



Organ Donation File

CONTACT: Carol Schadelbauer 202/626-2342
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**STATEMENT ON THE ADMINISTRATION'S INITIATIVE
TO INCREASE ORGAN DONATIONS**

Dick Davidson
December 15, 1997

The Administration wants to increase the number of organ donations. So do the nation's hospitals and health systems. We appreciate the Vice President's long-standing leadership on this issue, and support the proposed public-private partnerships to improve public awareness of the need for organ donation, and the effort of the government to show leadership as an employer by providing information on organ donation to federal employees. Further, we look forward to Secretary Shalala's conference next spring. All parties need to work harder to improve the record on organ donation.

The reality is, organ donation is an issue that requires great sensitivity and is extremely personal. It needs to be worked out case by case on a local basis - family, doctor and chaplain working together. The decision to donate organs comes at a time when the families must face the painful loss of a loved one. Hospitals should retain their flexibility to treat each individual with sensitivity.

Hospitals have policies for discussing the option of organ donation with families of potential donors, and will continue to work with their staffs and communities to increase the number of donors. The proposed rule would replace these hospital local initiatives with policies established by an outside organ procurement organization. But hospitals and health systems must be free to manage in ways that work for the communities we serve, not based on regulations that may be good for one but not another.

So while we share the Administration's goals on this critical issue, we question whether there is significant research and evidence to show that, as currently constructed, the proposed regulatory approach is the best way to achieve our shared goals. AHA believes that other options should be explored before regulations are made final, and appreciates the Administration's commitment to work collaboratively with us through the rulemaking process to identify alternatives. Our members want to find the best practices to increase organ donation, but they should be allowed to use their best judgment in treating patients.

Washington, DC Center for Public Affairs

Chicago, Illinois Center for Health Care Leadership

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DRAFT

**ORGAN AND TISSUE DONATION INITIATIVE
December 15, 1997**

Questions and Answers

General:

Q: Why is a new national initiative needed? Don't we already have campaigns for organ donation?

A: With advances in medicine and technology, the number of people waiting for organs has grown dramatically. Even with the increases we've seen in organ donation, we still have a growing gap between the number of available organs and the need. Some 4,000 Americans die each year while awaiting an organ transplant. We can do better, and a broad public/private partnership will achieve significant new results.

Q: How can you expand the supply of organ donors? Aren't we already getting as many as are available?

A: We're missing literally thousands of potential donations each year. There are an estimated 10,000 to 15,000 deaths each year that could result in donation - but the number of donors is around 5,500 (cadaveric donors). In many cases, the reason is that the family doesn't know that the individual would have wanted to be a donor. In some cases, deaths that could result in donation are not being identified or families aren't being asked. We need to encourage individuals to make the choice, AND encourage them to share that choice with their families -- and then we need to make sure our medical system works successfully to identify potential donors and to be sure families are given the opportunity to donate.

Q: Are hospitals to blame for the shortage?

A: No. Our most important job is to encourage individuals to make their choice about organ donation AND to share it with their families. Then we need to work with the transplant community across the board to make sure there is collaboration and cooperation, so that opportunities are not missed unnecessarily.

hospitals, consumers, physicians

DRAFT

Q: Explain the proposed hospital regulation.

A: In order to ensure that potential organ donors are identified and that their families are given the opportunity to decide on donation, HHS is proposing an approach for a collaborative relationship between hospitals, organ procurement organizations and others in the transplant community. Basically we want to make better use of the expertise of the nation's 63 organ procurement organizations. The proposal is that hospitals use policies and procedures set by the OPOs in identifying those deaths that could result in organ donation. It would also require that hospitals and OPOs collaborate on how best to carry out the delicate task of helping families understand how their loss can become another family's gift of life. Again, we want hospitals to have the benefit of the expertise of the organ procurement organizations, and we want the transplant community to work collaboratively to ensure that families or potential donors are given the opportunity to donate.

Q: Are hospitals supporting or opposing the proposed regulation that would require them to adapt the policies of organ procurement organizations?

