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001. list	VPOTUS Organ Donation Event meeting clearance list (partial) (10 pages)	12/15/1997	b(6)

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Organ Procurement and Transplantation Network (OPTN): Vice President Event 12-15-97

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Organ & Tissue

COALITION ON DONATION

Share your life. Share your decision.®

December 18, 1997

Mr. Jerry Mande
Senior Policy Analyst
Office of Science and Technology Policy
Department of Health and Human Services
17th and Pennsylvania Avenues
Washington, D.C. 20502

Dear Jerry:

On behalf of the Coalition on Donation, and the more than 55,000 Americans who are currently awaiting a lifesaving organ transplant, I would like to extend my sincere thanks and gratitude for your important contribution to the success of the National Organ and Tissue Donation Initiative launch on Monday, December 12, 1997. The Coalition on Donation is appreciative of the opportunity to work in partnership with the Department of Health and Human Resources, Health Resources Service Administration in this very important, and solvable, health crisis – the critical shortage of organ donors.

Our unified message, "Share your life. Share your decision"™ is a call to action, encouraging all Americans to decide to become an organ donor and to discuss their decision with family members and loved ones. Through a strong network of local coalitions and national members, we are able to bring this message to millions of individuals. Finally, through the dynamic partnerships we have forged with major organizations in the health care and transplantation community, and now with the Department of Health and Human Services, we can bring the combined efforts of many to serve those in need.

I look forward to our continuing relationship and joint efforts to increase organ and tissue donation in the United States. Please accept the enclosed Coalition on Donation hat as a small token of our gratitude and heartfelt wishes that you wear it in good health and continue to spread our unified message. Again, thank you for fine efforts and continued support.

Sincerely,



Howard M. Nathan
President, Coalition on Donation

Encl.

Abbott Laboratories

Amer Assn of Blood Banks

Amer Assn of Critical-Care Nurses

Amer Assn of Kidney Patients

Amer Assn of Tissue Banks

Amer Diabetes Assn

Amer Heart Assn

Amer Hospital Assn

Amer Kidney Fund

Amer Liver Foundation

Amer Medical Assn

Amer Nephrology Nurses Assn

Amer Red Cross Tissue Services

Amer Soc for Histocompatibility
and Immunogenetics

Amer Soc of Minority Health
and Transplant Professionals

Amer Soc of Nephrology

Amer Soc of Transplant Physicians

Amer Soc of Transplant Surgeons

Assn of Organ Procurement Org

Children's Organ Transplant Assn

Cryolife, Inc

Div of Organ Transplantation, ILLS

DuPont Merck Pharmaceutical

Eye Bank Assn of America

Forum of ESRD Networks

Fujisawa Pharmaceutical Company

Health Management, Inc

Int Soc for Heart and Lung
Transplantation

Int Soc for Organ Sharing

Musculoskeletal Transplant
Foundation

Natl Assn of Medical Examiners

Natl Kidney Foundation

Natl Minority Organ Tissue
Transplant Education Program

Natl Selected Marriages

Natl Transplant Assistance Fund

North Amer Transplant
Coordination Org

Novartis Pharmaceuticals
Corporation

Organ Transplant Fund, Inc.

Ortho Biotech Inc

The Partnership for Organ
Donation, Inc

Pharmacia and Upjohn, Inc

Roch Laboratories, Inc.

SangStat Medical Corporation

Soc for Heart and Lung
Transplant Social Workers

South-Eastern Organ
Procurement Foundation

Transplant Recipients Int Org

United Network for Organ Sharing

Wendy Max Foundation

Wyeth-Ayerst Laboratories

and 50 local coalitions

3RD STORY of Level 1 printed in FULL format.

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Los Angeles Times

December 16, 1997, Tuesday, Home Edition

SECTION: Part A; Page 26; National Desk

LENGTH: 595 words

HEADLINE: U.S. PLAN ADDRESSES SHORTAGE OF ORGAN DONORS

BYLINE: ALISSA J. RUBIN, TIMES STAFF WRITER

DATELINE: WASHINGTON

BODY:

The Clinton administration on Monday proposed to increase the number of organ transplants by ordering hospitals to cooperate with donor organizations.

Under the plan, hospitals would be required to inform federally certified donor organizations when patients die so the organizations can ask the families about organ and tissue donations. The program would also include a wide-ranging campaign to publicize the need for organ donations.

The shortage of kidneys, hearts, livers and other vital organs has become increasingly acute as medical advances expand the pool of transplant candidates. Administration officials say about 4,000 people died last year while waiting for transplants and 55,000 remain on transplant waiting lists.

The federal initiative builds on a Pennsylvania program that has resulted in a 40% increase in organ donations and a 51% increase in transplants. When Pennsylvania passed a law in 1994 requiring hospitals to call donor procurement organizations after every death, the number of donated organs rose sharply.

"Almost all Americans support organ donation, and families almost always consent to organ donation when loved ones have expressed that wish, but not all families have thought about organ donation or discussed it," said Vice President Al Gore in announcing the administration's plan.

Hospitals promptly voiced their objections to the proposal as interfering with the relationship between doctors and their patients.

"Organ donation is an issue that requires great sensitivity and is extremely personal," said Dick Davidson, president of the American Hospital Assn. "It needs to be worked out case by case on a local basis--family, doctor and chaplain working together. . . . This proposed rule would replace these hospital local initiatives with policies established by an outside organ-procurement organization."

The administration's plan took the form of a proposed rule under the government's authority to regulate all hospitals that accept federal Medicare reimbursement--a category that includes all acute-care hospitals. After the public has had a chance to comment on the proposed rule, the administration

Los Angeles Times, December 16, 1997

will make it final or modify it. No congressional action is needed.

Gore, a leading sponsor of the 1984 National Organ Transplant Act when he served in the Senate, noted that 27% of potential donors' families are not asked if they would be willing to participate in organ donations. The 1984 act set up the first national computerized matching program for donors and transplant candidates.

