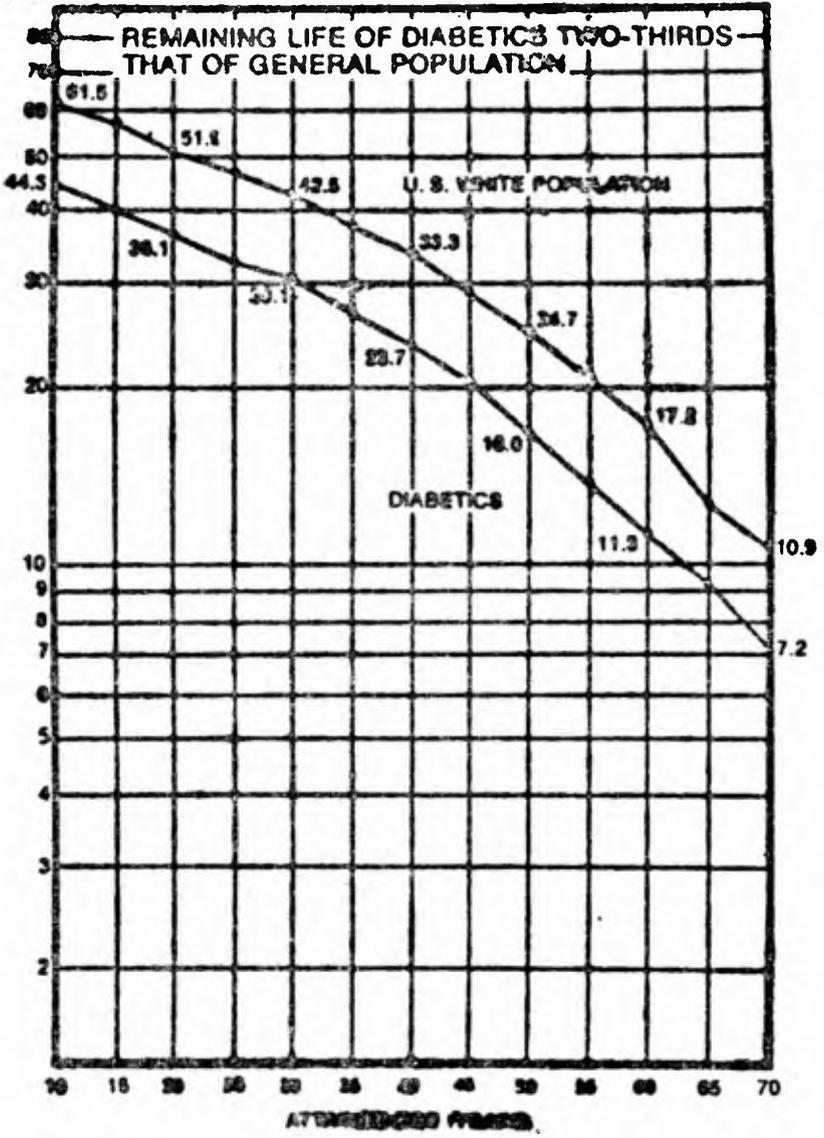
Heart and kidney transplants and advances in vascular surgery may improve our ability to deal with the toll of diabetic complications.

There is need for research in developing means of preventing or delaying the onset of clinical diabetes, and improving our capabilities of treating the disease and its complications.

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REMAINING LIFE YEARS



## DIABETES AND MATERNITY—MATERNITY AND THE DIABETIC MOTHER

A report prepared for the Commonwealth of Pennsylvania Committee on Diabetes and Blindness, by Charles R. Shuman, M.D., Professor of Medicine, Temple University School of Medicine, Chief, Metabolic Section, Temple University Hospital, Philadelphia, Pa.

During pregnancy metabolic adjustments occur to support the needs of the fetus as a growing organism. The maternal host must supply the energy sources and nutrients to promote intensive anabolic processes within the entire conceptus while preserving and maintaining the physiological integrity of her own tissues. The diversion of glucose and amino acids for fetal energy and growth requirements increases the rate of utilization of fatty acid as maternal fuel. These adjustments are facilitated by enhanced activity of fat mobilizing hormones which decrease the effectiveness of insulin during pregnancy. In normal women, a compensatory rise in insulin secretion maintains normal gluco-regulatory balance. In women with reduced insulinogenic potential the elevated requirements for insulin result in glucose intolerance of increasing intensity throughout gestation.

During the past few decades improvement in the treatment of diabetes has increased the fertility of the diabetic patients of child-bearing age and has virtually eliminated maternal mortality. The primary problem in the diabetic pregnancy involves an increased neonatal morbidity and perinatal mortality which are attributed to the abnormal maternal metabolic milieu. In addition, problems inherent in the diabetic process may be accelerated during pregnancy such as infection, vascular complications, hypertension and fluid retention. Strict medical supervision throughout the gravid period is essential to prevent or correct these and other complications commonly seen in the diabetic pregnancy.

### PREVALENCE

With the improved fertility rate for diabetic women, the number of maternal diabetics is essentially the same as the estimated prevalence of diabetes in women of child-bearing age. White estimates that 10% of the diabetic females develop the disease during the years of potential maternity. (1) The probable frequency of diabetes is one in 350 pregnancies. In a large screening program using oral glucose tolerance testing to detect gestational diabetes the incidence of abnormal results was one per 116 prenatal registrants. In this study progression to frank diabetes was observed in 28.5% of patients over a period of 5½ years. (2)

### DIABETES SYNDROMES AND PREGNANCY

Prediabetes has been defined as that stage in which glucose tolerance is normal in an individual with a genetic predisposition to diabetes. It may be manifested by a reduced level of rapid insulin release following glucose stimulators. With the stress of pregnancy, as with other stresses, the condition may progress to the stage of latent or subclinical diabetes in which abnormalities in glucose tolerance appear.

Gestational diabetes is recognized as a form of prediabetes or subclinical diabetes during pregnancy in which the fasting blood glucose is normal with glucose intolerance manifested following an oral or intravenous glucose load. Following parturition normal glucose tolerance is restored and the diagnosis may be made retrospectively using the cortisone glucose tolerance test. Patients with undetected or untreated gestational diabetes like the overt diabetic may have large babies or stillborn fetuses exhibiting beta cell hyperplasia and eosinophilic infiltration.

Classifications of the diabetic status of the maternal diabetic has been provided by Dr. White. (1) This system is useful in establishing prognostic and therapeutic guidance in the management of these cases.

Class A—Abnormal glucose tolerance test only.

Class B—Onset of diabetes after age 20 years with duration less than 10 years. No vascular involvement.

Class C—Onset of diabetes between ages 10–19 or duration of more than 10 years with no vascular involvement.

Class D—Onset of diabetes before age 10 years or duration more than 20 years or mild vascular involvement including leg calcification and minimal retinopathy.

Class E—Calcification of pelvic vessels.

Class F—Nephropathy.

Class R—Proliferative retinopathy.

In general, there is increasing fetal loss within each successive classification of diabetic pregnancy. There is no question of higher fetal mortality in Class A patients compared to the normal, although it is significantly less than that of insulin-dependent diabetics. Within Classes B and C there may be little variation in fetal mortality; the results being dependent to a great extent, upon the level of blood glucose control achieved during gestation. In some series with higher frequencies of diabetes aediosis in Class B patients, fetal mortality has exceeded that seen in Class C who have been on established treatment programs for longer periods. Because of the hazards of acceleration of nephropathy and of proliferative retinopathy, Class F and R patients are generally aborted except under unusual circumstances. The same is true for those known to have calcified pelvic vessels, Class E, because of impairment of uterine blood supply.

#### DIAGNOSTIC STUDIES

Screening procedures for diabetes should be conducted on all pregnant patients using the 2 or 3 hour postprandial blood sugar determination. A standard meal containing 75 to 100 gm. of carbohydrate or an equivalent amount of glucose may be employed for this test. Particular attention is given to the diabetes-prone patient identified as an obese female, one with a family history of diabetes, a history of previous glycosuria, large baby, hydramnios or perinatal mortality.

For those with borderline or suspicious screening tests, the oral glucose tolerance test (OGTT) is recommended for diagnosis. The intravenous glucose tolerance test has the advantage of reproducibility but suffers the disadvantage of eliminating the physiological response of substrate absorption from the gastrointestinal tract which may play a role in insulin secretory responses. Results with the OGTT correlate well with clinical data and provide an acceptable basis for the diagnosis of diabetes when two values exceeding the following maxima are obtained in the test:

F 110 mg. %;  $\frac{1}{2}$  hour—1 hour 170 mg. %; 2 hour 140 mg. %; 3 hour 120 mg. %.

These values are comparable to recommendations of O'Sullivan et al (2) and apply to venous whole blood; when plasma glucose determinations are used an additional 15% is added to venous whole blood values.

During the early months of pregnancy the metabolic effects of gestation are minimal. A normal screening test for diabetes in a diabetes-prone patient early in pregnancy should be followed by additional screening procedures in the second and third trimesters. Metabolic factors predisposing to hyperglycemia are increased as pregnancy advances. In the potential diabetic, multiparity enhances the likelihood of permanent diabetes. Patients who manifest gestational diabetes with return to normal glucose tolerance post-partum, have a high prevalence rate for overt diabetes in later years.