A: HHS has made a proposal which grows out of the successful experience that Pennsylvania has had in bringing together hospitals, organ procurement organizations and others in the transplant community. HHS has pledged to work with hospitals, OPOs, tissue banks and others to achieve a workable final rule as quickly as possible. It is our understanding that the hospital and other organizations share our goals for increased organ donation and have expressed the willingness to work together in shaping an approach that will help bring about that result.

Q: How much increase in donation do you believe is possible? How many fewer deaths would result?

A: HHS estimates that with a concerted effort, we can increase organ donation nationwide by as much as 20 percent in two years. This is based partly on the success that was observed in studies in southeastern Pennsylvania. There is really no way to set an absolute "goal," and we cannot make an estimate of the possible reduction in deaths, because too many factors come into play. But a 20 percent increase in donors would be about 1,000 more donors each year, and typically a donor provides more than one organ. So we are confident that we if we can make substantial increases in donation, this will result in significant decreases in death among those on the waiting list.

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Q: What will the "partners" in the Initiative do?

A: The object of the partnership is to make use of the particular strengths of each partner. For example, the American Bar Association can encourage its members to raise the subject of organ donation and other advance directives as part of the preparation of wills. The American Medical Association can encourage doctors to make organ donation materials available in their offices and to be ready to discuss this with patients. Other partners have the ability reach particular audiences. This is a very broad-based effort to encourage individuals to make the choice - AND to share it with their families.

Q: What kind of research do you envision?

A: We need to be more systematic in learning what works to bring about organ donation, and what barriers stand in the way. HHS is sponsoring a conference next spring to help focus this kind of research. *(man wants to say who you might bring in)*

Q: Is there money behind this initiative?

A: Following the President's request for an increase, the HHS budget for organ donation efforts in the Health Resources and Services Administration in FY 1998 is \$700,000, which is a 250 percent increase over FY 1997. These funds will be used to support organ donation activities, including those of the initiative. Of course our primary resource is the public/private partnership. The value of the volunteer services of our partners will be enormous, and we will get extra impact by unifying our messages with the those of the Coalition on Donation.

Other:

Q: What is the status of final regulations governing the Organ Procurement and Transplantation Network? Hasn't it been a year since special hearings took place? What will it do about liver allocation in particular?

A: HHS is finalizing its work on the final OPTN regulation. We expect it to be published soon. We cannot comment on the contents before it is issued. (The date of the hearings was Dec. 11-12.)

DRAFT

Q: Why did you announce a donation initiative before you published the OPTN regulations?

A: HHS has been preparing the National Initiative since earlier this year and now it is ready to be announced. Everyone agrees that the core, bottom-line problem is the availability of organs for transplantation. That's why this initiative is so important. Only by increasing donation can we really ameliorate the growing gap between the need and the supply.

Q: The "60 Minutes" program raised ethical concerns about one kind of organ donation, that which involves non-heart-beating donors. What is being done about that?

A: Non-heart-beating donors are a very small part of all organ donation – only in the range of one or two percent of all donation. HHS does not believe there are new or unusual ethical concerns in non-heart-beating donation, but the Department did ask the Institute of Medicine to review some specific medical questions, especially involving the appropriate use of certain drugs that can help preserve organs. IoM has not yet issued its response to HHS.

Q: Under the current regulations or the proposed rule for hospitals, can organ procurement organizations require hospitals to report potential donors who are not yet dead?

A: The current Medicare law requires hospitals to report potential donors to OPOs. The thrust of the new regulation we are proposing is to reflect the Pennsylvania statute which requires hospitals to report deaths. Under the proposed change, we expect that hospitals and OPOs would work collaboratively in each locale to develop policies and procedures that will result in properly identifying potential donors.

Q: Did tissue banks have appropriate opportunity to comment on the proposed regulation?

A: HHS plans to work with the entire transplant community to develop a good final rule.

The comment period opens with the publication of the regulation this week. We

look forward to working to ensure the best possible final rule.