"If a significant number of potential organ donors are being missed because these deaths are not identified or the family is not asked, then we need to work with the transplant community to immediately address this problem," said Health and Human Services Secretary Donna Shalala, who spoke with Gore.

The administration's new regulation would shift more responsibility to the 63 regional donor procurement organizations, which contact families about their interest in donations, match the organs of the deceased with transplant candidates and transport the organs to the patients.

Under the administration's proposal, hospitals would have to call donor organizations when a death occurred to allow the organization's staff to determine if there was potential for organ donation.

In 1996, according to the Health Resources and Services Administration, surgeons transplanted 20,000 vital organs, including 11,000 kidneys, 4,100 livers and 2,300 hearts. Transplant waiting lists continue to grow.

LANGUAGE: English

LOAD-DATE: December 16, 1997

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December 16, 1997

Gore Makes Push for Organ Donation

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Filed at 3:34 a.m. EST**By The Associated Press**

WASHINGTON (AP) -- The Rev. Dalton Downs stood before his congregation and told the sad truth: His arteries were twisted, and he'd need a heart transplant to survive. "I told them I was dying and I needed their prayers," he said.

On the way out of the church, Dawn Alexander put her arms around her minister and whispered: "If I had two hearts, I would give you one."

Oddly, Alexander died of an aneurysm a year later, and her heart was indeed donated to Downs.

"Anyone who receives a heart of an organ donor receives a very big heart indeed," Downs said Monday as he helped launch a new federal push to increase the number of organ donors.

The event featured emotional speeches, capped by Downs, of St. Timothy's Episcopal Church in Washington, who said Alexander's 12-year-old daughter always offers a hug and asks, "Can I listen to my mother's heart?"

The initiative hopes to encourage doctors, hospitals and families to talk about organ donation before and after death. About half of Americans who want their organs donated have not told their families, the Department of Health and Human Services said.

"Our message is very simple: Share your life -- share your decision," said Vice President Al Gore.

About 20,000 Americans received organ transplants last year, but some 4,000 died waiting for a donor. More than 55,000 people are on the transplant waiting list, up from 16,000 in 1988.

Yet, according to a study by the Harvard School of Public Health, 27 percent of potential donors are not identified or their families are never approached about donation.

The initiative announced Monday includes:

--A campaign by private, public and volunteer organizations to persuade Americans to agree to organ donations and then discuss their decisions with family.

--A proposed federal rule requiring hospitals to report all deaths to local organ procurement organizations, which can evaluate possible donors and discuss consent with family members. Before the rule becomes final, HHS and hospitals may work out an alternate system to achieve the same goal.

Before the rule becomes final, HHS and hospitals may work out an alternate system to achieve the same goal.

--An HHS-sponsored conference next spring to discuss strategies for donation.

Last week, HHS released a report showing patient survival rates are at an all-time high, with 94 percent of kidney recipients and 79 percent of liver recipients surviving at least one year.

This report, which gave data on individual transplant programs, also identified programs with lower-than-expected survival rates, but HHS has yet to release their names.

The government is expected in the next several weeks to announce new regulations surrounding the distribution of organs.

Most controversial is a proposed rule changing who is first in line to get new livers. Under the original plan, acute patients who are suddenly stricken with life-threatening liver failure would have priority over long-term liver failure typically suffered by alcoholics and drug addicts.

For more information about organ donation, call the Coalition on Donation at 1-888-90-SHARE.

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New plan to increase organ donations

WASHINGTON - The White House on Monday will unveil an initiative that's aimed at encouraging organ donations and reducing the number of Americans who die each year waiting for organ transplants.

While about 55 people received organ transplants each day in 1996, about 10 others on waiting lists died. In all, more than 4,000 died last year while awaiting hearts, lungs, kidneys and other organs.

The plan, to be announced by Vice President Gore and Health and Human Services Secretary Donna Shalala, will include:

- A national partnership of public, private and volunteer organizations to promote family discussion of individual wishes on the issue before a medical crisis.

Participants include the American Medical Association, the American Bar Association, the Chamber of Commerce and the Red Cross.

- A proposed federal regulation that would require hospitals to collaborate with regional Organ Procurement Organizations, which can help train medical personnel.
- A Health and Human Services Department conference on the issue next spring.
- A commitment by all federal Cabinet agencies to contact their employees six times each year about organ donations, perhaps through e-mail or reminders on pay stubs.

Transplant experts praise the White House initiative as likely to significantly increase organ donations.

"They've identified four areas where they can make an impact," says Dr. Lawrence Hunsicker, a University of Iowa professor and president of the United Network for Organ Sharing.

By Susan Page, USA TODAY

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December 11, 1997

Organ Transplant Survival Rates Up

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Filed at 7:13 p.m. EST**By The Associated Press**

WASHINGTON (AP) -- Patient survival rates have improved for nearly every type of organ transplant, with significantly better odds for liver, lung and heart-lung transplants, according to a government-sponsored report released Thursday.

"Virtually all of the numbers have improved," said Dr. Claude Earl Fox, acting administrator of the Health Resources and Services Administration, an agency of the Department of Health and Human Services. He cited improved technology, better drugs and more developed techniques.

The report by the United Network for Organ Sharing, which operates the nation's organ transplant program, compared the results of the 97,587 transplants performed in 1992-94 with the transplants done in 1988-92.

The most dramatic improvements were for heart-lung transplants. The one-year patient survival rate jumped 11 percentage points to 69.7 percent.

The report also found:

--One-year patient survival rates improved 5.3 percentage points for liver transplants to 82.2 percent, and 6.1 points for lung transplants to 74.5 percent.

--The percentage of livers and lungs still functioning a year later was up 6.8 percentage points for each, to 74.1 percent and 73.4 percent, respectively.

But there were wide disparities in the success rates of various transplant programs. The report found that 15 kidney programs, 13 liver programs and 15 heart programs had lower-than-expected survival rates for organs after a year.

HHS officials said the list identifying these centers was not available Thursday,

but Fox said about half were new programs with less experience doing transplants.

The number of transplant centers has grown 16 percent since the last report; there are now 742 programs around the country.

