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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. email	To Ruby Shamir from Marg Moore re: Diabetes Spending (partial) (1 page)	06/04/99	P6/b(6)
002. fax	To Neera Tanden from William T. Schmidt re: Invitation List (partial) (1 page)	06/02/99	P6/b(6)
003. list	Re: invitation list (partial) (1 page)	06/02/99	P6/b(6)

COLLECTION:

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FOLDER TITLE:

Health/Juvenile Diabetes 6-99 Event [4]

2012-0565-S

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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]
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- P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

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- b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
- b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
- b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]



FACSIMILE TRANSMISSION COVER SHEET

DATE: 6/3

TO: Neera Tanden

FROM: Sally Lippincott - JDF Child Congress

FAX NUMBER: 202-456-6244

COMPANY NAME: DEOB - First Lady's Office

NUMBER OF PAGES (including cover page): 12

COMMENTS:

Neera -
here are the bios/info on speakers
scheduled for the JDF event on
June 7th

- Mary Tyler Moore
- Dr. Doug Melton
- Miss Samantha Mandel

Call with questions.

- Sally
703-288-8680

1320 Old Chain Bridge Road, Ste. 330 • McLean, Virginia 22101 • 703.556.9402 703.442.8336 FAX

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Talking Points for Mary Tyler Moore:

- Has lived with juvenile diabetes for over 30 years.
- Has served as the International Chairman of the Juvenile Diabetes Foundation for the past 15 years.
- Knows first hand the devastating complications of diabetes having suffered severe retinopathy that threatened her eyesight.
- Proud to be in the vanguard of JDF, leading its efforts to find a cure for diabetes and its complications through the support of research.
- JDF is the leading non-profit, non-governmental supporter of diabetes research in the world, giving over \$340 million to research since its inception in 1970. This year alone JDF has awarded over \$55 million to diabetes research and is projecting a figure of \$75 million to diabetes research for next year.
- Champions JDF's longstanding partnership with the Federal government and its agencies to solve the needs of people with diabetes...partnerships, which are helping, build a bridge from the laboratory bench to the bedside of those with diabetes, translating research advances into longer and healthier lives for all who suffer from this disease.
- Insulin is not a cure, simply life support until the cure is found.
- JDF's efforts to double NIH's commitment to biomedical research over the next five years, implement the recommendations from Diabetes Research Working Group (DRWG).

Draft Remarks

Doug Melton, Ph.D.
First Lady/JDF Event

My son, Sam, was diagnosed with juvenile diabetes when he was just six months old. The date of his diagnosis is clear in the memories of both myself and my wife, Gail.

Taking care of the needs of a six-month old is challenging enough, but when you add diabetes to the mix, the challenge becomes much more serious.

Sam is now eight-years old. By any measure, he is a wonderful, well-adjusted, and brave child. However, he still must go through the daily regimen of injections, blood tests, and a proper mix of diet of exercise to survive each day. And, he must face a very uncertain future. This is more than any child should have to think about.

We can cure diabetes. I say that not just as a loving father whose desire for a cure exceeds everything else, but also as a scientist who has devoted my professional career to finding a cure. I am unwilling to accept the enormity of the medical and psychological burden that diabetes poses on children, and I am personally devoted to bringing it to an end for Sam and everyone who suffers from this awful disease.

As Chairman of the Molecular and Cellular Biology Department at Harvard University, my research has taken me in many different directions. For many years, much of my focus was on basic research that applied most directly to cancer research. However, since Sam's diagnosis, my personal interests and professional curiosity has driven me to focus my efforts on curing diabetes for Sam and all of the children who suffer from the disease.

I am a principal investigator at the JDF Center for Islet Cell Transplantation at Harvard Medical School where we our goal is to transplant insulin-producing islet cells into individuals with diabetes without the need for immunosuppressive drugs. The Center is supported by a \$20 million JDF grant and is a multi-disciplinary research effort based on a business model approach that combines a scientist's curiosity with a patient's desire for a cure.

The work that JDF is doing is only one piece of the puzzle. JDF's partnerships with the National Institutes of Health are also critically important in achieving a cure. The NIH has a responsibility to see that every diabetes research opportunity is fully explored, and the ongoing effort to double funding for the NIH in five years along with the implementation of the recently released Diabetes Research Working Group report is critically necessary in our effort.

Through the continued work of JDF, the world's leading non-governmental, non-profit supporter of diabetes research, and increased diabetes research at NIH, the world's pre-eminent research institute, we will truly be on the fast track to a cure.

Samantha Mandel's Speech

1. Hi, I'm Samantha Mandel
2. I was diagnosed when I was 2
3. How I do tests 6-7 times a day
4. Shots 3-6 times a day
5. Bad things can still happen even if I do it all right
6. Hope they find a cure for diabetes
7. We need help to pay for research to find cure
8. Children with diabetes, like me, are asking for help to pay for research
9. We need to find a cure for diabetes so bad things stop happening to so many good kids and adults
10. Introduce the First Lady



SUNTUM_M@A1
08/08/97 11:49:00 AM

Record Type: Record

To: See the distribution list at the bottom of this message
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Subject: 1997-8-8 remarks on diabetes

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release

August 8, 1997

REMARKS BY THE PRESIDENT
IN ANNOUNCEMENT ON DIABETES INITIATIVES

Georgetown University Hospital
Washington, D.C.

11:27 A.M. EDT

THE PRESIDENT: Thank you very much. I would like to thank Dr. Wiesel and all the people here at the Georgetown Medical Center for hosting us. I want to thank Mary Delaney and Chief Joyce Dugan and Sandra Puczynski for their speeches and for their example. As you might imagine, over the course of my tenure I have had occasion to come to quite a number of ceremonies like this. I don't believe I have ever heard three people back to back speak so powerfully, so clearly, so eloquently about a matter of great national concern. And I think we should give them all another hand. (Applause.)

I'd like to thank all of the people who are here today, diabetes patients, families, activists and advocates. Especially, I'd like to acknowledge the people on the platform -- Stephen Satalino, the Chair of the American Diabetes Association. Joan Beaubaire, the former head of the Juvenile Diabetes Foundation, is also here. Her son works for me at the White House, so I get a little extra prodding on this from time to time. (Laughter.)

I'd like to say a special word of thanks to Mary Tyler

Moore, who has awakened the conscience of our nation and indeed the entire world about this issue, for her long and tireless and selfless efforts. Thank you, Mary. (Applause.)

I want to thank Dr. Philip Gorden, the head of diabetes research at NIH. He's here with us today. And the NIH will play a major role in the work that we are discussing here.

None of us could write the history of the century that is about to end without a big chapter on the miracles modern medicine and science have wrought in our lives. Polio, mumps, diphtheria -- the diseases that robbed so many families of beloved infants and toddlers for centuries have been virtually eradicated. Premature babies who just a decade ago would not have had a chance at life beyond the intensive care unit are growing into happy and healthy children. Powerful treatments are prolonging the lives and improving the quality of lives of people with HIV and AIDS all across our country, raising new hopes for people living with the disease.

But there are still frontiers to conquer and still too many among us whose lives and futures are dimmed by disease and illness, as we have heard so powerfully today. Diabetes is the seventh leading cause of death in our country, and perhaps equally profoundly affects the lives of millions and millions of people who have it every day.

The historic balanced budget legislation I signed on Tuesday is about more than balancing the books; it also honors our values, increases our chances of keeping the American Dream alive in the 21st century and improves the lives of every American. There are some little-known but very important provisions in this new balanced

budget that will take us a tremendous step forward in our fight against diabetes. These investments total more than \$2 billion over the next five years. They will strengthen our efforts to find a cure, to help our most vulnerable citizens better manage the disease, to prevent some of its most traumatic, costly and life-threatening complications.

These investments represented the committed efforts of many members of Congress and our administration. But I must recognize, especially two: first, Congressman Elizabeth Furse, whose daughter is here and who has diabetes, led the Bipartisan Congressional Diabetes Caucus in an absolutely tireless fight to include the Medicare investments that are in this bill. And I thank her. She has done magnificently. Thank you. (Applause.)

And I must tell you, I wish very much that the Speaker of the House, Newt Gingrich, could be with us today. When we have a disagreement, it is normally well-publicized. (Laughter.) And widely understood. (Laughter.) But I

wish the American people could see the numerous private conversations that we have had together in quiet rooms about diabetes.

He 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, but the enormous percentage of our public funds in Medicare and, to a lesser extent, in Medicaid, that could be devoted to other purposes were it not for the crushing burden of diabetes-related problems directly resultant from our failure to invest as we begin to invest today. I know we play a leading role in making these new initiatives a part of the budget, and I appreciate both what he and Elizabeth and others have done.

Now, this new legislation will do three things. It expands Medicare benefits for the more than 3 million senior citizens diagnosed with diabetes. Mary talked about that. We all know that early investments in prevention can save us millions in expensive treatments down the line. If left untreated, diabetes can lead to devastating complications such as blindness, amputations and kidney disease. This new benefit will make testing strips and other methods of monitoring blood glucose levels, as well as instructions on how best to manage the complicated disease, available to all Medicare beneficiaries with diabetes.

It will empower Medicare patients to take better care of themselves at home and to avoid complications that can lead to costly hospital stays and destroy health.

Second, the new legislation will enable Health and Human Services Secretary, Donna Shalala, to boost funding for Type I or juvenile diabetes research by \$150 million over the next five years. Nearly one million Americans have Type I diabetes, and as many as half of them are children. Even when the disease is managed carefully, the patients almost always experience further complications. That's why we cannot rest until we find a cure that will free our children from this disease. And this unprecedented grant will help us to do that.

Third, we will provide a five-year, \$150-million grant to the Indian Health Service for diabetes prevention, research and treatment in our Native American communities. And I want to say a special word of thanks to Senator Domenici of New Mexico for his special efforts on this project.

As Chief Dugan has made it clear, Native Americans are three times as likely as white Americans to have this disease; far less likely to find adequate treatment for it. Too many Native Americans are suffering from the grimmest complications of diabetes. This grant will bring public health services, schools and nutrition

programs together to reach children and families living on

reservations, and to provide them with the information and tools to prevent and manage diabetes.

And I might say, I told Chief Dugan before I came up here that my grandmother's grandmother was a Cherokee who would be very proud that there is a woman chief who is doing such a magnificent job. (Applause.) Thank you.

Next month, our scientists at NIH will be hosting a workshop to bring researchers from all across the country to share ideas and discuss the most promising avenues of diabetes research. And we will establish a new and unprecedented public-private partnership to bring our nation's leading health care providers, purchasers, and consumers together to develop uniform guidelines for diabetes care. Through the guidelines, we can ensure that all doctors provide their patients with thorough and vigilant care, such as regular eye and foot exams, to stay as healthy as possible.

Taken together, these initiatives can make life-changing differences for millions of Americans. I was very heartened to hear the American Diabetes Association say that these new investments in diabetes are as important for people with diabetes as the discovery of insulin in 1921. Let us pray that it will be so.

Let me finally say that discussing this in rather clinical terms cannot possibly convey the human impact that Sandra did in talking about her child. On the way over here today, I was remembering that 23 years ago plus now, when I began my career in political life, the first chairman of my campaign was only a year older than me and was already a bank president at the age of 28 or 29, but he died a few years ago from complications from diabetes. When I lived in Arkansas, I used to sing in a church choir with a man who had to quit singing because of complications from diabetes, and 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.

This morning I got a note from a friend of mine I'd like to read to you. "For the last 17 years my son has gone to sleep scared; scared that his blood sugar would drop and his body would be ripped apart with a diabetic seizure. Every day for the last 17 years, my son and his family have worried about the opposite effects of having his blood sugar remain at too high a level and thereby causing the early onset of blindness, heart failure and loss of limb. Until today, there simply wasn't enough money available for scientific research to have a real hope to find a cure. Now there is."

It is easy to say that in the last 50 years we experienced in science the age of physics, the age of space travel and the beginning of genetic research; but that in the next 50 years, the 21st century in science will be an age of biology. The important thing is that for people and their families with diabetes, it can be an age of longer, happier, richer lives.

Thank you very much. (Applause.)

END

11:39 A.M. EDT

Message Sent To: _____

Withdrawal/Redaction Marker

Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
--------------------------	---------------	------	-------------

001. email	To Ruby Shamir from Marg Moore re: Diabetes Spending (partial) (1 page)	06/04/99	P6/b(6)
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COLLECTION:

Clinton Presidential Records
First Lady's Office
Ruby Shamir (Subject Files)
OA/Box Number: 20365

FOLDER TITLE:

Health/Juvenile Diabetes 6-99 Event [4]

2012-0565-S

ry1256

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 advice 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]
b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]



Marg Moore <MMOORE@niaid.nih.gov>

06/04/99 02:41:46 PM

Record Type: Record

To: Ruby Shamir/OPD/EOP

cc: Marg Moore <MMOORE@niaid.nih.gov>

Subject: Diabetes Spending

Ruby:

Here are the numbers for Diabetes research during the Clinton administration to date:

	FY 1992	FY 1999 Est.	Increase
NIAID	4,642,000	13,770,000	197%
NIH	278,412,000	448,994,000	61%

NIAID = National Institute of Allergy & Infectious Diseases

NIH = National Institutes of Health

Also, Dr. Daniel Rotrosen (Director, Division of Allergy, Immunology and Transplantation, NIAID) will attend the ceremony @ the Old Executive Office Building. Dr. Rotrosen's date of birth is: [P6/(b)(6)] and his social security number is [P6/(b)(6)]

[001]

If you need anything else, please do not hesitate to contact me.