This is only the beginning of a process

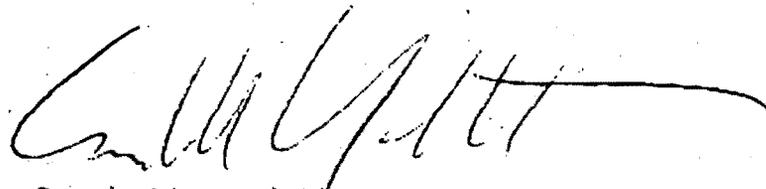
SPECIAL

December 11, 1997

NOTE TO:

Chris Jennings
Sarah Bianchi
Heidi Kukis
Toby Donenfeld
Barbara Woolley

In case everyone hasn't already seen this, here is the draft fact sheet for reporters who may want more background about the hospital regulation.



Campbell Gardell
HHS Press Office

cc: Melissa Skolfield
Kevin Thurm

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TRANSPLANT PHYSICIANS

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1997-1998

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17th Annual Meeting

May 10-13, 1998

Chicago Sheraton Hotel & Towers
Chicago, IL

December 12, 1997

Albert Gore, Jr.

Vice President

The White House

1600 Pennsylvania Avenue, NW

Washington, DC 20500

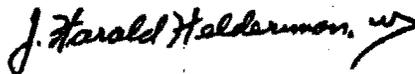
Dear Mr. Vice President:

On behalf of the membership of the American Society of Transplant Physicians, we want to thank you for the invitation to attend the launch of the President's Organ-Tissue Donation Initiative. We are particularly pleased that you are personally involved in this effort to increase organ donation in America. We remember very favorably your strong leadership when you were in the House of Representatives and the US Senate, in particular, your sponsorship of specific legislation including the landmark, Transplant Act of 1984. In that regard, we have enclosed the American Society of Transplant Physician's White Paper entitled, "The Decade of Transplantation", which reviews the state of transplantation since 1984.

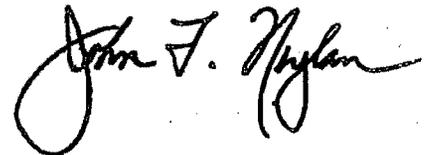
We applaud these new initiatives to be announced on Monday, December 15, 1997. We respectfully suggest that any new partnerships include medical transplant professionals as a cornerstone of these initiatives.

Mr. Vice President, we stand ready to serve as a partner to assist you and the President in all ways possible to increase organ donation so that the 56,000 Americans currently on waiting lists will have access to the "gift of life".

With warm best wishes to you and your important work for our Country, we are respectfully,



J. Harold Helderman, MD
President



John F. Neylan, MD
President-Elect

Enclosure (via messenger)

NATIONAL OFFICE

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E-mail: astp@slackinc.com • <http://www.astp.org/>

American Society of Minority Health & Transplant Professionals

Friday, December 12, 1997

The Honorable Al Gore
Vice President of the United States
The White House
Washington DC.

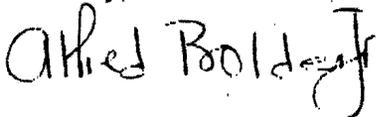
Dear Mr. Vice President:

I applaud and support the efforts of you and the Federal government to increase the awareness of the American public about the critical shortage of available organs and tissues for transplantation. As President of the American Society of Minority Health & Transplant Professionals, I am particularly pleased with this effort because minorities are disproportionately represented on transplant waiting lists across the nation.

The proposed public and private partnership initiative is an excellent opportunity to stem the current tide of the growing number of individuals who die waiting for a life saving transplant and for those life enhancing transplants that enables individuals to remain productive citizens. The introduction of legislation requiring hospitals to contact and involve the organ procurement staff is a monumental step in the right direction.

Thank you very much for giving the transplant community the needed support and direction in these proposed initiatives. I am honored to serve you in this initiative in any way possible, please don't hesitate to call upon me.

Sincerely,



Alfred Bolden Jr.
President, American Society of Minority Health & Transplant Professionals



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 that reads "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



NATCO
North
American
Transplant
Coordinators
Organization

December 12, 1997

The Vice President
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 Lenexa, KS 66285-6384

Dear Mr. Vice President:

Thank you for the invitation to attend the Washington, D.C. meeting Monday, December 15. We are very excited about the Clinton Administration's involvement in this initiative as the organ shortage is truly at a national crisis level and impacts significantly on the health of thousands of Americans.

