Withdrawal/Redaction Sheet
Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. list	Suggested Invitation List for Diabetes Event Social Security Numbers Redacted (1 page)	8/4/97	P6/b(6)

COLLECTION:
Clinton Presidential Records
Domestic Policy Council
Chris Jennings (Subject File)
OA/Box Number: 23753 Box 12

FOLDER TITLE:
Increase in NIH Funding for Biomedical Research [13]

gf31

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

P1 National Security Classified Information [(a)(1) of the PRA]
P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
P3 Release would violate a Federal statute [(a)(3) of the PRA]
P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
P5 Release would disclose confidential advise between the President and his advisors, or between such advisors [a)(5) of the PRA]
P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.
PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).
RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

b(1) National security classified information [(b)(1) of the FOIA]
b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
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b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

File: Diabetes

Summary of Diabetes-Related Provisions in the BBA of 1997

The Balanced Budget Act of 1997 includes two major diabetes-related provisions: 1) a $2.1 billion expansion of Medicare coverage for diabetes-related services; and 2) a $300 million provision in the children's health initiative, half of which will be used to expand research on Type I diabetes, with the other half dedicated to diabetes prevention and treatment services for American Indians and Alaska Natives.

This brief provides background information on current diabetes-related efforts and summarizes the two diabetes-related provisions of the BBA of 1997.

I. Expansion of Medicare Coverage for People with Diabetes

Extent of the Problem

Of the 16 million Americans with diabetes, only 8 million are aware that they need to treat early onset of this disease. Although approximately 1,700 people are diagnosed with diabetes each day, many do not know they are diabetic until after they have begun experiencing severe health problems associated with the disease. The host of potential health complications includes kidney disease, nerve disease, eye disease, coronary heart disease, stroke, and digestive and urologic disorders. Furthermore, minority populations are disproportionately affected by diabetes and its complications.

Approximately 40-45 percent of persons age 65 years of age or older have either Type II diabetes or Impaired Glucose Tolerance (IGT).

Nearly 11% of the United States population between 65 and 74 years of age has diabetes.

Approximately half of all diabetes cases occur in people older than 55 years of age.

Current Diabetes Initiatives at HCFA

HCFA is conducting a major pilot project to assess and improve diabetes care in 23 managed care plans in 5 states, serving roughly 200,000 Medicare beneficiaries with diabetes. Each participating plan has implemented at least one intervention to improve diabetes care, the results of which will be measured by HCFA in early 1998.

Several efforts are underway to develop performance measures, which will be important in enabling consumers to make informed choices in selecting a provider or managed care plan. These measures will allow consumers to compare the type and frequency of services furnished by different providers, including both diabetes-specific services and other general services that are particularly important for diabetes.

The American Diabetes Association (ADA), the National Committee for Quality Assurance (NCQA), and the Foundation for Accountability (FACCT) recently agreed to issue a common set of diabetes-related performance measures. This collaboration represents a major step toward enabling providers, plans, practitioners, researchers, HCFA, and other purchasers to give consumers standardized information (rather than 3 conflicting sets of guidelines) regarding performance in the provision of diabetes care.

Expansion of HCFA Diabetes Efforts in the BBA of 1997

The Balanced Budget Act (BBA) provides $2.1 billion over five years to expand Medicare's covered benefits to include diabetes outpatient self-management training services. These services would include educational and training services furnished to an individual with diabetes by a certified provider in an outpatient setting meeting certain quality standards.

In addition, the provision extends Medicare coverage of blood glucose monitors and testing strips to Type II diabetics without regard to a person's use of insulin. Currently, Medicare only covers these services for Type I diabetics.

The BBA calls for HHS to establish outcome measures for evaluating improvements in the health status of Medicare beneficiaries with diabetes, and to periodically submit recommendations to Congress on modifications to coverage of services for diabetics.

II. Diabetes Provision

The section of the BBA containing the Children's Health Insurance Program includes a provision funding $300 million over five years for research and for prevention and treatment of diabetes among Indians. The funds are mandatory and are included in the $24 billion children's health initiative. Half of the funding will be used to expand research on Type I (juvenile onset) diabetes, and the other half will pay for prevention and treatment services for American Indians and Alaskan Natives who suffer from diabetes. The provision also requires the HHS Secretary to evaluate the program and report to Congress by 2002.

A. $150 Million for Type I Diabetes Research

Current Efforts

According to the ADA, NIH spending for diabetes research is less than 1% of the "direct" costs of the disease -- "direct costs" are costs associated with the provision of health care services to individuals. The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) is expanding its research on preventing and treating diabetes and its complications. Past basic research efforts have led to diagnostic tests that help assess the risk of developing diabetes and to medical standards of patient care.

Benefits of the New Diabetes Research Funding

Under the BBA, $30 million will be available annually for research into the prevention and treatment of Type 1 (juvenile onset) diabetes. The Secretary will have discretion to target these funds to the HHS agencies that can fund the best available scientific opportunities.

In FY 1997, HHS will spend an estimated total of $345 million on diabetes research at the National Institutes of Health, Centers for Disease Control, and Agency for Health Care Policy and Research.[1] The new diabetes initiative will enable HHS to increase its annual funding for diabetes research by 9 percent. This will permit HHS to expand and improve on its current research efforts and to capitalize on the many outstanding diabetes research opportunities that lie ahead.

B. $150 Million for Diabetes Treatment for American Indians and Alaskan Natives

Extent of the Problem

A major health problem for American Indians and Alaska Natives (AI/AN), diabetes occurs at rates dramatically higher among AI/AN than in the general U.S. population. **One third to one half** of adults in various tribal groups have diabetes (420,000 to 630,000 individuals). When compared with other Americans, Native Americans develop type II diabetes at a younger age --as young as age eight --and suffer higher rates of complications including blindness, vascular insufficiency leading to amputation, and End Stage Renal Disease (ESRD). The death rate from diabetes is 2.7 times higher in the AI/AN population than in the U.S. population.

Current Diabetes-Related Efforts at IHS

The Indian Health Service (IHS) has had a special focus on diabetes since 1979. The IHS diabetes program has grown from five model care projects in rural, isolated Native American communities to a nation-wide program of 19 model care diabetes programs in 23 sites. IHS currently spends approximately $8 million for these model programs in addition to the significant resources spent on providing health care services to AI/AN with diabetes. Each of IHS' twelve regional areas has a diabetes coordinator responsible for reaching patients, health providers in IHS, Tribal, and Urban facilities, and leaders in over 500 Native American Communities. IHS diabetes control efforts focus on primary, secondary and tertiary activities combining scientifically-based standards of care with clinical implementation strategies. A unique surveillance system monitors the implementation of these preventive care practices.

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[1] HHS does not distinguish between expenditures for Type 1 (insulin-dependent) and Type 2 (non-insulin dependent) diabetes.

Additional Funding in BBA of 1997 for IHS Diabetes Efforts

The new funding provided to IHS ($30 million annually for five years) will be used to provide services for diabetes prevention and treatment in partnership with Tribes, Urban Indian Health Centers, IHS Facilities, and other agencies within the Department of Health and Human Services (HHS), such as the Centers for Disease Control and Prevention. The new diabetes program, which will have a special focus on children and youth, will test community-based interventions in an effort to increase knowledge about primary prevention, such as reducing obesity, promoting health and wellness, and reducing the onset of Type II diabetes. In accomplishing these objectives, the new program will seek to improve linkages between families, public health services, schools, and nutrition programs.

The Secretary expects to award two types of grants:

- Prevention Grants: ($350,000 to $500,000 each) will be awarded to evaluate a variety of interventions aimed at preventing diabetes (e.g., health education, exercise, nutrition);
- Medical Intervention/Prevention Grants: one or two larger grants ($5 to $8 million each) will combine prevention and medical interventions (including the use of new medications) to control glucose levels and prevent multi-system organ failure.

Juvenile Diabetes Foundation International
The Diabetes Research Foundation

FOR IMMEDIATE RELEASE

Contact: Eric Schutt
Juvenile Diabetes Foundation
202/371-9746
Vanessa McGowan
Juvenile Diabetes Foundation
212/479-7530

Juvenile Diabetes Foundation Applauds President Clinton's Leadership in Bi-Partisan Effort To Include $150 Million for Type I Diabetes Research in Balanced Budget

Mary Tyler Moore represents 16 million Americans threatened by diabetes at Presidential Announcement

New York, NY (August 8, 1997) – **Mary Tyler Moore and volunteers of the Juvenile Diabetes Foundation International (JDFI) gathered in Washington today to applaud President Clinton's leadership in a Bi-partisan effort to include $330 million for new diabetes programs in the Balanced Budget Act of 1997 – in particular, the $150 million that is provided for Type I diabetes research programs.**

In addition to other important initiatives, The Act provides for $30 million per year for five years for innovative research and treatment programs focusing on the prevention and cure of Type I diabetes.

"Insulin is not a cure," said Mary Tyler Moore, JDFI's International Chairman. "With this initiative, we can capitalize on years of research progress and start to move advances out of the laboratories to the bedsides of our loved ones."

"With the tremendous human and economic tolls taken by this devastating disease and its complications, it is more than appropriate that a full frontal attack on diabetes be launched by the federal government," said Robert Wood Johnson IV, Chairman of JDFI. "This long awaited increase contains a significant infusion of new funds for research into Type I diabetes, and provides renewed hope for millions of Americans."

"Diabetes has reached epidemic proportions worldwide and the numbers are steadily increasing," stated James E. Mulvihill, D.M.D., President and CEO of JDFI. "We know that this extraordinary initiative will help attract the attention of our leading scientists, and encourage them to apply their knowledge to the complex and myriad problems of diabetes in new and imaginative ways.

The mission of the Juvenile Diabetes Foundation International is to find a cure for diabetes and its complications through the support of research. JDFI was founded in 1970 by parents of children with diabetes who were convinced that through research, diabetes could be cured. With chapters from coast to coast and affiliates around the world, JDFI gives more money to diabetes research than any other non-profit, non-governmental health agency in the world. In 1996, JDFI awarded $30.3 million to diabetes research worldwide, bringing the cumulative dollar commitment to $220 million.

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PHOTOCOPY PRESERVATION

The National Council on Aging, Inc. Supports the President's Initiative on Diabetes

"According to The National Council on Aging, Inc.(NCOA) nearly 3.4 million older people have diabetes--but do not know it. Older people often suffer complications such as blindness, kidney problems and amputation related to diabetes. Better screening is essential to make sure cases are correctly diagnosed. NCOA strongly supports efforts to develop and disseminate diabetes guidelines to health professionals for appropriate disease management."

-NCOA, 8/6/97

PHOTOCOPY
PRESERVATION

File Diabetes Event

To : Mr. Chris Jennings

Fax Number: 202/456-5557

Date : 30 July 1997

From : Robert W. Johnson IV

THE JOHNSON COMPANY, INC.
630 Fifth Avenue, Suite 1510
New York, New York 10111

Telephone: 212/332-7500
Fax : 212/332-7510

Message :

Total Number of Pages 6
(including this cover sheet)

Draft Comment by JDFI on Type I Diabetes Research Initiative:

"The Juvenile Diabetes Foundation International (JDFI) salutes Speaker Gingrich for his leadership in securing additional funding of $150 million over five years for research into the prevention and cure of Type 1 diabetes. We are delighted that the Balanced Budget Act of 1997 contains a significant infusion of new funds for research into Type I diabetes, one of the most common chronic diseases of childhood", said Robert Wood Johnson IV, Chairman of JDFI. "Every parent of a child with diabetes knows too well that insulin is not a cure for this devastating disease. But twenty-five years of research progress has brought us to the threshold of that cure."