The report helps identify centers with poor performance records, Fox said. The United Network for Organ Sharing, which produced the report, will follow up with centers with poor records, he said.

"It's not like the report's done, will be put on a shelf and that's the end of it," he said.

The nine-volume report may be useful to patients choosing a center for a transplant procedure. It offers specific information about each program, and its survival rates for each organ.

Patients may obtain copies of the data for up to 10 centers at no charge by calling 888-TX-INFO1.

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December 11, 1997

FDA OKs Kidney Transplant Drug

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Filed at 4:07 p.m. EST**By The Associated Press**

WASHINGTON (AP) -- Kidney transplant patients gained a new weapon Thursday to improve the chances their organs will survive -- an especially poignant advance for the doctor who pushed it through rigorous testing. Her toddler son will one day receive one of her kidneys, along with the genetically engineered therapy his mother helped produce.

"It helped me cope by knowing ... I could do something that has potential not just for Jake, but I have a kinship for all the other kids who have this disease," said Dr. Susan Light, Hoffman-La Roche's lead researcher for Zenapax.

The Food and Drug Administration approved the monoclonal antibody that blocks immune cells from attacking the new kidney during the first eight weeks after transplant, the riskiest period.

Most important: Zenapax is administered together with standard anti-rejection drugs, but its highly specific target means it causes no additional side effects, the FDA said. For the first time, doctors can strengthen organ protection without additional risk.

In a six-month study of 260 patients, 35 percent on standard anti-rejection treatment showed signs of kidney rejection compared to just 22 percent of patients with Zenapax, known chemically as daclizumab, added to the standard mix.

"Adding daclizumab to other standard immunosuppressive treatments can be very beneficial for patients," acting FDA commissioner Dr. Michael Friedman said.

Zenapax ultimately may help more than just kidney patients, because the immune system cells it blocks can attack any transplanted organ, explained Dr.

Ezio Bonvini, head of FDA's immunobiology lab. "We don't have the data at the moment," he said, "but this is very likely to" work on other transplants.

Roche is preparing to test liver transplant patients, later heart transplants.

About 38,000 Americans are on a waiting list for kidney transplants, and 11,100 received them last year. For the rest of their lives, patients take strong drugs to suppress the immune system so it cannot attack the new organ. The drugs leave patients vulnerable to severe infections and can cause other serious side effects.

Still, 40 percent of kidney recipients show signs of organ rejection that require additional drug treatment or even, in severe cases, another transplant or kidney dialysis.

Light, a pediatrician, knew those statistics too well when, in 1994, her newborn son Jake Margolis was diagnosed with a type of polycystic kidney disease, a genetic disorder that destroys the kidneys during childhood. So far Jake is doing well, but eventually he'll receive a kidney from his mother.

In 1992, Roche had put Light in charge of the clinical development of Zenapax, a sort of genetically engineered bloodhound made by fusing a mouse antibody with human immune components. It sniffs out activated T-cells, immune system cells programmed by the body to attack foreign substances -- in this case, the new kidney -- and blocks their attack.

But Light had no idea yet if Zenapax worked.

"I was a little skeptical," she said. After all, monoclonal antibody research had been touted for years but none had yet succeeded. She even considered turning Zenapax over to colleagues after Jake's birth, because the work had become too emotional.

The baby was almost 1 when the first human tests showed Zenapax held promise for kidney transplants. Light raced to design tests that would give FDA the final proof -- and started seeing the first successful results in adults last year.

Now Roche is testing children. In the first 25, only one has suffered organ rejection. On standard therapy, 30 percent do, Light said.

Unlike other anti-rejection drugs that must be taken for life, kidney patients get five intravenous infusions of Zenapax during the first eight weeks after transplant. That's when the body is most furiously programming T-cells to attack the kidney and when anti-rejection drugs need a boost.

"The analogy here is that T-cell activation is like a rocket ship taking off. It's harder to stop after it's cleared the launch pad," Light explained.

As for Jake, Light says he'll get Zenapax with his transplant. "It's a no-brainer,"

she said. "How ironic that this happened in my life. At least now, I can feel I made a difference."

Well almost.



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Arthur L. Caplan, Ph.D.
Director

Center for Bioethics

December 15, 1997

Organ and tissue donation in the United States rely on the voluntarism, generosity, compassion and altruism of the American people. As a nation we owe it to those who desperately need transplants to do everything we can to insure that every American understands that the need is great, they have the power to help those in need and that the opportunity is presented to them to do so. That is why I am so pleased and enthusiastic that Vice President Gore has chosen to reiterate this nation's commitment to do all that it can to help those disabled or dying as a result of diseases and disorders by announcing new initiatives aimed at maintaining and enhancing the availability of human organs and tissues for transplantation.

The transplant community has had no better friend than Al Gore. He has been a staunch advocate for patients seeking transplants, their families and friends. When, more than a decade ago, he was in the House of Representatives he became concerned about the plight of those seeking transplants. Al took the lead in making sure that the transplant community understood the importance of insuring that the distribution of freely donated organs and tissues be fair and equitable. He read and reflected on the idea of a then much younger bioethics professor to promote legislation requiring that every family that has suffered a death be made aware of the option of organ and tissue donation by a properly trained health care professional. He moved this idea forward and saw to it, when he himself moved on to the United States Senate, that Federal law guarantees that the offer of organ and tissue donation become a routine and widely accepted part of the process of coping with the tragedy of the loss of a loved one. The commitment to doing everything possible to help those in need of transplants has continued throughout his tenure as Vice President.

I have been studying and wrestling with the subject of organ and tissue donation for many, many years. I remain more convinced than ever that the keys to maintaining and increasing the supply of cadaver organs and tissues available in this country is to insure that the public understands the importance of serving as organ and tissue donors, has every opportunity to donate, and that those who seek the altruism of the American people when death occurs are properly trained, experienced and sensitive to individual emotions, values and sensitivities about the loss of a loved one. The policies and partnerships announced today by the Vice President well serve these ends.