For your information, the North American Transplant Coordinators Organization (NATCO) is the largest group of transplant professionals in North America. With 1,750 members, we represent coordinators working in both the clinical transplantation and organ donation arenas. Initiatives to increase the awareness of the need for organ donors impact all of the families we deal with on a daily basis. You have our support and our willingness to contribute to this initiative in any way possible.

To emphasize the plight of many Americans today, following is an electronic mail which I received from a concerned party.

"Mel is the 38-year-old wife of Glen Mitchell and mother of three children; Sean 10, Bret 7, and Connor 3. Mel was diagnosed with acute liver failure on December 7th and is on the waiting list for a new liver. Her fabulous team of physicians has given Mel 3-7 days to receive a life saving liver transplant."

"Mel is currently in an induced state of coma in order to extend the time needed for her transplant. Her family and friends from all over the nation have come to provide emotional support for Mel and her family in this time of waiting for a viable transplant."

Vice President Gore

Page 2

"This message is a plea from a friend, neighbor, and father of four that values the complete family unit. Any assistance you can provide in securing this transplant would make this a Christmas to remember for the Mitchell family and all those close to them. Please help make this a Christmas of Joy for this needy family."

Mr. Gore, unfortunately all of us in transplantation know of the agony that this family is suffering right now. As you well know, ten people die each day waiting for donated organs forcing too many family and friends to endure what is so clearly depicted by Mel's story. As NATCO's President, I appreciate the opportunity to applaud your efforts to increase organ (and tissue) donation in the United States.

On behalf of the NATCO membership and all of the patients and donor families we serve, thank you for spearheading such an effort. We will look forward to having your continued input and enthusiasm to bring this initiative to fruition.

Sincerely,



Laurel Williams Todd
President
North American Transplant
Coordinators Organization

AOPO

Association of
Organ Procurement
Organizations

December 12, 1997

Albert Gore, Jr.
Vice President
Old Executive Office Building NW
Washington, DC 20501

Donna Shalala
Secretary of Health and Human Services
200 Independence Ave, SW
Washington, DC 20201

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Executive Director

Dear Mr. Vice President and Madam Secretary,

The Association of Organ Procurement Organizations (AOPO) represents 49 of the nation's 63 organ procurement organizations (OPOs). Our mission is to recover organs for transplantation, thus saving lives.

AOPO is aware of your long interest in organ transplantation and the important role you played in the passage of the National Organ and Transplantation Act when you were in the Senate. Implementation of this Act has strengthened OPOs and increased organ and tissue donation awareness. We appreciate this effort.

Now, you are preparing to announce a government initiative to increase awareness about organ and tissue donation. We applaud you and Secretary Shalala for undertaking this initiative. We support a change in regulation which will assure that potential donors are appropriately referred. We encourage the private/public partnerships which the Department of Health and Human Services will forge with groups throughout the country. Such partnerships are essential if we are to fulfill our objective of increasing awareness about donation. An effort to make federal employees aware of and sensitive to donation can only help OPOs in achieving their objective of increasing the number of organs recovered.

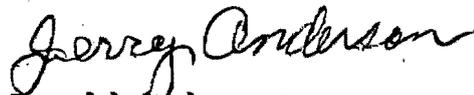
Continued page 2 Vice President Albert Gore, Jr. and Madam Secretary Donna Shalala

AOPO looks forward to participating in the donor awareness conference which is being planned for next spring.

AOPO and its member OPOs will do our part to make this initiative a resounding success. We applaud you and thank you for your interest in organ and tissue donation.

Best wishes.

Sincerely,



Jarold Anderson
President



Daniel F. Whiteside, D.D.S.
Executive Director

cc: AOPO Executive Directors



Jerold R. Mande

12/12/97 11:03:06 AM

Record Type: Record

To: Christopher C. Jennings/OPD/EOP, Barbara D. Woolley/WHO/EOP, Toby Donenfeld/OVP @ OVP
cc: Sarah A. Bianchi/OPD/EOP
Subject: Caplan Statement on VP Transplant Event

Here is a draft statement from Caplan. Please get me any comments by 1pm so I can get the final letter to Barbara by COB. Thanks.

PS I am in contact with Jim Childress and I hope to have a statement later today. I can get additional ethicists to make affirming statements. Let me know if you think it would be helpful to do so.