However, important gaps in our knowledge still prevent us from realizing our dream to move research advances out of the research laboratory and into the clinical setting. We know this extraordinary special initiative will help attract the attention of our leading scientists, encourage them to apply their new knowledge to the complex problems of diabetes, and help us build a needed bridge from the laboratory bench to our loved ones' bedside", said Mr. Johnson.

ROBERT WOOD JOHNSON IV
630 FIFTH AVENUE, SUITE 1510
NEW YORK, NEW YORK 10111

TELEPHONE 212/332-7500
FAX 212/332-7510

17 July 1997

Mr. Erskine B. Bowles
Chief of Staff
The White House
First Floor, West Wing
Washington, D.C. 20502

Dear Erskine:

Thanks for meeting with Mike Overlock and me yesterday in your office. Demands on your time are great, and we appreciate your involvement.

As agreed, the Juvenile Diabetes Foundation International has prepared the enclosed proposal for a Federal Initiative in Transplantation Research. While implementing the initiative will take some additional work, the need is immediate.

JDFI, Mike, and I would be happy to help with this proposal. Thanks again for your participation in this project, Erskine.

Sincerely,

Woody

Robert W. Johnson IV

RWJIV:gg
Enclosure
By Fax/Federal Express

Proposal: Federal Initiative in Transplantation Research

Overview

- In order to address the multiple problems posed by increasing incidence of diabetes and many other autoimmune diseases, the federal government would spearhead a collaborative, multi-disciplinary initiative in transplantation-related science. The ultimate goal would be to cure these diseases, thereby alleviating human suffering and reducing health care costs. While the primary focus would be on islet cell transplant (diabetes), many of the research projects would also apply to and benefit other serious diseases as well (e.g., rheumatoid arthritis, lupus, and multiple sclerosis).

- Through new National Institutes of Health (NIH) dollars and re-direction of existing funds, $100 million could be provided for this initiative as one of the NIH Director's "Special Areas of Emphasis." An alternative approach would be a multi-departmental collaboration involving NIH, Department of Defense, Department of Commerce, NASA, and the Department of Veterans Affairs. The President and Vice President could make an announcement of this effort at the White House, ideally in November during National Diabetes Month, with bipartisan representation from Congress, the diabetes community, and other interested parties.

Burden of Diabetes

- Diabetes is a major public health problem affecting approximately 16 million Americans from all walks of life. An estimated 650,000 new cases of diabetes will be diagnosed this year alone. According to the NIH, the direct and indirect costs of diabetes exceed $137 billion per year, making it the single, costliest, chronic disease in the U.S. It is estimated that people with diabetes account for approximately 25 percent of Medicare expenditures.

- Diabetes reduces life expectancy by up to 30 percent. This year alone, diabetes and its complications will contribute to the deaths of over 170,000 Americans. It is a leading cause of blindness, amputations, kidney failure, and cardiovascular disease, and disproportionately affects African American, Hispanics, and Native Americans.

Scientific Rationale

There have been significant advances in our understanding of how the immune system behaves in rejecting a "foreign" organ or tissue. An upcoming NIH-sponsored conference on the state of diabetes research will likely highlight many of these advances. The challenge in this area now is to translate the knowledge gained from basic research to clinical application. The goal of this research would be to develop treatment which would "fool" the immune system into accepting an organ or tissue without causing dangerous side effects. A significant breakthrough in this area would result in the ability to:

- transplant islet cells in people with both Type 1 and Type 2 diabetes (and other diseases) without use of toxic immunosuppression drugs; and

- significantly extend the life of transplanted organs, and thereby improve the outcomes of other solid organ transplants.

Finally, almost every single institute at the NIH, as well as research programs across other agencies of the federal government, has an interest in the clinical application of transplantation tolerance. A coordinated approach, which provides funds for the "translational" research necessary to move knowledge from the research lab to the patient's bedside, and which puts into place a system for monitoring and expediting new discoveries, would have an enormous impact on American science and medicine.

Other Complementary Federal Efforts

- Secretary of HHS Donna Shalala is planning new initiatives in the area of organ donation and allocation that are designed to address the critical shortage of organs. To the extent that new breakthroughs in transplantation science can extend the life of transplanted organs, the proposed research initiative would support these important efforts on organ donation and allocation.

- Similarly, the Institute of Medicine (IOM, part of the National Academy of Sciences) is holding a conference this week on the state of transplantation. This IOM-headed effort will focus on: development of strategies for increasing organ donations; ways to improve efficient and ethical uses of existing transplant materials; and identification of scientific and technical advances in cell and tissue transplants.

- Other complementary efforts include NASA's support of cell engineering, cell growth and differentiation, and islet cell transplantation; and the Commerce Department's tissue engineering initiative with private industry which seeks, among other things, to stimulate islet cell transplantation technology.

File "Diabetes Events"

National Center, 1660 Duke Street, Alexandria, VA 22314
(703) 549-1500 Telex: 901132

FACSIMILE TRANSMISSION
FACSIMILE TELEPHONE NUMBER: (703) 836-7439

SCIENTIFIC AND MEDICAL DIVISION

TO: Sarah Bianchi	**FROM: Richard Kahn, PhD**
FAX NO: 202-456-5557	**EXT: 2065**
OFFICE NO:	**DATE: 8/4/97**

Should be separate from regular diabetes folder

Please call if you have any trouble receiving transmission or did not receive the number of pages shown below:

Total of 7 page(s), including this cover

MESSAGE FOLLOWS: Sarah, call me this afternoon to let me know the next step. Thanks. Richard.

The mission of the American Diabetes Association is to prevent and cure diabetes and to improve the lives of all people affected by diabetes.

Withdrawal/Redaction Marker
Clinton Library

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001. list	Suggested Invitation List for Diabetes Event Social Security Numbers Redacted (1 page)	8/4/97	P6/b(6)

This marker identifies the original location of the withdrawn item listed above. For a complete list of items withdrawn from this folder, see the Withdrawal/Redaction Sheet at the front of the folder.

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Domestic Policy Council
Chris Jennings (Subject File)
OA/Box Number: 23753 Box

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Suggested Invitation List

American Diabetes Association Representatives (contact R. Kahn for other details)

Stephen J. Satalino
SSN [redacted] DOB P6/b(6)

John H. Graham IV
SSN [redacted] DOB P6/b(6)

Christine A. Beebe, MS, RD, CDE
SSN [redacted], DOB P6/b(6)

Richard Kahn, PhD 703-299-2065
SSN [redacted], DOB P6/b(6)

Michael Mawby
SSN [redacted] DOB P6/b(6)

National Committee for Quality Assurance

Cary Sennett, MD, PhD 202/955-5170
SSN [redacted], DOB P6/b(6)

Foundation for Accountability

David J. Lansky 503/223-2228
SSN [redacted], DOB P6/b(6)

Health Care Financing Administration

Barbara Fleming, MD, PhD 410/786-6863
SSN [redacted], DOB P6/b(6)

Key Representative from the American Indian Community

Lillian Tom-Orme, PhD, RN (she is member of the Navajo tribe)
301/496-8579
SSN [redacted], DOB P6/b(6)

Sarah

— I've discussed this list with each of the organizations listed.

— I realize that who, amongst the Executive Branch, gets invited is a complicated issue, but I wish to reiterate that of all the people of HHS, Dr. Fleming stands well above the others working to improve diabetes care (via medicine). It would be a real injustice to have others present & not her.

August 4, 1997

The Diabetes Quality Improvement Project

Background

Diabetes is a serious disease that affects over 16 million Americans, and over 150,000 people die each year because of it. It strikes individuals of all ages and socioeconomic groups, and individuals of African, Asian, and American Indian descent are particularly vulnerable. The annual cost of diabetes has been reported to be nearly 100 billion dollars and thus it ranks as one of the deadliest and most costly diseases known to mankind.

Most of the morbidity and mortality of diabetes is due to the complications associated with the disease: blindness, kidney failure, nerve damage, and cardiovascular disease. Diabetic retinopathy is the leading cause of new blindness in people under 65; diabetic nephropathy is the leading cause of end stage renal disease (kidney failure) in the United States; neuropathy results in the second leading cause of lower extremity amputation with over 50,000 Americans annually losing a limb because of diabetes; diabetic macrovascular disease leads to accelerated coronary heart disease and peripheral vascular disease, both of which result in premature death.

Studies show that many, if not all, of the complications of diabetes can be slowed or even prevented by better management on the part of the health care team and the patient. Improved blood glucose control, and regular eye and foot examinations are but three of the practices that have been unequivocally shown to reduce complications and thereby diminish the heavy personal and financial toll attributed to diabetes.

August 4, 1997

Fueling the heavy burden of diabetes is the fact that diabetes care in America is suboptimal. Numerous studies and reports have documented that physicians are not delivering the care known to be beneficial. For example, the rate of an annual eye exam in managed care plans averages less than 40%. People with diabetes deserve better.

The inability of consumers and health care purchasers to determine if medical care is appropriate and necessary has given rise to the concept that the health care system should be held accountable for what is done, and the outcomes achieved. This principle of accountability has resulted in the development of so called "performance and outcome measures," administered through "report card" systems. Except for HCFA's requirement for managed care plans to submit limited performance measurement data, all such systems in effect today are voluntary, and all are administered by non-profit organizations dedicated to improving the health care provided to Americans.

The multiplicity of report card systems, each with their own measures, has created unnecessary work and confusion. A consolidation of measure sets would be greatly appreciated, and would be a powerful tool to improve care and allow comparison of care across all delivery systems (e.g., managed care vs. fee-for-service).

The Diabetes Quality Improvement Project is a coalition of public and private entities whose aim is to develop a set of diabetes-specific performance and outcome measures to

be adopted nationwide by consumers, purchasers of health care, and health care professionals.

Structure and Scope of Work

The coalition is comprised of four "organizations:" the American Diabetes Association (ADA), the Foundation for Accountability (FACCT), the Health Care Financing Administration (HCFA), and the National Committee for Quality Assurance (NCQA). The ADA is the nation's largest and leading voluntary health agency dedicated to improving the lives of people with diabetes. The FACCT is dedicated to ensuring that consumers and purchasers of health care have the necessary information to make health care decisions; its Board of Trustees includes large consumer groups and purchasers, who collectively represent over 80 million Americans. The HCFA is the largest purchaser of health care in America. Through its Medicare and Medicaid programs purchases health care for about one-fourth of all people with diabetes (the largest single purchaser of care for the diabetic population). Since the cost of diabetes has been shown to be as much as three to four times greater than the cost of care for similar, but unaffected, persons, HCFA has considerable interest in reducing the burden of diabetes, not only to reduce the cost of care but also to improve quality of care, enhance outcomes of care, and receive value for the money spent. NCQA is dedicated to assessing and reporting on the quality of care delivered by managed care plans. Its primary mission is to make true competition, based on the

value of care and not simply the price, possible in the market for health care services. NCQA develops and maintains a set of standardized performance measures used by more than 90% of health plans. More than three-quarters HMO enrollees are in a plan that has been reviewed by NCQA.

The coalition has agreed to work through a committee of leading experts in the field of diabetes care and performance measurement. The project will be funded largely by HCFA. Although each of the coalition entities has, in some form or fashion, independently developed and promulgated diabetes measures, most are very incomplete. It is thought that a common set of comprehensive measures, supported by ADA, FACCT, NCQA, and HCFA, will have a tremendous impact on health care delivery, and the ability of patients to seek out and receive the most effective and appropriate care.