We are still working on the remarks -- I'll have them to you asap. Thanks.

Marg.

Margaret Moore

Special Assistant to the Director

National Institute of Allergy & Infectious Diseases

31 CENTER DR MSC 2520

Building 31, Room 7A03

Bethesda, MD 20892-2520

Telephone: 301 496-2263

Telefax: 301 496-4409

Voice mail: 301 435-8581

e-mail: mm52s@nih.gov

Over the course of this admin
budget for diabetes at the
not lost to All + Infect. Diseases
increased by approx 200%
and also diabetes res at the
NIH nearly doubled

278
448
170

Public Affairs
1400 I Street, N.W., Suite 530
Washington, D.C. 20005
Phone: 202/371-9746
Fax: 202/371-2760

Fax

To: Ruby Shamir From: Larry Selin
Fax: Date:
Phone: Pages:
Re: CC:

☒ Urgent ☐ For Review ☐ Please Comment ☐ Please Reply ☐ Please Recycle

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Ruby - Here is the lay explanation.
Call with questions.

JDFI's mission is to find a cure for diabetes and its complications
through the support of research.

Lay Explanation of First Lady's Research Announcement

Type 1 diabetes (or insulin-dependent diabetes) results from a combination of inherited susceptibility (*i.e.*, genetic predisposition) and exposure to an environmental trigger (*e.g.*, a virus or environmental exposure, though the precise trigger or set of triggers is not known). The genetic predisposition is necessary for development of the disease, but is not the cause. The combination of genetic predisposition and environmental trigger results in a signal to the body's immune system to destroy the insulin-producing islet cells of the pancreas. The islet cells are responsible for production and regulation of the hormone insulin, which enables one to metabolize glucose and turn it into energy. People with Type 1 diabetes must take injections of insulin to stay alive.

This sequence of events – genetic susceptibility plus exposure to an environmental trigger, followed by an abnormal immune response – is common not only to Type 1 diabetes, but also to other so-called autoimmune diseases such as lupus, multiple sclerosis and rheumatoid arthritis. With each of these diseases, the destructive immune response affects different body organs. If we were to discover how to eliminate or control this autoimmune response, we could presumably treat many different autoimmune diseases.

In recent years, scientists have discovered that they can produce very specific "blocking" antibodies that can prevent the autoimmune response from occurring while leaving the rest of the immune system unaffected. This is called "tolerance induction", which consists of instructing the immune system to respond, or not respond, when a trigger is present. If the immune response is turned "off", the destruction of tissues such as islet cells can be avoided.

Applying this knowledge in experimental human clinical trials to learn more about which "blocking" antibodies are effective and the safety of such agents would represent a major advance in treatment and prevention of Type 1 diabetes and other autoimmune diseases. The NIAID research initiative is designed to foster collaborative clinical trials in autoimmune diseases, including Type 1 diabetes, with the goal of bringing these potential drugs into clinical use.

In addition, the ability to induce tolerance (or instruct the immune system not to respond destructively) is also important in preventing organ rejection following whole organ transplants. For example, people who currently receive kidney transplants must take highly toxic immunosuppressive drugs to prevent organ rejection. Although kidney transplantation is quite successful, the long-term use of immunosuppressive drugs can cause serious side effects.

Scientists have discovered certain blocking agents that show promise in stopping the immune system from rejecting an organ. This would permit transplant recipients to receive organs with specific treatments that would eliminate toxic side effects. This would be important not only for organ transplant recipients, but also for people with diabetes receiving islet cell transplants.

In a person who already has Type 1 diabetes, it is unfortunately too late to prevent the damage. One possible solution to restoring normal islet cell function is to transplant healthy insulin-producing islets into people with Type 1 diabetes. To date, these transplants have not been very successful in part due to the current need to use toxic immunosuppressive drugs. New drugs that are more targeted in blocking rejection and that produce no, or minimal, side effects would be a major scientific advance in organ transplants and islet cell transplantation for people with diabetes.

The NIAID research initiative is designed to carry out the necessary clinical trials in humans in order to learn which agents will be successful and possible side effects. The knowledge gained from these clinical trials will also be applied to all people suffering from, or at risk for, autoimmune disease, as well as those receiving whole organ transplants.

Prepared by Juvenile Diabetes Foundation International
6/4/99

OFFICE OF THE DIRECTOR
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES
NATIONAL INSTITUTES OF HEALTH

FACSIMILE TRANSMISSION

DATE: June 3, 1999

TO: Ms. Neera Tanden
Office of the First Lady
The White HouseFROM: Anthony S. Fauci, M.D.
Building 31, Room 7A03
31 CENTER DR MSC 2520
Bethesda, MD 20892-2520
Phone: 301 496-2263

OUR FAX #: 301 496-4409

TOTAL NUMBER OF PAGES BEING TRANSMITTED INCLUDING THIS COVER
SHEET: 3

REMARKS:

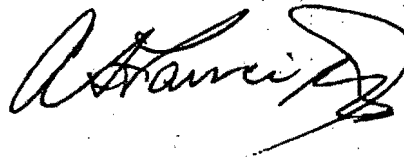
Dear Ms. Tanden:

As per our recent telephone conversation, I am attaching bullets related to the upcoming NIH activities on clinical trials that may have a potentially important impact on Diabetes. The details are discussed in the attached sheet. In brief, the NIH plans to award, before the end of FY1999, a multi-year (7 years) contract for a consortium of researchers to conduct clinical trials on immune tolerance. In lay language, this means that we will be developing and testing molecules/medications that can induce the immune system that would otherwise reject transplanted tissues to accept this tissue by rendering the recipient "tolerant" to the transplanted tissue, hence the terminology "immunologic tolerance". If successful, this will be extremely important since it may remove the requirement for life-long immunosuppressive drugs (which are always dangerous) to block rejection of transplants. In addition, it would allow a broader scope of tissues that are not exactly matched between donor and recipient to be potentially used in transplantation.

All of this must obviously be tested in well-designed clinical trials. However, this initiative is an important first step in that direction. If you have any questions, please give me a call.

Thank you and best regards.

Sincerely,



301-496-4461

Upcoming NIH initiative with potential benefits for Diabetes Research

- Just last week, the lay and scientific press reported the development and testing in non-human primates of a revolutionary new approach to organ transplantation. Called "Induction of Immune Tolerance," this new approach is an outgrowth of more than two decades of NIH-supported basic and pre-clinical research on the immune system. Tolerogenic therapies promise to increase the availability of acceptably matched organs for transplantation, diminish the chances of organ rejection, and eliminate the lifelong need for broad-spectrum immunosuppression following transplantation.
- To capitalize on these striking advances, the NIH (National Institute of Allergy and Infectious Diseases) plans to award in FY 1999 a multi-year contract valued at over \$120 million over seven years. This contract will support an international consortium of investigators who will conduct clinical trials of new tolerogenic approaches for transplantation and autoimmune diseases.
- The initial focus of the consortium (The NIAID Network for Clinical Research on Immune Tolerance) will be on:
 - (1) The development and clinical evaluation of new tolerogenic therapies that promise to diminish or eliminate the lifelong dependence of kidney and islet recipients on broad-spectrum immunosuppressive agents. The major limitations of currently used immunosuppressive agents are that they are costly, difficult to take, and are associated with heightened risks of serious infections and cancer; and
 - (2) Application of tolerogenic approaches to turn off and prevent the immune attack and destruction of tissues and organs that occur in all autoimmune diseases, including Type 1 diabetes.
- These clinical studies represent a critical first step in the possible discovery of a cure for children with immune mediated diabetes.

- Funding for this consortium was made possible, in part, by the recent Congressional interest in autoimmune diseases and the allocation of an additional \$30 M in FY1999 to NIH for research in this area.
- The NIAID Network for Clinical Research on Immune Tolerance is an example of how NIH is extending what the federal government can do through partnerships with private foundations (the Juvenile Diabetes Foundation International) and industry.

Public Affairs
1400 I Street, N.W., Suite 530
Washington, D.C. 20005
Phone: 202/371-9746
Fax: 202/371-2760

Fax

To: Ruby Shemir From: Larry Soler

Fax: Date:

Phone: Pages:

Re: CC:

☐ Urgent ☐ For Review ☐ Please Comment ☐ Please Reply ☐ Please Recycle

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See if this helps - This is some
of what is going on in the field.

**JDFI's mission is to find a cure for diabetes and its complications
through the support of research.**

New research could lead to
cure for juvenile diabetes

June 1, 1999

Web posted at: 11:46 p.m. EDT (0346
GMT)

From Medical Correspondent

Rhonda Rowland

MIAMI (CNN) -- Researchers at
the University of Miami successfully
transplanted insulin-producing cells
to six monkeys with diabetes,
bringing them one step closer to a
possible cure for humans.

The cell transplants, taken from a donor reas, enabled the monkeys to stay off insulin shots for a year or more, the scientists said Tuesday.

As part of the study, researchers tested a new drug known as anti-CD154, which appears to protect the insulin-producing cells, known as islet cells, from rejection.

"We've found a novel drug that may be a key part to actually be able to do islet cell transplants without the need for long-term use of anti-rejection drugs," said Dr. Norma Kenyon of the Diabetes Research Institute at the University of Miami.

The findings will soon be published in the medical journal Proceedings of the National Academy of Sciences.

"It's too early to say if our research will lead to a cure, and we don't want to raise false hopes," said Kenyon. "But it could be part of an eventual cure."

Type 1 diabetes, also known as insulin-dependent and juvenile diabetes, is the most severe form of the disease and can lead to complications affecting almost every part of the body. Most patients develop it during childhood.

Anti-rejection drugs often harmful

Researchers have been searching for ways to carry out islet cell transplants without the need for long-term anti-rejection drugs.

"We don't want patients to trade insulin for these toxic drugs," said Dr. Hugh Auchincloss, director of the Juvenile Diabetes Foundation Center for Islet Cell Transplantation at Harvard Medical School.

"More than 300 islet cell transplants have been done in the last decade, but only a handful of patients have been able to stay off of insulin for a significant amount of time," he added.

While Auchincloss is excited about the new research, he pointed out that a number of questions need to be answered.

"For instance, can the islet cells survive long-term once the monkeys are taken off the new drug?" he asked.

Since diabetes in monkeys is not the same as Type 1 diabetes in humans, medical experts are not sure how well anti-CD154 will work on humans. Researchers at the University of Miami hope to soon test the new drug on humans with insulin-dependent diabetes.

Diabetes Drug Is Promising In Islet-Cell Transplants

By LAWRENCE K. AITMAN

Scientists reported yesterday that they had cured diabetes in monkeys by giving them transplants of insulin-producing cells along with an experimental drug that prevented rejection of the donor tissue.

The findings are an important advance in diabetes research, "strikingly different" from all previously tested strategies, and a step toward the ultimate goal of curing diabetes in humans, the scientists said. Their findings involving the experimental drug known as anti-CD154 are to be reported this year in *The Proceedings of the National Academy of Sciences*, which made the paper available ahead of publication.

Anti-CD154 is an artificially made antibody intended to thwart a key part of the immune system to ward off foreign tissue.

Experimental trials of the therapy in humans have been approved by ethics committees and the Food and Drug Administration. They are expected to begin soon with support from the National Institutes of Health, said the researchers and the drug's manufacturer, Biogen of Cambridge, Mass. But they refused to give details like the starting date of the trial or the number of patients to be included.

Dr. Norma S. Kenyon, the lead author of the report, from the University of Miami and the Navy, said the findings represented the most promising advance she had seen in 20 years.

"This may be something that is part of an eventual cure, but we do not want to mislead people by saying we have a final answer at this point and I do not want to raise false hopes," Dr. Kenyon said in an interview.

But Dr. Camillo Ricordi, a co-author of the report, said, "It is a major reason for cautious optimism."

The islet cells, which were transplanted into the monkeys, are the parts of the pancreas gland that produce insulin to control blood sugar. Islet-cell transplants have been carried out in more than 300 people in recent years but with limited success, Dr. Ricordi said. After a year, the graft has functioned in fewer than 35 percent of such patients and fewer than 10 percent have been able to stop taking insulin. Thousands more people have received transplants of the entire pancreas gland, located deep in the abdomen.

However, a major problem with both islet-cell and pancreas transplants is that each recipient would have to take a combination of powerful anti-rejection drugs for the rest of his life. The drugs increase the risk of infection and other complications, and can also promote development of diabetes, even in those without the disease.

To the Miami team, the most exciting finding was that they could safely prevent rejection with only one drug, not a cocktail of drugs. Also, the animals grew normally and suffered no infections or other complications. Anti-CD154 did not produce diabetes in the monkeys.

The experiments involved seven monkeys that were made diabetic by removing their pancreas glands.

Seven monkeys received islet cells from other monkeys even though they were severely mismatched in blood and immune tests. The cells were injected through a tube into blood vessels leading to the liver where the cells took up residence. The procedure took about a half hour and could be done as an outpatient procedure in humans, Dr. Ricordi said.

Six monkeys received injections of anti-CD154 on the day before the islet-cell transplant, the day of the transplant and four additional times in the next 28 days. Then the monkeys received anti-CD154 each month thereafter. Islet-cell function improved over time.

The experiment is intended in part

to test whether the islet cells will continue to thrive after anti-CD154 is stopped, a year after the transplant. Three of the six monkeys that have lived for such a period no longer require injections of insulin or anti-CD154. Anti-CD154 will also be stopped when the remaining three reach the one-year anniversary.