----- Forwarded by Jerold R. Mande/OSTP/EOP on 12/12/97 10:55 AM -----



caplan @ mail.med.upenn.edu
12/11/97 11:14:32 PM

Record Type: Record

To: jmande
cc:
Subject: cannot get there on monday at 11 but here is a statement--edit away and send it back

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 the 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 committment 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 then 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 Caplan
Center for Bioethics
University of Pennsylvania

<http://www.med.upenn.edu/bioethics>

DEC. -12'97(FRI) 14:59 ABA PUBLIC AFFAIRS

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P. 002

A B A M E R I C A N B A R A S S O C I A T I O N

NEWS RELEASE**STATEMENT OF JEROME J. SHESTACK PRESIDENT OF THE AMERICAN BAR ASSOCIATION ON NEW NATIONAL ORGAN AND TISSUE DONATION INITIATIVE**

December 15, 1997

The American Bar Association is pleased to join the Federal government in its national initiative to increase organ and tissue donation in the United States. Thousands of individuals die each year waiting for an organ to become available. To increase the rate of donation, public and professional awareness of the need for donors must be encouraged.



United
Network
for
Organ
Sharing

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Richmond, Virginia 23225-8770
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Fax 804-330-8517

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December 12, 1997

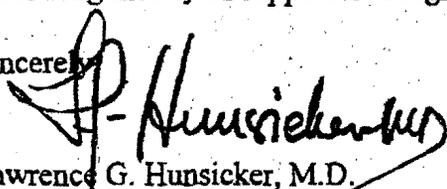
Vice President Al Gore
The White House
1600 Pennsylvania Avenue, N.W.
Washington, D.C. 20500

Dear Vice President Gore,

We applaud the Vice President's efforts to increase the awareness of the American public about organ donation. UNOS is well aware of the proposed regulation that asks hospitals to inform OPO's of certain hospital deaths and supports this regulation.

Your long history of support is recognized and appreciated.

Sincerely,


Lawrence G. Hunsicker, M.D.
UNOS President

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Executive Director Emeritus

File
organ donation

American Medical Association

Physicians dedicated to the health of America



DRAFT

Statement

FOR IMMEDIATE RELEASE

December 15, 1997

AMA APPLAUDS CLINTON INITIATIVE TO INCREASE ORGAN DONATIONS

Urges Americans to "become organ donors and make a life-or-death difference"

Statement attributable to:

Yank Coble, MD
AMA Trustee

"The American Medical Association is deeply concerned about the need to increase organ donations in America. More than 55,000 people in the United States are waiting for life-saving organ transplants. Tragically, more than 4,000 people will die this year because organs will not become available to them in time.

"Every adult should become an organ and tissue donor. With both government and private-sector attention focused on this urgent need, we can make a life-or-death difference.

"We applaud Vice-President Gore and Secretary Shalala for the Administration's leadership in addressing this critical public health issue. The AMA is encouraged by the Administration's commitment to use its strong bully pulpit to highlight the importance of organ donation.

"Just last week, during our policy-making meeting, the AMA reaffirmed its commitment to educate physicians and patients on the importance of becoming organ donors. The AMA will work with specialty and state medical societies to encourage physicians to discuss organ donation with their patients, and we will work with HHS to identify the most effective ways to increase organ donations in our nation.

"We look forward to working collaboratively with the Administration, hospitals, the transplant community, and patients to ensure that the Health Care Financing Administration's final regulation on Medicare Conditions of Participation for Hospitals is a balanced and effective way to increase organ donations and save lives."

#

For more information, please contact:

Brenda L. Craine
202/789-7447

1101 Vermont Avenue, NW
Washington, DC 20005
202 789-7400

Handwritten note:
Brenda L. Craine
202/789-7447

Organ Transplant File**LIGHTLE, BEEBE, RANEY AND BELL**

ATTORNEYS AT LAW

211 WEST ARCH AVENUE

SEARCY, ARKANSAS 72143-5331

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501-268-5306 (FAX)

MIKE BEEBE
DONALD P. RANEY
A. WATSON BELLJ.E. LIGHTLE, Sr. (1932-45)
J.E. LIGHTLE, Jr. (1936-88)

JAMES A. SIMPSON, Jr.