The work of the coalition is expected to be completed by the end of 1998, at which time a comprehensive diabetes measurement set will be released. Shortly thereafter, consumers and others will be able to make important decisions about diabetes care, at the individual provider and health plan levels, based on objective quality information.

August 4, 1997

Summary and Significance

The concept of accountability for performance has recently emerged as a major force to guide and influence health care delivery. Consumers and purchasers of health care want value and benefit, and are asking for the development of systems whereby the critical information to make necessary decisions is readily available and widely understood.

Diabetes is costly and very serious and, most notably, relatively few people with diabetes get the care they need to avoid the medical problems directly associated with the disease. High quality care for people with diabetes has been shown to make a difference and thus, health care providers and health care organizations should be held accountable for what is done, and what is achieved.

The ADA, FACCT, and NCQA currently have leading roles in promoting and assuring high quality health care. Each organization has carved out a unique role in the health care system. For the first time, they are combining their experience and expertise and using it to improve diabetes care. In addition, they are joined by the HCFA, a powerful force in health care, and one that often sets the tone and direction for the entire health care system, not just the delivery of care for older Americans. Never before has such a coalition from the public and private sectors been assembled to make such a concerted effort to directly affect the health care given to so many Americans.

Acting together, this coalition has the opportunity and ability to improve the lives of people with diabetes more than any other single activity or action in this decade. Given the countless failed attempts to assure the delivery of high quality diabetes care, even though a wide variety of drugs and medical supplies and equipment are available that have great utility, the nationwide implementation of one set of diabetes-specific performance and outcome measures could likely rank among the most significant advances in diabetes care in this century. In addition, the work of this unique coalition, and its application to one of our nation's leading chronic diseases, will serve as an important model for how care given for other chronic diseases can be improved.

DIABETES EVENT

Briefing Book
August 8, 1997

List of Speakers

Sandy Puczynski

Her daughter, Michelle, is 13 and has diabetes. Michelle has been faced with many hardships due to the disease, including numerous injections and fingerstick blood tests, a structured meal plan, and constant fear of persistent high blood sugar levels which could lead to death. She is thankful for the commitment by the President towards a research initiative that would hopefully find a cure for diabetes.

Mrs. Mary Delaney

She is an elderly, African–American woman that has a history of diabetes in her family and suffers from the disease. She cannot afford many of the treatments and medicine she needs in order to combat diabetes. She thanks the President for the Medicare benefit that will help older Americans get the health care they need to manage diabetes.

Chief Joyce Dugan

She is the Chief of the Eastern Band of Cherokee Indians. She is concerned with the way diabetes has become an epidemic in Native American communities recently. She is thankful for the education and prevention initiatives, in the form of a Dialysis Center and Wellness Center for her community, and for the establishment of a special diabetes program for Native Americans.

Other VIPS Meeting with POTUS

Stephen J. Satalino, Chair of the American Diabetics Association

Mary Tyler Moore, the Juvenile Diabetes Foundation International's International Chairman

Other Validators

Dr. Richard Kahn, Medical Director of the American Diabetic Association
703–299–2065

Dr. Philip Gorden, Head of the National Institute of Diabetes and Digestive and Kidney Diseases
301–496–5877

Eric Schutt, Juvenile Diabetes Foundation
202–371–9746

DIABETES
EVENT MEMO

August 7, 1997

DIABETES EVENT

DATE:	August 8, 1997
LOCATION:	Georgetown University Medical Center
BRIEFING TIME:	10:00 am - 10:30 am Oval Office
EVENT TIME:	10:50 am - 11:50 am
FROM:	Bruce Reed/Chris Jennings

I. PURPOSE

To highlight the significant investment in diabetes research and treatment within the balanced budget.

II. BACKGROUND

You will be announcing an unprecedented national commitment to fighting diabetes in an address to leaders from the diabetes activist and research communities; Native-American, African-American, Hispanic, and Senior health care organizations; and families affected by diabetes. You will be making the following four announcements:

- **Expanding Medicare to Help People With Diabetes Better Manage Their Care** The balanced budget provides $2.1 billion over five years to expand Medicare coverage of diabetes self-management education, which is an essential component of diabetes care. Medicare previously covered this training only in hospital-based programs; it now will cover training furnished by physicians and other certified providers as well.

- **A New $150 Million Investment in Research for Type I (Juvenile) Diabetes.** This new investment provides $30 million annually for five years for research to help find the cure for diabetes. Secretary Shalala will have discretion to target these funds to the most promising scientific opportunities. This new initiative increases HHS's annual funding for diabetes research by about 10 percent.

- **A New $150 Million Investment for Native American Prevention and Treatment.** This new investment provides the Indian Health Services $30 million annually for five years for diabetes prevention and treatment. The death rate from diabetes among Native Americans is almost three times higher than in the

population as a whole.

- **A New Diabetes Quality Improvement Project**
  You will announce an unprecedented new collaborative effort to develop standards for the treatment of diabetes. The partners in the effort are: HCFA; the American Diabetes Association; NCQA, which develops and maintains a set of standardized performance measures used by more than 90 percent of health plans; and the Foundation for Accountability (FACCT). Such measures could detail the care that should be delivered (for example, an annual eye exam) or health outcome that should be achieved (such as appropriate blood glucose levels). Studies have documented that many physicians are not delivering the care known to reduce diabetes complications, such as blindness and amputations. Those new standards will help ensure that doctors have the necessary information to provide patients with high-quality diabetes care.

III. PARTICIPANTS

Briefing Participants:
Erskine Bowles
Bruce Reed
Chris Jennings

Event Participants:
Sam W. Wiesel, (WEE-ZEL) Executive Vice President for Heath Services at Georgetown University Medical Center
Mary Delaney, D.C. Medicare patient
Chief Joyce Dugan, Principal Chief, Eastern Band of Cherokee Indians
Sandra Puczynski, Mother of a child with juvenile diabetes

Also Seated on Stage:
Mary Tyler Moore, International Chairman of the Juvenile Diabetes Foundation International.
Stephen Satalino, Chair of the Board of the American Diabetes Association

IV. PRESS PLAN

Open Press.

V. SEQUENCE OF EVENTS

- Upon arrival, you will briefly meet and greet stage participants and their families.
- You will be announced onto the stage accompanied by stage participants.
- **Dr. Sam Wiesel**, V.P. Georgetown University Medical Center, makes welcoming remarks.
- **Mary Delaney**, Medicare patient, makes remarks and introduces Chief Dugan.
- **Chief Joyce Dugan**, Principal Chief, Eastern Band of Cherokee Indians makes remarks.
- **Sandra Puczynski**, parent of child with diabetes, makes remarks and introduces you.
- **You** will make remarks and then depart.

VI. REMARKS

Remarks Provided by June Shih in Speechwriting.

QUOTES

QUOTES SUPPORTING PRESIDENT CLINTON'S ANNOUNCEMENT ON UNPRECEDENTED DIABETES INITIATIVE

"President Clinton's announcement today ends an extraordinary week in the history of diabetes in America. Because of the President's support of bi-partisan initiatives, nearly $3 billion of new money will be invested into research and treatment. Finally, diabetes is getting the recognition it deserves as a major public health problem facing America."

"By investing now in the tools and services that can help seniors manage their diabetes, we anticipate that Medicare can help reduce the enormous human and financial cost that accompanies diabetes complications. This is a dramatic step forward since Medicare traditionally has paid for diabetes-related hospitalizations, but nor for the means that would help keep seniors out of the hospital."

American Diabetes Association

"With the tremendous human and economic tolls taken by this devastating disease and its complications, it is more than appropriate that a full frontal attack on diabetes be launched by the federal government. This long awaited increase contains a signficant infusion of new funds for research into Type I diabetes, and provides renewed hope for millions of Americans."

"We know that this extraordinary initiative [announced by the President today] will help attract the attention of our leading scientists, and encourage them to apply their knowledge to the complex and myriad problems of diabetes in new and imaginative ways."

– Juvenile Diabetes Foundation International

"Insulin is not a cure. With this initiative, we can capitalize on years of research progress and start to move advances out of the laboratories to the bedsides of our loved ones."

– Mary Tyler Moore
International Chairman
Juvenile Diabetes Foundation International

"President Clinton is to be commended for providing leadership in improving the quality of life for the 16 million Americans who suffer from Diabetes. This significant development is a positive step forward in expanding the life expectancy for the millions of African Americans who have been victims of this dreaded disease."

-- The National Caucus and Center on
Black Aged, Inc.

"For the approximately 3 million African Americans affected by diabetes and who suffer a disproportionate burden from its complications, the initiatives announced by President Clinton will prompt a shift in the quality of care and access to services that can improve outcomes. The National Medical Association feels strongly that this is a health initiative that will strike a major blow to the debilitating effects of a silent killer in high-risk minority communities, and reduce the enormous drain on human and fiscal resources caused by diabetes."

"The National Medical Association enthusiastically applauds President Clinton for the provisions in the balanced budget package directed towards cure of Type I diabetes, more intense preventive services and treatments for Native Americans, and improved coverage for self-management of older and other high-risk populations. For the almost 3 million African Americans with diabetes, who suffer higher rates of amputations and kidney failure, these initiatives signal a major shift in the direction of bringing much of our new knowledge to bear on relief of a costly and debilitating disease, while hastening our quest to eradicate it completely."

-- National Medical Association

"President Clinton is the first President to understand the importance of diabetes to so many people. We know that the President's diabetes initiative will improve the quality of life for the 1.3 million Hispanic diagnosed with this chronic disease. As Hispanics are twice as likely as the general population to have diabetes we know that our communities welcome this major step from the President."

-- Jane L. Delgado, Ph.D.
President and CEO
National Coalition of Hispanic Health and
Human Services Organizations (COSSMHO)

"The National Council on Aging, Inc. Supports the President's Initiative on Diabetes. Better screening is essential to make sure cases are correctly diagnosed. NCOA [The National Council on Aging, Inc.] strongly supports efforts to develop and disseminate diabetes guidelines to health professionals for appropriate disease management."

-- The National Council on Aging, Inc.

NATIONAL MEDICAL ASSOCIATION
COMMENTS ON
NEW DIABETES INVESTMENTS TO IMPROVE TREATMENT, PREVENTION, AND RESEARCH FOR AMERICANS WITH DIABETES

announced by President Clinto

(Statement 1)

For the approximately 3 million African Americans affected by diabetes and who suffer a disproportionate burden from its complications, these initiatives will prompt a shift in the quality of care and access to services that can improve outcomes. The National Medical Association feels strongly that this is a health initiative that will strike a major blow to the debilitating effects of a silent killer in high-risk minority communities, and reduce the enormous drain on human and fiscal resources caused by diabetes.

(Statement 2)

President Clinton for

The National Medical Association enthusiastically applauds the provisions in the balanced budget package directed towards cure of type 1 diabetes, more intense preventive services and treatments for Native Americans, and improved coverage for self-management of older and other high-risk populations. For the almost 3 million African Americans with diabetes, who suffer higher rates of amputations and kidney failure, these initiatives signal a major shift in the direction of bringing much of our new knowledge to bear on relief of a costly and debilitating disease, while hastening our quest to eradicate it completely.