#### DIABETOGENICITY OF PREGNANCY

Gestational metabolism is influenced by 1) development of insulin antagonism; 2) an increased rate of insulin degradation by placental "insulinase"; 3) the diversion of substrate from maternal to the fetal circulation and 4) failure of insulinogenesis to keep pace with physiological requirements. (3) The latter is seen when the rising serum insulin levels are no longer proportional to the increasing glycemia. Hyperinsulinemia following glucose or tolbutamide stimulation as well as beta cell hyperplasia during pregnancy provide evidence that these responses are adaptive to increasing needs for the hormone. (4)

Insulin antagonism as a principal diabetogenic force in pregnancy may be ascribed to the production of human placental lactogen by syncytiotrophoblasts.

This hormone, also known as human chorionic somatommatrophic (HCS), is detected early in pregnancy at 5 to 6 weeks and rises progressively to a plateau during the final 4 weeks. (5) There is a marked synergism between this hormone and growth hormone which enhances the rate of free fatty acid release through lipolysis. (6) The enhanced utilization of glucose as fuel for the conceptus signals the need for fatty acids as energy substrate for the maternal tissue. Thus the increase availability of fatty acids through lipolytic effects of HCS and by similar action of the increased blood levels of free cortisol during pregnancy provide the energy-yielding substrate for the mother. The impedance of maternal glycolysis by increased fat utilization may represent an important stimulus for increased insulinogenesis. (7)

In summary, diabetogenic factors during pregnancy involve the homeostatic adjustments necessary to provide the nutrients, amino acids and glucose, to the growing fetus while insuring adequate substrates, fatty acid and glucose, for maternal energy requirements. These metabolic alterations are maintained by hormones which enhance maternal lipolysis, placental lactogen and cortisol, while glucose and amino acids are diverted to the fetus. The functional response of the maternal islets dominates this interrelationship by increasing insulin release to maintain normoglycemia in the presence of factors opposing the actions of insulin. As a balancing mechanism, the insulin-degrading system of the placenta represents a potential diabetogenic influence. These various insulin antagonistic factors account for the increased requirements for the injected hormone in 70% of insulin-dependent maternal diabetics as well as explain the appearance of gestational diabetes in those with latent diabetes in the non-gravid state.

#### EFFECT OF DIABETES UPON OESTATION

The risk factors associated with diabetes during pregnancy are related to the abnormal maternal environment and its effect upon the fetoplacental unit. Not only hyperglycemia but also the vascular and neurologic changes associated with the disease affect the pregnancy. Functional and morphological changes within the small vessels are seen in early stages of diabetes, and progress with duration and may be accelerated with poor control of the disease.

Serious hazards to fetal survival are recognized as occurring with increased frequency in diabetics. These have been emphasized by Pederson (8) as prognostically bad signs during pregnancy (PBSP) and include febrile urinary tract infection, toxemia, diabetic acidosis, and unregistered or neglectful patients. Fluid retention, toxemia and hydramnios occur in approximately 25% of patients. The combined use of White's classification and the PBSP permits increased prognostic accuracy in dealing with problem patients.

During pregnancy, elevated rates of glomerular filtration and reduced  $T_m$  for glucose result in a lowered renal threshold so that glycosuria may occur at lower than normal blood sugar levels. This phenomenon may lead to significant errors in insulin dosage if adjustments are made on the basis of glycosuria. Nonglucose reducing substances do not present problems except near term when lactosuria may occur. The use of glucose oxidase reagents aids in identification of glucose at this time.

#### EFFECT OF DIABETES ON CONCEPTUS

The fetus of the diabetic mother may respond to hyperglycemia and aminoacidemia with significantly increased islet cell activity. These factors lead to macrosomia, hypermature placentae and decreased fetal survival. Hyperplasia of fetal islets appears to be related to the body weight of the fetus. The abnormal weight is associated with increased fat and glycogen in the fetus; the body water is slightly decreased, representing 70% of body weight compared to 78% for the normal. Although the infants appear cushingoid, abnormal levels of corticosteroids have not been demonstrated. Fetal anomalies are seen in approximately 10% of the infants, a phenomenon which has not been accounted for on the basis of either hyperglycemia or hypoglycemia in insulin-treated diabetic patients. Fetal hyperinsulinemia in the presence of normal fetal glycemia indicates that amino acids may represent a significant insulinogenic factor.

Premature delivery of the infant is associated with markedly increased morbidity and significant mortality which decreases as the 37th week is approached. Following this interval there is a rise on the neonatal mortality as the result of continuing exposure to the abnormal maternal environment. Among the problems involving the newborn of diabetic mothers are pulmonary hyaline membrane

disease, metabolic and respiratory acidosis, hypoglycemia and hypocalcemia. Perinatal mortality is related also to maternal febrile states, ketoacidosis, toxemia, all of which may be related to poor control of diabetes in some instances; in others, these problems arise without apparent explanation.

Among the hormonal alterations observed during the diabetic pregnancy are reduced levels of estrogen and progesterone excretion. Because of the bulk of estrogenic substance excreted during pregnancy is estriol and a marked decrease in its levels is seen with fetal non-viability, studies have been directed toward its measurement in serum or in 24 hour urinary excretion rates as a marker for fetoplacental integrity in diabetic patients. While there are no significant differences between normal and successful diabetic pregnancies, a rapid fall in estriol from previously normal levels presages a disturbance in the fetus or placenta which may result in fetal mortality unless delivery is achieved promptly. On the other hand, a persistence of normal values will permit the continued development *in utero* of a presumably healthy fetus.

In addition to measurement of estriol and pregnandiol as markers of fetoplacental viability, amniocentesis has been helpful in determining the gestational age, degree of maturity and physiological status of the fetus.

Optimal results are achieved by the close supervision of the patient throughout gestation. Combined efforts of general physician, obstetrician and pediatrician are needed in order to achieve maximum fetal salvage. Patients are examined every two or three weeks until the third trimester and then weekly or biweekly until the 32nd week to 34th week, at which time hospitalization is recommended. Earlier admission is advocated for those requiring treatment of excessive weight gain, fluid retention, poor metabolic control or other complications.

The following points represent a summary of the overall program of diabetic management and recommendations for delivery:

1. Initial evaluation including medical examination, funduscopic, neurological and vascular status for diabetic and medical data base. Obstetrical consultation is obtained.

2. Diet: 1200-2200 calories depending upon caloric needs based on Ideal weight protein 1.5gm/kg. and sodium 1 to 3 gm. daily. Restrict weight gain to approximately 16 pounds. If ketonuria appears (starvation ketosis) increase carbohydrate ration to inhibit lipolysis, replacing glucose losses determined in 24 hour urine glucose measurements.

3. Patients are seen every 2 or 3 weeks for determination of blood glucose, diet review, weight, urinalysis and blood pressure throughout pregnancy.

4. Insulin-dependent patients: dosage is adjusted on basis of blood glucose using fasting or late afternoon values. Use intermediate insulin alone if satisfactory, otherwise give combined intermediate-regular insulin in single or twice daily doses. The two-hour postprandial blood sugar used for gestational diet-treated patients; if over 150 mg.% administer insulin. Low renal threshold for glucose obviates the use of glycosuria as guide for insulin therapy.

5. Prompt recognition and treatment of fluid retention, febrile infections, hyperemesis, hypertension and ketoacidosis is required. Hospitalization for complications and routinely at 35th week.

6. During hospitalization measurement of 24-hour urinary estriol levels is performed serially. If satisfactory, continue pregnancy until maternal status suggests need for delivery for which induction may be used. During induction with Pitocin 5% glucose solution replaces feedings and insulin dose is reduced by 50% or greater. At time of delivery, 10% glucose solution is given to avoid neonatal hypoglycemia.

7. Indications for Caesarian section:
  - (a) fetal distress—low estriol or pregnandiol excretion; change in heart rate or fetal movement, sudden drop in insulin requirements.
  - (b) abnormal presentation, dysproportion, placenta praevia, failure of induction, prolonged labor, previous Caesarian section, prolonged diabetes or poor control.

8. Caesarian section performed with 50 gm. of intravenous glucose replacing each feeding while insulin doses are reduced by 50% or greater using the usual type of insulin given to the patient.

9. Expert pediatric care is arranged prior to delivery in order to provide proper treatment of the newborn of the diabetic mother.

Following early convalescence, most patients will receive the dose of insulin required in the nongravid state. Reversion to a normal GTT is the usual rule for the gestational diabetic patient with abnormalities detected only by cortisone-

primed GTT. These patients are usually treated with diabetic diet calculated to meet nutritional needs and reduce body weight if obese. Breast feeding is not recommended owing to increased caloric needs for lactation and the attendant problems in diabetic control.

Skillful management of the many problems encountered in the newborn infant is essential for its survival during the neonatal period. Several systems of treatment have evolved, each demanding meticulous care of the infant with aspiration of respiratory passages and stomach. The newborn is placed in an incubator with temperature, humidity and oxygen carefully controlled. Apgar scores are measured successively after delivery following which neonatal complications of respiratory distress, hyperbilirubinemia, hypoglycemia, acid-base with other disturbances are noted and corrected if possible.