Unanswered is the length of time that the recipients of the anti-CD154 islet-cell therapy can stay off insulin, the researchers said.

The seventh monkey served as a scientific control and did not receive anti-CD154. That animal began rejecting the islet cells six days after the transplant and needed daily insulin treatment.

In another paper published last week in the journal *Diabetes*, Dr. Kenyon's team reported that anti-CD154 could reverse individual episodes of islet-cell rejection in animals if and when they occurred.

Dr. Ricordi said islet-cell transplants had survived for more than eight years in a human liver.

A spokesman for the American Diabetes Association did not return a phone call.

Anti-CD154 has been tested for safety in a small group of people, a spokeswoman for Biogen said. It has also shown promise among monkeys that have received kidney transplants.

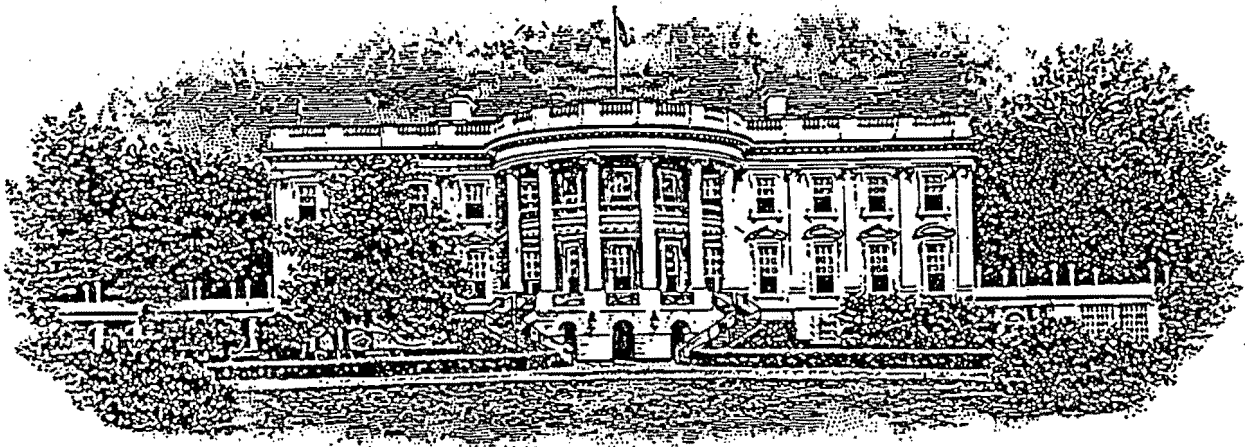
NY Times
6/3/99

Don't

First Lady HRC will ~~also~~ hold an event
with

The White House

DOMESTIC POLICY COUNCIL



FAX COVER SHEET

To: Larry Sotter

Phone: _____ Fax No: 371-2760

From: Ruby Shamir

Phone: _____

Comments: _____

MS-y

Record Type: Record

To: Ruby Shamir/OPD/EOP@EOP
cc:
bcc:
Subject: Re: Juvy Diabetes 

Mary

Fabulous organizing -- here's what I have:

1. I left a message with Ann, I expect she'll call in the am
2. Good work on set up of the room. Let's set up a conference call for 1 or so, so we can talk about a backdrop from the group. They had something in mind last week, let's see if that will still work.
3. Can you call Dr. Fauci's office and find out if they want to send people -- we'll probably be able to do as many as they want. Also, HHS' Liz Summi was supposed to call you with names from HHS. →
4. Make sure we talk to Toby or Julie about the press for this -- we're not expecting too much.

690-7431

I'll be here bright and early because of the GMA interview, so let's talk first thing about everything else we need to get done. Thanks very much.

Ruby Shamir



Ruby Shamir
06/03/99 05:41:45 PM

Record Type: Record

To: Neera Tanden/WHO/EOP@EOP
cc:
bcc:
Subject: Juvy Diabetes 

Sure.

I want to make sure I have everything right here with regard to what I am responsible for and what needs to get done! Let me know what you think of this:

- I will have a draft of the briefing for you to review by tomorrow around noonish
- Do we need to invite NIH people [for audience, or on stage] and add them to acknowledgments?
- Laura suggested that we find out/make sure that we know that MTM does not talk too much/at all about the Children's Congress so that HRC could.
- Can you send me the diabetes accmps when you get them? and also, have you been able to talk to Ann at NIH? I have been working on the paragraph, but I am not sure of my technical language.
- With regard to the room, I will get it set up with podium, 4 chairs on stage etc. do we need a backdrop? I am not sure if I am the person to think about these things, but there is no advance person or anything.
- I can set up a call with JDF people. Let me know if I should.

-- I can set up a quick conf call/walk through for tomorrow.

I think that's it. Unfortunately, I have to go to class, but page me if you need anything, and I will be in early tomorrow.

Neera Tanden



Record Type: Record

To: Ruby Shamir/OPD/EOP@EOP

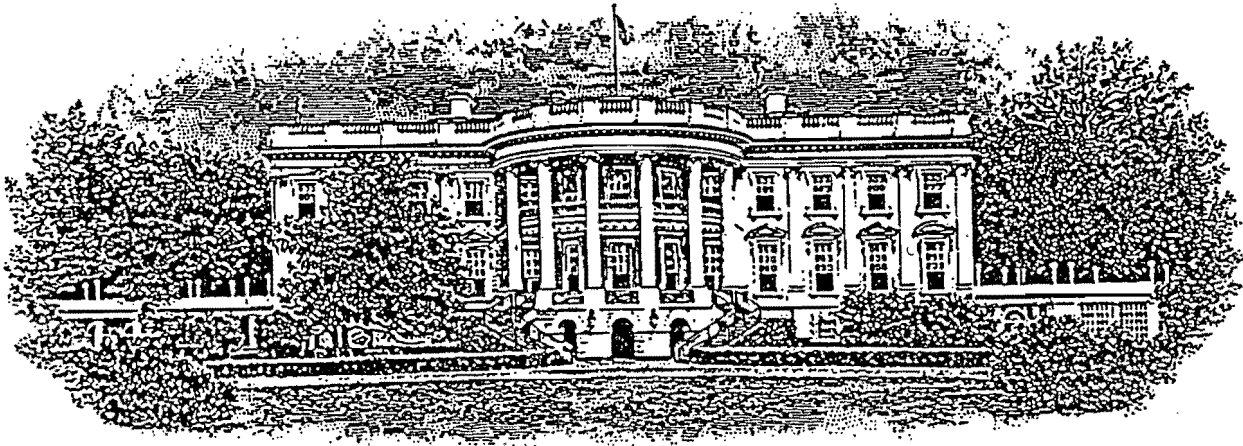
cc:

Subject:

Can you get a holding room for Mary Tyler Moore for the event -- it can be room 476 or something-

The White House

DOMESTIC POLICY COUNCIL



FAX COVER SHEET

To: Laura Schiller

Phone: _____ Fax No: 65709

From: Ruby

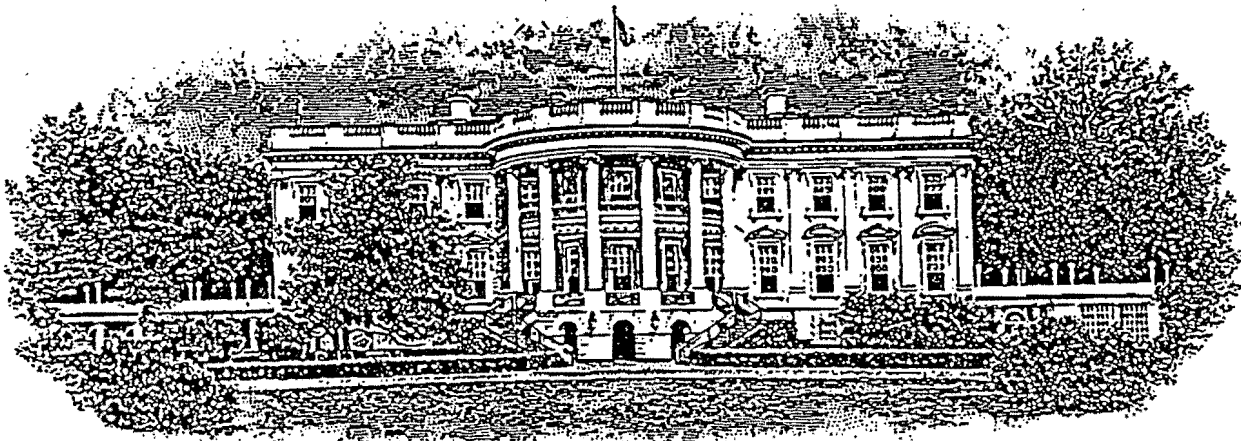
Phone: _____

Comments: The fox disobeys president & just had
a great conversation & they are sending this
"Mug" with a

Other speakers to Kay
Parks

The White House

DOMESTIC POLICY COUNCIL



FAX COVER SHEET

To: DON ROBUSHKY

Phone: _____ Fax No: 301-496-0017

From: Neera Tanden & Ruby Shamir

Phone: 202-456-5696 or 456-6275

Comments: The First Lady will be making this announcement on
Monday. Can you help us put it in lay terms for her
remarks? Thanks

JUVENILE DIABETES

June 7, 1999

NIH Funding

The FY 2000 Budget proposes \$15.9 billion for NIH -- a \$320 million (2%) increase above the FY 1999 level. Last year, the President proposed that the funding for the National Institutes of Health increase by nearly 50 percent over five years. The FY 2000 Budget puts us on path to meet this commitment.

From 1997 to 1999, NIH increased funding for diabetes-related research by approximately 40 percent, from \$320 million to \$449 million. The FY 2000 Budget for NIH proposes \$460 million for research on diabetes. In addition, the Administration strongly supported a dedicated stream of funding -- \$300 million over five years -- for diabetes research, prevention, and related health services in the Balanced Budget Agreement. This money will support research at NIH on juvenile diabetes.

Juvenile Diabetes Facts

- Juvenile Diabetes, or Type I diabetes, is caused by autoimmune destruction of insulin-producing beta cells in the pancreas. This process leads to a deficiency of insulin, and as a result individuals with Type I need to take injected insulin. Advocates for diabetes research -- including the Juvenile Diabetes Foundation (JDF) -- argue strongly that insulin-injection is not a cure for diabetes, and that research is vital to find a cure for the disease.
- Diabetes affects 16 million Americans, or between 6 and 7 percent of the population. Of these, one-third do not even know they have the disease.
- The number of people with diabetes continues to grow by nearly 800,000 persons each year, and will reach 23 million in 10 years, unless drastic changes occur.
- Over 13,000 new cases of Type I diabetes are diagnosed each year in the U.S. in children and young adults under age 20, representing about .3 percent of this population.
- Children with diabetes are most prone to acute complications such as coma, and must endure lifelong treatment and related physical and psychological complications. The prevalence of Type I diabetes in the pediatric population has risen steadily over the last 50 years.
- Diabetes disproportionately impacts children, women, the elderly, African Americans, Hispanic Americans, Native Americans, and Asian and Pacific Islander Americans.
- All forms of diabetes can cause blindness, kidney failure, changes in the ability of nerves to function normally, heart attacks, strokes, coma, and other complications.
- At a time when medical research is having a major impact in reducing death rates due to cardiovascular disease and stroke, the age-adjusted death rate due to diabetes has increase 30 percent.

- Life expectancy averages up to 15 years less in people with diabetes.
- In 1997, conservative estimates placed the cost of diabetes in the U.S. at \$98.2 billion annually, and based on modest calculations, the number is estimated at \$105 billion today. More than one of every ten U.S. health dollars, and about one of every four Medicare dollars, is spent for the care of people with diabetes.
- Maternal mortality, which was once greater than 50 percent in pregnant women with diabetes, has been nearly eliminated by insulin-replacement and other therapies. Perinatal infant mortality rates have fallen from more than 50 percent to three to five percent in pregnancies complicated by preexisting diabetes.

Diabetes Research

In 1998, the Diabetes Research Working Group (DRWG), established at the direction of Congress, first convened to develop plans for diabetes research. The DRWG notes extremely promising scientific prospects, and urges bold action, and strong financial support of research, that could save thousands of lives. The Strategic Plan for diabetes developed by the DRWG sets the goal of developing new approaches for prevention, cure, and improved treatment of all forms of diabetes and their complications.

[Source: "Conquering Diabetes: A Strategic Plan for the 21st Century, Diabetes Research Working Group, 1999]

* I am pleased to kick off the first ever Juvenile Diabetes Foundation Children's Congress and welcome the 100 children with diabetes who will come to Washington, DC to advocate for a cure.

* I want to recognize a few special people in the audience whose hard work and dedication towards curing diabetes has helped make the JDF Children's Congress possible. Tommy Solo is a nine-year old from Boston who last year asked his mom why can't the kids who have diabetes come to Washington and tell the government to support research to find a cure. Tommy, see how your idea has become a reality! Also, I want acknowledge the work of Sandra and Alan Silvestri and their eight-year old son Joey. The Silvestri family is chairing the JDF Children's Congress and for the better part of a year have led and shaped this historic event. Alan, who is an Academy Award nominated composer, even wrote a beautiful song, "Promise to Remember Me" that has become the theme of the JDF Children's Congress.

* Although insulin does provide life support for people with diabetes, it is not a cure. The juvenile diabetes research announcement that I am making today will help put us on the fast track towards a cure for this disease which affects more than 1 million Americans and targets the young.