News Release

National Service Center 1660 Duke Street Alexandria, Virginia 22314 (703) 549-1500 Telex: 901132 Fax: (703) 549-6294

For Release **Embargoed**
August 8, 1997- 11AM

Contact: **Kenneth Inchausti**
703/299-5506

PRESIDENT'S ANNOUNCEMENT OF NEW PUBLIC/PRIVATE DIABETES QUALITY IMPROVEMENT COALITION CAPS DRAMATIC WEEK FOR MILLIONS WITH DIABETES

American Diabetes Association Also Applauds Bi-Partisan Efforts Resulting In Dramatic Spending To Improve Diabetes Treatment and Prevention

ALEXANDRIA, VA (August 8, 1997) -- Today, President Clinton announced a groundbreaking initiative spearheaded by the American Diabetes Association, bringing together leading public and private sector organizations to develop universal criteria intended to improve the health care outcomes of people with diabetes. He also took this opportunity to recap [illegible]tic diabetes initiatives outlined in the Balanced Budget Act, signed August 5.

The Diabetes Quality Improvement Project aims to improve diabetes care in America by establishing a set of diabetes-specific performance and outcome measures that providers and plans must strive to achieve for their diabetes patients. Currently, a universal set of outcomes measures does not exist, leaving diabetes patients unable to determine if the care they receive is adequate.

The members of the Diabetes Quality Improvement Project are the American Diabetes Association, the Health Care Finance Administration (HCFA), the National Committee for Quality Assurance (NCQA), and the Foundation for Accountability (FACCT). This coalition -- consisting of the nation's largest diabetes advocacy organization, the nation's largest health care payor, and the leading organizations that develop and implement outcome criteria -- will set diabetes care on an unprecedented course, where providers will be accountable for the diabetes care they deliver, and give diabetes patients confidence in the quality of health care they receive.

-more-

"President Clinton's announcement today ends an extraordinary week in the history of diabetes in America," said Stephen J. Satalino, Chair of the American Diabetes Association. "Because of the President's support of bi-partisan initiatives, nearly $3 billion of new money will be invested into research and treatment. Finally, diabetes is getting the recognition its deserves as a major public health problem facing America."

President's Signature Expands Medicare Diabetes Policy

Due to a six year advocacy effort by the American Diabetes Association, Medicare will now spend $2.4 billion in additional services over five years by expanding its reimbursement of diabetes supplies and self-management training for over three million senior citizens with diabetes.

Previous Medicare regulations restricted reimbursement only to diabetes recipients treated with insulin despite the fact that not all diabetes cases require insulin. Many Medicare recipients with diabetes are treated with an exercise and diet regimen, oral medications, or both. They could not qualify for coverage necessary to help prevent devastating and costly complications, such as amputations, kidney disease, heart disease, stroke, or blindness.

Now, all Medicare recipients with diabetes will qualify for reimbursement for the purchase of blood glucose monitors and their accompanying strips, regardless of their use of insulin. As before, Medicare will not reimburse for medications or insulin.

Additionally, Medicare will reimburse certified providers who offer training services in an outpatient setting meeting certain quality standards. Such education and training will have to be deemed necessary to diabetes care by the patient's physician. Previously, only educational services provided within a hospital setting were covered.

"By investing now in the tools and services that can help seniors manage their diabetes, we anticipate that Medicare can help reduce the enormous human and financial cost that accompanies diabetes complications," said Satalino. "This is a dramatic step forward since Medicare traditionally has paid for diabetes-related hospitalizations, but not for the means that would help keep seniors out of the hospital."

-more-

These new policies will take effect on July 1, 1998. Quality standards for providers, as well as outcome measures used to review the entire Medicare package, will be designed by the Secretary of Health and Human Services in consultation with the American Diabetes Association and other diabetes organizations.

President's Signature Gives Diabetes Programs Dramatic Boost

The Balanced Budget Act will dramatically increase the level of spending on diabetes by the Department of Health and Human Services. Grants totaling $150 million will be awarded over five years towards research into the prevention and cure of type 1 diabetes.

An additional $150 million in grants over five years will be awarded by the Department of Health and Human Services for providing services for the prevention and treatment of diabetes among the Native American population. Programs benefiting will include the Indian Health Service (IHS) and other programs operated by tribes or tribal organizations in cooperation with IHS.

"With this critical investment for research and a new concerted effort to improve care, these measures may be as important as the discovery of insulin in 1921," said Satalino. "Thank you, President Clinton, for your leadership in making these measures a reality. And our thanks to Speaker Gingrich, Congresswoman Furse, Congressman Nethercutt and all of our allies in Congress for your outstanding leadership in providing people with diabetes the support and resources necessary to help stop diabetes' incredible devastation."

In the United States, 16 million people have diabetes -- eight million of whom are diagnosed. At least three million of the diagnosed are senior citizens. Nearly 1 million Americans have type 1 diabetes. Finally, diabetes disproportionately affects the Native American population at rates as high as 50 percent in some tribes.

Each year, diabetes drains the economy of $92 billion in direct health care and indirect productivity costs. Diabetes patients make up only 9 percent of Medicare's recipients, while their care, under previous regulations, eats away nearly 25 percent of Medicare's budget.

Diabetes is a group of serious diseases characterized by high blood sugar levels that result from defects in the body's ability to produce and/or use insulin.

The American Diabetes Association is the nation's leading voluntary health agency supporting diabetes research, information and advocacy. Founded in 1940, the Association is a community-based organization that provides services in every region of the country.

For more information on the American Diabetes Association's advocacy program, *Delegates for Diabetes*, or on diabetes, visit us on the world wide web at www.diabetes.org or call toll-free at 1-800-DIABETES (1-800-342-2383).

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National Coalition of Hispanic Health and Human Services Organizations

1501 Sixteenth Street, NW • Washington, DC 20036 • (202) 387-5000

Date: August 8, 1997
To: Barbara Woolley
From: Jane L. Delgado, Ph.D.
President and CEO
National Coalition of Hispanic Health and Human Services Organizations (COSSMHO)
Re: Short statement

President Clinton is the first President to understand the importance of diabetes to so many people. We know that the President's diabetes initiative will improve the quality of life for the 1.3 million Hispanics diagnosed with this chronic disease. As Hispanics are twice as likely as the general population to have diabetes we know that our communities welcome this major step from the President.

Board [illegible]ectors: Cynthia Ann Telles, Ph.D., *Chairperson*, Los Angeles, CA • Mari Carmen Aponte, Esq., Washington, DC • Augustine C. Baca, M.A., Albuquerque, NM • [illegible] Duarte, El Paso, TX • Henry A. Fernandez, J.D., Arlington, VA • Rosa Maria Gil, D.S.W., New York, NY • Honorable Margaret M. Heckler, Arlington, VA • Jorge [illegible]orinos, Los Angeles, CA • José Martinez, San Antonio, TX • Hugo Morales, Fresno, CA • **Corporate Advisory Council:** Karen Katen, *President, U.S. Pharmaceuticals Group*, Pfizer Pharmaceuticals • David W. Anstice, *President, Human Health U.S./Canada*, Merck & Co. • Aldrage B. Cooper, *Vice President, Community Relations*, Johnson & Johnson • James L. Craig, M.D., *Vice President and Director, Health and Human Services*, General Mills, Inc. • Jack J. Florio, *Executive Director, Marketing Plans*, Eli-Lilly and Company • Van G. Hindes, *Director, Corporate Affairs*, Gerber Products Company • Alan Milbauer, *Vice President, External Affairs*, Zeneca Pharmaceuticals • John Moorhead, *Vice President, Business Management*, Best Foods, CPC International • Robert E. Padgett, Jr., R.Ph., *Vice President, Public Affairs*, Pharmacia & Upjohn Inc. • Peter Stalker III, *Managing Director*, E.M. Warburg, Pincus & Co., Inc. • **President and Chief Executive Officer:** Jane L. Delgado, Ph.D.

Juvenile Diabetes Foundation International
The Diabetes Research Foundation

FOR IMMEDIATE RELEASE

Contact: Eric Schutt
Juvenile Diabetes Foundation
202/371-9746
Vanessa McGowan
Juvenile Diabetes Foundation
212/479-7530

Juvenile Diabetes Foundation Applauds President Clinton's Leadership in Bi-Partisan Effort To Include $150 Million for Type I Diabetes Research in Balanced Budget

Mary Tyler Moore represents 16 million Americans threatened by diabetes at Presidential Announcement

New York, NY (August 8, 1997) – **Mary Tyler Moore and volunteers of the Juvenile Diabetes Foundation International (JDFI) gathered in Washington today to applaud President Clinton's leadership in a Bi-partisan effort to include $330 million for new diabetes programs in the Balanced Budget Act of 1997 – in particular, the $150 million that is provided for Type I diabetes research programs.**

addition to other important initiatives, The Act provides for $30 million per year for five years for novative research and treatment programs focusing on the prevention and cure of Type I diabetes.

"Insulin is not a cure," said Mary Tyler Moore, JDFI's International Chairman. "With this initiative, we can capitalize on years of research progress and start to move advances out of the laboratories to the bedsides of our loved ones."

"With the tremendous human and economic tolls taken by this devastating disease and its complications, it is more than appropriate that a full frontal attack on diabetes be launched by the federal government," said Robert Wood Johnson IV, Chairman of JDFI. "This long awaited increase contains a significant infusion of new funds for research into Type I diabetes, and provides renewed hope for millions of Americans."

"Diabetes has reached epidemic proportions worldwide and the numbers are steadily increasing," stated James E. Mulvihill, D.M.D., President and CEO of JDFI. "We know that this extraordinary initiative will help attract the attention of our leading scientists, and encourage them to apply their knowledge to the complex and myriad problems of diabetes in new and imaginative ways.

The mission of the Juvenile Diabetes Foundation International is to find a cure for diabetes and its complications through the support of research. JDFI was founded in 1970 by parents of children with diabetes who were convinced that through research, diabetes could be cured. With chapters from coast to coast and affiliates around the world, JDFI gives more money to diabetes research than any other non-profit, non-governmental health agency in the world. In 1996, JDFI awarded $30.3 million to diabetes research worldwide, bringing the cumulative dollar commitment to $220 million.

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The National Council on Aging, Inc. Supports the President's Initiative on Diabetes

"According to The National Council on Aging, Inc.(NCOA) nearly 3.4 million older people have diabetes--but do not know it. Older people often suffer complications such as blindness, kidney problems and amputation related to diabetes. Better screening is essential to make sure cases are correctly diagnosed. NCOA strongly supports efforts to develop and disseminate diabetes guidelines to health professionals for appropriate disease management."

-NCOA, 8/6/97

The National Caucus and Center on Black Aged, Inc.

1424 K Street, NW, Suite 500, Washington, DC 20005 · 202-637-8400 · FAX # 202-347-0895

CELEBRATING 25 YEARS OF SERVICE

Dr. Aaron E. Henry
Chairman Emeritus

Carl F. West
Chairman

Samuel J. Simmons
President

Hobart C. Jackson

MEMORANDUM

TO: Mr. William White
Office of Public Liaison
The White House

FROM: Samuel J. Simmons, President and CEO

DATE: August 7, 1997

SUBJECT: PROPOSED STATEMENT FROM NCBA RE: PRESIDENT'S MESSAGE ON DIABETES

Here is a proposed statement from The National Caucus and Center on Black Aged, Inc. (NCBA) relating to the President's message on Diabetes.

"President Clinton is to be commended for providing leadership in improving the quality of life for the 16 million Americans who suffer from Diabetes. This significant development is a positive step forward in expanding the life expectancy for the millions of African Americans who have been victims of this dreaded disease."

SJS:msm

Q's + A's

DIABETES Q&As

Q: WHY ARE YOU INVESTING $30 MILLION ANNUALLY OVER FIVE YEARS IN TYPE I DIABETES WHEN ONLY A SMALL PORTION OF THE DIABETES POPULATION HAS THIS DISEASE?