Patients with established diabetes are advised to have their pregnancies as early as feasible and should be limited to two or three in order to avoid acceleration of diabetic complications and to reduce the hardship of caring for a family. Diabetogenicity is enhanced by increasing parity in susceptible patients; in some instances tubal ligation is advised after three pregnancies in either diabetic or gestational patients with diabetes. Therapeutic abortions have been advocated infrequently, the indications being severe retinopathy, nephropathy, hypertension or psychiatric disturbance.

The major clinical problem remains the excessively high fetal loss in maternal diabetes. While maternal mortality is negligible, fetal mortality is approximately 12% for known diabetics and 7% for the combined overt and gestational diabetic patients. There is need for a vast effort in research and study of the metabolic problems seen in the pregnant diabetic; such research will enhance immeasurably our knowledge of the biochemical and physiologic disturbances of diabetes generally.

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## GENETICS OF DIABETES

A report prepared for the Commonwealth of Pennsylvania Committee on Diabetes and Blindness, by Arthur G. Steinberg, Herrick Professor of Biology, Department of Biology, Professor of Human Genetics, Department of Reproductive Biology, Case Western Reserve University, Cleveland, Ohio

Although it has been known at least since 1574 that diabetes mellitus occurs more frequently among the relatives of patients than in the general population (Rondelet, 1574), it is only since the early 1930's that genetic explanations for this pattern of distribution have been offered (reviewed in Steinberg and Wilder, 1952). The expression "genetic explanations" is used deliberately, because many explanations have been offered, and none has been universally accepted. Controversy continues, because the data for a definitive analysis are not available (Steinberg et al., 1970).

The difficulties of analysis arise from the nature of diabetes and from our lack of understanding of the basic defect in this disease. Diabetes has a variable age at onset, and it is probable that some individuals with a genetic predisposition to the disease never develop it; there is no satisfactory method of determining, before clinical symptoms appear, who is liable to develop the disease; diabetes may not be a single disease, and if it is not, more than one genetic mechanism is concerned in determining susceptibility to it (Steinberg and Wilder); there is considerable uncertainty of diagnosis when elderly patients are examined, because we do not know the normal glucose level for the aged individual. However, see later for a discussion of the last point.

The problem of the pattern of inheritance of susceptibility to diabetes will be rapidly and directly solved when the prediabetic individual can be identified at an early age. (A more important result would be that such identification would also permit the institution of appropriate measures, when such have been formulated, to prevent the disease from developing.) Until the prediabetic individual can be identified, complicated statistical approaches must be used in attempts to solve the genetics of diabetes. Such methods have been and are being used, but they suffer the handicap that it is extremely difficult to obtain the data required for their application (Steinberg et al., 1970).

Despite the controversy and the uncertainties, it is my opinion that the hypothesis which best fits the data, gathered in many centers in the U.S.A., Canada, and Europe, is that susceptibility to diabetes, in most cases, is due to an autosomal recessive gene. The interaction between this genetically determined susceptibility and as yet incompletely defined environmental factors leads to clinical diabetes. On the basis of the assumption that an autosomal recessive gene causes susceptibility to diabetes, it has been estimated that about five percent of our population (10,000,000 people!) is genetically liable to the disease (Steinberg and Wilder, 1952).

How does this theoretical estimate compare with figures determined by population surveys? According to the National Center for Health Statistics, Public Health Service, the total number of diabetics estimated from known cases reported in the 1965-66 National Health Interview Survey is 4.4 million (Tokulata, 1972). Since about 70 percent of diabetics are diagnosed after 44 years of age (U.S. Department of Health, Education and Welfare, 1967) it is clear that less than half of those liable to diabetes have developed the disease. Hence the estimate based on genetic considerations seems reasonable. Diabetes is probably the most common disease with a major genetic component as its cause.

It is important to note that only about one percent of our population is known to have diabetes and that another one percent is believed, on the basis of population surveys, to have diabetes that has not yet been diagnosed. If the genetic calculations are correct, this means that another three percent of our population is genetically liable to diabetes, but has not yet developed it. Three percent of our population means 6,000,000 people!

Another consequence that follows from the assumption of recessive inheritance is that 100%, 50%, or 25% of the siblings of a diabetic patient are genetically

liable to diabetes, depending upon whether both, one or neither parent, respectively, is diabetic. Data showing the liability of other relatives to diabetes have been developed (Steinberg, 1955; Tokuhata, 1972). As stated earlier, something in these individuals' environment, in addition to the genetic susceptibility, is required to precipitate their diabetes. Knowledge of these precipitating factors could lead to methods for preventing the development of clinical diabetes.

A long-range study of the offspring of families with both parents diabetic and of the non-diabetic co-twin of a diabetic member of a pair of twins could provide highly useful data for genetic analysis and, therefore, for predicting liability to diabetes. A more ambitious, more useful, and entirely feasible project is a long-range study of all offspring aged 30 years or more, of all families in a given community. My colleagues and I are undertaking such a study of Pima Indians (Steinberg et al, 1970). An important finding uncovered thus far is that the values for plasma glucose level two hours after a glucose challenge are distributed bimodally (a curve with two peaks). The lower peak represents those with a normal response to a glucose challenge, the upper peak represents those with hyperglycemic response. The mean value of the glucose level for those with normal response rises approximately linearly with age while that for those with a hyperglycemic response does not (Steinberg et al., 1970). If this finding is confirmed, hyperglycemia for older individuals will start at a higher level than for younger individuals.

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## ANESTHETIC CONSIDERATIONS IN DIABETIC PATIENTS

(Prepared for the Commonwealth of Pennsylvania Committee on Diabetes and Blindness, by Stephen J. Galia, M.D., Associate Professor of Anesthesiology, University of Pittsburgh Medical School)

In general, the problems posed by the patient with diabetes mellitus, who requires anesthesia for a surgical procedure, may be divided into two categories: 1) problems related to the diabetes *per se*, and 2) those related to complications of diabetes. Since surgery is rarely performed on patients in insulin shock or diabetic coma, the first group is limited to such conditions as: 1) alteration of normal food and insulin intake patterns, 2) post-operative nausea and vomiting, and 3) hormonal imbalance in hypophysectomized patients.

Ideally, diabetics should be operated upon early in the morning, so that the intravenous glucose infusion time can be kept as short as possible and oral food intake can be resumed early. Unfortunately, many diabetics with infected extremities (gangrenous) for amputation are scheduled in the afternoon, when all other surgery is finished, to lessen the danger of cross-infection. This problem could be alleviated by having extra operating rooms available, or one designated exclusively for infected patients.

Conflicting opinions exist as to whether diabetics should receive insulin on the morning of surgery. Those who favor giving insulin argue that surgery raises the blood sugar and aggravates the diabetes. However, at the other extreme, an insulin reaction is difficult to detect in the anesthetized patient. It may be better to give the insulin after surgery when the patient is conscious. A high blood sugar *per se* is not nearly as serious a complication as hypoglycemia.

Fortunately, with modern anesthetic agents and methods, nausea and vomiting occur rarely. However, if they do, patients must be watched carefully for signs of acidosis, electrolyte disturbances and hypoglycemia (if they have received insulin). Patients who have had the pituitary gland removed (hypophysectomy) because of retinopathy will present special problems in replacement therapy with hydrocortisone. Unless these patients receive increased amounts of hydrocortisone during times of stress, serious circulatory problems may develop.

The second problem group of diabetic patients are those who have serious complications, such as myocardial, vascular, renal or hypertensive disease. No matter how carefully performed, anesthesia and surgery may place a severe stress on these patients. The combination of light anesthesia and muscle relaxants is ideal. The blood pressure, pulse and electrocardiogram must be monitored continuously. For operations performed below the umbilicus (bladder and extremities) spinal anesthesia may be advantageous. If the patient has severe peripheral neuropathy the choice of spinal anesthesia must be balanced against the inherent risks of general anesthesia. Insofar as the general health of this group of patients can be improved prior to surgery, the risk of morbidity and mortality will be lessened.

### CONCLUSIONS

Although all general anesthetic agents are potent drugs which produce unconsciousness, they are quite safe when used by competent, trained persons. We must continue our efforts to train anesthesiologists and nurse anesthetists who understand the special problems of diabetics. Greater communication must be encouraged between the anesthesiologist, internist and surgeon in caring for the patient. The diabetes must be under the best possible control and the surgery should be performed early in the day. Finally, well-designed clinical investigations should be undertaken to determine how best to manage the diabetes just before and during surgery, and in the immediate post-operative period.

## PODIATRY AND THE DIABETIC

A Report Prepared for the Commonwealth of Pennsylvania Committee on Diabetes and Blindness, by Sheldon M. Weltraub, D.P.M., A.A.C.F.S., Chief, Resident Training Program in Podiatry, Kensington Hospital, Philadelphia, Pa., and Residents, 1972-73, Irwin D. Cohen, D.P.M.; Sheldon A. Cohen, D.P.M.; Marshall R. Feldman, D.P.M.; Thomas Neuman, D.P.M.