* Children who have diabetes suffer greatly. While these kids look healthy from the outside, they require multiple injections of insulin each day, must prick their fingers to test blood sugar levels on a regular basis, and must live a carefully regulated lifestyle to ensure that their blood sugar levels don't drop too low possibly leading to a coma or even death, or become too high putting the child at risk for the long-term health consequences of the disease. Kids with diabetes need more to look forward to than an uncertain future...they need to believe that a cure is possible and today's announcement and our commitment for the future should give every child and everyone else who suffers from diabetes the knowledge that we will do everything possible to find a cure as quickly as possible.

* Today's announcement is only one step in the process necessary to move us to a cure. Our Administration two years ago signed into law legislation which provided \$150 million over five years specifically for juvenile diabetes research. In the future, we will continue to aggressively fight this disease by implementing the recommendations of the Diabetes Research Working Group which has produced a blueprint to move us down the path towards a cure.

* The child delegates of the JDF Children's Congress will bring thousands of letters to Capitol Hill on June 22 to explain the perspective of life of a child with diabetes. Their mantra, "Promise to Remember Me," will be a powerful call to action for all of us in Washington, DC to remember children with diabetes and their struggle and the urgency of finding a cure for diabetes.

* I was touched by a letter I received from Joey Silvestri of Carmel California. Joey wrote the following, "Every night my little brother and I say our prayers. My little brother James always prays for a pooky man toy. My sister prays for good grades. But I pray for a cure for diabetes. My mom says I can ask for other things but I don't want anything as much as I want a cure for diabetes." Through the voices of young advocates like Joey and the work that our Administration has done and is committed to do in the future, we will answer Joey's prayers.

* The JDF Children's Congress delegates will bring their message to Capitol Hill June 22 by testifying at a Senate Appropriations Subcommittee hearing, singing the JDF Children's Congress song, "Promise to Remember Me," on the Capitol steps, and by meeting with their own representatives and senators to ask for their commitment in finding a cure for juvenile diabetes.

* Bill and I are committed to do everything that we can to ensure that everything possible is being done to find a cure for diabetes and to ensure that the NIH is leading the effort to cure diabetes and its complications. We "promise to remember" each of the children who come to Washington, DC and the millions of Americans that they will represent.

→ Time
→ Her

White House - JDF Children's Congress Event
June 7, 1999

Proposal - Meeting - May 27, 1999

I Purpose

- announce kick-off of the JDF Children's Congress, June 20 - 22, 1999
- major research announcement → new initiatives - on fast track
- reinforce prevention and early detection messages - to cure

II Speaker outline

- Mrs. Clinton
 - welcome
 - kick-off JDF Children's Congress
 - the President and Mrs. Clinton are Honorary Patrons
 - Children advocating for themselves
 - research announcement

- Mary Tyler Moore - JDF International Chairman
 - JDF background
 - her personal story of diabetes

- Erskine Bowles
 - personal story, 2 sons with diabetes

- JDF Children's Congress delegate from New York
 - personal story, living with diabetes
 - need for a cure

III Logistics (requested)

- time?
- location - East Room?
- invitations, number of people? (East Room - 100 guests)
- reception request
- photo opportunities with Mrs. Clinton for participants

IV Guests

- children with diabetes - 30
- JDF volunteers -
- members of congress →
- celebrities connected to the cause →
- staff members 7

→ WH photographers

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child

large -
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V

Press requests

- bring in photographer / ~~videographer~~
- lighting for t.v.
- listing in White House day book
- listing on White House webpage → ask
- technical needs – press riser, moult box...

check on whether
videographer

Time
→ Here

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→ ask



Juvenile Diabetes Foundation International
The Diabetes Research Foundation

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NEWS NEWS NEWS NEWS NEWS NEWS

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Juvenile Diabetes Foundation International

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**New Multimillion Dollar Center to Create a Fast Track
for Diabetes Cure Focused on Islet Cell Transplantation**
Diabetes Research Initiative Funds 32 Scientists

BOSTON, MA—September 10, 1998—Hoping to put a cure for Type 1 diabetes on a fast track, the Juvenile Diabetes Foundation International (JDF) and Harvard Medical School have focused an unprecedented combination of experts in diabetes and many other scientific fields on finding a cure for diabetes.

The new JDF Center for Islet Cell Transplantation at Harvard Medical School will launch an ambitious multidisciplinary attack on one of diabetes' most tantalizing yet frustrating fields of research—replacing the body's natural insulin-producing cells, which have been destroyed in people with Type 1 diabetes.* The Foundation will provide approximately \$20 million over the next five years to the researchers, who include Harvard faculty at nine institutions.

"We at JDF are proud to see our dream of successful islet cell transplantation without immunosuppression put on the fast track," said JDF Chairman of the Board John J. McDonough. "As someone who has had Type 1 diabetes for 56 years, and as the parent of a daughter with Type 1, I want to assure her, and all those who suffer from diabetes, that we are doing everything possible to find the cure.

"For 28 years the tireless support of our volunteers has helped advance diabetes research worldwide. Now, thanks to the Florence DeGeorge Islet Research Challenge Grant, which provided initial funding for this Center, we are able to fund this highly collaborative, goal-oriented approach, which we hope will act as a model for all of our research programs," added McDonough.

The new Center is made possible through a \$5 million pledge named the Florence A. DeGeorge Islet Research Challenge Grant. The DeGeorge family foundation has provided these funds to help find a cure for diabetes and its complications through the support of research. "Our concern has always been to accelerate a cure for this devastating disease through islet cell research. We believe that the initiative with the Harvard Medical School and associated researchers points the way in accelerating islet cell research and transplantation as a potential way of accomplishing our goal," said Lawrence DeGeorge. "My wife, Florence, and our whole family are pleased to be able to make this contribution to this important and innovative Center."

—more—

Diabetes kills one American every three minutes and reduces life expectancy by as much as one-third. It consumes one out of every eight U.S. health-care dollars. Millions of people with diabetes—including many infants—depend on several insulin injections a day to stay alive, while facing a future of severe disability and premature death.

The new center's goal is a cure. The 32 researchers at the JDF Center for Islet Cell Transplantation at Harvard Medical School will work collaboratively to discover how to transplant insulin-producing islet cells without the recipients needing a lifetime of immunosuppressants, which can have even more devastating long-term effects than the disease itself.

Until now, many of these world-renowned researchers had not applied their expertise directly to diabetes. "My entire career has been focused on basic developmental biology, until now," said Doug Melton, professor of molecular and cellular biology at Harvard University, Howard Hughes Medical Institute investigator, and one of the Center's lead researchers. "My seven-year-old son, Sam, has diabetes and I think the new Center provides us with the chance to extensively and collectively study—and hopefully find a cure for—this chronic and complex disease."

The Center will follow a business-oriented model to tackle the major obstacles that still block safe, workable islet cell transplants. Researchers, their projects, and the Center will receive annual performance reviews; funding is contingent upon progress achieved towards the Center's goals; and attendance at monthly think-tank style meetings is required to identify promising approaches and ensure continued coordination. Collaboration means individual work will be guided by both positive and negative outcomes of others.

"The most interesting and productive science today is multidisciplinary," said Harvard Medical School Dean Joseph B. Martin. "The level of detailed knowledge in most fields is now so vast that the next advances will come through intertwining knowledge from diverse fields. This work in Type 1 diabetes is a great example of the opportunities for multidisciplinary science when the broad Harvard medical community collaborates."

Key gaps in diabetes research knowledge were identified last year when a JDF task force mapped out what was known about the disease, the current state of diabetes-related research, and its founders' main goal of a cure in their children's lifetime. Center scientists will focus on major strategies to close knowledge gaps in four high-priority areas identified in the JDF maps: specifically, islet transplantation, tolerance induction, autoimmunity, and expansion of islet cell supply.

In order to cure Type 1 diabetes via islet cell transplantation, researchers have to figure out how to conquer two different types of immune problems, autoimmunity and tolerance. They must turn off the autoimmune response that destroyed the patients' original islet cells so that the new ones aren't attacked; they also have to create tolerance to the foreign cells that would otherwise be destroyed by the type of immune response that attacks any transplanted organ. Scientists then must find a plentiful source of replacement islet cells, from tissue culture, animals, or genetic manipulation.

Most of the center's 32 researchers are Harvard faculty at the University, Medical School, School of Public Health, and Harvard-affiliated Boston medical institutions, such as Beth Israel Deaconess Medical Center, Brigham and Women's Hospital, Dana-Farber Cancer Institute, Joslin Diabetes Center, and Massachusetts General Hospital. Additional expertise was recruited from Charlestown, Mass.-based Diacrin, Inc., the Massachusetts Institute of Technology, and the University of Minnesota.

Scientists are optimistic about the progress possible with this mission-oriented center, but they remain cautious about building up false hope in patients. "Diabetes presents a set of large and complex problems," said Center director Hugh Auchincloss, Jr., associate professor of surgery at Harvard Medical School and transplant surgeon at Massachusetts General Hospital. "But huge progress has been made in the last five years, and there's every reason to believe that the rate of progress will continue and accelerate."

Because other diseases share some of the same underlying problems, advances toward a cure for diabetes may also help people with arthritis, lupus, and multiple sclerosis.

JDF is the leading non-profit, non-governmental funding source for diabetes research in the world. "JDF was founded by the parents of children with diabetes who promised to find a cure in their children's lifetime," said McDonough. "We will keep that promise."

* Diabetes is a chronic, genetically determined, debilitating disease affecting every organ system. Insulin is not a cure, but merely life support. Type 1 diabetes is caused by the autoimmune destruction of the insulin producing cells of the pancreas and is usually, though not always, diagnosed in childhood.

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The Juvenile Diabetes Foundation International (JDF) was founded in 1970 by parents of children with diabetes who were convinced that diabetes could be cured through research. They were and still are determined to make that cure happen in their children's lifetime.



Juvenile Diabetes Foundation International
The Diabetes Research Foundation

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The Juvenile Diabetes Foundation Center for Islet Cell Transplantation at Harvard Medical School

How Is the Center Unique?

- The goal of the new Juvenile Diabetes Foundation Center at Harvard is to cure Type 1 diabetes by pancreatic islet cell replacement. More specifically, the goal is to achieve successful islet transplantation for people with Type 1 diabetes without the need for long-term immunosuppression, which can have complications worse than the disease.
- The Center is organized as a collaborative, coordinated effort. It is science with a mission. This approach can only be pursued if the funding mechanisms and administrative structure are established to promote interaction and collaboration between investigators. Only this drives research toward a well-defined goal.
- The Center is broadly multidisciplinary, pulling together researchers with many different perspectives on the disease.
- Until now, many of the 32 world-renowned researchers, who include Harvard faculty from nine institutions, have not applied their expertise directly to diabetes.
- The Center is organized on a business-world model:
 - All long-term research goals are defined by the Center, rather than by the individual researchers.
 - Researchers will receive annual performance reviews.
 - Funding is contingent on progress achieved toward solving targeted problems related to islet cell transplantation.
 - Attendance at monthly think-tank style meetings is required to identify promising approaches and ensure coordinated research.
- An outside panel of internationally recognized diabetes experts, working with JDF volunteer leaders, will conduct critical reviews of the Center's work. A different outside expert will address the researchers each quarter.

What Will the Center Do?

The Center will address four main obstacles that must be overcome to restore normal blood sugar levels in people with Type 1 diabetes, through islet replacement which are:

1) ISLET TRANSPLANTATION

Replacement of islet tissue will not ultimately involve whole organ pancreas transplantation, which is too cumbersome, too invasive, and is associated with too many complications. Further progress in refining the optimum technical approach to islet cell transplantation is an essential step along this path to a cure for people with Type 1 diabetes.

2) TOLERANCE INDUCTION

Even if technical problems of islet transplantation are overcome, it will still not be appropriate therapy for most people with Type 1 diabetes. This is because the immunosuppressive drugs currently needed for transplant survival can themselves be quite toxic and is associated with potentially devastating long-term side effects and complications. Thus, achieving tolerance to donor tissue without the need for toxic immunosuppression is key.

3) AUTOIMMUNITY

Even if transplantation of foreign tissues could be achieved without immunosuppressive drugs, evidence strongly suggests that the transplanted islets will still be destroyed—causing a recurrence of diabetes—unless treatment of the underlying autoimmunity is provided. People with Type 1 diabetes have previously developed an immune response to islet cells. This response must be blocked if new islets are to survive in these people.

4) EXPANSION OF ISLET SUPPLIES

Islet transplantation for large numbers of people with Type 1 diabetes will require the use of cells obtained from a variety of sources or from islet cells grown in culture since the number of potential human donors is not sufficient. Thus, finding a cure requires more progress in developing alternative islet cell resources and/or growing islet cells in culture.

Some Center laboratories will serve as a world-wide resource for other researchers working toward a cure. They will supply islet cells, a unique mouse model for diabetes, vectors for getting new genes into cells, and techniques for identifying key immune system genes.

How Does the Center Fit Into JDF's Overall Research Plan?

The Juvenile Diabetes Foundation Center at Harvard is a model for future JDF centers. Since JDF's founding in 1970, our volunteers have focused on ways to achieve successful islet transplantation as a potential cure. It is only with the progress made from its intense investment of time and resources over the years that JDF is now able to fund such a large mission-oriented Center. The Center also directly responds to JDF's call for a bold, new plan to speed research advances to people with diabetes.