October 29, 1997**VIA FAX TRANSMITTAL**

Mr. Chris Jennings
Adviser to the President on Healthcare Policy
The White House
1600 Pennsylvania Avenue, N. W.
Washington, D.C. 20500

Dear Chris:

Some of my organ transplant colleagues reported what they felt was an excellent meeting with you and OMB representatives last week. Because of your openness and fairness in our previous discussions, I was not surprised to hear such positive remarks.

One comment they made, though, was of concern to me. They sensed some displeasure with UNOS, particularly regarding the issue of data release. This prompted me to write to you because of my longstanding involvement with UNOS and my lengthy personal friendship with UNOS Executive Director, Walter Graham. (You may remember from our visit several months ago that Walter is an Arkansas native who attended the same college and law school as I.)

As a member of the UNOS Board of Directors, I want to pledge my continuing commitment to improving the information UNOS makes available to transplant patients. In three years chairing the UNOS Patient Affairs Committee, I devoted countless hours of volunteer time to that issue.

I am saddened by what I see as an undeserved negative image of UNOS regarding data release. As any organization in the public eye, UNOS has made its share of mistakes. But, no organization anywhere in the world publishes as much patient-oriented information. The UNOS center-specific report of survival rates is a one-of-a-kind report that is of tremendous benefit to patients – it is literally the envy of the world.

I have watched UNOS' reputation take an unfair pasting since last year when HRSA gave a newspaper reporter a copy of a computer report containing preliminary, unvalidated data. UNOS has provided that initial report to HRSA management for program review purposes. Because it was preliminary, the report did not include proper analysis and explanation that would accompany public dissemination of such complex information. As a result, it was grossly misleading to anyone who was not directly involved with its preparation. Further, it contained confidential information that

Mr. Chris Jennings

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the OPTN data policies prevent from release. Nevertheless, HRSA gave it to a reporter and did so, I am told, without following HHS's FOIA regulations requiring notification prior to release.

UNOS and its members were completely blind-sided by this unprecedented action. As a result, UNOS was thrown into a classic "no-win" position. The *Cleveland Plain Dealer's* outrageous portrayal of the data, complete with inflammatory and sensational headlines, made false assertions based on a fabrication of the data, attributed erroneously to UNOS in the story.

In my estimation, this shameful affair caused irreparable harm to transplantation. The reputations of excellent institutions and professionals were savaged needlessly, hurting the very people I have dedicated myself to helping -- transplant patients. I understand that in at least one transplant program, this unseemly episode resulted in the loss of surgical capability, leaving patients at that center in a quandary.

I remember Walter's personal distress over the grossly unfair picture painted by the scurrilous attacks. He and I have both advocated greater emphases on patient information. During my tenure as Chair of Patient Affairs, a subcommittee of patients from around the country developed excellent recommendations for greater information that met patient's most urgent needs. The UNOS Board approved those recommendations unanimously, and they are being implemented.

Perhaps the most telling aspect of this whole affair was the action taken by the UNOS Board. The Board, including the patient and donor representatives, voted unanimously on two separate occasions to instruct the staff to not release the so-called "turndown data" because it was so misleading. It is deeply ironic that the driving force behind those votes was the strong desire and commitment by UNOS to do what is in the best interest of transplant patients. Yet, that action is depicted by UNOS' detractors as quite the opposite.

I am extremely proud that a third of the UNOS Board comprises patients, donors, and family members like Jean Ann or me. Our collective voice is a powerful force in UNOS -- more than any such body I have ever encountered. On three different occasions in the past two years, I was humbled and deeply moved by the rousing ovation given by the entire UNOS Board to remarks I made advocating patient needs.

At its last meeting, the UNOS Board voted to get the organ acceptance data into good enough shape to be released. A special scientific committee has been working at an accelerated pace to complete an in-depth risk-adjusted analysis of the 1995 and 1996 data for public presentation at the November Board meeting. At UNOS' invitation, HRSA has been participating in this analysis with HRSA staff participating in four of the committee's six working conferences.