According to Joslin from the world famous Joslin Clinic in Boston, Massachusetts, "Increased emphasis must be placed on prevention of foot lesions. These are wasteful in terms of health, loss of time, and expense."<sup>1</sup> He goes on to state that the Podiatrist is essential to the treatment of diabetes when it concerns lesions of the lower extremities in order to prevent gangrene. In vascular and diabetic clinics around the Country, where Podiatrists are present, the incidence of gangrene and death due to gangrene has decreased appreciably.<sup>2</sup>

In a study done at the New England Deaconess Hospital in 1969 in which there were 10,321 admissions of all types, the average stay was 11.6 days. This number included 417 diabetic patients with foot lesions, whose average length of stay was 25.8 days. Hospital *per day* costs during 1969 averaged \$101.08, not including medical fees. Therefore, the hospital cost in 1969 for this one hospital alone amounted to more than \$1 million for the care of foot problems severe enough to require hospitalization.<sup>3</sup>

### THE CONSERVATIVE MANAGEMENT OF DIABETES AFFLICTING THE LOWER EXTREMITIES

In a general podiatric practice more than 30% of the patients seen suffered from disorders indirectly or directly related to diabetes mellitus. The practitioner has a great deal of responsibility in controlling this patient for not only does he have to contend with the systemic problem of diabetes but with its local manifestations which entails his multifaceted ability in neurological, dermatological, and peripheral vascular diseases. Podiatrists coordinate their efforts of treating the local manifestations of this disease with the allied members of the health profession who treat the basic systemic infirmity.

Among the local disorders requiring the practitioner to use his abilities to the utmost are preulcerous lesions, diabetic ulcers, diabetic neuropathies, gangrenous digits, as well as his ability to evaluate a good surgical risk in a diabetic. Not only is the Podiatrist called upon to treat these manifestations of the disease but it is also within his scope to prevent these conditions before they occur. The Podiatrist in his so-called "maintenance treatment" of debriding hyperkeratotic lesions and reducing mycotic nails in the diabetic, is thus precluding future avenues of breakdown in the body. An innocuous callous can become an intractable ulcerous lesion that may eventually end up gangrenous. The diabetic patient, who has thickened nails due to a fungus infection and who has great difficulty cutting his nails properly, thus sets up avenues of foci of infection by accidentally lacerating his own skin. This is due to the fact that diabetics cannot ward off pathogenic organisms as well as a non-diabetic patient.

And perhaps equally as important, if not more so, is the likelihood of the Podiatrist being the first practitioner to diagnose the diabetic condition in the patient by the symptomatology. Frequently, the first symptoms of diabetes may appear in the lower extremity. Thus, the Podiatrist in the course of his complete physical examination of the lower extremity can discern the subtle or at times overt changes in dermatological, neurological and peripheral vascular diseases.

Early dermatologic manifestations of diabetes found on the lower extremity, are usually first seen by the Podiatrist in the course of a patient's so-called maintenance foot care. As was noted previously, loss of work and money results from incapacitating foot problems in the diabetic. But if the diabetes is brought

<sup>1</sup> *Joslin's Diabetes Mellitus* (Joslin), Page 618.

<sup>2</sup> *How much medicine and physical diagnosis in the Podiatry Curriculum* (Lemont).

<sup>3</sup> *Op. cit.* (Joslin), Page 618.

promptly under control, this minimizes the chance of complications. The lesions seen include diabetic dermopathy, which are discrete pigmented macular lesions occurring on the anterior portions of the legs; necrobiosis lipoidica diabetorum distinguished by atrophic, yellow depressed areas with telangiectastic blood vessels coursing through them. One other harmless manifestation of diabetes is carotenosis, which exhibits a yellow discoloration of the skin.<sup>4</sup>

A later complication of diabetes is the diabetic ulcer which is caused by minor trauma, either by mechanical means, as from ill-fitting shoes, by thermal burns, due to application of hot water bottles, or by chemical means, by the use of topical home remedies.<sup>5</sup> These irritants cause chronic ulcerations which become secondarily infected. The infection may then bring on diabetic acidosis and coma in a formerly well-controlled diabetic. "Thus, the importance of proper prophylactic foot care and correct therapeutic measures for specific problems cannot be overemphasized."<sup>6</sup>

The ulcerous lesion is treated by the Podiatrist by placing the patient on bed-rest, performing a culture and sensitivity test to detect the bacteria involved, saline soaks, enzymatic ointment application, and above all, patience. Skin grafts are sometimes necessary to close the area, but conservative therapy is the procedure of choice.<sup>7</sup>

The innocuous seeming, lay term of the disease "athlete's foot", can have grave consequences in the diabetic. There is a much higher incidence of fungus infections of the feet in the diabetic than the general population. The fissures and erosions which result in the skin from these fungal pathogens, allow bacteria a portal of entry into the body. And since diabetics have a lower resistance to fight infection, the results can be kept under control if properly and promptly treated by a Podiatrist.<sup>8</sup>

Another dermatologic problem frequently associated with diabetes is chronic paronychia. This condition is evidenced by swelling and erythema of the posterior nail fold. The infectious process spreads and causes a cellulitis if not promptly and adequately treated.<sup>9</sup>

The neurotrophic foot is yet another sequelae of diabetes. The neurotrophic foot is a peripheral neuropathy impairing the patient's local awareness of local trauma, which occurs in 20 to 70 percent of patients with diabetes mellitus.<sup>10</sup>

The severity of the diabetic state is not necessarily related to the development of gangrene. As a matter of record, the more severe peripheral vascular complications occur in the so-called "milder diabetic". These are diabetics whose control is easily obtained by diet alone, small doses of insulin, or small doses of oral hypoglycemic drugs.<sup>11</sup>

There are certain pertinent features which make the entity "neurotrophic foot" stand out and differentiate from other diseased states:

1. the history given by the patient is usually one in which there is no awareness of recent trauma or pain;
2. bulbous deformity of toes, feet or ankles;
3. typical ulcerative lesions in weight bearing areas on the sole, particularly in the region of the first or fifth metatarsal heads; or at frequent sites of pressure on the lateral aspect of the fifth toe or on medial aspect of the great toe; or on the dorsum of any toe or heel;
4. lesions which are not initially ulcerous, are often found on the plantar aspect of the feet beneath a callous which upon exploration, may show a long, deep sinus tract extending to the bony structures below;
5. gangrene, when present, is often superficial and debridement reveals viable underlying tissue with a good blood supply;
6. the bony changes on X-ray are pathognomonic and are often the determining factor in postponing major amputation; the bony changes seen are destruction, deformity, dislocation, demineralization, fracturing, and tapering.

Bone destruction will not occur in the foot of a diabetic unless the circulation is adequate. Therefore, the prognosis in a diabetic with soft tissue infection and even gangrene is better if there is evidence of bone involvement.<sup>12</sup>

<sup>4</sup> *Cutaneous lesions of the lower extremities* (Samitz-Dana), Page 101.

<sup>5</sup> *Ibid.*, Page 104.

<sup>6</sup> *Ibid.*, Page 104.

<sup>7</sup> *Ibid.*, Page 105.

<sup>8</sup> "Dermatological problems in the diabetic patient" (Rhodes).

<sup>9</sup> *Ibid.*

<sup>10</sup> "The Neurotrophic Foot", (Skversky), lecture notes.

<sup>11</sup> *Ibid.*

<sup>12</sup> *Ibid.*

"The deleterious effect of the diabetic state upon the overall integrity of the vascular supply to the heart and lower extremities seems incontrovertible."<sup>13</sup> In a paper published by E. T. Bell in 1952, the author found that gangrene of the lower extremities was about forty times as common in the diabetic as opposed to the non-diabetic patient.<sup>14</sup>

About 20 years ago, surgeons believed that an adventurous approach to diabetic gangrene was worthwhile. Common practice was to perform a below-the-knee amputation for ischemia of a single toe. And of those patients who underwent amputations, 15% died during surgery, or within twenty-eight days of the operation; 16% died within the first year; 29% died within two years; 38% died within three years. The importance of the adoption of a conservative treatment and the prompt and early diagnosis of diabetic foot lesions is emphasized by the above and also the poor results of artificial limb fitting.<sup>15</sup>

Foot abnormalities in the diabetic stem from two primary areas—the first being a neuropathy with decreased sensation of all modalities: pressure, position, pain, and thermal reception. This nerve damage leads to mechanical and caloric injuries that result in callous formation, ulceration, and eventually a "Charcot type" of joint destruction. These areas of traumatic openings in the epidermis allow entrance of bacteria which result in rapid advancement of the disease process.<sup>16</sup>

Early and rapid atherosclerotic changes make up the second major pathogenic abnormality in the diabetic extremity.<sup>17</sup> These changes generally reveal themselves in the geriatric diabetic who is least able to handle them for a variety of reasons. Among them is the fact that peripheral vascular disease is neglected to a greater degree than vascular problems of the heart or even the brain. This is the result of several factors. One is that these problems receive scant attention in medical schools. Few teachers in medicine are deeply interested in the geriatric patient with a gangrenous toe and mild diabetes even though this and allied problems constitute a major cause of long-term disability.<sup>18</sup> This can be evidenced by the fact that at the New England Deaconess Hospital, admission of diabetic patients for surgical treatment of the lower extremity accounts for 53% of all admissions for any other type of surgery.<sup>19</sup>

What happens too often is that the resident staff, deficient in training in geriatrics, resists having these patients admitted to their service. Thus, they begrudge the space and time these patients require. These physicians consider that amputation is the logical solution for the patient with gangrenous lesions of the feet, thus exhibiting their overt inadequacy in the techniques which may save the limb. Today, interest at all levels seems to decrease with the increased age of the patient. This may be the early manifestations of a faceless medicine of the future, or it may represent the deep-rooted tradition of our tribal past when the aged were cast out to fend for themselves. "We cannot accept this attitude as worthy of this affluent and generally compassionate society."<sup>20</sup>

I shall not attempt to say that the Podiatrist is the sole guardian of the diabetic geriatric in the organized health care delivery system. But the fact remains that the Podiatrist sees the greater proportion of these people than the rest of the allied health organizations combined. And his interest is perhaps more acute by virtue of the fact that he is limited to the treatment of infirmities of the lower extremities. But this limitation enables him to develop his skills to the utmost.