A: Increasing our research efforts for Type I diabetes will actually help improve our knowledge about all types of diabetes. In fact, currently NIH does not even distinguish between their research dollars spent on Type I and Type II diabetes.

This initiative, which allows the HHS Secretary to allocate $30 million annually for five years to research a cure for Type I diabetes, however, could make a significant difference in how scientists understand this disease. We have talked to scientists at NIH who believe that an intensified effort on diabetes could lead to some important breakthroughs in our understanding of how we can cure diabetes.

There are between 700,000 and one million Americans who suffer from Type 1 diabetes, as many as half of whom are children. These Americans -- even those who receive the proper treatment -- are likely to develop at least one of severe diseases associated with diabetes, such as blindness, heart disease, or kidney problems later in life. We will not be able to eliminate the serious consequences and costs of this disease until we develop a cure.

Q: WHY IS ARE YOU SUPPORTING AN APPROACH THAT IS OUTSIDE THE NORMAL APPROPRIATIONS PROCESS THAT SUPPORTS THE NATIONAL INSTITUTES OF HEALTH (NIH)?

A: The $150 million allocated by the HHS Secretary for Type I diabetes will be given out by the Secretary -- with the help of the top scientists at HHS -- to the most promising research scientific research projects. NIH is currently in the process of administering a clinical trial for Type I diabetes and is making significant progress in research on Type I diabetes. Scientists at NIH believe that this new intensified effort will provide more resources in a tight budget to take the next steps in understanding this disease.

Q: DO YOU PLAN TO ALLOW THE HHS SECRETARY TO ALLOCATE GRANTS FOR OTHER DISEASES AS WELL?

A: This is an intensified effort to help research a cure for one of our nation's most costly diseases and to help reduce the impact of diabetes on Native Americans since it is devastating this population. There are not currently any plans to extend this kind of allocation to other diseases.

Q: WHY ARE WE FOCUSING SO MUCH OF THIS EFFORT ON DIABETES CARE FOR NATIVE AMERICANS?

A: The death rate for Native Americans with diabetes is nearly three times that of other Americans. In some tribes more than one-third of the population suffers from this dreadful disease. Native Americans are also far less likely to receive adequate treatment to manage this disease and therefore are more likely to get some of the serious complications associated with diabetes, such as kidney disease and heart disease more frequently.

This disease is devastating this population, and it is important that we make a concentrated effort to eliminate some of its damaging effects. We believe that this significant investment in preventing, treating, and researching diabetes in Native Americans will take a significant step towards improving this serious problem.

Q: WHY IS THE NEW MEDICARE BENEFIT FOR PEOPLE WITH DIABETES SO IMPORTANT? DON'T MOST BENEFICIARIES GET THEIR DIABETES CARE PAID FOR BY SUPPLEMENTAL INSURANCE?

A: Many older Americans with diabetes -- even many of those with supplemental insurance -- are not getting the proper care they need to prevent the costly devastating complications associated with diabetes. Medicare beneficiaries report that they are unsure how to properly manage their diabetes care.

Moreover, Medicare does not currently cover some of the most critical services that beneficiaries with diabetes need to manage their disease. It does not pay for blood glucose monitors or for the strip tests that people with diabetes need to monitor their blood sugar.

The balanced budget expands Medicare's coverage of benefits for people with diabetes by $2.1 billion over five years. In so doing, it expands the number of people able to take advantage of self-management tools will increase the number of Americans who properly manage their diabetes, thereby helping to prevent the debilitating and costly complications too often associated with the disease.

Q: WILL WE BE ABLE TO CURE DIABETES WITH THIS INVESTMENT?

A: No investment in research can guarantee that a cure can be discovered. However, scientific researchers are making significant progress in the area of diabetes and scientists at NIH say that this new investment will help these important efforts.

PRESIDENT'S SPEECH

HHS
TESTIMONY

(Synopsis of)
David Roos Statement
(Parent of Child who Died of Diabetes)
Before the House Labor, HHS Subcommittee
April 16, 1997

Mr. Roos's Daughter, Debbie, died of Juvenile Diabetes complications at the age of 32. Debbie was diagnosed at 12 years old with IDDM (juvenile diabetes). Mr. and Mrs. Roos knew that this would mean a major health change for Debbie, but they were not aware of the heavy toll Diabetes would take on their lives. As parents they thought they would be able to protect their little girl from the daily and long-term threats of diabetes, but they were wrong. Eventhough Debbie followed her diabetic diet, administered her daily allowance of insulin shots, and performed her blood glucose testing numerous times a day nothing could cure her of this dreadful disease. The fear of insulin shock, or comas induced by otherwise normal illnesses such as the flu, and not so normal conditions such as the crushing litany of kidney failure, neuropathy, heart disease and blindness, were medical problems endured by Debbie in her thirty-two years. Debbie died, not because she did not receive all of the known treatment, but because she had a disease that does not have a cure.

Debbie was married for four happy years and considered these years to be the best years of her life. However the last eighteen months of her life was like watching a tragedy unfold for the Roos's. At 30 years old she started to lose her sight and eventually became legally blind because of diabetes. A graduate of the Univesity of Texas with Honors, she could no longer function in the corporate world because of her disease, so Mr Roos's hired her as his assistant. In addition to being legally blind she had developed gastroparesis, a paralysis of the stomach caused by diabetic neuropathy which caused her to be nauseated for the better part of each day. Debbie passed away on January 5, 1997 at the age of 32 because of heart problems caused by diabetes.

REMARKS

DRAFT

DIABETES AND THE EASTERN BAND OF CHEROKEE INDIANS

My name is Joyce Dugan and I serve as the Principal Chief of the Eastern Band of Cherokee Indians. Our reservation is located in western North Carolina next to the Great Smoky Mountains National Park. My people have lived in this area for thousands of years.

It is with mixed emotions that I appear today. I am delighted that President Clinton ~~will be~~ announcing an initiative to combat diabetes and that this initiative will have a special component in it to address the staggering problem that American Indian people have in this area. But I am also saddened, not just because of the scope of the issue in Indian country but due to the personal effects this disease has had on my people and on my direct family. After losing both her legs to diabetes, my mother died at the rather young age of 62 from the complications of this disease. I believe I can safely say that every family on my reservation is either directly or indirectly affected by this diabetes. ~~It is bad enough that~~ Nationally 1 out of every 5 American Indians has diabetes. At Cherokee 1 out of every 3 tribal members suffer from some form of diabetes. These astonishing statistics are even more incredible when you realize that 100 years ago, diabetes did not exist among Indian people. ~~Fifty years ago it was considered a rare finding in our people.~~ Today it is an epidemic in Indian communities.

For reasons that appear to be genetic, diabetes occurs at younger ages among Indians than it does in the general population and we develop complications from diabetes at a higher rate. One third of our cases occur in people who are under 40 years of age and Indian children born to mothers with diabetes have a nine fold greater chance of developing diabetes than any other group.

At Cherokee, the number of patients on dialysis has doubled in the last 7 years and diabetes related amputations have tripled in the past 10 years.

Must it be this way? We believe the answer is NO. For too long attention has been focused on efforts at treatment of this disease but not preventing it. This has promoted an acceptance and a belief that we are inevitably doomed by it. It is time to commit ourselves to stopping this epidemic before it reaches future generations. ~~It is time for us to take on the challenge of diabetes and make a pledge for prevention in all its forms.~~

My Tribe, and others, have begun the process of education and prevention through collaborative efforts with various agencies and community groups. We are focusing our efforts on both providing support for those who already suffer from the complications of diabetes and on preventing the spread of the disease. We have initiated support groups and weekly special clinics ~~which use~~ a

team ~~approach to prevention education,~~ and we are presently planning a Diabetes Center which will encompass a Dialysis Center and a Wellness Center that emphasizes prevention. A dialysis center is essential. We have 44 tribal members with "end stage renal failure" who are presently traveling many hours a day to off-reservation facilities for treatment.

Even with these efforts, we know we need to increase our focus on the children. ~~I truly believe that it is through the children that we will be able to succeed in this effort.~~ While we recognize the problems and have made progress addressing them though our own initiatives, we have been constrained by the lack of funds needed to move forward at the pace required to stop the epidemic and save this generation of children.

We clearly need a special program to address the unique epidemic facing our people. By establishing a special diabetes program for Indian people, the President and the Congress have recognized this fact. We are hopeful that through the grant mechanism the President will announce, that we will at long last find the funding for our Diabetes Center and a brighter future for our people.

Introduce

Sandy's Speech –

1/3

I would like to thank the President for inviting me to be a part of this important announcement today.

At 6:30 in the morning, on March 12 1985, our daughter Michelle was diagnosed with diabetes. She was just 13 months old, critically ill, and my husband, Mark, and I were devastated... Parents of children with diabetes never forget the day their child was diagnosed and neither have we...because that moment in time changed our lives forever.

Today, Michelle is 13 years old. She has lived each day of her life since then with diabetes. [Through her infancy and toddlerhood, to the young teenager she is today,] she has required three injections of insulin and four to six fingersticks to test her blood sugar level each day. In other words, during her brief lifetime, Michelle has endured more than 13,000 injections and over 21,000 fingerstick blood tests just to keep her alive. Imagine the paradox in having to inflict pain on your young child in order to protect ~~them~~ her from harm. At the same time, Michelle has had to balance this with following a structured meal plan and exercise program to keep her blood sugar levels within a prescribed range. Persistent high blood sugar levels lead to devastating small and large blood vessel damage and blood glucose levels that drop too low can lead to seizures, unconsciousness, and death. Under the best of circumstances, this is a very difficult balance to achieve.

Throughout her life, we have strived to ~~insure~~ ensure that Michelle live as normal a life as possible, ~~to~~ participated in sports, ~~to~~ excelled in school, and to engaged in activities

normal for children her age. But she has been robbed of the carefree and spontaneous existence of childhood, and she faces an uncertain future. A future life expectancy that may be reduced by 30% and may be shadowed by blindness, kidney failure, and nerve damage. These are daunting prospects for a beautiful young child like Michelle. cut

Yet Michelle is not alone with this disease.

Millions of Americans, many of them children, have diabetes. More than 600,000 people are diagnosed with diabetes each year and the numbers are rising. This is a disease that exacts an enormous toll, both in human suffering and costs to our country. cut

As ~~a parent~~ parents, we quickly learned that we were powerless to change the course of this disease. Research, such as that supported by the Juvenile Diabetes Foundation and the National Institutes of Health, remains our only hope for a cure and a future free of diabetes and its complications. Diabetes is a disease of amazing complexity. The prevention and cure of diabetes requires the best and most rigorous science from the fields of genetics, metabolism, transplantation, and clinical research. We have the research expertise in this country to achieve this goal and now we have the ultimate initiating event. cut

Until today, I could never completely assure Michelle that a cure was within ~~her~~ reach. ~~This Research Initiative~~ This new investment ~~being~~ announced today gives us all greater reason to hope and sends a positive message that a cure will be found. This Research Initiative demonstrates a commitment to change the course of this disease and sends a powerful and compassionate message to millions of Americans. On behalf of Michelle, the many

to help research a cure for diabetes

(3)/(3)

children and adults who suffer with this devastating disease, and the Juvenile Diabetes Foundation, I thank you Mr. President and Speaker Gingrich, for this extraordinary commitment.