I want to offer my full support for the Vice President's initiatives. I want to congratulate him for continuing to strive to improve this nation's performance in helping those who need transplants. And I want to thank him for his unwavering determination to do what is necessary to insure that organ and tissue donation in this country reflect the core values of choice, altruism, and voluntarism.

Arthur L. Caplan Ph.D.
Trustee Professor of Bioethics
Professor of Philosophy
Professor of Cellular and Molecular
Engineering
Director, Center for Bioethics
University of Pennsylvania
Philadelphia PA



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Arthur L. Caplan Ph.D.
Trustee Professor of Bioethics
Professor of Philosophy
Professor of Cellular and Molecular
Engineering
Director, Center for Bioethics
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Philadelphia PA



DEPARTMENT OF RELIGIOUS STUDIES
COCKE HALL

December 12, 1997

TEL: (804) 924-3741
FAX: (804) 924-1467

The Honorable Albert Gore
Vice President of the United States
Washington, DC

Dear Vice President Gore:

I have learned, with great excitement, about the organ procurement initiatives that you and Secretary Shalala will announce on Monday.

Having served as vice chair of the national Organ Transplantation Task Force in the mid-1980s, as a member of the UNOS Board of Directors for a term, and as a member of the UNOS Ethics Committee for several terms (including the present), I have followed developments in organ transplantation with both great interest and great concern about our inability to increase the number of donated organs. I am confident that the public/private partnership and the requirement of referral to Organ Procurement Organizations (OPOs), along with the other planned initiatives, will serve to increase the supply of transplantable organs and thus save lives and enhance the quality of those lives.

I look forward to your presentation on Monday and to improvements in organ procurement and transplantation as a result of the initiatives that you and Secretary Shalala plan to propose.

All best wishes.

Sincerely,

A handwritten signature in cursive script, reading "James F. Childress".

James F. Childress
Kyle Professor of Religious Studies
Professor of Medical Education
Co-Director, Virginia Health Policy Center
Member, National Bioethics Advisory
Committee

Remarks for Vice President Al Gore
Announcement of National Organ Donor Initiative
Monday, December 15, 1997

[acknowledgments by advance]

Rev. Downs receiving the heart of a generous friend -- Dr. Herrera's son Christian giving life to seven -- both these tragic and triumphant stories teach us the almost miraculous power of donation, and the crucial importance of a family conversation. If neither of our guests had ever known or talked about organ donation, Rev. Downs might not be with us today, and Christian Herrera might not have saved seven lives. That's why we've gathered here this morning: to announce a new initiative that will encourage more people to become organ donors, talk about it with their families, and help more patients get the life-saving transplants they need.

It was a story similar to these that first engaged me in the cause of organ donation. Fifteen years ago, a family in Tennessee sought my assistance in finding a liver donor for a dying ^{child} ~~family member~~. I did everything I could to help that family, but I also wanted to do something that could help every family caught in those awful circumstances. No one should have to leave the bedside of a loved one to search for a life-saving organ.

This led to my role in writing and passing the National Organ Transplant Act of 1984. That -- along with subsequent legislation I was honored to help write and pass -- has created a fair and equitable national system that families now count on for recovering and distributing organs. We have come a long way since 1984. But we cannot rest. Not when 10 people a day are losing their lives waiting for an organ. And not when we can save those lives with a little more effort, a little more information, and a little more teamwork.

That's why I am proud to announce today, our new National Organ and Tissue Initiative, which we believe can make a significant increase in the number of organ donors across the country.

First, I am pleased to announce several prominent new members in a national partnership committed to increasing organ and tissue donation all across America. The American Medical Association and the American Association of Family Physicians have agreed to encourage their members to discuss donation with patients. The American Bar Association will encourage its members to discuss donation with clients during the preparation of wills and estate planning. And the American Red Cross -- already one of the nation's largest providers of human tissue -- has pledged to mount an enhanced effort to encourage organ and tissue donation.

These organizations will join the Coalition on Donation, the Department of Health and Human Services, and many longtime partners in the clergy, the transplant community, the health care community, and the business community to ensure that organ donation is discussed all across America. These partners are here with us today, and I would like to publicly thank each and every one of them for their commitment to this cause.

assure, through the OPO with which...

Second, we are taking a significant new federal action to help increase organ donation.

We are proposing a regulation designed to ensure that hospitals notify Organ Procurement Organizations in the case of a death that could result in organ donation. Currently, 27% of all deaths that could result in organ donation, do not result in organ donation -- because the family is never asked. We hope to work with the entire transplant community -- including providers, ^{transplant center} consumers, and physicians -- to see that the final regulation ensures that all families in those circumstances are offered the option of organ donation -- so that they might have the opportunity to offer a life-saving gift to others.

Third, I am pleased to announce a new effort of the Federal government to increase awareness among federal employees. All of the major cabinet agencies have agreed to promote awareness about organ donation by sending out six messages a year to their employees -- some to be included with employee pay stubs. I hope this effort encourages private sector employers to join us in doing more to raise awareness about organ and tissue donation.

Finally, I am pleased to announce that the Department of Health and Human Services will sponsor a conference in the spring to help us identify the practices that are most effective in encouraging donation.

Here on the eve of the 21st-century, advances in science, medicine, and technology have brought us great life-saving powers, but also a keen awareness of our life-saving limits: no matter how impressive our technology, we still cannot create a human heart -- a liver, a lung, a kidney. We cannot even preserve them outside a living body for more than a few hours. That means the power of our newest technology depends upon the strength of our oldest values: love of life, and love of neighbor.

Those values are strong in America. Surveys have shown that almost all Americans support organ donation, and families almost always consent to organ donation when loved ones have expressed that wish. But not all families have thought about organ donation or discussed it. In fact, only half of those who want to be organ donors have told their families about their decision. That's why we're here today: To make a public commitment to inform every American about the fantastic life-giving opportunity of organ donation. To make sure all willing organ donors inform their families. And to make sure we can recover every single organ of every willing donor -- so that the loss of life for one, may result in the gift of life for many.