Care of the diabetic foot requires adherence to surgical principles even in the presence of minor infections. A rapidly advancing area of diabetic gangrene may usually be retarded by adequate drainage of any infected sites. These patients are extremely intolerable to heat, because of the attendant neuropathy and reduced circulation. Therefore, heat is never applied directly to the affected limbs, whereas wet compresses at room temperature are used.<sup>21</sup>

The Podiatrist can evaluate the need for an amputation of a toe or limb by examining the pulses in the extremity, and by plethysmography which evaluates blood flow and volume in a digit.<sup>22</sup>

<sup>13</sup> *Vascular Considerations of Diabetes Mellitus* (Kimura and Caygill), Page 277.

<sup>14</sup> "A post-mortem study of disease in diabetics". (Bell), Pages 444-445.

<sup>15</sup> "A trial of conservative amputations for lesions of the feet in diabetes mellitus", (Bradley and Fulford), Pages 38-43.

<sup>16</sup> "Care of the diabetic foot". (Piper), Page 91.

<sup>17</sup> *Ibid.*, Page 92.

<sup>18</sup> "Peripheral vascular disease problems in the aged—considerations regarding prevention". (Wright).

<sup>19</sup> *Op. cit.* (Joslin), Page 607.

<sup>20</sup> *Op. cit.* (Piper), Page 93.

<sup>21</sup> *Op. cit.* (Wright).

<sup>22</sup> *Ibid.*, Page 94.

It is also within the realm of the Podiatrist to prevent repeated ulcerations on the feet from becoming gangrenous by performing surgical techniques. Diabetes itself is certainly not a deterrent to foot surgery, if the patient is properly evaluated and good surgical technique is employed.

The surgeon must never be casual in his approach to the diabetic foot. Certain protocols should be followed which include "gentle handling of tissues and the tissue layers should not be separated more than is necessary since the vascularity of the superficial layers is often dependent on the tissue beneath. Rough retraction is likewise harmful. Mass ligation of tissues to control bleeding leaves areas of devitalized tissue. Vessels should be individually clamped and ligated with the finest suture material. Never suture tissues under tension, and use the minimal number of sutures possible. Drain should be avoided or used sparingly since they act as foreign bodies. Dry gauze dressings should be avoided as they dehydrate wound margins and cause gangrene. The operative site should be inspected frequently since failure to open an infected wound or relieve tension may result in extensive gangrene within twenty-four hours."<sup>23</sup> Therefore, if these protocols are followed, the Podiatrist can prevent future disability in the diabetic, and not run into postoperative complications. Because the hyperkeratotic tissues which break down in the diabetic foot are the result of pressure, these lesions can only be relieved in many, by proper podiatric surgery.

A case history will now be presented as an example of how the Podiatrist interacts in the organized health care field.

A 62-year-old negro female presented herself to the clinic with a chief complaint of a burning callous on the bottom of her foot. Upon examination, the callous was found to have a reddish center representing dried blood, a characteristic found in diabetes. A neurologic examination revealed an inability of the patient to perceive the vibrations of a tuning fork on her ankles or toes. The patient also complained about burning feet, clinically known as a diabetic polyneuropathy, thought by the patient to be due to her callouses. The results of her laboratory tests revealed the patient to have an elevated blood sugar, and she was referred to the nearest diabetic testing center for corroboration and treatment. These podiatric clues enabled early detection of a diabetic patient, early treatment, and prolongation of life.<sup>24</sup>

In a monograph by Paul Brand, there is a cartoon in the introduction in which a patient who is bandaged from toes to mid-thigh is walking on a pathway named "Amputation Road" with a hungry looking buzzard perched on the road sign.<sup>25</sup> This picture can only be changed by prompt and correct treatment of diabetics by the health professions.

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<sup>24</sup> *Op. cit.* (Wright).

<sup>25</sup> *In sensitive Feet* (Brand), Page 8.

## DIABETES AND ORAL DISEASE

A report to the Governor's Committee on Diabetes, by Ronny S. Taschner, D.D.S., Research Assistant, Department of Periodontology, Temple University School of Dentistry; and Merwyn A. Landay, D.D.S., Professor and Chairman, Department of Periodontology, Temple University School of Dentistry

There is a vast literature of clinical reports and scientific studies relating diabetes mellitus to different types of oral disease, pulpal and periapical pathology, enamel hypoplasia, fungal infections, neurologic disorders, salivary gland disturbances, and periodontal disease.

In all instances the exact relationship between these various oral diseases and diabetes mellitus is not clearly defined. Much of the literature is contradictory and confusing, and a large portion of the literature is pure speculation. Many of the studies are inadequately controlled or poorly designed. A small portion of the available data is excellent, but in more instances than not the literature raises more questions than it provides answers.

In spite of this, we have attempted to review and assess the literature in this area and draw conclusions on the relationships of diabetes and oral disease. The following report reflects the current status of knowledge on oral diseases that have been linked to diabetes.

### DENTAL CARIES

A marked increase in dental caries was a commonly reported clinical observation in the pre-insulin era. (1) Borghelli and others, in a well performed study, have shown this same relationship to exist in 87 pancreatectomized rats. (2) However later studies have contradicted these findings. Shannon and Kilgore found no significant correlation between decayed, missing and filled surfaces of teeth and the serum glucose level among 510 male subjects. (3) These subjects were not however uncontrolled diabetics. A well-designed study by Kjellman et al failed to show any statistically significant difference in the frequency of caries among 105 human subjects with diabetes mellitus and 52 controls. (4)

Based on these studies there does not appear to be an increased frequency of dental caries in controlled diabetes. At the present time there is insufficient evidence available to support either a positive or negative statement about the relationship between uncontrolled diabetes mellitus and the incidence of dental caries.

### PULPAL AND PERIAPICAL PATHOLOGY

Inflammatory and degenerative changes have been reported by Seltzer in the pulps of human teeth. He states that pulpal arteritis may be the etiology of these changes, and that they may then cause odontalgia in non-carious teeth. He further states that the healing of a periapical lesions in an uncontrolled diabetic will not take place even after endodontic therapy. However, when the diabetes is controlled, the lesion may heal normally. (6) He presents no evidence in his report to support his impressions.

Generalized atrophy of the pulp in non-carious teeth of Chinese hamsters with hereditary diabetes mellitus has been reported by Cohen, et al. (5) Unfortunately, there are flaws in the study, and since it was conducted with hamsters would, even if done well, be difficult to extrapolate to human pathology.

The exact relationship between pulpal and periapical pathology and diabetes mellitus is not clear at this time. At least one prominent clinician believes diabetes can cause inflammatory and degenerative changes in the pulp. (8) No good evidence for this relationship has yet been presented.

### ENAMEL HYPOPLASIA

Edland and Grahnen found that 25% of children from diabetic mothers had symmetrical external enamel hypoplasia, while only 3% of the children from non-

diabetic mothers exhibited this anomaly. This difference was shown to be statistically significant ( $P > 0.01$ ). (7) This was a well done study but it is the only one of its nature reported in the last ten years.

Based on this study, it appears that diabetes in the mother, predisposes the child to a greater likelihood of enamel hypoplasia. Further studies are needed to substantiate and clarify this relationship.

#### FUNGAL INFECTIONS

Early investigators reported that *Candida albicans* was isolated in greater quantity from the saliva of patients with diagnosed diabetes, than from those without a diagnosis of diabetes. (8) However, in a later, more adequately performed investigation, *Candida albicans* was isolated as frequently from the oral cavity of 200 non-controlled and 200 controlled diabetics, as from the oral cavity of 200 non-diabetics. (9)

It appears unlikely at this time that there is any relationship between diabetes and fungal infection of the oral cavity. Dental microbiologists feel more evidence is needed before this relationship can be totally discounted. With this we would agree.

#### NEUROLOGIC DISORDERS

A possible relationship between trigeminal neuralgia and diabetes mellitus has been suggested by Finestone and others. They found the incidence of diabetics and suspected diabetics to be higher among a group of 92 patients with trigeminal neuralgia, than that found among the general population. (10) This is the only report in the literature which attempts to establish a relationship between diabetes and trigeminal neuralgia, and it suffers from numerous design defects.

More research is needed in this area before any strong statements of relationship are acceptable.