Last week, UNOS was completely surprised to be told that it would receive an official notice the next day stating that HRSA had decided to release even more of the old, confusing data. You can

Mr. Chris Jennings

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imagine the shock and dismay when we learned that unless ordered by a court within five days, as their letter put it, to not release the data, HRSA would release the data without further analysis or explanation.

After frantic negotiations over several days involving numerous volunteers as well as staff, HRSA agreed to a week's extension. This would permit UNOS to meet with senior HRSA management to discuss the study – the same study in which HRSA staff have been participating for the past several months.

It is encouraging that HRSA has agreed to meet and discuss this issue. However, I am at a loss to explain why the Government places UNOS in such awkward and adversarial positions. I cannot help but think that UNOS' image has been unfairly affected by such instances. I know I speak for Walter and those in UNOS' volunteer leadership when I say that we truly desire a productive and mutually supportive relationship. If there were a role I can play in bringing that about, I would be most happy to do so.

Thank you again for all of your support of organ transplantation. Please feel free to call me at any time if I can be of service.

Very truly yours,


A. Watson Bell

AWB/jo

cc: Senator Mike Beebe

File organ re-allocation meeting.

Vanderbilt University Medical Center

Nashville, TN 37232-2104
(615) 322-2151

FAX TRANSMISSION

FAX: 615-343-7285

To: Chris Jenkinson Date: 10/22/97

Fax #: 202-456-5557 Page: 3

From: Marilee Yager

Subject: attached

COMMENTS:

If you have any questions about this fax please call:

WHITE HOUSE MEETING ON TRANSPLANT REGS
THURSDAY, OCTOBER 23
1:00PM, ROOM 211 (EOB)

ATTENDEES:

John Clifton McDonald, M.D.
Louisiana State University

Bonnie Jean Hymel, Government Relations
Louisiana State University

Clifford Holly Van Meter, Jr., M.D.
Ochsner Medical Institution

Mark William Beckstrom, Government Relations
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John M. Rabkin, M.D.
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Vanderbilt University Medical Center

 **Vanderbilt University Medical Center**

Vice-Chancellor for Health Affairs

D-3300 Medical Center North
Nashville, TN 37232-2104
(615) 322-2151

OCTOBER 21, 1997

MEMORANDUM

TO: SALLY KATZEN, CHRIS JENNINGS, AND BARBARA WOOLLEY

FROM: MARILYN YAGER, DIRECTOR, HEALTH POLICY DEVELOPMENT

RE: MEETING ON HHS LIVER ALLOCATION REGS ON OCTOBER 23

Thank you for your willingness to meet with a group of eight transplant directors representing a coalition of sixty regional transplant centers at 1:00pm on Thursday, October 23. It is my understanding that we will be meeting in Room 211 of OEOb.

I have attached the list of individuals attending, but wanted to provide you with an outline of issues we plan to address:

- o Our hope these the regulations will be proposed and therefore provide an opportunity for public comment.
- o A brief summary of steps UNOS has taken to respond to problems raised during the HHS hearing last year, particularly in response to disparity in waiting times.
- o Studies regarding National versus regional allocation.
- o The importance of regional centers in serving large numbers of Medicaid and uninsured transplant patients who don't get accepted by centers outside of their state.
- o The ability of regional centers to generate homegrown interest in organ donation.

If I have failed to touch on issues that you wish us to come prepared to discuss, please do not hesitate to contact me.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Deputy Secretary

Washington, D.C. 20201

FACSIMILE

Organ Allocation & Donor File

(put copy on liver in this file)
DATE June 12, 1997 for

TO: (NAME, ORGANIZATION, CITY/STATE AND PHONE NUMBER):

Chris Jennings
202/456-5593

FROM: (NAME, ORGANIZATION, CITY/STATE AND PHONE NUMBER):

Lisa Gilmore
Special Assistant to the
Deputy Secretary
DHHS

202/690-6133
202/690-7755 (Fax)

RECIPIENT'S FAX NUMBER (202) 456-5557

NUMBER OF PAGES TO SEND (INCLUDING COVER SHEET): 27

COMMENTS:

Background materials for tomorrow's discussion

Lisa

NOTE TO CHRIS JENNINGS

From: Lisa A. Gilmore *L.A.G.*
Subject: Draft National Organ and Tissue Donation Initiative
Date: June 12, 1997

Here is the draft Initiative for our discussion tomorrow. It is an early draft subject to further Departmental review and significant revision. Also attached is a summary of the draft Initiative.