Our partnership is large, our mission lofty, but our message very simple: "Share your life; share your decision." Thank you very much.

**VICE PRESIDENT GORE LAUNCHES NEW ORGAN AND TISSUE
DONATION INITIATIVE
December 15, 1997**

Today, the Vice President is announcing a series of new Administration initiatives to increase organ donation. These initiatives, which build on the Administration's longstanding efforts to improve awareness about organ donation and are led by the Department of Health and Human Services, include: (1) new unprecedented private/public partnerships with businesses, consumers, physicals, health care organizations and others to increase awareness about organ donation across the country; (2) a commitment from the Federal government to do its share, by sending out six messages per year to its employees about organ donation; (3) a proposed regulation to ensure health care providers commit to a patient/family-sensitive process to encourage, where appropriate, organ donation; and (4) an ongoing commitment from the Administration to improve donation, including a conference at the Department of Health and Human Services this spring to examine the best ways to encourage donation.

BACKGROUND

More than 20,000 Americans each year receive organ transplants that save or enhance their lives. However, 4,000 Americans people die each year, approximately 10 per day waiting for an organ transplant. Today, more than 55,000 people are on the national organ transplant waiting list.

Only about half of Americans who want to become an organ donor have told their families of their wishes. The latest national Gallup study indicates that nearly all Americans would consent to donation if they know their loved one had requested it. Currently, when families are asked if their loved one wants to be an organ donor, only about half give consent, and often, its because the family does not know their loved ones' wishes. Another study found that 27 percent of families of potential donors were never approached about donation. Today the Vice President is announcing a series of new initiatives to help ensure that families have discussed the issue of becoming an organ donor and to ensure that family members of potential organ donors are asked to consider donation. These initiatives include:

An Unprecedented Commitment for New Private/Public Partnerships to Increase Awareness. The Vice President and Secretary Shalala are announcing a series of partnerships the federal government has made with organizations to promote organ donation.

The American Medical Association and The American Academy of Family Physicians have made a new commitment to encourage physicians to make organ donation materials available their offices and to discuss donation with

their patients.

The American Red Cross will use its extensive community outreach network in a new campaign to promote awareness about organ donation.

The American Bar Association will make a new commitment to encourage attorneys to discuss organ donation with their clients during estate planning through the distribution of materials, by providing continuing legal education programs, and through the encouragement of state and local bar associations to adopt resolutions resolution that urge attorneys to get involved in donor education efforts.

These new partners join others who have already made impressive commitments to improve awareness about organ donation including: **the Congress of National Black Churches, the Union of American Hebrew Congregations, The U.S. Chamber of Congress, the Washington Business Group on Health, the Home Depot, the American Association of Health Plans, the American Nurses Association, and the American College Health Association.**

A New Commitment From the Federal Government To Do Its Share to Increase Awareness About Organ Donation.

All fourteen major Cabinet Agencies and the Executive Office of the President have agreed to provide their employees with information about organ donation six times per year, including information about donation on employee pay stubs. This effort will reach millions of federal employees as well as their families. The Administration also challenges all private entities to spread awareness about organ donation to their employees.

A New Proposed Regulation to Ensure Families Discuss Organ Donation.

The Vice President is also announcing a proposed regulation by the Health Care Financing Administration (HCFA) to revise its conditions of participation for Medicare hospitals to ensure that the families of potential donors are asked to consider donation. HHS will work closely with hospitals, OPOs, tissue banks and others in the transplant community to produce final rules that will ensure that opportunities for donation are not lost due to failure to identify potential donors. **The Joint Commission on the Accreditation of Healthcare Organizations**, which provides accreditation for most of the nation's hospitals, has also agreed to incorporate this approach.

Ongoing Efforts to Find New Ways to Increase Organ Donation.

The Administration will continue to work to identify the best approaches to increasing donation and priorities for future research. In this regard, the Department of Health and Human Services will hold a National Research Conference on organ and tissue donation in the spring of 1998 to discuss the best practices for increasing organ donation.

(4) The governing body, other organized group, or individual that assumes full legal authority and responsibility for the operation of the hospital appoints the medical staff's members and approves its bylaws.

(c) Standard: Organ procurement responsibilities.

(1) The governing body, other organized group, or responsible individual must ensure that the hospital has written protocols that--

(i) Identify potential organ donors as defined by the OPO with which the hospital has an agreement;

(ii) Assure, through the OPO with which the hospital has an agreement, that the family of each potential organ donor knows of its option either to donate organs or tissues or to decline to donate;

(iii) Encourage discretion and sensitivity with respect to the circumstances, views and beliefs of the families of potential donors; and

(iv) Ensure that the hospital works cooperatively with the OPO with which the hospital has an agreement, in educating staff on donation issues, reviewing death records to improve identification of potential donors, and maintaining potential donors while necessary testing and placement of potential donated organs take place;

(2) The hospital must notify the OPO designated by the Secretary under § 486.316(c) of this chapter of all potential organ donors using protocols defined by the OPO.

(3) A hospital in which organ transplants are performed must be a member of the Organ Procurement and Transplantation Network (OPTN) established and operated in accordance with section 372 of the Public Health Service (PHS) Act (42 U.S.C. 274) and abide by its rules. The term "rules of the OPTN" means those rules provided for in regulations issued by the Secretary in accordance with section 372 of the PHS Act. No hospital is considered to be out of compliance with section 1138(a)(1)(B) of the Act, or with the requirements of this paragraph, unless the Secretary has given the OPTN formal notice that he or she approves the decision to exclude the hospital from the OPTN and has notified the hospital in writing.

(4) For purposes of this standard, the term "organ" means a human kidney, liver, heart, lung, or pancreas.

§ 482.115 Condition of participation: Infection control.

The hospital maintains an effective infection control program that protects patients and hospital staff by preventing and controlling infections and communicable disease.