#### SALIVARY GLAND DISTURBANCES

Many authors have reported an alteration in salivary flow, saliva properties, dry burning mouth, and other vague oral symptoms in patients with diabetes mellitus. Brody et al found that 35% of 142 patients presenting with varied oral complaints including burning, dry mouth and gingival tenderness, had glucose tolerance curves indicative of diabetes. This, he points out, is significant when one considers that the incidence of diabetes among the general population is only 7%. (11) Other studies have shown that diabetics exhibit a significantly lower salivary secretion rate than non-diabetics. (12, 13) Krzycka has reported varying degrees of xerostomia in 61% of diabetic patients and enlarged parotid glands in 81%. (14)

Recent studies by Kjellman have shown alterations in the glucose content and buffering capacity of the saliva of diabetic patients. (13,15) Also, abnormal electrolyte composition was seen in the saliva of 53% of 100 diabetic patients. (12)

The relationship between diabetes mellitus and decreased salivary flow resulting in xerostomia or dry burning mouth, appears to be substantiated. That an increase in blood glucose is accompanied by a concomitant increase in salivary glucose content is also established. More research is required before any conclusions can be drawn concerning changes in the buffering capacity of saliva and how it might affect the oral environment.

#### THE INCIDENCE OF PERIODONTAL DISEASE

An unusually high incidence of periodontal disease has been reported as a clinical finding in patients with uncontrolled diabetes. (1) Cheraskin and Ringsdorf have also shown, in a group of 290 routine dental patients, that those with gingival disease had a significantly higher mean blood glucose level. (16) Kjellman reported an increased frequency of gingivitis in a diabetic group. (4,13) However, Benveniste and his group in a well-performed study found no significant difference in periodontal scores between a group of well controlled diabetics and their non-diabetic relatives. (17) Also no significant correlation was found between the periodontal status of healthy, young male subjects and their fasting, two hour post-prandial blood glucose levels, (18) or glucose tolerance test results. (19)

The previous studies, which examined the relationship between diabetes mellitus and the incidence of periodontal disease, were done either on controlled diabetics or on young healthy soldiers. Given these set of circumstances, the studies are still contradictory enough that it is difficult to draw any conclusions.

None of the investigations were performed on uncontrolled diabetics. Since it is a widely held impression by many clinicians, and case reports have frequently occurred in the literature, it must still be assumed that uncontrolled diabetics will experience a higher incidence of periodontal disease. Firm evidence is needed to substantiate this clinical impression.

#### THE SEVERITY OF PERIODONTAL DISEASE

In a well-performed study, Kjellman has reported an increased gingival index among diabetics (13). Other well-performed studies have been done by Belting et al, who found that the severity of periodontal disease is significantly greater among diabetics than among non-diabetics (20), and by Glavind et al., who found this to be true only after the age of 30. Up until the age of 30, the rate of destruction was the same for the controlled diabetic and non-diabetic group. After the age of 30, the rate of destruction increased in the diabetic group. They also found that patients suffering from overt diabetes for more than 10 years showed greater loss of periodontal structures than those of less than 10 years. It was also reported in this paper that diabetics with retinal changes showed greater loss of attachment than others (21). In a more recent report of a two-year longitudinal study, Cohen et al, found that while the hard and soft deposit scores were significantly lower among the diabetic group, the gingival, periodontal and mobility scores were consistently and significantly higher than the non-diabetic controls (22).

In reporting their clinical observations, Valnshteln et al, observed that among 584 patients with periodontal disease, 55 had previously undiagnosed glucose tolerance curves that were indicative of diabetes. Among this same group, unsatisfactory results of periodontal therapy were reported in only 3.3% of the normal patients, whereas results of periodontal therapy were unsatisfactory in 24.3% of the diabetic group (23).

In a clinical study, the radiographs of diabetics reportedly showed widened periodontal ligament spaces, and blurring of the outlines of the crests of the interdental septa at an early stage of the diabetes. Atrophy and rarefaction of the bone were seen as the disease progressed, and in patients with diabetes over 10 years, advance atrophy of the alveolar process led to early loss of the teeth (24). Studies conducted on hamsters with hereditary diabetes mellitus have reported that the diabetes lowered the tissues' resistance to local irritation rendering the animals highly susceptible to severe periodontal involvement with pocket formation and severe alveolar resorption. (5, 25) In alloxin diabetic rats, Glickman has shown osteoporotic changes in the alveolar bone. (26) In a later study, Bissada et al reported that the reaction to local irritants was greatly increased in his alloxin diabetic rats meaning that the diabetic state had a modifying effect on the resistance to periodontal disease. (27) These studies, even though well performed, must be kept in proper perspective since they were done on distantly related experimental animals.

The previously cited literature would lead one to conclude that there is a well established relationship between the presence of diabetes mellitus, even in the controlled state; and the presence of the more severe and advanced types of periodontal disease. Unfortunately there is a large body of contradicting literature.

Shannon and Gibson found no significant relationship between the glucose tolerance test results and the periodontal status of 300 healthy young males. (19) Kjellman and his group found no difference in the marginal bone loss between diabetic and non-diabetic subjects. (4) The strongest negative evidence presented so far is a well-performed study done by Hove and Stallard. In twenty-eight diabetic patients they found that periodontal disease increased with age, and was directly related to the accumulation of plaque and calculus, and not to the diabetes. (28) A study using mice with inbred diabetes failed to show any cause and effect relationship between diabetes and periodontal disease in the absence of local irritation. (29) Studies have been done in an attempt to disclose the basic pathologic defect in the periodontal tissues of diabetics in an attempt to clarify any existing relationship. In 1948, Ray using the light microscope, described what he considered to be the histopathology of human diabetic gingival. He reported many degenerative changes often seen in the pathologic lesions of periodontal disease. He also reported a thickening or hyalinization of the vessel walls, and obliteration, and thrombosis of the vessels. He suggested that the increased protein breakdown seen in the diabetic state along with the vascular changes seem to lower the resistance of the gingival tissues. (30) Ray's findings were erroneous

in many respects, but since then, many well-conducted studies have described gingival capillaropathies, not unlike the vascular changes seen in the kidney and retina of the eye in diabetics. (31)

These studies describe a thickening of the basement lamina of the small vessels. (32, 33, 34) Compbell in a well done electronmicroscopic study of the gingiva of diabetic, found an increased thickness of basement membrane beneath the stratified squamous epithelium. (35) That the capillaropathy may be related to increased periodontal breakdown has been suggested by Barret et al. He pointed out that subjects with thicker capillary walls show progressively more alveolar bone loss with advancing age than do subjects with thinner walls. (36) The possibility that an alteration in the properties of bacterial plaque, which is the major etiologic factor in periodontal disease, occurs in diabetics has been reported in a well performed study by Kjellman. He showed that plaque in a diabetic group had a lower pH than that of the non-diabetic controls. He also observed a correlation between the lowered pH and an increase in the degree of gingivitis. (37) He also found, in a separate study, that the hyaluronidase activity of plaque was significantly higher in diabetic patients than in controls. (37) In 1966, the World Workshop in Periodontics, after reviewing the literature, concluded that "periodontal tissues respond to any alteration in tissue metabolism that affects similar tissues at other body sites. However, that such changes usually do not produce marginal gingival ulceration, and that the typical gingival lesion is initiated by local insults to that tissue, but that the resultant lesion may be modified and more probably accentuated by systemic disease which alters the hosts resistance or repair potential to local injury". (38)

At the present time the exact nature of the relationship between diabetes and the severity of periodontal disease is still controversial. It is the impression of most periodontists that there is no direct cause and effect relationship between diabetes and periodontal disease. Instead it is felt that the diabetic state may alter the resistance of the periodontium to local irritation, rendering it more vulnerable to breakdown. That capillaropathy exists in the periodontium of a diabetic is fairly well substantiated, but its relation to a lowered tissue resistance has yet to be shown. Obviously more research is necessary in order to reveal the exact nature of the relationship diabetes mellitus and the progression and severity of periodontal disease.

#### CONCLUSIONS

In this report, we have reviewed and presented the research and literature of the past ten years on the relationship of diabetes and oral disease.

Diabetes mellitus has been linked in the literature to dental caries, pulpal and periapical pathology, enamel hypoplasia, fungal infection, neurologic disorders, salivary gland disturbances, and periodontal disease.

Most of the literature on the relationship of diabetes and oral disease is contradictory and confusing, and a large portion of it is pure speculation. Many of the studies are inadequately performed or poorly designed. In more instances than not the literature raises more questions than it provides answers.

The only oral changes that are well substantiated in their relationship to diabetes mellitus at this time are the following:

- 1) a decreased salivary flow resulting in xerostomia or a dry burning mouth
- 2) an increase in the glucose content of saliva, and
- 3) a thickening of the basement lamina of the small vessels of the gingiva.

It is most disheartening that very few other substantiated statements can be made about the relationship of diabetes and oral disease after one carefully reviews the vast literature in this area. It is difficult to believe that so much literature would be generated if some relationship did not exist. Further, since most of the excellent clinicians hold strong impressions that relationships between diabetes and various oral diseases do exist, it is unwise to discount these relationships.

What is needed is a significant increase in the amount of research funds available for studies of this type. An increased number of good investigations should be able to readily clarify any existing relationships. This is important to the health of the public.

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## DIABETIC RETINOPATHY: HOW TO ATTACK THE PROBLEM

A report written for the Chairman of the Commonwealth of Pennsylvania Committee on Diabetes and Blindness, by C. L. Shepens, M.D., President, Retina Foundation, Associate Professor of Ophthalmology, Harvard School of Medicine, Boston, Mass.