This cutting-edge effort at Harvard is a direct outcome of JDF's innovative mapping of diabetes completed by its Research Task Force in 1998. This task force received input from leading scientists worldwide, and pro-bono guidance from McKinsey & Co. The maps spotlighted gaps in research knowledge. The objective of JDF sponsored research is to close gaps in high-priority areas and accelerate progress down the many potential paths to a cure. The new \$20 million Center at Harvard, has been designed to bridge gaps along one of these paths. Based on the mapping and results of the Research Task Force, JDF intends to fund additional centers worldwide to focus on similar and other priority areas.

The new Center at Harvard complements other JDF research efforts. JDF is the leading non-profit, non-governmental funder of diabetes research in the world. The Foundation has targeted several pathways to find a cure for Type 1 diabetes and its complications. The new Center at Harvard was designed to accelerate progress down one of those paths. Additional high priority areas of JDF research support include:

- Prevention of Type 1 diabetes through a vaccine given at birth, at the time a child is diagnosed, or later in the course of disease.
- Bioengineering of insulin-producing cells.
- Autoimmunity not related to islet transplantation.
- Preventing or reversing the complications of diabetes.
- Bio-mechanical approaches to restoration of normal blood sugar.

FOR INFORMATION CONTACT:

Contact: Julie Kimbrough, 212-479-7536

New Islet Cell Transplantation Centers Boost Research on Diabetes Cure
*Juvenile Diabetes Foundation's Eight World-Class Programs Mean
More Research, Clinical Trials with Insulin-Producing Cells*

CHICAGO, May 18, 1999 – At the annual meeting of the American Society for Transplantation, the Juvenile Diabetes Foundation International (JDF) today announced a major boost towards a cure for Type 1, or juvenile, diabetes: eight new programs on human islet transplantation research. Funded by JDF grants totaling more than \$10 million, the programs will dramatically increase laboratory research on the insulin-producing cells, and put clinical trials of islet cell transplants on a fast track. JDF is the first foundation to organize a campaign of this size and scope aimed at generating new knowledge about human islet cells.

"About two years ago, JDF began a national initiative to jumpstart islet cell transplantation," said Robert A. Goldstein, M.D., Ph.D., JDF's Vice President for Research. Islet cells are the body's natural insulin-producing cells, which have been destroyed in people with Type 1 diabetes. Scientists have been tantalized for 25 years with the idea of curing diabetes by transplanting healthy islet cells, but also frustrated by the lack of progress. One major problem was a shortage of islet cells. "The result was that laboratory research was limited and clinical trials of cell transplants were few and far between," said Goldstein. "The new programs will help break through these barriers."

The JDF programs focus an unprecedented array of talent and resources on islet cell transplants as a diabetes cure. The eight programs—six in North America, and two in Europe—bring together the world's top researchers in the field and add investigators from a variety of disciplines who have not previously applied their expertise directly to diabetes. The programs will prepare and study more islet cells than ever before, and promote much more information sharing among clinical investigators and scientists. Most importantly, the programs mean researchers will be able to gear up for clinical trials a lot sooner.

"These programs are not just good news for diabetes research, but for transplantation research in general," said Goldstein. Clinical trials of islet cell transplants will let researchers do much wider testing of experimental new drugs that prevent the body from rejecting transplants. The new drugs don't shut down the whole immune system, but control a specific part of the body's immunologic graft rejection response (allograft rejection). The knowledge gained from these trials will help scientists understand how the new drugs can be used in heart, liver, and other transplant procedures.

One of the other major benefits of the JDF programs, according to Goldstein, will be quality control. "By developing common quality standards for islet cells that meet FDA regulations, the programs make it easier for one laboratory to prepare islets another laboratory can use," Goldstein said. "Quality control standards combined with greater information sharing will improve islet research and move us closer to successful human islet cell transplants," said Bernhard Hering, M.D., director of the JDF Islet Distribution Program at the University of Minnesota.

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"As someone who has Type 1 diabetes and who has taken more than 55,000 insulin shots to control my blood sugar and stay alive, I'm excited about the hope that these new programs bring," says John J. McDonough, Vice Chairman and CEO of Newell Rubbermaid Inc. and Chairman of the Board of JDF. "Because my daughter also has Type 1 diabetes and my grandfather died from the complications of the disease, no one knows better than I do how urgently we need a cure. I believe the men and women at these JDF programs will bring us closer to it."

All of the programs have begun or are about to begin approved research protocol trials, transplanting human islets into patients. In the next few years, if the protocol trials are successful, the programs will move toward clinical trials with a diverse range of diabetes patients.

The eight programs are:

- JDF Human Islet Distribution Program at the JDF Center for Islet Cell Transplantation at Harvard Medical School
- JDF Human Islet Distribution Program at the Diabetes Research Institute at the University of Miami
- JDF Human Islet Distribution Program at the Diabetes Institute of Immunology and Transplantation of the University of Minnesota
- JDF Human Islet Distribution Program at the Diabetes Research Training Center of Washington University
- JDF Human Islet Distribution Program at the JDF Center for Human Islet Transplantation in Seattle
- JDF Human Islet Distribution Program at the JDF/Medical Research Council Diabetes Research Network on Islet Transplantation at the University of Alberta, Canada
- JDF Human Islet Distribution Program at Beta Cell Transplant at Vrije Universiteit Brussel, Belgium
- JDF Human Islet Distribution Program at the University of Giessen, Germany

JDF is the world's leading nonprofit, nongovernmental funder of diabetes research. It was founded in 1970 by parents of children with diabetes. JDF's mission is to find a cure for diabetes and its complications through the support of research, and since its inception has given more than \$290 million to diabetes research worldwide. JDF awards research grants for laboratory and clinical investigations and sponsors a variety of career development and research training programs for new and established investigators. JDF also sponsors international workshops and conferences for biomedical researchers. Local JDF chapters offer information and other activities for families affected by diabetes. For more information, visit our website: www.jdfcure.org or call 800-JDF-CURE, ext. 536.

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JUVENILE DIABETES FOUNDATION INTERNATIONAL (JDF)
HUMAN ISLET DISTRIBUTION PROGRAMS

US. AND CANADA

JDF Human Islet Distribution Program at the JDF Center for Islet Cell Transplantation at Harvard Medical School

Gordon C. Weir, M.D., Director
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The JDF Human Islet Distribution Program at the JDF Center for Islet Cell Transplantation at Harvard Medical School is working to greatly expand the supply of human islet cells for research, so that investigators will have the islet cells they need, when they need them. The Harvard program is cooperating closely with other JDF centers to develop quality control approaches that will help all diabetes investigators. "Quality control and regular communication among centers will raise the quality of islet research and help improve the results of islet transplantation," says program director Gordon C. Weir. The JDF Islet Distribution program is part of the larger JDF Center for Islet Cell Transplantation at Harvard Medical School. That center's goal is to close knowledge gaps in islet transplantation, tolerance induction, autoimmunity, and expansion of the islet cell supply.

JDFI Human Islet Distribution Program at the Diabetes Research Institute at the University of Miami

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Miami, FL 33136
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cricordi@mednet.med.miami.edu

The DRI/University of Miami/JDF program is a regional center for islet cell distribution that has pioneered human islet isolation techniques. It has the distinction of being the first JDF-sponsored islet distribution program in the country. The program's goal is to enable investigators around the world to use islet cells in the laboratory and ultimately, in clinical research. The center has, for example, been shipping viable islets successfully, sending some shipments as far away as Australia. The center is also very successful in attracting researchers new to the field of diabetes research. "The program's activities are important because human islets are vital to so many aspects of the search for a diabetes cure," says Camillo Ricordi, M.D., program director.

JDF Human Islet Distribution Program at the Diabetes Institute of Immunology and Transplantation of the University of Minnesota

Bernhard J. Hering, M.D., Director
University of Minnesota Medical School
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420 Delaware Street, SE
Minneapolis, MN 55455-0392
(612) 626-5697
bhering@tc.umn.edu

The JDF Program at the University of Minnesota is providing diabetes investigators with human islets to support their search for a cure in a wide range of areas, including both treatment and prevention. To support clinical transplantation trials, the Minnesota program is preparing to provide institutions in its region with high-quality human islets that meet federal regulations and standards. In addition, in May, 1999 the University of Minnesota program will perform its first human islet transplants using islets from

the JDF program. "The goal of our program is to support laboratory research and clinical transplantation trials that are consistent with the mission of JDF: to find a cure for diabetes," says program director Bernhard Hering, M.D.

JDF Human Islet Distribution Program at the Diabetes Research Training Center of Washington University

Thalachallour Mohanakumar, Ph.D., Director
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The overall goal of the Washington University JDF program is to isolate islet cells from the human pancreas and make them available to researchers in laboratories all over the country. The center works to establish cost-effective protocols for islet isolation, train investigators in islet isolation and transplantation, and provide human islets for research. The primary objective is to understand diabetes and develop new strategies for its control and cure. "We continue to strive for the best isolation of human islet cells possible," says director T. Mohanakumar, Ph.D.

JDF Human Islet Distribution Program at the JDF Center for Human Islet Transplantation in Seattle

R. Paul Robertson, M.D.
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The JDF Program in Seattle includes an islet isolation and cell processing facility established at the Puget Sound Blood Center—a long-time leader in bone marrow and other tissue transplant research. The program supports studies of human islet cell transplantation at six research institutions, as well as research and clinical trials at the University of Washington, Swedish Medical Center, and Virginia Mason Hospital. The hospitals will use the Center's islet cells in a series of clinical trials. In the first trials, the hospitals will perform islet cell transplants using no steroids and reduced amounts of cyclosporin, drugs that can be toxic to islets. The second trials will attempt to improve transplant tolerance by transplanting bone marrow stem cells along with the islet cells. The third series of trials will attempt to use a unique monoclonal antibody, now being developed at Fred Hutchinson Cancer Research Center. "One attraction of this program is that Seattle has many excellent scientists and many of these talented people are working together on curing diabetes through islet transplantation," says program director R. Paul Robertson, M.D.

JDF Human Islet Distribution Program at the JDF/Medical Research Council Diabetes Research Network on Islet Transplantation at the University of Alberta, Edmonton, AB, Canada

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The JDF Program at the University of Alberta is providing researchers and clinicians at the University with human islets, and will provide islets to other research centers worldwide. The Edmonton group has pioneered cryopreservation of islets and has established a low-temperature bank for use in their clinical trials, as well as be used for research at various centers around the world. The program is also training islet cell investigators from around the globe. Investigators at the University are now carrying out clinical islet transplants in diabetes patients who do not yet have kidney failure. In preliminary studies using newer, safer, and more effective immunosuppressive drugs without any steroids, investigators have been

able to achieve more rapid early graft function with complete insulin independence. "The practicality of clinical islet transplantation is rapidly reaching the stage where it may now be applied safely – earlier in the course of diabetes," says clinical program director James Shapiro, M.D.

EUROPE

JDF Human Islet Distribution Program at Beta Cell Transplant at Vrije Universiteit Brussel, Belgium

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The JDF center in Brussels prepares human tissue and cells for use as grafts or in laboratories. It is now organizing a clinical trial of beta cell transplantation in close collaboration with research laboratories in Belgium, France, The Netherlands, Denmark, the UK and the US. "Islet transplantation in diabetic patients poses a number of complex questions; we're trying to find answers for some of them in our laboratories" says director Daniel Pipeleers, M.D., Ph.D. JDF makes this research possible by supporting preparation of human islet cells in the central facility in Brussels and collaborative projects in laboratories at the Vrije Universiteit Brussel, the Inserm Unit U457 in Paris, the University of Leiden, Uppsala University, and the University of Washington. More research centers have recently joined this program with the intention of developing ways to induce tolerance towards the beta cells and of producing more beta cells for clinical use.

JDF Human Islet Distribution Program at the University of Giessen, Germany

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49-641-99-42750
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The JDF Program at the University of Giessen supports both basic and clinical research on islet cell transplantation. Current methods allow scientists to "harvest" only about 50% of the islets from human pancreas. The investigators from the Giessen program are researching ways to raise that percentage, by improving methods of isolating the islet cells and strengthen their ability to survive in a petri dish. In clinical trials at the University, the islet cells are being used in research on ways to improve the ability of transplanted cells to survive in a new body. Almost 60 islet transplantations have been performed at Giessen in patients with Type 1 diabetes mellitus, with an average of about 15 a year. "We like to see ourselves as a teaching center, both for the process of isolating islet cells and for patient treatment," says Mathias Brendel, the University of Giessen's coordinator of clinical and experimental islet transplantation. "To help find a cure for diabetes, we will continue to explore alternate beta-cell sources, and to research ways to isolate, strengthen and transplant human islet cells," added director Reinhard Bretzel, M.D., Ph.D.

JDF is the world's leading nonprofit, nongovernmental funder of diabetes research. It was founded in 1970 by parents of children with diabetes. JDF's mission is to find a cure for diabetes and its complications through the support of research and since its inception has given more than \$290 million to diabetes research worldwide. For more information, visit our website: www.idfcure.org or call 1-800-JDF-CURE, ext. 536.

THE
JDF
Children's Congress

"Promise to remember me..." Children with diabetes, advocates for a cure.