(a) Standard: Sanitary environment. The hospital must provide a sanitary environment by following acceptable

HCFA would need to review the new service site to assure that it meets the level of integration required for inclusion of the new site as a part of the provider. This will ensure that appropriate payment is made. We have issued instructions outlining the criteria that must be met in order to demonstrate integration inherent in classification of an offsite service as part of the hospital in Program Memorandum A-96-7.

Proposed § 482.110(b)(3) and (4) restate with only minor editorial changes current requirements concerning the governing body's responsibilities for an institutional plan and budget, as well as the medical staff's bylaws. We propose to retain these requirements, in accordance with section 1861(e) of the Act.

Under proposed § 482.110(c), we would redesignate, with changes, the requirements under existing § 482.12(c)(5) concerning a hospital's responsibility to identify potential organ donors. We recognize that these provisions, in particular the requirement that a hospital have written protocols addressing various aspects of its organ procurement responsibilities, are more prescriptive and process-oriented than other parts of these proposed rules. However, we believe it is necessary to retain these regulations in their existing form to implement section 1138 of the Act, which specifically requires written hospital

protocols for organ procurement. The changes to this section are discussed below.

We are revising § 482.110(c)(11) (formerly § 482.12(c)(5)(i)(A)) and adding a new requirement under § 482.110(c)(1)(iv) concerning organ procurement organizations (OPOs) and hospitals. The development of these requirements is in response to issues raised during public hearings held by the Department on December 11 through 13, 1996, to examine the allocation policies for liver transplantation and to receive comments regarding methods to increase organ donation. During those hearings, it became abundantly clear that there is a critical shortage of organs available for lifesaving transplantation. While the science of transplantation has made progress over the last two decades, lives that could be saved continue to be lost because of an inadequate supply of donor organs. For example, an estimated 12,000 to 15,000 deaths occur in the United States each year that could yield suitable donor organs, yet in 1996 no more than 5,400 resulted in donations. In April 1997, approximately 52,000 Americans were waiting for organ transplants. Therefore, we believe it is appropriate to propose revisions to the current hospital conditions relating to organ donation.

The existing regulations merely repeat the language in section 1138 of the Social Security Act which requires hospitals to assure that families are advised of the right

to donate or not donate organs, encourage discretion and sensitivity to family values, and notify an OPO of potential donors. We are proposing to revise the hospital conditions of participation regarding organ donation to emphasize the role and relationship of the OPO in the process.

Specifically, we are proposing to specify that the hospital must ensure that the family is advised, through the OPO with which the hospital has an agreement, of their right to donate or decline to donate (§ 482.110(c)(1)(ii)). This proposal is based on research in the field of organ donation that indicates that consent to donation is highest when the request is made by the staff of the OPO rather than the hospital. OPO staff are specialty trained medical personnel. They have training in bereavement counseling and extensive experience in dealing with families undergoing the loss of a loved one. They have knowledge of brain death and are particularly skilled in making complicated medical terminology understandable to a grieving family. Most importantly, organ donation is their principal field, whereas hospital staff have numerous other responsibilities. Further, donor consent rates tend to be higher when there is a time lapse between the hospital notifying the family of a death and the request for organ donation. In proposing this change, we considered the possibility that we might be viewed as holding hospitals responsible for ensuring that a function, such as advising a family of their organ donation

rights, be performed without providing them with the ability to control the situation. That is, the hospital cannot control the OPO and may consider that it may be a victim of poor OPO performance. The conditions of coverage for OPOs include performance standards that hold OPOs accountable for achieving a specified number of donors and organs based on the size of the population it serves. We believe these performance standards will motivate OPOs to provide satisfactory service to hospitals. Moreover, we note that the proposed hospital conditions hold hospitals accountable for ensuring that they have written protocols and do the following:

- Identify potential organ donors as defined by the OPO with which the hospital has an agreement;
- Notify the OPO of such potential donors;
- Assure, through the OPO with which the hospital has an agreement, that the family of each potential organ donor knows of its option either to donate organs or tissues or to decline to donate;
- Encourage discretion and sensitivity with respect to the circumstances, views and beliefs of the families of potential donors; and
- Ensure that the hospital works cooperatively with the OPO with which the hospital has an agreement, in educating staff on donation issues, reviewing death records to improve identification of potential donors, and

maintaining potential donors while necessary testing and placement of potential donated organs take place.

We expect that if the hospitals and OPOs are not achieving the desired results the hospitals would reevaluate and revise their protocols. Hospitals would not be cited for a deficiency of this standard if the hospital has appropriate protocols, regardless of the success of OPO staff in acquiring donors.

We also are proposing to revise an existing requirement that specifies that the hospital must notify OPOs of potential organ donors. There is a good deal of variability among hospitals in referral patterns. Some hospitals do not call the OPO unless they have determined that the patient is medically suited to be a donor and the family has consented. On the other hand, some hospitals refer all deaths to the OPO. Most hospitals have established criteria, such as age or absence of systemic disease, to determine if a potential donor should be referred to the OPO.

In evaluating the organ donor shortage and the actions that hospitals may take with regard to donor referral, we considered the following options:

- Maintain the current requirement which provides hospitals with the flexibility to determine appropriate referrals through their written protocols;
- Require mandatory reporting of all death of patients under age 75 to the OPOs; and

- Require mandatory reporting of deaths to OPOs using protocols defined by the OPOs.

During our analysis, we identified a number of advantages and disadvantages to each of these alternatives before we concluded with the proposal to require mandatory reporting of deaths to OPOs using protocols defined by the OPO as discussed below. However, we are specifically soliciting comments on the advantages and disadvantages of the various options, and inviting identification of additional alternatives and empirical data supporting various opinions, during the public comment period.

The advantages of the current requirement, which specifies that hospitals have a protocol for referring potential donors, are that it provides hospitals with desired flexibility and it reiterates the language of the statute. However, there are significant disadvantages to this approach. The primary concern is that many hospitals have never referred a potential donor. As noted above, we believe that there has been a large number of potential donors that have been missed; that is, we believe the number of potential donors is double to triple the number of current donors. We are concerned that this flexibility has resulted in a significant number of hospitals failing to refer all potential donors and some hospitals not referring any donors. Some hospitals view as potential donors only those in whom consent to donate has already been obtained

and do not even attempt to ask other families about the possibility of donating; others refer only when they consider the deceased to be a good candidate or when they believe the family may consent to the donation. This leads to a loss of opportunity for families for whom the gift of a loved one's organ may be the first step in the healing process as well as the loss of a substantial number of life-saving organs.