Charles L. Shepens, M.D. is an established authority on retinal degeneration. He is one of the most conceptional doctors I have met.

Diabetic Retinopathy: How To Attack the Problem? was written at my request.

As of this time The National Eye Institute is expending 50% of its research money allocated to diabetic retinopathy for a 10 year multi-institution evaluation of photocoagulation. After ten tenuous years we will have an accumulation of facts and figures that will add to our knowledge but the diabetic with retinopathy will remain in exactly the same dire predicament as today.

Photocoagulation is "stopgap" or temporary and at best can, for a time, help only one out of every three affected diabetics.

While I can understand the National Eye Institute desire to determine to what extent diabetic retinopathy will benefit by the use of photocoagulation . . . I think it is essential to develop other programs which could provide safe refuge from "ultimate blindness".

Is Dr. Shepens proposal valid? I do not have the answer. I do know there is a consensus among important ophthalmologists that there is sufficient knowledge to begin extensive cooperative research that could in near years provide the miracle that would preserve sight and life for the approximate two million diabetics who brink blindness.

I believe this statement is worthy of reproduction in the Public Records . . . if for nothing more than provoking public interest, public discussion and medical discussion that hopefully will be heard and understood by the lay public and those who determine dollar support for needed research.

CARL STENZLER, *Chairman.*

\* \* \*

The commonest cause of totally disabling blindness in Pennsylvania is diabetes mellitus. This Frankenstein situation has developed over the past two decades as thousands of patients saved from acute diabetic disease by the discovery of insulin fell victim to one of the complications of chronic diabetes. Conservative statistical projection show that almost a half-million Americans will be blind from diabetic eye disease within 27 years and most of those will be blinded by diabetic retinopathy. (The retina is the film located at the back of the eye, which is sensitive to light. The word retinopathy means disease of the retina). The blindness, unfortunately, affects teenagers and young adults as well as the elderly.

Although blindness among the elderly brings forth its share of misery, its occurrence in young adults usually causes much greater social and economic dislocation. All too often, a young man starting to buy a house and become established in a trade or a business has his future destroyed, not only for himself, but also for his wife and young children, because of disabling blindness. The loss of vision in a young mother is almost equally destructive to a family, to say nothing of her anguish at her inability to help her children and see them grow.

There is a disheartening picture of multiple complications from long-standing diabetes in addition to blindness. These include hypertension, severe arteriosclerosis with peripheral artery occlusion requiring amputation of limbs, coronary artery diseases, strokes, peripheral nerve disability and kidney failure. All of these, plus the retinopathy often occur in the young. However, only the eye complications appear amendable to corrective treatment in the fairly near future, except for hopes for renal dialysis or kidney transplantation.

### THE PROBLEM

The problem is how can we decrease the mounting numbers of those affected with diabetic retinopathy. For this purpose, it is important to be aware of what essential knowledge is already available about diabetic retinopathy.

There are actually two distinct stages in this disease. The first, and most frequent is called background retinopathy: the blood vessels in the retina suffer from damage caused by diabetes. In this respect the retinal damage is similar to that observed in the blood vessels of nearly the whole body. To cure background retinopathy would mean curing diabetes. This is a formidable problem whose solution is a long way off. Background retinopathy while damaging to the eye is rarely the cause of disabling or incurable blindness.

The second stage of diabetic retinopathy is called active or proliferative retinopathy. This stage of development of the disease is unique to the eye. No other organ in the body suffers from it. It consists in myriads of new vessels growing into the retina and vitreous. (The vitreous is a transparent jelly that fills the back of the eye). These new vessels are abnormally fragile and tend to bleed. The new vessels and their repeated bleedings inside the eye are the cause of blindness in cases of diabetic retinopathy.

The problem then consists *not* in attempting to solve the overall damage caused by diabetes, but in attacking its unique eye complications which are the cause of blindness. This problem is socially and economically important because many blind diabetics are still young and would be economically independent if they could see.

#### THE PLAN FOR A SOLUTION

The only hope to solve the problem of blindness caused by diabetic retinopathy is through an innovative plan of research. The eye as a very specialized organ is the target of unique forms of disease. It is also an ideal organ in which to study certain problems that may affect other organs. In particular, the transparency of its structures make it an ideal organ for the study of vascular diseases. In the retina the smallest blood vessels can be studied under high magnification and with extremely sensitive methods. This will be explained in greater detail later in this presentation.

Having acknowledged the existence of unusual research opportunities in the eye how can a coherent plan be made to exploit them?

Such a plan must achieve two main objectives. The first objective is to gain new insight into the mechanisms of production of diabetic retinopathy, by properly oriented programs of laboratory research. The second objective is to study large groups of patients in order to learn how existing methods of diagnosis and treatment can be improved in the immediate future.

#### *1. Laboratory Research into Mechanisms of Production of Diabetic Retinopathy*

The most widely accepted hypothesis as to the cause of diabetic retinopathy is that insufficient circulation of blood in the retina causes chronic asphyxia of this most active tissue. As a result, new vessels grow into the retina and vitreous, and these new vessels tend to bleed. There are many possible causes to insufficient blood circulation in diabetics:

(a) It could be that the blood itself is of poor quality and is not flowing properly through small vessels called capillaries. It is also possible that the blood of diabetics is incapable of releasing to the tissues the oxygen it contains.

(b) It could be that the walls of the capillaries are damaged and therefore impede exchanges between the blood and the tissues.

(c) It could be that enzymes (specialized proteins) in the retina are functioning poorly and cannot utilize the nutrients supplied by the blood.

(d) It could be that certain hormones are affecting the permeability of the retinal capillaries thereby disturbing the exchanges between blood and retinal cells. Hormones could affect nutrition of the retina through other mechanisms also.

For each one of these possible mechanisms there is scientific evidence, but not enough to be totally convincing. Similarly, there are still other possible mechanisms of action of diabetic retinopathy, but none can be either proved or disproved at this time.

One method of approaching such a complex problem is to engage into an integrated but multidisciplinary research program. Such a program consists in attacking each possibility listed above and others if indicated. Each possibility must be investigated in depth by the best experts in the field. There should be teams of blood specialists, hormone biochemists, enzyme biochemists, specialists in the study of the permeability of blood vessels walls, etc., each working on its own specialized aspect of the problem of diabetic retinopathy. The work of these multiple teams should be integrated, which means that the team members

should meet and discuss their findings and plan future work with the full benefit of the discoveries and constructive criticisms made by the members of other teams.

Several such integrated teams should be working concurrently in the medical centers of the country that have the highly specialized manpower needed. Of course the various integrated teams should also meet at intervals, to discuss findings and further planning.

## *2. Clinical Research for Immediate Improvement of Diagnosis and Treatment*

Aside from the above integrated research effort into the causes of diabetic retinopathy, highly specialized eye surgeons must continue their efforts in clinical research, mainly for two purposes.

The first purpose is to improve our presently unsatisfactory methods of control of diabetic retinopathy. Until now only palliative methods of treatment have been available. These are largely surgical: photocoagulation, pituitary ablation, and scleral resection. There is no unanimity as to the therapeutic value of these measures, none of which is curative anyway. Many improvements are possible in these techniques and more effective techniques can be derived.

The second purpose of the effort in clinical research relates to an ongoing and retrospective study of patients with diabetic retinopathy in the hope of discovering factors predictive of the natural course of the disease, its development, and of the effect of therapeutic measures.

### HOW ATTRACTIVE IS THE PLAN

To a superficial observer this plan is the routine type of plan one would follow for attempting to eradicate any of the crippling chronic diseases. In the case of diabetic retinopathy however there are present unusual ingredients that make it a program of high promise.

It has already been said that the eye is attacked in a unique fashion by diabetes and that the transparency of the eye structures afforded unique opportunities for the study of small blood vessels.

Let us now look in greater detail at how these opportunities were exploited in the laboratories of the Retina Foundation, in Boston.

Since diabetic retinopathy is generally ascribed to relative asphyxia of the retina it is essential to be able to measure in the living retina of man, such basic data as the speed of blood circulation, blood flow, quantity of oxygen transported by this flow, and quantity of oxygen actually delivered to the tissues. So far it has been impossible to make such measurement in man as a routine clinical practice. Today, Dr. Charles Riva and his co-workers seem to have solved all these problems by techniques that are relatively simple to apply yet highly sensitive.

This means that as soon as Dr. Riva's techniques are fully adapted to measurements in patients, actual blood flow and indeed consumption of oxygen by discrete areas of retina will become measurable in many at will, under many different conditions. We have therefore reached a momentous period, in the history of diabetic retinopathy where, for the first time, the most widely accepted hypothesis concerning diabetic retinopathy can be submitted to a decisive test: is blood flow and/or oxygen consumption decreased in a measurable fashion when background retinopathy enters into its actively slight destructive phase?