March 23, 1999

Ms. Neera Tanden
Office of the First Lady
100 Old Executive Office Building
Washington, DC 20500

Dear Neera:

It was a pleasure meeting with you on Friday to discuss the possibility of the First Lady's participation in the Juvenile Diabetes Foundation's First Children's Congress. We know an event with the First Lady will draw attention to the plight of children who suffer from Type 1 (juvenile) diabetes and JDF's mission to find a cure for the disease. The event also will bring excitement and hope to the families across the country that are impacted by the disease. Mrs. Clinton's participation will provide encouragement that our government is working with JDF to find a cure.

As we discussed, we are requesting an event with the First Lady to kick off the JDF Children's Congress—an historic gathering of 100 children with diabetes who will make a pilgrimage to Washington from their homes throughout America to convey a heartfelt plea to Washington decision-makers to help fund research for a cure for diabetes. We recommend scheduling the event with the First Lady one to two weeks prior to the Children's Congress at her convenience since she will be out of town during the actual event on June 20th - 22nd.

The event could be held in the East Room of the White House. It could focus public attention on a number of possible initiatives including new research findings and consumer messages such as the importance of early detection of Type 1 diabetes. We have identified several initiatives that could be announced at the event:



Juvenile Diabetes Foundation International
The Diabetes Research Foundation

1. Research Announcement

Until recently, diabetes research at NIH grew very slowly. This has resulted in years of missed opportunities and a significant slowdown in progress toward a cure or new treatments for diabetes and its complications. Between fiscal year 1988 and fiscal year 1997, the NIH budget grew by nearly 100 percent while NIH-supported diabetes research grew by only 31 percent.

Through the work of Erskine Bowles and other leaders, things have begun to change. Beginning in fiscal year 1996, diabetes research at NIH began to grow faster than the overall NIH average. While this is making a significant difference in our ability to invest funds in areas that were neglected in the past due to insufficient resources, more can be done. A congressionally mandated report released last February by the Diabetes Research Working Group (DRWG) has recommended an NIH diabetes research budget of \$827 million in fiscal year 2000 to take advantage of missed research opportunities. This would be a substantial increase over the \$450 million currently projected for diabetes research at NIH in fiscal year 1999.

The attached chart provides funding trends over the past twenty years for diabetes research at NIH. Please note that this chart and the other figures I have provided include all research that NIH has designated as diabetes or diabetes-related. The amount of research associated with just Type 1 diabetes is substantially smaller.

We believe that our proposal to announce the creation of regional centers for islet cell replacement—that was sent to your office last week—could provide a unique research-angle announcement. This idea or an alternative one would be a key part of our desire to give all children participating in the JDF Children's Congress—both in Washington, DC and at home—the sense that their advocacy is leading to more research to move us closer to a cure.

2. Prevention/Vaccine

The development of a vaccine to prevent diabetes in future generations and to prevent its recurrence in persons with the disease would be a major advance. An announcement regarding a research initiative or investment in this area could be part of the event.

Alternatively, the First Lady could promote the national effort now underway to prevent the onset of Type 1 diabetes in future generations of Americans. The Diabetes Prevention Trial (DPT) screens relatives of individuals who have Type 1 diabetes. If a blood test shows that those screened are beginning to show signs of developing the disease, they can enter a trial to see if certain strategies may delay onset of diabetes compared to a control group.

Tanden, page 3

3. Early Detection

Every year, an unknown number of children with Type 1 diabetes die before they are diagnosed with the disease. Anecdotal evidence shows that this number may be larger than previously thought. In addition, a substantially greater number of children are close to death or in comas before they are diagnosed.

As children with diabetes are being diagnosed at earlier ages than ever before and as the rate of diabetes rises, better education about the symptoms of the disease could help American families diagnose the illness earlier rather than face a crisis. The First Lady could use the JDF Children's Congress to tell the story of a family whose child was close to death and what the warning signs are for diagnosis.

To round out the event, we could assist in securing the participation of JDF children with diabetes, JDF celebrities (including Mary Tyler Moore and others), congressional supporters of diabetes research, and NIH Director Harold Varmus among others. We also recommend that Erskine Bowles be invited to attend the event. As you know, Mr. Bowles is a former President of the Juvenile Diabetes Foundation International, and has two sons with Type 1 diabetes (his second son, a junior at Princeton, was just diagnosed this year).

We are delighted at the prospect of working with you and the First Lady's office on this event! We believe the children who attend the JDF Children's Congress, as well as all those who have Type 1 diabetes, will be gratified and encouraged to see how much attention the Clinton administration is focusing on curing diabetes.

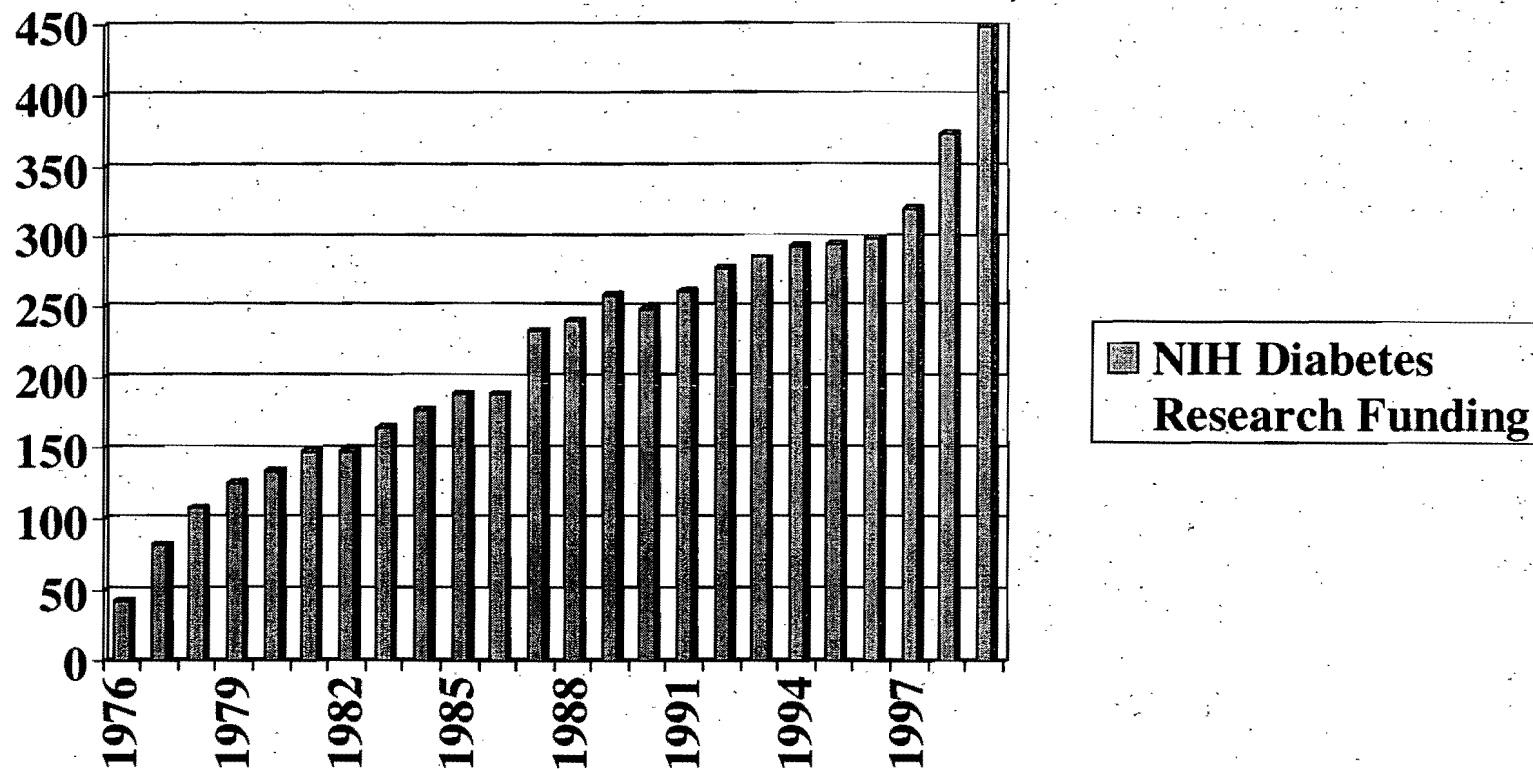
We look forward to our next meeting or conference call to plan next steps. Please call me at any time for additional information or to provide further assistance. I can be reached at 202-371-9746 x. 12.

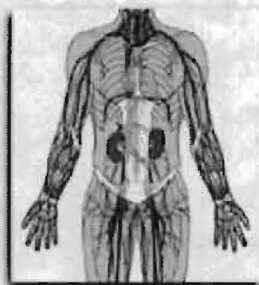
Sincerely,



Lawrence A. Soler
Senior Legislative Counsel

NIH Diabetes Research 1976 to 1999 (in millions)





Diabetes Overview

**NIDDK**

National Diabetes Information Clearinghouse

Publications**NIDDK**

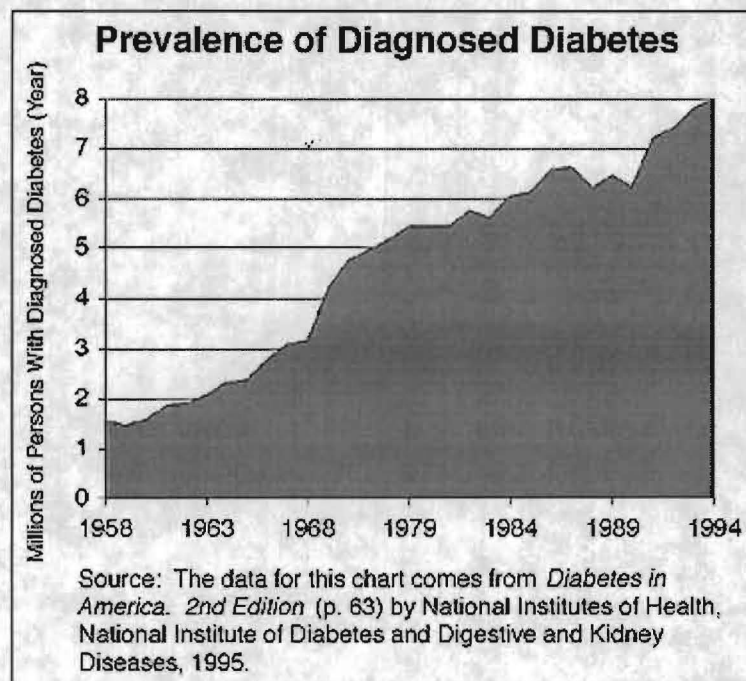
Also see:

Easy-to-Read
Do Your Level
Best: Start
Controlling Your
Blood Sugar Today

- What Is Diabetes?
- What Are the Different Types of Diabetes?
- What Is the Scope and Impact of Diabetes?
- Who Gets Diabetes?
- How Is Diabetes Managed?
- What Is the Status of Diabetes Research?
- What Will the Future Bring?
- Where Is More Information Available?
- Points to Remember

Almost every one of us knows someone who has diabetes. An estimated 16 million people in the United States have diabetes mellitus--a serious, lifelong condition. About half of these people do not know they have diabetes and are not under care for the disorder. Each year, about 798,000 people are diagnosed with diabetes.

Although diabetes occurs most often in older adults, it is one of the most common chronic disorders in children in the United States. About 123,000 children and teenagers age 19 and younger have diabetes.



What Is Diabetes?

Diabetes is a disorder of metabolism--the way our bodies use digested food for growth and energy. Most of the food we eat is broken down by the digestive juices into a simple sugar called glucose. Glucose is the main source of fuel for the body.

After digestion, the glucose passes into our bloodstream where it is available for body cells to use for growth and energy. For the glucose to get into the cells, insulin must be present. Insulin is a hormone produced by the pancreas, a large gland behind the stomach.

When we eat, the pancreas is supposed to automatically produce the right amount of insulin to move the glucose from our blood into our cells. In people with diabetes, however, the pancreas either produces little or no insulin, or the body cells do not respond to the insulin that is produced. As a result, glucose builds up in the blood, overflows into the urine, and passes out of the body. Thus, the body loses its main source of fuel even though the blood contains large amounts of glucose.

What Are the Different Types of Diabetes?

The three main types of diabetes are

- Type 1 diabetes
- Type 2 diabetes
- Gestational diabetes.

Type 1 diabetes

Type 1 diabetes (once known as insulin-dependent diabetes mellitus or **juvenile diabetes**) is considered an autoimmune disease. An autoimmune disease results when the body's system for fighting infection (the immune system) turns against a part of the body. In diabetes, the immune system attacks the insulin-producing beta cells in the pancreas and destroys them. The pancreas then produces little or no insulin.

Someone with type 1 diabetes needs daily injections of insulin to live. At present, scientists do not know exactly what causes the body's immune system to attack the beta cells, but they believe that both genetic factors and viruses are involved. Type 1 diabetes accounts for about 5 to 10 percent of diagnosed diabetes in the United States.

Type 1 diabetes develops most often in children and young adults, but the disorder can appear at any age. Symptoms of type 1 diabetes usually develop over a short period, although beta cell destruction can begin years earlier.

Symptoms include increased thirst and urination, constant hunger, weight loss, blurred vision, and extreme tiredness. If not diagnosed and treated with insulin, a person can lapse into a life-threatening coma.

Type 2 diabetes

The most common form of diabetes is type 2 diabetes (once known as noninsulin-dependent diabetes mellitus or NIDDM). About 90 to 95 percent of people with diabetes have type 2 diabetes. This form of diabetes usually develops in adults over the age of 40 and is most common among adults over age 55. About 80 percent of people with type 2 diabetes are overweight.