We also considered the alternative of requiring referrals of all deaths to the OPO. The State of Pennsylvania has implemented this practice. The resulting increase in donation in Eastern Pennsylvania has been at least 10-percent. We believe telecommunication technology currently exists to permit low-cost and efficient implementation of a policy requiring referrals of all deaths. OPOs that have implemented such programs indicate that reporting of an individual's death and relevant medical information takes only 5 to 10 minutes of time by hospital staff. Under such a system of mandatory death reporting, it is reasonable to assume that no potential donor will go unidentified and few, if any, families of potential donors will go without being given the opportunity to donate. This system also has the advantage of relieving hospital staff of the burden of making any assessment of donor suitability or the families' willingness to donate. Finally, as more families are educated about organ donation, even if they

decide not to donate, myths that inhibit organ donation may be dispelled.

Despite the major advantages to this alternative, there are two potential problems. First, there is clearly a significant cost involved in providing and interpreting information on over 1 million deaths annually. Conservative implementation estimates of this alternative are about \$4 million annually (1 million deaths times 5 minutes of hospital and OPO time at an assumed average salary cost of \$50,000), and may be as great as \$8 to \$10 million. Arguably, the saving of even a single statistical life would justify such a cost, using standard benefit-cost analysis assumptions. Nonetheless, we recognize that these costs should not be imposed if less costly approaches can also achieve increased organ donation. Second, such a system of mandatory reporting could create difficulties where hospital-OPO relations are strained. OPOs that have implemented systems for reporting of all deaths (either mandated by State law or voluntarily) have reported that mandatory reporting has been difficult at some hospitals. In discussing this alternative with the OPO industry, we have been advised by some OPOs that they are concerned about implementing such a system because they would have to handle a large number of unproductive referrals. That is, of the approximately 1 million deaths annually, only about 12,000 to 15,000 are potential organ donors. The problem of

strained relationships would be exacerbated in areas where the OPO does not desire to implement mandatory referral of all deaths.

This proposed regulation includes the requirement that hospitals report all potential donors using protocols as defined by the OPO. This alternative has the advantage of providing support for OPOs in dealing with recalcitrant and low referral hospitals, while providing a great deal of flexibility for OPOs to respond to local community situations and resource limitations. As noted above, we solicit comments on alternatives that could be more responsive to the national organ shortage. We also welcome comment on whether an outcome standard could be used to determine hospital compliance. In principle, procedural standards related to organ procurement could be replaced by an outcome standard related to organ recovery. However, we are not clear as to how to design or implement an effective, low-cost standard.

Finally, we are proposing to add a new requirement that specifies that hospitals work cooperatively with the designated OPO in educating hospital staff on donation issues, reviewing death records to improve identification of potential donors, and maintaining patients while necessary testing and placement of potential donor organs take place (proposed § 482.110(c)(1)(iv)). We do not believe this requirement is unduly burdensome on hospitals since all

reasonable hospital costs incurred with respect to any organ procurement effort are paid. We invite comments on the content of this new requirement.

13. Infection Control (\$ 482.115)

The present requirements on infection control (\$ 482.42) were promulgated as a separate COP largely due to the seriousness of the problem of nosocomial infections. Nosocomial infections subject patients to significant additional pain and risk, prolong hospital stays, and lead to significant additional costs in health care spending.

We propose to maintain a separate COP on infection control because we believe it is vital for protecting patient health and safety. We propose to retain most of the standards under the current COP, but we would strengthen its focus by requiring hospitals to take appropriate actions that result in improvement when problems are identified in their infection control programs. This is in concert with the proposed quality assessment and performance improvement COP, of which infection control must be an integral part.

The proposed infection control condition places accountability on hospitals to prevent, control, and investigate infections and communicable diseases, and take actions that result in improvements. However, the proposed condition allows flexibility for hospitals to determine how to meet these objectives. This includes the flexibility to

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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. list	VPOTUS Organ Donation Event meeting clearance list (partial) (10 pages)	12/15/1997	b(6)

COLLECTION:

Clinton Presidential Records
Office of Science and Technology Policy
Jerald Mande
OA/Box Number: 13034

FOLDER TITLE:

Organ Procurement and Transplantation Network (OPTN): Vice President Event 12-15-97

2008-1524-F
kc1222

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]

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Paul Hegarty

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Vice President Organ Donation Event
 Monday, December 15, 1997
 Room 450, OEOB

Aiken-O'Neill, Patricia	(b)(6)	Eye Bank Association of America (202) 775-4999
Anderson, Jarold		Regional Organ Bank of Illinois (312)431-3600
Armata, Thomas		SEOPF (804) 342-1412
Bagby, Stephen G.		Recipient
Beasley, Carol		The Partnership for Organ Donation (617)482-5746
Bernstein, Toby Devens		Tissue Bank International
Bolden, Alfred		Amer. Soc. Of Minority Health 313-369-0398
Borowiecki, Marion		Transplant Resource Center of Maryland, Inc. (410)242-7000
Bottenfield, Helen W. Leslie		Life Net 757-474-1275
Brownstein, Alan P.		American Liver Foundation
Breznick, Brian		Center for Organ Recovery & Education
Callender, Clive O.		Howard University
Campbell, John		Lifelink (813)253-2640