Remarks for Mrs. Mary Delaney
Presidential Announcement on Diabetes Investment
August 8, 1997

Thank you. Mr. President I am honored to be here today to celebrate this announcement and to tell you and others here with us what an important difference the new diabetes investment you signed into law this week will make in my life and in the lives of the 16 million Americans who suffer from diabetes.

I was diagnosed with diabetes 11 years ago. I am not the first in my family to get this disease. Before me, my father had diabetes. This disease affects too many of our families. Nearly half of all people with diabetes are older Americans. It is also all too common among African-Americans who suffer from this disease at nearly double the rate.

Managing this disease has not been easy for me or my family. It has also been a difficult financial burden on my family. Neither Medicare nor my supplemental insurance covers my blood glucose monitor, which can cost $60 or more. It also does not cover the box of strips that I need to monitor my blood sugar which costs as much as $50 each month.

In addition, there are other things such as needles and rubbing alcohol and a host of other costs associated with my diabetes care that my family must pay for. These costs may not seem significant but combined with our family's other health care costs, it has been at times too much to manage.

In fact, there have been many times when I have tested my blood sugar less frequently than recommended by my doctor because I simply cannot afford to buy more testing strips. And just last week, my monitor stopped working. I will not be able to test my blood sugar until I get the resources to have it fixed.

I know that I am luckier than many diabetes patients, however. My supplemental insurance did pay for a class that taught me how to use the monitor and how to manage my own diabetes. But many of my friends and millions of other Americans have not been so fortunate. They do not have health coverage which pays to teach them how to care for themselves at home to help them avoid some of the horrible complications that can come with this disease.

Mr. President, the new Medicare benefit that you signed into law this week will help millions of older Americans like myself get the health care they need to manage this disease. For me, it will ensure that I can always afford the strips and monitors that I need to test my blood sugar and manage my illness. It will mean that I never have to compromise my diabetes care. For millions of others, it will mean that they learn the tools to manage their diabetes and live longer.

By increasing the number of Americans who can treat their diabetes at home, we will reduce the number of Americans who suffer from the difficult and costly complications, such as kidney disease or blindness. This will not only reduce the financial burdens for many, but it will also help save the Medicare program money as fewer beneficiaries will need more extensive, costlier care.

Mr. President, diabetes affects too many vulnerable Americans. Your leadership will improve the lives of so many of them. Thank you.

And now I am pleased to introduce Chief Joyce Dugan, the Chief of the Eastern Band of Cherokee Indians.

Remarks for Mrs. Mary Delaney
Presidential Announcement on Diabetes Investment
August 8, 1997

Thank you. Mr. President I am honored to be here today to celebrate this announcement and to tell you and others here with us what an important difference the new diabetes investment you signed into law this week will make in my life and in the lives of the 16 million Americans who suffer from diabetes.

I was diagnosed with diabetes 11 years ago. I am not the first in my family to get this disease. Before me, my father had diabetes. This disease affects too many of our families. Nearly half of all people with diabetes are older Americans. It is also all too common among African-Americans who suffer from this disease at nearly double the rate.

Managing this disease has not been easy for me or my family. It has also been a difficult financial burden on my family. Neither Medicare nor my supplemental insurance covers my blood glucose monitor, which can cost $60 or more. It also does not cover the box of strips that I need to monitor my blood sugar which costs as much as $50 each month.

In addition, there are other things such as needles and rubbing alcohol and a host of other costs associated with my diabetes care that my family must pay for. These costs may not seem significant but combined with our family's other health care costs, it has been at times too much to manage.

In fact, there have been many times when I have tested my blood sugar less frequently than recommended by my doctor because I simply cannot afford to buy more testing strips. And just last week, my monitor stopped working. I will not be able to test my blood sugar until I get the resources to have it fixed.

I know that I am luckier than many diabetes patients, however. My supplemental insurance did pay for a class that taught me how to use the monitor and how to manage my own diabetes. But many of my friends and millions of other Americans have not been so fortunate. They do not have health coverage which pays to teach them how to care for themselves at home to help them avoid some of the horrible complications that can come with this disease.

Mr. President, the new Medicare benefit that you signed into law this week will help millions of older Americans like myself get the health care they need to manage this disease. For me, it will ensure that I can always afford the strips and monitors that I need to test my blood sugar and manage my illness. It will mean that I never have to compromise my diabetes care. For millions of others, it will mean that they learn the tools to manage their diabetes and live longer.

By increasing the number of Americans who can treat their diabetes at home, we will reduce the number of Americans who suffer from the difficult and costly complications, such as kidney disease or blindness. This will not only reduce the financial burdens for many, but it will also help save the Medicare program money as fewer beneficiaries will need more extensive, costlier care.

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LEGISLATIVE LANGUAGE

1 **"SEC. 330C. SPECIAL DIABETES PROGRAMS FOR INDI-**
2 **ANS.**
3 "(a) IN GENERAL.—The Secretary shall make grants for
4 providing services for the prevention and treatment of diabetes
5 in accordance with subsection (b).
6 "(b) SERVICES THROUGH INDIAN HEALTH FACILITIES.—
7 For purposes of subsection (a), services under such subsection
8 are provided in accordance with this subsection if the services
9 are provided through any of the following entities:
10 "(1) The Indian Health Service.
11 "(2) An Indian health program operated by an Indian
12 tribe or tribal organization pursuant to a contract, grant,
13 cooperative agreement, or compact with the Indian Health
14 Service pursuant to the Indian Self-Determination Act.
15 "(3) An urban Indian health program operated by an
16 urban Indian organization pursuant to a grant or contract
17 with the Indian Health Service pursuant to title V of the
18 Indian Health Care Improvement Act.
19 "(c) FUNDING.—Notwithstanding section 2104(a) of the
20 Social Security Act, from the amounts appropriated in such
21 section for each of fiscal years 1998 through 2002,
22 $30,000,000 is hereby transferred and made available in such
23 fiscal year for grants under this section.".
24 **SEC. 4023. REPORT ON DIABETES GRANT PROGRAMS.**
25 (a) EVALUATION.—The Secretary of Health and Human
26 Services shall conduct an evaluation of the diabetes grant pro-
27 grams established under the amendments made by this chapter.
28 (b) REPORTS.—The Secretary shall submit to the appro-
29 priate committees of Congress—
30 (1) an interim report on the evaluation conducted
31 under subsection (a) not later than January 1, 2000, and
32 (2) a final report on such evaluation not later than
33 January 1, 2002.

1 **SEC. ___. TECHNICAL CORRECTIONS.**

2 The Balanced Budget Act of 1997 is amended—

3 (1) in the table of contents for title IV, in the item
4 relating to section 4921, by striking "children with";

5 (2) in the heading for section 4921, by striking
6 "CHILDREN WITH"; and

7 (3) in the section added by section 4921—

8 (A) in the heading for such section, by striking
9 "CHILDREN WITH"; and

10 (B) by amending subsection (a) to read as follows:

11 "(a) IN GENERAL.—The Secretary, directly or through
12 grants, shall provide for research into the prevention and cure
13 of Type I diabetes.".

SHERATON - WAIKIKI
RESORT

2255 Kalakaua Ave., Honolulu, Hawaii, 96815
Telephone No.: (808) 922-4422, ext. 72173
Fax No.: (808) 923-8785

FAX INFORMATION SHEET

To Company: White House Office of Public Liaison **Date:** Aug 7, 1997

Person: whoever called me at 5am this morning **Time:**

Fax Phone: 202 456-6218

From: Dr. Lorraine Cole / National Medical Assn

Total Pages: 2 *(Including Cover Sheet)*

MESSAGE:

I received a message that the comments I submitted this morning per your requested did not mention President Clinton. Please accept the insertions and again please feel free to use either or any combination or extraction from the two.

Again, thank you. If you need to reach me again, please leave a message at extension 3028

Sender's Name: Lorraine Cole **Room No.** 3028

Form FAXCVRSHT - DTT

NATIONAL MEDICAL ASSOCIATION
COMMENTS ON
NEW DIABETES INVESTMENTS TO IMPROVE TREATMENT, PREVENTION, AND RESEARCH FOR AMERICANS WITH DIABETES

announced by President Clinto

(Statement 1)

For the approximately 3 million African Americans affected by diabetes and who suffer a disproportionate burden from its complications, these initiatives will prompt a shift in the quality of care and access to services that can improve outcomes. The National Medical Association feels strongly that this is a health initiative that will strike a major blow to the debilitating effects of a silent killer in high-risk minority communities, and reduce the enormous drain on human and fiscal resources caused by diabetes.

(Statement 2)

President Clinton for

The National Medical Association enthusiastically applauds the provisions in the balanced budget package directed towards cure of type 1 diabetes, more intense preventive services and treatments for Native Americans, and improved coverage for self-management of older and other high-risk populations. For the almost 3 million African Americans with diabetes, who suffer higher rates of amputations and kidney failure, these initiatives signal a major shift in the direction of bringing much of our new knowledge to bear on relief of a costly and debilitating disease, while hastening our quest to eradicate it completely.

File Diabetes
(CJ)

MEMORANDUM

May 5, 1997

TO: Bruce Reed

FR: Chris Jennings

RE: Meeting on Diabetes and AIDS vaccine

Today we are meeting with Kevin Thurm and Nancy-Ann Min to discuss possible new Presidential investments and announcements on the AIDS vaccine and diabetes. In this meeting, we will discuss possible options for a new investment or some other type of Presidential involvement in stepping up effort towards finding an AIDS vaccine, including proposals that Secretary Shalala intends to send into the President following the meeting. We will also discuss a possible investment in diabetes research and prevention strategies. (Nancy-Ann and I have already discussed our proposed $50 million with Kevin and today he will report back on the Department's reaction.)

Diabetes

Nancy-Ann and I have been looking into the possibility of a $50 million investment in diabetes for FY 1998. $30 million of this investment would be allocated to research at the National Institutes of Health (NIH). An additional $20 million would be allocated to enable the Centers for Disease Control (CDC) to develop comprehensive prevention programs in all 50 states.

There is some evidence that diabetes research at the NIH is currently underfunded. While there is a great deal of debate in the public health community as to how best to evaluate whether a specific disease is adequately funded, investments in diabetes as a portion of overall cost of this disease (a fairly typical form of measurement) is far lower than many other diseases, including heart disease, cancer, and AIDS.

We would not specify what type of research this $30 million of funding would go towards (i.e. clinical or basic). NIH would have the flexibility to invest the money as they see fit. Nevertheless, Dr. Varmus has clearly stated his opposition to this additional funding (both to me and again to Kevin). He opposes the concept of earmarking funds in general, arguing that these kinds of decisions should be based on purely scientific grounds rather than politically motivated. He also has argued that Congressional appropriators strongly oppose this type of earmarking. That being said, moving in this direction will clearly be an explicit decision to override him.

We are also proposing to invest $20 in CDC, which would enable them to expand their current core prevention programs to comprehensive programs in all fifty states. Unlike with NIH, CDC believes that this money could make an enormously positive contribution to their program. Currently, CDC runs a "core" diabetes prevention in all fifty states, which consists of a few staff members and some basic outreach strategies in certain areas of the state to help people already diagnosed as diabetics avoid some of the costly, and often avoidable, side effects of this disease. Core programs have usually identified a plan for statewide outreach, but have not been able to fully implement the plan due to limited resources. By investing an additional $20 million (over the $36 million proposed in the President's FY1998 budget -- already a $10 million increase over FY 1997), CDC will be able to expand all of their programs to comprehensive nationwide programs, with a far more expansive staff with more outreach capabilities throughout the state.