In type 2 diabetes, the pancreas usually produces insulin, but for some reason, the body cannot use the insulin effectively. The end result is the same as for type 1 diabetes--an unhealthy buildup of glucose in the blood and an inability of the body to make efficient use of its main source of fuel.

The symptoms of type 2 diabetes develop gradually and are not as noticeable as in type 1 diabetes. Symptoms include feeling tired or ill, frequent urination (especially at night), unusual thirst, weight loss, blurred vision, frequent infections, and slow healing of sores.

Gestational Diabetes

Gestational diabetes develops or is discovered during pregnancy. This type usually disappears when the pregnancy is over, but women who have had gestational diabetes have a greater risk of developing type 2 diabetes later in their lives.

What Is the Scope and Impact of Diabetes?

Diabetes is widely recognized as one of the leading causes of death and disability in the United States. According to death certificate data, diabetes contributed to the deaths of more than 193,140 persons in 1996.

Diabetes is associated with long-term complications that affect almost every major part of the body. It contributes to blindness, heart disease, strokes, kidney failure, amputations, and nerve damage. Uncontrolled diabetes can complicate pregnancy, and birth defects are more common in babies born to women with diabetes.

Diabetes cost the United States \$98 billion in 1997. Indirect costs, including disability payments, time lost from work, and premature death, totaled \$54 billion; medical costs for diabetes care, including hospitalizations, medical care, and treatment supplies, totaled \$44 billion.

Who Gets Diabetes?

Diabetes is not contagious. People cannot "catch" it from each other. However, certain factors can increase one's risk of developing diabetes. People who have family members with diabetes (especially type 2 diabetes), who are overweight, or who are African American, Hispanic, or Native American are all at greater risk of developing diabetes.

Type 1 diabetes occurs equally among males and females, but is more common in whites than in nonwhites. Data from the World Health Organization's Multinational Project for Childhood Diabetes indicate that type 1 diabetes is rare in most Asian, African, and American Indian populations. On the other hand, some northern European countries, including Finland and Sweden, have high rates of type 1 diabetes. The reasons for these differences are not known.

Type 2 diabetes is more common in older people, especially older women who are overweight, and occurs more often among African Americans, Hispanics, and American Indians. Compared with non-Hispanic whites, diabetes rates are about 60 percent higher in African Americans and 110 to 120 percent higher in Mexican Americans and Puerto Ricans. American Indians have the highest rates of diabetes in the world. Among Pima Indians living in the United States, for example, half of all adults have type 2 diabetes. The prevalence of diabetes is likely to increase because older people, Hispanics, and other minority groups make up the fastest growing segments of the U.S. population.

How Is Diabetes Managed?

Before the discovery of insulin in 1921, all people with type 1 diabetes died within a few years after the appearance of the disease. Although insulin is not considered a cure for diabetes, its discovery was the first major breakthrough in diabetes treatment.

Today, daily injections of insulin are the basic therapy for type 1 diabetes. Insulin injections must be balanced with meals and daily activities, and glucose levels must be closely monitored through frequent blood sugar testing.

Diet, exercise, and blood testing for glucose are also the basis for management of type 2 diabetes. In addition, some people with type 2 diabetes take oral drugs or insulin to lower their blood glucose levels.

People with diabetes must take responsibility for their day-to-day care. Much of the daily care involves trying to keep blood sugar levels from going too low or too high. When blood sugar levels drop too low--a condition known as hypoglycemia--a person can become nervous, shaky, and confused. Judgment can be impaired. Eventually, the person could pass out. The treatment for low blood sugar is to eat or drink something with sugar in it.

On the other hand, a person can become very ill if blood sugar levels rise too high, a condition known as hyperglycemia. Hypoglycemia and hyperglycemia, which can occur in people with type 1 diabetes or type 2 diabetes, are both potentially life-threatening emergencies.

People with diabetes should be treated by a doctor who monitors their diabetes control and checks for complications. Doctors who specialize in diabetes are called endocrinologists or diabetologists. In addition, people with diabetes often see ophthalmologists for eye examinations, podiatrists for routine foot

care, dietitians for help in planning meals, and diabetes educators for instruction in day-to-day care.

The goal of diabetes management is to keep blood glucose levels as close to the normal (nondiabetic) range as safely possible. A recent Government study, sponsored by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), proved that keeping blood sugar levels as close to normal as safely possible reduces the risk of developing major complications of diabetes.

The 10-year study, called the Diabetes Control and Complications Trial (DCCT), was completed in 1993 and included 1,441 people with type 1 diabetes. The study compared the effect of two treatment approaches--intensive management and standard management--on the development and progression of eye, kidney, and nerve complications of diabetes. Researchers found that study participants who maintained lower levels of blood glucose through intensive management had significantly lower rates of these complications.

Researchers believe that DCCT findings have important implications for the treatment of type 2 diabetes, as well as type 1 diabetes.

What Is the Status of Diabetes Research?

NIDDK supports basic and clinical research in its own laboratories and in research centers and hospitals throughout the United States. It also gathers and analyzes statistics about diabetes. Other institutes at the National Institutes of Health also carry out research on diabetes-related eye diseases, heart and vascular complications, pregnancy, and dental problems.

Other Government agencies that sponsor diabetes programs are the Centers for Disease Control and Prevention, the Indian Health Service, the Health Resources and Services Administration, the Bureau of Veterans Affairs, and the Department of Defense.

Many organizations outside of the Government support diabetes research and education activities. These organizations include the American Diabetes Association, the Juvenile Diabetes Foundation International, and the American Association of Diabetes Educators.

In recent years, advances in diabetes research have led to better ways to manage diabetes and treat its complications. Major advances include:

- New forms of purified insulin, such as human insulin produced through genetic engineering.
- Better ways for doctors to monitor blood glucose levels and for people with diabetes to test their own blood glucose levels at home.
- Development of external and implantable insulin pumps that deliver appropriate amounts of insulin, replacing daily injections.

- Laser treatment for diabetic eye disease, reducing the risk of blindness.
- Successful transplantation of kidneys in people whose own kidneys fail because of diabetes.
- Better ways of managing diabetic pregnancies, improving chances of successful outcomes.
- New drugs to treat type 2 diabetes and better ways to manage this form of diabetes through weight control.
- Evidence that intensive management of blood glucose reduces and may prevent development of microvascular complications of diabetes.
- Demonstration that antihypertensive drugs called ACE-inhibitors prevent or delay kidney failure in people with diabetes.

What Will the Future Bring?

In the future, it may be possible to administer insulin through nasal sprays or in the form of a pill or patch. Devices that can "read" blood glucose levels without having to prick a finger to get a blood sample are also being developed.

Researchers continue to search for the cause or causes of diabetes and ways to prevent and cure the disorder. Scientists are looking for genes that may be involved in type 2 diabetes and type 1 diabetes. Some genetic markers for type 1 diabetes have been identified, and it is now possible to screen relatives of people with type 1 diabetes to see if they are at risk for diabetes.

The new Diabetes Prevention Trial-- type 1 diabetes, sponsored by NIDDK, identifies relatives at risk for developing type 1 diabetes and treats them with low doses of insulin or with oral insulin-like agents in the hope of preventing type 1 diabetes. Similar research is carried out at other medical centers throughout the world.

Transplantation of the pancreas or insulin-producing beta cells offers the best hope of cure for people with type 1 diabetes. Some pancreas transplants have been successful. However, people who have transplants must take powerful drugs to prevent rejection of the transplanted organ. These drugs are costly and may eventually cause serious health problems.

Scientists are working to develop less harmful drugs and better methods of transplanting pancreatic tissue to prevent rejection by the body. Using techniques of bioengineering, researchers are also trying to create artificial islet cells that secrete insulin in response to increased sugar levels in the blood.

For type 2 diabetes, the focus is on ways to prevent diabetes. Preventive approaches include identifying people at high risk for the disorder and encouraging them to lose weight, exercise more, and follow a healthy diet. The Diabetes Prevention Program, another new NIDDK project, will focus on preventing the disorder in high-risk populations.

Where Is More Information Available?

For more information about type 1 diabetes, type 2 diabetes, and gestational diabetes, as well as diabetes research, statistics, and education, contact:

National Diabetes Information Clearinghouse
1 Information Way
Bethesda, MD 20892-3560
(301) 654-3327.

The following organizations also distribute materials and support programs for people with diabetes and their families and friends:

American Association of Diabetes Educators
100 West Monroe, 4th Floor
Chicago, IL 60603
(800) 832-6874
(312) 424-2426

American Diabetes Association
ADA National Service Center
1660 Duke Street
Alexandria, VA 22314
(800) 232-3472
(703) 549-1500

Juvenile Diabetes Foundation International
120 Wall Street
19th Floor
New York, NY 10005
(800) 223-1138
(212) 785-9500.

Points to Remember

What Is Diabetes?

- A disorder of metabolism--the way the body digests food for energy and growth.

What Are the Different Types of Diabetes?

- Type 1 diabetes
- Type 2 diabetes
- Gestational diabetes.

What Is the Scope and Impact of Diabetes?

- Affects 16 million people
- A leading cause of death and disability
- Costs \$98 billion per year.

Who Gets Diabetes?

- People of any age
- More common in older people, African Americans, Hispanics, and American Indians.

National Diabetes Information Clearinghouse

1 Information Way
Bethesda, MD 20892-3560
E-mail: ndic@info.niddk.nih.gov

The National Diabetes Information Clearinghouse (NDIC) is a service of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). The NIDDK is part of the National Institutes of Health under the U.S. Department of Health and Human Services. Established in 1978, the clearinghouse provides information about diabetes to people with diabetes and their families, health care professionals, and the public. NDIC answers inquiries; develops, reviews, and distributes publications; and works closely with professional and patient organizations and government agencies to coordinate resources about diabetes.

Publications produced by the clearinghouse are reviewed carefully for scientific accuracy, content, and readability.

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Publications

NIDDK

NIH Publication No. 96-3873
November 1998

e-text last updated: April 1999

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002. fax	To Neera Tanden from William T. Schmidt re: Invitation List (partial) (1 page)	06/02/99	P6/b(6)
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COLLECTION:

Clinton Presidential Records
First Lady's Office
Ruby Shamir (Subject Files)
OA/Box Number: 20365

FOLDER TITLE:

Health/Juvenile Diabetes 6-99 Event [4]

2012-0565-S

ry1256

RESTRICTION CODES

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

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

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P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [(a)(5) of the PRA]
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b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

Bill

Attention: **Neera Tanden**

Date: 6/2/99

Company: The White House

Number of Pages: 6

Fax Number: 456-2878

Voice Number: 456-6275

From: **William T. Schmidt**

Company: Juvenile Diabetes Foundation

Fax Number: (202) 371-2058

Voice Number: (202) 371-9746, x19

Subject: Invitation List

Comments:

Neera,

Here are the lists. Let me know if you have any questions on anything. If you cannot reach me in the office, feel free to call me on my cell phone at [REDACTED] P6/(b)(6).

Bill Schmidt

[002]

www.
JDFare.org

Withdrawal/Redaction Marker

Clinton Library

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adults / # children

S. Robert Levine, MD and Mary Tyler Moore	2
Mr. And Mrs. Robert Wood Johnson, IV	2
Mr. And Mrs. John J. McDonough	2
Mr. And Mrs. Leo Mullin	2
Sandra and Alan Silvestri and Joey	2 1
Erskine and Crandall Bowles and sons Sam and Bill	4
Eileen Burgin and George Young and Phillip	2 1
Carol and Erwin Lurie	2
Anita and Jack Saltz	2
Mr. And Mrs. Mike Overlock and Garrett	2 1
Mr. And Mrs. Mark Warner and Child	2 1
Dr. and Mrs. Doug Melton and Sam and Emma	2 2
Pam Solo and Tommy	1 1
Gail Pressberg	1
Allison McDonough	1
Lou and Beth Holtz	2
Jim Lovell	1
Alan and Amy Meltzer and Child	2 1
Carlos Del Toro and Betty and Christopher	2 1
Wes and Kelly Mahr and MacKenzie	2 1
Kimberly and Thomas Gibson and Lucy	2 1
Stuart and Lyn Langbein and Jamie	2 1
Crystal Jackson and Spouse and Child	2 1
Rick and Karen Davis and Lauren	2 1
Jon and Patrice Mandel and Samantha	2 1
Susan Solomon and Paul Goldberger and Ben Goldberg	2 1
Tina Cohoe and Spouse and Will Smith	2 1
Larry and Betsy Sorrell and Robby	2 1
Mr. And Mrs. Gordon Barker and Child	2 1
Larry and Sherry Benaroya and Michael	2 1
Mr. And Mrs. Roy Berggren, MD	2
Mr. and Mrs. Arnold Chase and child	2 1
Sanford and Diane Cloud	2
Mr. And Mrs. Ross Cooley	2
Mr. And Mrs. Don A. Corrao	2
Mr. And Mrs. Lawrence DeGeorge	2
Sam and Brenda Ewing	2
William and Precilla Fuller	2
Eileen and Michael Gelick	2
Mr. And Mrs. Rob German and child	2 1
Richard and Margaret Himelfarb	2
Jon and Mary Kay Huntsman and Liddy	2 1
Joann Letherby and Dr. Greg Bates	2
Jay and Ingher Leeuwenburg	2
Penn Payne and Spouse	2
Charles and Toni Peebler and Toby	2 1
Karen Peterson and Paul	2
Sandra Puczynski, PhD and spouse and Michelle	2 1
Mr. And Mrs. Kenneth M. Rich	2
Mr. And Mrs. Harold Smethills and Ross	2 1
Mr. And Mrs. Roy C. Smith	2