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Chandler, Susan Diane	(b)(6)	Mid-America Transplant service (314)991-1661
Chianchiano, Gandolfo		National Kidney Foundation 703-524-2797
Childress, James Franklin		UVA
Cipriano, Pamela		Med University of S. Carilina (803)792-2123
Clarke, George		Nat. Selected Morticians (847)559-9569
Coble, Yank D.		American Medical Association (904) 388-9345
Cochran, Lawrence		Tennessee Donor Services (615)327-2247
Coolican, Margaret B.		National Kidney Foundation
Cooper, Mary Lisa		Carolina Lifecare (910) 774-4450
Coppo, Patricia A.		National Marrow Donor Program (612) 627-5815
Critchfield, Donald		Awaiting a liver transplant
Cutler, James Allen		Southwest Transplant Alliance 214-821-1931
Danneffel, Mary Beth		Eye Bank Assoc. Of America (713)798-5849
Downs, James		Family member of recipient

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Downs, Ana Jo	(b)(6)	Family member of recipient
Ferguson, Ronald		ASTS (614)293-8701
Fields, Vikki Montgomery		Seventh Day Adventists (301) 680-6733
Fischer, Karen S.		Association of American Medical Colleges (202) 862-6140
Fiske, Charles		Family member of transplant recipient
French, Lynn		African-American Community Health Network (206)860-9883
Fuller, Richard		Tissue Donor International (410)752-3800
Fung, John		U of Pitt Med Center
Ganikes, Margaret D.		American Medical Association (202) 789-7409
Gleeson, Susan		Blue Cross/ Blue Shield Association (312) 297-5577
Goldstein, Robert A.		Juvenile Diabetes Fd. 212-479-7523
Gorden, Phillip		National Institute for Diabetes 301-365-0288
Graham, Walter K.		United Network for Organ Sharing (804) 330-8500

Gunderson, Susan Raether	(b)(6)	Life Source 612-603-7800
Harrington, Baxter		Lifenet Transplant Services
Harter, Charles		Awaiting a liver transplant (712-366-9553)
Heinrichs, Dennis		Lifelink
Hill, Shaun Lynette		National Medical Association 301-431-4155
Hoffman, Robert		University of Wisconsin Hospital and Clinic
Holtzman, Samuel M.		Life Gift Organ Donation Center (713) 523-4438
Howe, Craig		National Marrow Donor Program (612)627-5850
Hulnick, Warren		TRIO
Hulnick, Ellen		TRIO
Hunsicker, Lawrence		United Network for Organ Sharing 319-356-4763
Ignagni, Karen		American Association of Health Plans 202-778-3206
Irwin, Robert		Recipient
Irwin, Craig		National Transplant Action Committee
Isham, George		American Association Of Health Plans 202-778-3206

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Jarvis, Dorothy G.		Recipient
Jones, Eleanor		TransWeb 313-998-7394
Jones, Linda		Lifeline of Ohio (614)291-5667
Joyce, Michael J.		American Association of Tissue Banks (216)444-4282
Kay, Nancy A.		ACOED
Klintmaum, Goran B.		Baylor University
Knight, Monique		Organ Tissue and Acquisition Center 619-486-4088
Kory, Lisa Rene		Transplant Recipients
Lacey, Joan R.		NJ Organ and Tissue Sharing Network
Lane, Janet Pursell		American Red Cross
Leino, Edward Victor		American College Health Association
Lewis, David		LifeCenter
Linderer, Rob		Midwest Organ Bank (913)262-1666
Luskin, Richard		New England Organ Bank 617-244-8755
Lynch, Jackie D.		Regional Organ Bank of Illinois
Manley, Michael		501-224-2623

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Mattice, Burt		Life Connection of Ohio 1-800-535-9206
May, S. Randolph		American Red Cross (202) 728-6407
McCartt, William Lee		Life Resources Regional Donor Center (423)929-1638
McCluskey, Charles		U. Of Florida 800-535-4483
Medina, Mary		Mt. Sinai 201-343-0881
Merion, Robert M.		TransWeb
Miller, Charles M.		Mt. Sinai
Mongoven, Ann		Indiana University (812)855-6669
Morgan, Rudolph		Upstate New York Transplant Service (716)853-6667
Morien, Marsha		University of Nebraska Med Center (402)895-9562
Moritsugu, Erika		Donor family member (301) 593-3005
Moritsugu, Kenneth		Dept. Of Justice (202)307-3055
Mowe, Jeanne		American Association of Tissue Banks

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Nathan, Howard			Delaware Valley Transplant Program	
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Nelson, Kristine A.			LifeBanc (216) 752-5433	
Neylan, John Francis			American Society of Transplant Physicians	
Nichols, Jackie Lynn			American Medical Women's Association	
Norman, Andrea			Life Connection of Ohio (419)893-4891	
Olson, Leslie C.			Univ. Of Miami 305-243-7622	
Orrico, Katherine O.			AANS/CNS	
O'Flynn, Paul			Kentucky Organ Donor Affiliates (502)581-9511	
Parker, Wendy			American Association of Nurse Anesthetists (202-484-8400)	
Patrick, Charles H.			Alabama Organ Center	
Pilotoski, Gisele			National Kidney Foundation	
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Reardon, Clare			Wisconsin Donor Network	

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Rossi, Lisa			Recipient
Schaeffer, Margaret			Washington Regional Transplant Consortium (703) 759-6799
Semple, Nathaniel			Recipient
Shipman, Judy			Mid-South Transplant Fdn.
Singh, Rajwant			InterFaith Conference of Metropolitan Washington
Sparrow, Cassandra			Congress of National Black Churches
Stachelski, Stephen J.			American Red Cross (703) 312-5515
Stanton, Nancy			Lions Eye Bank
Stoner, Eugenia			U of Pitt Med Center (412)647-8481
Stroeve, Bruce			Musculoskeletal Transplant Foundation
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Tomasic, Sharon			Family member of recipient
Trautwein, Edward Neil			Chamber of Commerce
Vladeck, Bruce			Mt. Sinai 212-241-6868
Watson, Janice			Virginia's Organ Procurement Agency (804)794-4122
Webb, Toni			Washington Regional Transplant Consortium
Weber, Phyllis			California Transplant Donor Network in San Fran. (415)837-5888
Weir, Gamble Bruce			TRIO
Whiteside, Daniel Fowler			Assoc. Of Organ Procurement 301-231-5330
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