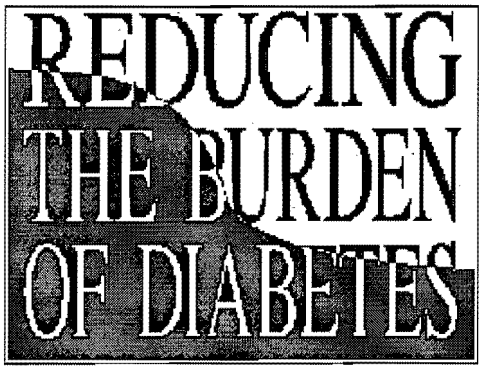
This additional funding would also enable these prevention programs to target populations that are at risk for diabetes, but have not yet been diagnosed with the disease. This kind of outreach is extremely important for two reasons: first, of the approximately 16 million Americans who have diabetes, only eight million have been diagnosed, meaning that millions of Americans live for years unaware that they are suffering from this disease; second, diabetes can have extremely costly, serious complications which often lead to death, amputations, heart attacks, etc. Many people do not learn they suffer from this disease until they experience one of these dangerous complications. However, studies (including an recent clinical trial at NIH) have shown that when this disease is recognized and properly treated, these side effects are largely avoidable.

When CDC made their wish list of how they might spend additional resources, they stated that expanding core programs in the states was their top priority. However, they also stated a preference for investing some of the new dollars in some of their other programs, including their new National Education Action Plan ($2-$5 million) which is designed as a public education program to target different audiences, including people with diabetes and others at risk for this disease as well as providers and the general population. They have also asked for additional funding for public health surveillance ($2-$5 million) and conducted applied research ($2-$5 million). We chose to fund only the state programs because it was CDC's top priority and because a $20 million investment is enough for CDC to implement comprehensive state plans in all fifty states (according to OMB's estimates).

If we choose to make this kind of an investment, we could announce it at the American Diabetes Association's nationwide conference on June 22 in Boston. This site would be particularly appropriate because CDC intends to announce their National Education Action Plan at that meeting as well. We also need to make a decision as how best to propose this increase, whether it be through a budget amendment, the budget negotiations, or some other avenue. With regard to NIH, we will need to make a decision as to whether this funding would come from an additional investment or from existing NIH funds in the President's proposal.

AIDS Vaccine

We are also planning to discuss possible options for the President to heighten is involvement in the search for an AIDs vaccine. We are awaiting the memo from HHS on their proposals that they intend to send into the President. We will forward you more information in this area later on this morning.



For release November 1, 1997

National Diabetes Fact Sheet

National estimates and general information on diabetes in the United States

- What is Diabetes?
- Prevalence of Diabetes
- Incidence of Diabetes
- Deaths Among Persons With Diabetes
- Prevalence of Diabetes by Age
- Prevalence of Diabetes by Sex in People 20 Years or Older
- Prevalence of Diabetes by Race/Ethnicity in People 20 Years or Older
- The Four Types of Diabetes
- Complications of Diabetes
- Cost
- New Diagnostic Criteria for Diabetes
- Treatment of Diabetes
- Impaired Fasting Glucose
- Appendix
- Acknowledgments

What is diabetes?

Diabetes mellitus is a group of diseases characterized by high levels of blood glucose resulting from defects in insulin secretion, insulin action, or both. Diabetes can be associated with serious complications and premature death, but persons with diabetes can take measures to reduce the likelihood of such occurrences.

Prevalence of diabetes*

Total: 15.7 million people -- 5.9% of the population -- have diabetes.
- **Diagnosed:** 10.3 million people
- **Undiagnosed:** 5.4 million people

*** For further information on prevalence, see the Appendix.**

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Incidence of diabetes

New cases diagnosed per year: 798,000

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Deaths among persons with diabetes

- Studies have found death rates to be twice as high among middle-aged people with diabetes as among middle-aged people without diabetes.
- Based on death certificate data, diabetes contributed to 187,800 deaths in 1995.
- Diabetes was the seventh leading cause of death listed on U.S. death certificates in 1995, according to CDC's National Center for Health Statistics.
- Diabetes is believed to be underreported on death certificates, both as a condition and as a cause of death.

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Prevalence of diabetes by age

- **Age 65 years or older:** 6.3 million. *18.4% of all people in this age group have diabetes.*
- **Age 20 years or older:** 15.6 million. *8.2% of all people in this age group have diabetes.*
- **Under age 20:** 123,000. *0.16% of all people in this age group have diabetes.*

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Prevalence of diabetes by sex in people 20 years or older*

- **Men:** 7.5 million. *8.2% of all men have diabetes.*
- **Women:** 8.1 million. *8.2% of all women have diabetes.*

These figures do not include the approximately 123,000 cases of diabetes in children and teenagers in the United States.

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Prevalence of diabetes by race/ethnicity in people 20 years or older*

- **Non-Hispanic whites:** 11.3 million. *7.8% of all non-Hispanic whites have diabetes.*
- **Non-Hispanic blacks:** 2.3 million. *10.8% of all non-Hispanic blacks have diabetes.*
  On average, non-Hispanic blacks are 1.7 times as likely to have diabetes as non-Hispanic whites of similar age.
- **Mexican Americans:** 1.2 million. *10.6% of all Mexican Americans have diabetes.*

On average, Mexican Americans are 1.9 times as likely to have diabetes as non-Hispanic whites of similar age.

- **Other Hispanic/Latino Americans:** On average, Hispanic/Latino Americans are almost twice as likely to have diabetes as non-Hispanic whites of similar age. (Sufficient data are not currently available to derive more specific estimates for 1997.)
- **American Indians and Alaska Natives:** Prevalence varies among tribes, bands, pueblos and villages, and ranges from <5% to 50% for diagnosed diabetes. There are more than 550 federally recognized tribes, bands, pueblos, and villages in the United States.
- **Asian Americans and Pacific Islanders:** Prevalence data for diabetes among Asian Americans and Pacific Islanders are limited. Some groups within this population are at increased risk for diabetes. For example, data collected from 1988 to 1995 suggest that Native Hawaiians are twice as likely to have diagnosed diabetes as white residents of Hawaii.

These figures do not include the approximately 123,000 cases of diabetes in children and teenagers in the United States.

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The four types of diabetes

- **Type 1 diabetes** was previously called insulin-dependent diabetes mellitus (IDDM) or juvenile-onset diabetes. Type 1 diabetes may account for 5% to 10% of all diagnosed cases of diabetes. Risk factors are less well defined for type 1 diabetes than for type 2 diabetes, but autoimmune, genetic, and environmental factors are involved in the development of this type of diabetes.
- **Type 2 diabetes** was previously called non-insulin dependent diabetes mellitus (NIDDM) or adult-onset diabetes. Type 2 diabetes may account for about 90% to 95% of all diagnosed cases of diabetes. Risk factors for type 2 diabetes include older age, obesity, family history of diabetes, prior history of gestational diabetes, impaired glucose tolerance, physical inactivity, and race/ethnicity. African Americans, Hispanic/Latino Americans, American Indians, and some Asian Americans and Pacific Islanders are at particularly high risk for type 2 diabetes.
- **Gestational diabetes** develops in 2% to 5% of all pregnancies but disappears when a pregnancy is over. Gestational diabetes occurs more frequently in African Americans, Hispanic/Latino Americans, American Indians, and persons with a family history of diabetes. Obesity is also associated with higher risk. Women who have had gestational diabetes are at increased risk for later developing type 2 diabetes. In some studies, nearly 40% of women with a history of gestational diabetes developed diabetes in the future.
- **"Other specific types"** of diabetes result from specific genetic syndromes, surgery, drugs, malnutrition, infections, and other illnesses. Such types of diabetes may account for 1% to 2% of all diagnosed cases of diabetes.

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Complications of diabetes

Heart disease

Heart disease is the leading cause of diabetes-related deaths. Adults with diabetes have heart disease death rates about 2 to 4 times as high as that of adults without diabetes.

Stroke

The risk of stroke is 2 to 4 times higher in people with diabetes.

High blood pressure
An estimated 60% to 65% of people with diabetes have high blood pressure.

Blindness
-- Diabetes is the leading cause of new cases of blindness in adults 20 to 74 years old.
-- Diabetic retinopathy causes from 12,000 to 24,000 new cases of blindness each year.

Kidney disease
-- Diabetes is the leading cause of end-stage renal disease, accounting for about 40% of new cases. 27,851 people with diabetes developed end-stage renal disease in 1995.
-- In 1995, a total of 98,872 people with diabetes underwent dialysis or kidney transplantation.

Nervous system disease
-- About 60% to 70% of people with diabetes have mild to severe forms of nervous system damage (which often includes impaired sensation or pain in the feet or hands, slowed digestion of food in the stomach, carpal tunnel syndrome, and other nerve problems).
-- Severe forms of diabetic nerve disease are a major contributing cause of lower extremity amputations.

Amputations
-- More than half of lower limb amputations in the United States occur among people with diabetes.
-- From 1993 to 1995, about 67,000 amputations were performed each year among people with diabetes.

Dental disease
Periodontal disease (a type of gum disease that can lead to tooth loss) occurs with greater frequency and severity among people with diabetes. Periodontal disease has been reported to occur among 30% of people aged 19 years or older with type 1 diabetes.

Complications of pregnancy
-- The rate of major congenital malformations in babies born to women with preexisting diabetes varies from 0% to 5% among women who receive preconception care to 10% among women who do not receive preconception care.
-- Between 3% to 5% of pregnancies among women with diabetes result in death of the newborn; the rate for women who do not have diabetes is 1.5%.

Other complications
-- Diabetes can directly cause acute life-threatening events, such as diabetic ketoacidosis* and hyperosmolar nonketotic coma.*
-- People with diabetes are more susceptible to many other illnesses. For example, they are more likely to die of pneumonia or influenza than people who do not have diabetes.

**** Diabetic ketoacidosis and hyperosmolar nonketotic coma are medical conditions that can result from biochemical imbalance in uncontrolled diabetes.***

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Cost

- **Total (direct and indirect):** $92 billion (United States, 1992)
- **Direct medical costs:** $45 billion
- **Indirect costs:** $47 billion (disability, work loss, premature mortality)

This estimate is in contrast to higher estimates cited elsewhere that are based on all health care costs incurred by people with diabetes, including costs not resulting from diabetes. New cost estimates are expected to be released within 6 months.

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New diagnostic criteria for diabetes*

The new diagnostic criteria for diabetes include the following changes:

- The routine diagnostic test for diabetes is now a fasting plasma glucose test rather than the previously preferred oral glucose tolerance test. (However, in certain clinical circumstances, physicians may still choose to perform the more difficult and costly oral glucose tolerance test.)
- A confirmed** fasting plasma glucose value of greater than or equal to 126 milligrams/deciliter (mg/dL) indicates a diagnosis of diabetes. Previously, a value of greater than or equal to 140 mg/dL had been required for diagnosis.
- In the presence of symptoms of diabetes, a confirmed** nonfasting plasma glucose value of greater than or equal to 200 mg/dL indicates a diagnosis of diabetes.
- When a doctor chooses to perform an oral glucose tolerance test (by administering 75 grams of anhydrous glucose dissolved in water, in accordance with World Health Organization standards, and then measuring the plasma glucose concentration 2 hours later), a confirmed** glucose value of greater than or equal to 200 mg/dL indicates a diagnosis of diabetes.
- In pregnant women, different requirements are used to identify the presence of gestational diabetes.