[003]

P6/(b)(6)

Emily Spitzer and Becca (Guiterman)	1 1
Barry and Mimi Sternlicht and William	2 1
Judith Terra	1
Max and Jinx Chapman	2
Ann Zaring and Spouse and Lisa	2 1
Mr. And Mrs. Richard Linn	2
Ron and Barbara Rappaport	2
Casey Johnson	1
Mr. And Mrs. Charlie Queenan and Child	2 1
Alan and Lisa Schusterman and son	2 1
Mr. And Mrs. Brad Evans and Son	2 1
Mr. and Mrs. Bill Timmons	2
Linda Russell	1
Mr. And Mrs. Bill Russell	2
Pam and Nils Gokemeijer	2
Dr. and Mrs. Mark Atkinson	2
Julie Thurmond	1
Fran Carpentier	1
Michael DeMeyer	1
Mr. And Mrs. Dayton Cotes	1
Sec. Of Navy Richard Danzig	1
Susan Fuge and Tom Faries and Jeffrey	2 1
Michael and Karen Wojcikowski and Michael	2 1
Jane and Robert Morris and Stockton	2 1
Beth Bacall and Haylee Lenkey	1 1
Eric and Sheryl Eaton and Anthony	2 1
Tina and Robert LaRocca and Lia	2 1
Jill Agonis and Jim Murphy and Catherine Agonis	2 1
Eileen and Mike Hendren and Ruth	2 1
George and Mirni Gavagan	2
Richard and Patti Linn	2
Randi Meyrowitz and Marty and Child	2 1
Joseph Rigolizzo and Rose	2
Adam and Suzanne Singer	2
Brian and Judy Madden	2
Mr. And Mrs. Ed Kohn and Child	2 1
Joy Bunch and Child	1 1
Charlene Meyer and Child	1 1
Terry and Rob Kircher and Child	2 1
Bob and Sue Lockoff and Child	2 1
Wendy and John Herman and Child	2 1
Rob and Sharon Casullo and child	2 1
Mr and Mrs. Sheridan Kramer and child	2 1
Mr. And Mrs. Richard Green and child	2 1
Mr. And Mrs. Richard Cogan and child	2 1
Mr. And Mrs. Max Rosen and child	2 1
Mr. And Mrs. Tom Borger and child	2 1
Amy Flachbart	1
Amy Jensen	1
Mary Booth	1
Priscilla Hanley	1

P6/(b)(6)

Ellen Murray	224-3254	1
Bettilou Taylor	224-7216	1
Rebecca Shimkus	224-3744	1
Carolyn Slutsker	224-3542	1
Martha Carmen	225-3701	1
Clare Coleman	225-6506	1
Angela Rogers	225-4511	1
David Kim	225-3976	1
Dan Turton	225-0100	1

Juvenile Diabetes
Eut

Members of Congress

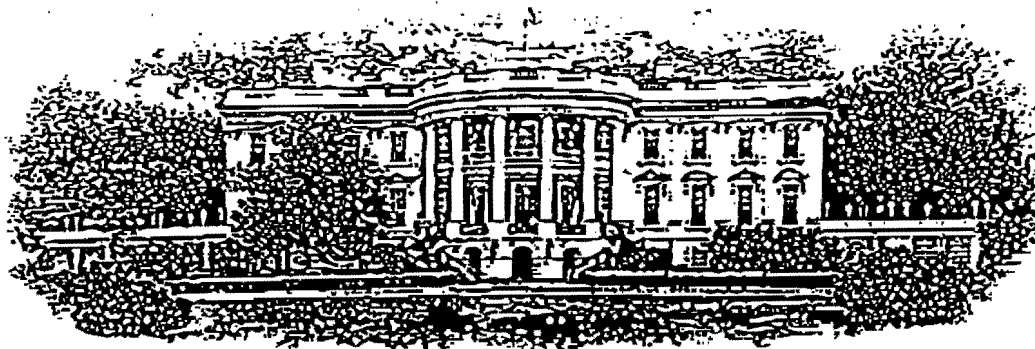
Representative George R. Nethercut	225-2006	1	JDF Children's Congre
Representative Diana DeGette	225-4431	1	JDF Children's Congre
Senator Arlen Specter	224-4254	1	JDF Children's Congre
Senator Harry Reid	224-4642	1	JDF Children's Congre
Senator Susan Collins	224-2523	1	Senate Diabetes Cauc
Senator Pete Domenici	224-6621	1	Senate Diabetes Cauc
Senator Chuck Grassley	224-3744	1	Senate Diabetes Cauc
Senator John Breaux	224-4623	1	Senate Diabetes Cauc
Senator Kent Conrad	224-2043	1	Senate Diabetes Cauc
Representative John Porter	225-4853	1	House Labor/HHS/Ed
Representative CW Bill Young	225-5961	1	House Labor/HHS/Ed
Representative Henry Bonilla	225-4511	1	House Labor/HHS/Ed
Representative Ernest Istook	225-2132	1	House Labor/HHS/Ed
Representative Dan Miller	225-5015	1	House Labor/HHS/Ed
Representative Roger Wicker	225-4803	1	House Labor/HHS/Ed
Representative Jay Dickey	225-3772	1	House Labor/HHS/Ed
Representative Anne Northup	225-5401	1	House Labor/HHS/Ed
Representative Duke Cunningham	225-5452	1	House Labor/HHS/Ed
Representative Nita Lowey	225-6506	1	House Labor/HHS/Ed
Representative David Obey	225-3365	1	House Labor/HHS/Ed
Representative Steny Hoyer	225-4131	1	House Labor/HHS/Ed
Representative Nancy Pelosi	225-4965	1	House Labor/HHS/Ed
Representative Nita Lowey	225-6508	1	House Labor/HHS/Ed
Representative Rosa DeLauro	225-3661	1	House Labor/HHS/Ed
Representative Jesse Jackson	225-0773	1	House Labor/HHS/Ed
Senator Thad Cochran	224-5054	1	Senate Labor/HHS/Ed
Senator Slade Gorton	224-3441	1	Senate Labor/HHS/Ed
Senator Judd Gregg	224-3324	1	Senate Labor/HHS/Ed
Senator Larry Craig	224-2946	1	Senate Labor/HHS/Ed
Senator Kay Bailey Hutchison	224-5922	1	Senate Labor/HHS/Ed
Senator Ted Stevens	224-3004	1	Senate Labor/HHS/Ed
Senator Jon Kyl	224-4521	1	Senate Labor/HHS/Ed
Senator Tom Harkin	224-3254	1	Senate Labor/HHS/Ed
Senator Ernest Hollings	224-6121	1	Senate Labor/HHS/Ed
Senator Daniel Inouye	224-3934	1	Senate Labor/HHS/Ed
Senator Herb Kohl	224-5653	1	Senate Labor/HHS/Ed
Senator Patty Murray	224-2621	1	Senate Labor/HHS/Ed
Senator Dianne Feinstein	224-3841	1	Senate Labor/HHS/Ed
Rep. Maurice Hinchey	225-6335	1	House Member
Senator Strom Thurmond	224-6233	1	Senate Pro Tem
Rep. Bill Lipinski		1	House Member
Rep. Joe Hoeffel III		1	House Member
Rep. Curt Weldon		1	House Member
Rep. Sam Gejdenson		1	House Member

JDF/HD&A Staff

Sue Bliss	212-479-7500	1
Mark Monty	212-479-7549	1
Karen Brownlee	212-479-7509	1
Bill Schmidt	202-371-9746x19	1
Bob Goldstein	212-479-7523	1
Lawrence Soler	202-371-9746x12	1
Julie Kimbrough	212-479-7536	1
Jane Adams	202-371-9746x17	1
Catherine Schelln	22-371-9746x20	1
Robert Molthroup	212-479-7531	1
Jim Digan	202-371-0044	1
Rose Ann Domenici	703-556-9402	1
Kim Davis	703-556-9402	1
Jeanle Chang	703-556-9402	1
Sally Lippincott	703-556-9402	1

Other Diabetes Organizations

John Graham (ADA)	703-299-2001	1
Jim Balijs (AADE)	312-424-2426	1
Chief Joyce Dugan (Eastern Band Cherokee Indians)	704-497-2771	1
Ken Quickel (Joslin Diabetes Center)	617-732-2400	1
Debbie Hohlt (Eli Lilly and Co.)	202-434-1037	1
Barbara Davis (Barbara Davis Center)	800-695-2873/310-285-1389	1



THE WHITE HOUSE CONFERENCE CENTER

PHONE: (202) 456-7666
FAX: (202) 456-6791

TO: Ruby
FROM: Shella
RECEIVER FAX: 62878
RECEIVER PHONE: _____
NUMBER OF PAGES (INCLUDING COVER SHEET): 3

COMMENTS:

Thanks



OEOb CONFERENCE & ROOSEVELT ROOM RESERVATION

Date of Meeting: _____

Time: _____ To: _____

All reservation forms should be submitted at least 48 hours prior to events.

Name of Individual Hosting Event:		Office/Agency:	
Staff Contact:	Extension No.:	Pager No.:	Room No.:
Type of Event: ☐ Meeting ☐ Reception ☐ Other _____			
Name/Description of Event:			
Number of Outside Guests: _____		In Attendance:	
Total Number of Attendees: _____		☐ President ☐ First Lady ☐ Vice President ☐ Mrs. Gore	
Room(s) Requested:			
☐ Roosevelt Room *		☐ Room 180	
☐ Room 476		☐ Room 472	
		☐ Room 450	
		☐ Room 459	
General Services: ☐ Elevator Service (elevator #4)			
Time Reserved: _____ ☐ Podium ☐ Flags			
Special Room Arrangements for the Indian Treaty Room:			
☐ Conference Style ☐ Theatre Style ☐ Other _____			
Number of Chairs: _____		Number of Table(s): _____	
Entrance/Gate Preferred:			
☐ Pennsylvania Avenue (OEOb)		☐ East Visitors Gate	
Note: the 17th & "G" Street entrance is wheelchair accessible.			
Additional Requirements or Requests: _____			

* Roosevelt Room Reservation Forms must be returned to the West Wing receptionist (FAX # 6-1210)

OEOb Room Reservation Forms must be returned via FAX at 456-6791

All reservation forms should be submitted at least 48 hours prior to events.



WHITE HOUSE CONFERENCE CENTER ROOM RESERVATIONS

Date of Meeting: _____

Time: _____ To: _____

This form must be submitted within 24 hours after making your reservation.

Name of Individual Hosting Event: _____		Office/Agency: _____	
Staff Contact: _____	Extension No.: _____	Pager No.: _____	Room No.: _____
Type of Event: ☐ Meeting ☐ Reception ☐ Other _____			
Name/Description of Event: _____			
Number of Outside Guests: _____		In Attendance: _____	
Total Number of Attendees: _____		☐ President ☐ First Lady ☐ Vice President ☐ Mrs. Gore	
White House Conference Rooms Requested: ☐ TRUMAN ROOM ☐ WILSON ROOM ☐ EISENHOWER ROOM ☐ JACKSON ROOM ☐ LINCOLN ROOM			
General Services: Time Reserved: _____ Floors Reserved: _____ ☐ Podium ☐ Flags			
Special Room Arrangements: ☐ Conference Style ☐ Theatre Style ☐ Other _____ Number of Chairs: _____ Number of Table(s): _____			
Additional Requirements or Requests: _____ _____ _____ _____			

Form must be returned to FAX # 456-6791 or to 726 Jackson Place within 24 hours after making your reservation.

Please feel free to duplicate this form for future use.



OEGB CONFERENCE & ROOSEVELT ROOM RESERVATION

Date of Meeting:

June 7, 1999

Time: 11 am

To: 4:30 pm

All reservation forms should be submitted at least 48 hours prior to events.

Name of Individual Hosting Event:		Office/Agency: <u>OPD</u>	
Staff Contact: <u>RUBY SHAMIR</u>	Extension No.: <u>65696</u>	Pager No.:	Room No.:
Type of Event: ☐ Meeting ☐ Reception ☒ Other <u>FIRST LADY EVENT</u>			
Name/Description of Event:			
Number of Outside Guests: <u>2000</u>	In Attendance:		
Total Number of Attendees: <u>130</u>	☐ President ☒ First Lady ☐ Vice President ☐ Mrs. Gore		
Room(s) Requested:			
☐ Roosevelt Room *	☐ Room 180	☐ Room 472	☐ Room 474 (Indian Treaty Room)
☐ Room 476	☒ Room 450	☐ Room 459	
General Services: ☐ Elevator Service (elevator #4)			
Time Reserved: ☒ Podium ☐ Flags			
Special Room Arrangements for the Indian Treaty Room:			
☐ Conference Style ☐ Theatre Style ☒ Other <u>Set up</u>			
Number of Chairs: <u>4 on stage</u> Number of Table(s): _____			
Entrance/Gate Preferred:			
☒ Pennsylvania Avenue (OEGB) ☐ East Visitors Gate Note: the 17th & "G" Street entrance is wheelchair accessible.			
Additional Requirements or Requests: <u>Water not podium</u>			
<u>TBD</u>			

* Roosevelt Room Reservation Forms must be returned to the West Wing receptionist (FAX # 6-1210)

OEGB Room Reservation Forms must be returned via FAX at 456-6791

All reservation forms should be submitted at least 48 hours prior to events.