Assuming that Dr. Riva's methods confirm that relative asphyxia of the retina is the cause of diabetic retinopathy what can be done next? Through a highly rewarding collaborative program with the Blood Research Laboratory at the Chelsea Naval Hospital, Dr. M. A. Castany has already blazed a trail toward therapy in this field. Experimentation so far indicates that it is possible to "force" the patient's blood to release more oxygen to the tissues when the tissues begin to suffer from asphyxia and before diabetic retinopathy actually develops. Such indications are based on the development of a new technique that permits to keep an eye removed from the animal's body, alive and functioning with artificial circulation of whole blood. The chemical variations of the blood can be measured and the finest blood vessels of the retina are observed directly under a microscope's high magnification. The isolated perfused animal eye will be used as a laboratory model to study the influence of diabetic blood upon the circulation in the capillaries of the retina. It will also serve as an indicator of the potential effects of changes in blood composition upon the retinal circulation.

By building a research program around Drs. Riva's and Castany's research it is therefore possible to check in detail the current hypothesis that explains diabetic retinopathy. If this hypothesis proves true, the basis of *preventive* therapy already exists in their current research.

The above results were obtained through the intelligence, hard work, and devotion of a team of young investigators, at the Retina Foundation. By necessity, the financial means at their disposal were grossly insufficient. There are indications that similar research efforts made in other areas pertaining to the field of diabetic retinopathy could be as fruitful. This should justify fully the approach I recommend for "Laboratory research into mechanisms of production of diabetic retinopathy."

#### BASIC NEEDS FOR THE PLAN: TRAINING AND MONEY

In order to put the plan concerned with clinical research into action an intensive program of training is necessary. This should involve training on the postgraduate level of a sufficient number of eye surgeons to diagnose and treat diabetic retinopathy, and also to investigate better techniques to achieve these purposes. Such a training program is indispensable for two basic reasons: First, there must be an adequate number of trained specialists to take care of the patients now requiring care; and second, through contact with these specialists laboratory researchers will become better oriented in the problems that face patients with diabetic retinopathy.

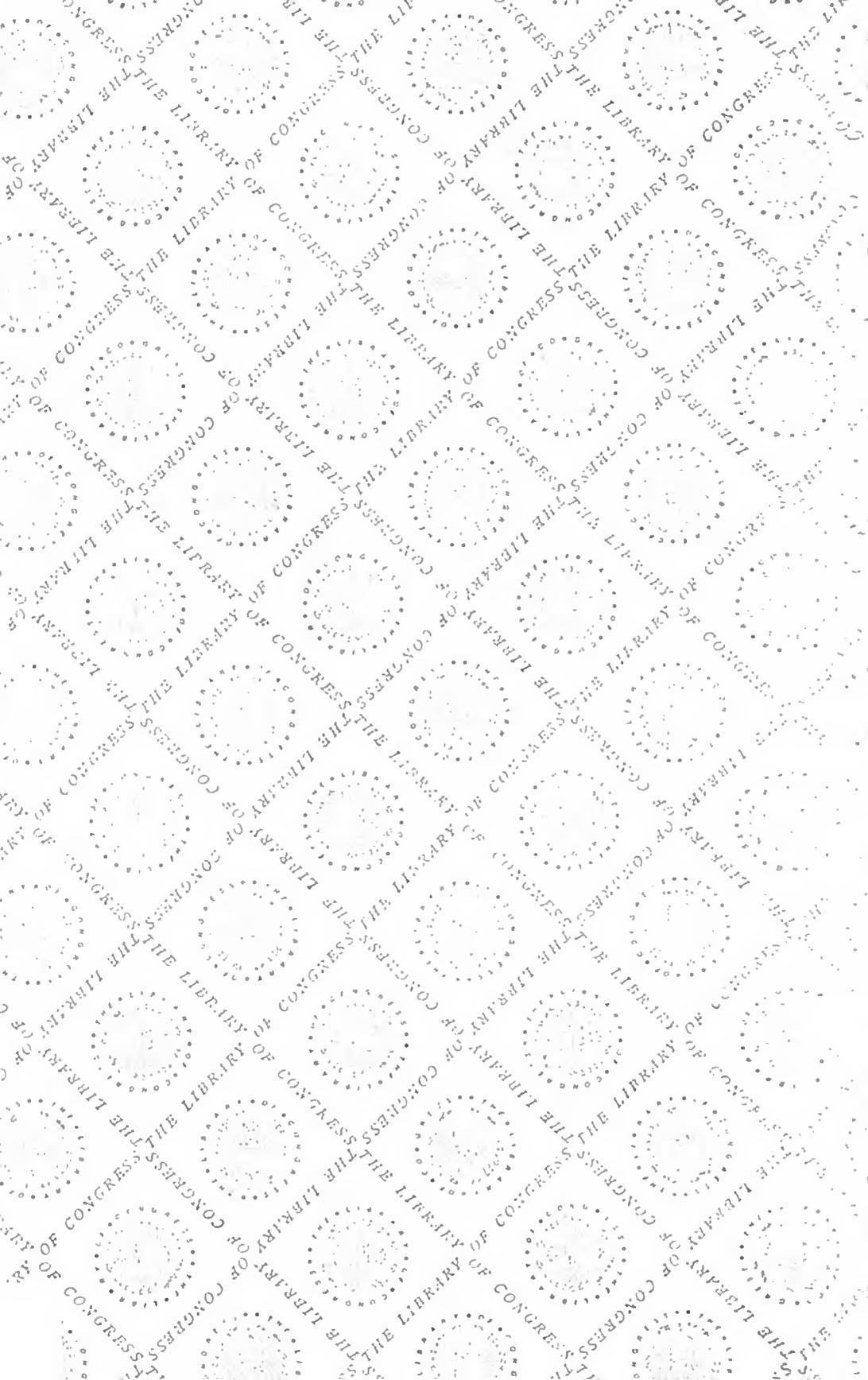


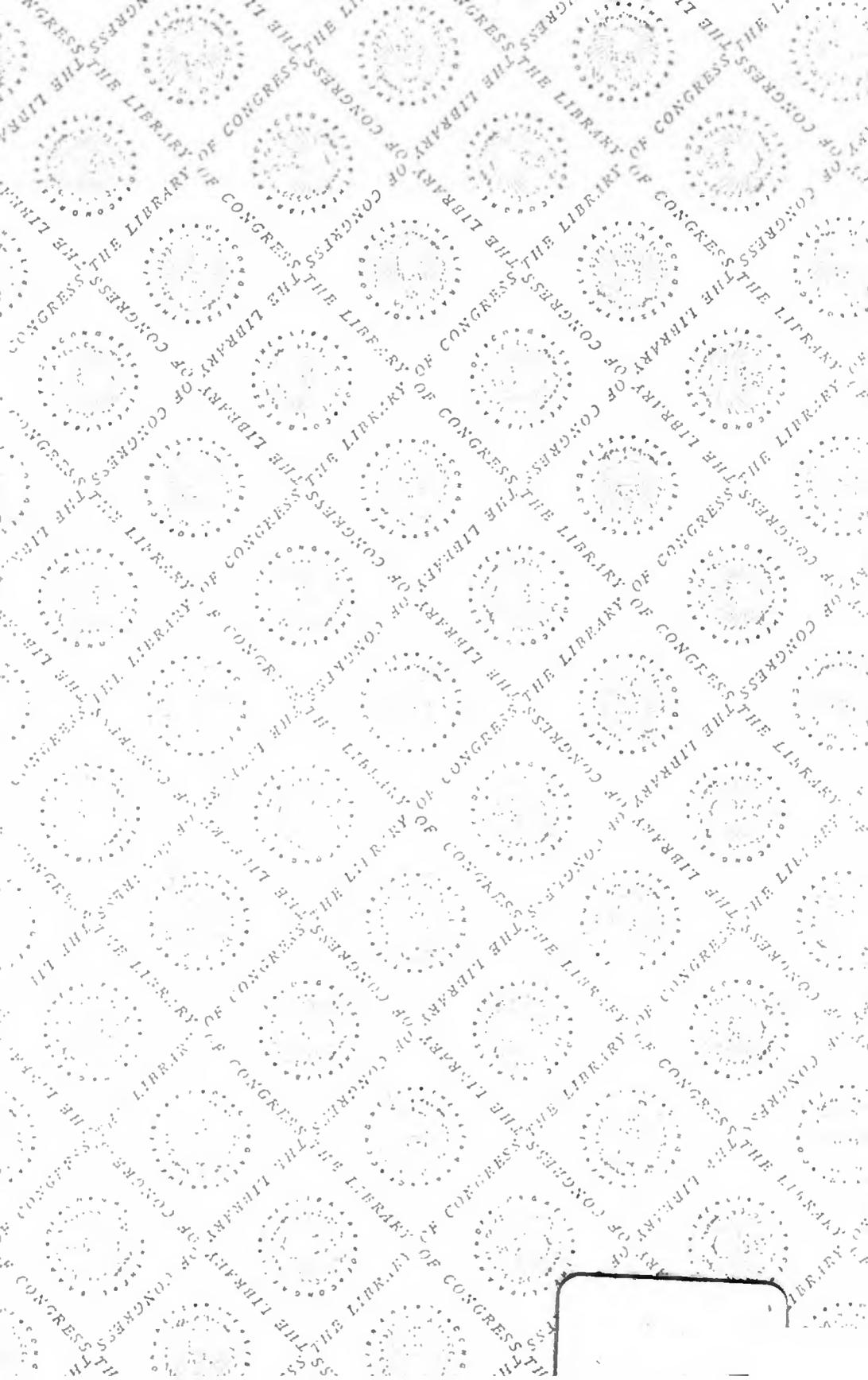
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