*** For further information about the new diagnostic criteria for diabetes, please refer to the Report of the Expert Committee on the Diagnosis and Classification of Diabetes Mellitus, as referenced in the Appendix.**

**** Except in certain specified circumstances, abnormal tests must be confirmed by repeat testing on another day.**

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Treatment of diabetes

Diabetes knowledge, treatment, and prevention strategies advance daily. Treatment is aimed at keeping blood glucose near normal levels at all times. Training in self- management is integral to the treatment of diabetes. Treatment must be individualized and must address medical, psychosocial, and lifestyle issues.

- Treatment of type 1 diabetes: Lack of insulin production by the pancreas makes type 1 diabetes particularly difficult to control. Treatment requires a strict regimen that typically includes a carefully calculated diet, planned physical activity, home blood glucose testing several times a day, and multiple daily insulin injections.
- Treatment of type 2 diabetes: Treatment typically includes diet control, exercise, home blood glucose testing, and in some cases, oral medication and/or insulin. Approximately 40% of people with type 2 diabetes require insulin injections.

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Impaired fasting glucose

Impaired fasting glucose is a new diagnostic category in which persons have fasting plasma

glucose values of 110-125 mg/dL. These glucose values are greater than the level considered normal but less than the level that is diagnostic of diabetes. It is estimated that 13.4 million persons, 7.0% of the population, have impaired fasting glucose. Scientists are trying to learn how to predict which of these persons will go on to develop diabetes and how to prevent such progression.

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Appendix

How were the estimates in this fact sheet derived?

Periodically, the federal government conducts surveys to determine the health of Americans. Such surveys involve questionnaires and medical tests. The diabetes prevalence and incidence estimates presented in this fact sheet were developed by analyzing the newest available national survey data and then adjusting for changes in the population based on 1997 census estimates. The prevalence of diagnosed diabetes represents the number who said they had diabetes. The prevalence of undiagnosed diabetes represents the number of people who said they did not have diabetes, but when given a fasting plasma glucose test, they did in fact have abnormally elevated blood glucose levels (defined as fasting plasma glucose levels greater than or equal to 126 mg/dL). Other estimates presented in this fact sheet were based on individual surveys, research projects, and registry data. A listing of references and additional data sources are at the end of this fact sheet.

Has the number of persons with diabetes changed since the previous National Diabetes Fact Sheet, which was issued in 1995?

Between the 1995 and 1997 fact sheets, the number of persons with diagnosed diabetes increased from 8 million to 10.3 million, but the number of persons with undiagnosed diabetes decreased. For the 1995 National Diabetes Fact Sheet, the number of persons with undiagnosed diabetes was estimated from research using the oral glucose tolerance test to identify undiagnosed diabetes. In contrast, for the 1997 National Diabetes Fact Sheet, the number of persons with undiagnosed diabetes was estimated from research using the fasting plasma glucose test, according to recently enacted recommendations. These tests are not equivalent, however, and fewer cases of undiagnosed diabetes are identified using the fasting plasma glucose test under current recommendations.

An enhanced national effort to identify previously undiagnosed persons may also have contributed to a decrease in the number of persons with undiagnosed diabetes. Continued efforts to identify persons with undiagnosed diabetes, the implementation of new guidelines for screening, and the use of an easier and less expensive diagnostic test are all likely to lead to even further decreases in the number of persons with undiagnosed diabetes and increases in the number of persons with diagnosed diabetes.

References

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- National Diabetes Data Group, National Institutes of Health. Diabetes in America, 2nd Edition. Bethesda, MD: National Institutes of Health, 1995. NIH Publication No. 95-1468.
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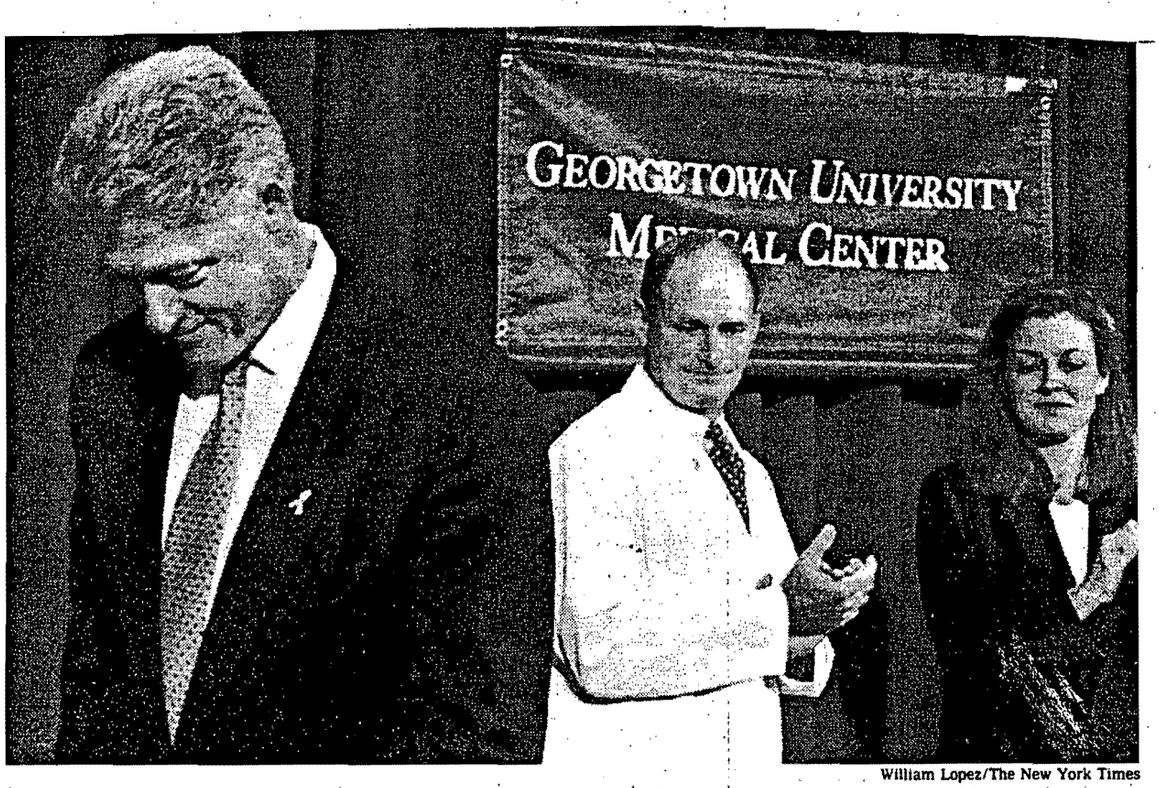
- U.S. Department of Health and Human Services. Physical activity and health: a report of the Surgeon General. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, 1996.
- U.S. Renal Data System. USRDS 1997 Annual Data Report. Bethesda, MD: National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Disease, 1997.

Additional sources

- Calculations were performed by the National Institutes of Health and the Centers for Disease Control and Prevention using data from various surveys including the Third National Health and Nutrition Examination Survey (NHANES III), the National Health Interview Survey (NHIS), and U.S. Census estimates for current population. The national prevalence estimates for diabetes were based on Harris MI, Unpublished Data from NHANES III, 1988-1994.
- Information about Native Hawaiians was provided by the Hawaii Diabetes Control Program and is based on Wen M, Unpublished Analysis of Data from the Behavioral Risk Factor Surveillance System (BRFSS) from

File Diabetes Event



William Lopez/The New York Times

President Clinton leaving the stage at Georgetown University Medical Center in Washington yesterday after announcing a $2 billion plan of research and treatment to fight diabetes in the next five years.

Clinton Unveils Plan to Battle Diabetes

By IRVIN MOLOTSKY

WASHINGTON, Aug. 8 — President Clinton today announced an effort to combat diabetes.

In a ceremony at Georgetown University Medical Center, the President called attention to $2.1 billion in Federal spending over the next five years for diabetes treatment and research, included in the newly signed balanced budget legislation.

Most of the money will pay for expanded medical benefits for the estimated 3.2 million diabetics who are covered by Medicare. For the first time, Medicare will cover the purchase of monitors that enable patients to check their own blood sugar levels. It will also pay health-care providers to teach diabetics how to control the disease and keep blood sugar levels from rising or falling precipitously.

Self-management training had been permitted only in hospital programs, while blood glucose monitors were covered only for diabetics who cannot control blood sugar by adjusting their diet and were required to take insulin.

The measure also provides $150 million for research into the prevention and cure of Type I diabetes, often known as juvenile diabetes because half of its sufferers are children, and $150 million for the treatment and prevention of rampant diabetes among American Indians.

The White House said that 16 million Americans had diabetes, which results from defects in the body's ability to manufacture the insulin it needs to process glucose in the blood. It can cause kidney, nerve, heart or blood vessel failure.

For reasons that are unclear, American Indians are particularly vulnerable, with 1 out of every 5 suffering from the disease.

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The New York Times

SATURDAY, AUGUST 9, 1997

Clinton Hails Budget Deal for Its Support of Fight Against Diabetes

By John F. Harris
Washington Post Staff Writer

President Clinton yesterday hailed a lesser-known part of the balanced-budget deal—new federal funds that will be devoted to helping research and treat diabetes.

Clinton, speaking at the Georgetown University Medical Center, struck an emotional note in highlighting the new initiatives against diabetes, which claims the lives of some 150,000 Americans annually, making it the nation's seventh-leading cause of death.

Clinton described how a friend who was his campaign manager in his first political campaign—a failed bid for the U.S. House of Representatives in 1974—succumbed a few years ago to diabetes complications.

And he recalled how a person who used to sing in the choir at his Little Rock church had to stop when his diabetes became too severe. "I have these vivid memories every Sunday, of standing there looking at him sitting in the church with the pain on his face of not being able to do it anymore."

The recently enacted budget accord contained three diabetes-related provisions.

The largest, costing $2.1 billion over five years, expands Medicare coverage to allow more people to be reimbursed for monitoring their own diabetes with blood-glucose test.

Under current law, Medicare pays for the blood-glucose strips needed for self-monitoring only for those patients on insulin treatment programs. Under the new law, all diabetes patients, regardless of their treatment regimen, can be reimbursed for blood-glucose monitoring.

Also, the bill allocates $150 million, over five years, for the Health and Human Services Department to spend on research for juvenile diabetes research. The agency will receive another $150 million over five years to spend on diabetes prevention and treatment among Native Americans, a group that suffers from diabetes at a rate three times higher than the population as a whole.

Finally, Clinton announced a public-private initiative known as the "Diabetes Quality Improvement Project." The federal government's Health Care Financing Administration will work with the American Diabetes Association and other groups to find ways to share information on treatments for diabetes, with an eye toward highlighting the most effective methods and ending what critics view as widely uneven levels of care.

Among the people who introduced Clinton was Mary Delaney, a District resident who suffers from diabetes and said because of cost she has not been able to monitor her blood sugar levels as often as her doctors have recommended; and Sandra Puczynski, an Ohio mother who described her distress when her child was diagnosed with diabetes several years ago.

On the stage, although she did not speak, was actress Mary Tyler Moore, who is a diabetes sufferer and is chairwoman of the Juvenile Diabetes Foundation International.

Clinton offered special praise yesterday for House Speaker Newt Gingrich (R-Ga.), who advocates for greater diabetes spending and was an ally in the budget debate. Gingrich was not present at Georgetown yesterday, but Clinton said the speaker has "watched his mother-in-law live with diabetes and became a great champion for people struggling with it, a tireless advocate for greater investments and research, prevention and care, and one of the very first people who ever spoke to me not only about the human dimensions of the disease."

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Saturday, August 9, 1997

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