Thank you.

Attachments (2)

DRAFT * National Organ And Tissue Donation Initiative *** DRAFT
Summary**

Although the potential for organ transplantation to help people live better and longer lives steadily improves, approximately ten people die each day while waiting for donated organs and about 53,000 people are now on the transplant waiting list. Although most Americans approve of organ donation, too few now share the gift of life when the opportunity arises.

HHS is proposing a five-year initiative to help ease the critical shortage of organs. HHS proposes to act as a catalyst to spur organizations and individuals across the nation to get involved in activities to increase organ and tissue donation. The broad participation of HHS and its public and private sector partners will enable us to reach tens of thousands more Americans with organ donation messages, including ethnic and racial minorities and tribal populations. These public education efforts, together with proposed regulatory and legislative changes to strengthen the relationships between hospitals and organ procurement organizations, will contribute to a more supportive environment for organ and tissue donation.

Proposed activities include:

- o **Building strong partnerships** with community, religious, educational, minority, and professional organizations. Collaboration with national or umbrella groups is essential for reaching target audiences with organ donation messages and for enhancing the credibility of those messages.
- o **Mobilizing federal agencies** to encourage organ donation from the American public and from federal employees.
- o **Fostering intra-Departmental collaboration** among and within HHS agencies, offices, centers, institutes, and regions to reach key audiences with organ donation messages.
- o **Stimulating regional and local activities** to increase organ donation in collaboration with organ procurement organizations (OPOs) and community and professional organizations.
- o **Investing in research and evaluation** to determine best practices in increasing organ donation, to expand the donor pool, to improve transplant outcomes and reduce the need for re-transplantation, and to find alternatives to transplantation.
- o **Strengthening relationships between hospitals and OPOs** to increase identification and reporting of potential donors by hospitals to OPOs as specified by the designated OPO.

The Initiative identifies opportunities for senior Administration officials to be visible spokespersons on organ donation, including speeches, site visits, radio and television interviews, op-eds or letters to the editor, public service announcements, and communications with federal employees. Senior officials can also make significant contributions by supporting a legislative or regulatory agenda, meeting with health care organizations and professional associations to encourage action, and encouraging the private sector and all levels of government to engage in activities to increase organ and tissue donation.

DRAFT**National Organ and Tissue Donation Initiative****INITIATIVE/OBJECTIVE:**

Organ donation is an important health issue for all Americans. Although the potential for organ transplantation to help people live better and longer lives steadily improves, approximately ~~nineteen~~ ^{more than} people die each day while waiting for donated organs and ~~more than~~ ^{about} 52,000 people are now on the transplant waiting list.

The good news is that this is a public health crisis that we can do something about. Many diseases have no cure, but for the tens of thousands of Americans waiting for organs and tissue, there is a cure – transplantation. Unfortunately, too few Americans realize that transplantation works. And too few share the gift of life when the opportunity arises. Of the families who are asked to donate a deceased relative's organs, only about half give their consent.

While increasing organ donation is the only real solution to the current organ shortage crisis, procuring all potentially available organs would still leave a considerable gap. Only a fraction of individuals who die in the United States are potential organ donors. To narrow the gap between organ demand and supply, efforts to prevent contributing diseases and conditions must continue, thereby reducing the demand for transplantation. Many, though not all, conditions that lead to transplantation are preventable. Finally, ongoing research is needed to expand the donor pool, to improve transplant outcomes, and to find alternatives to transplantation.

Building on our previous work in these areas, this three-year national initiative is designed to:

- I. Increase organ and tissue donation.
- II. Decrease the percent of the population needing transplantation. [TENTATIVE]
- III. Increase transplantation options.

Detailed objectives to achieve these goals are provided in Appendix I: Goals and Objectives.

This initiative lays the foundation for a focused, long-term commitment to addressing the critical need for increased organ and tissue donation in the United States. Government cannot accomplish this task alone. Success will require collaboration among all sectors of society, both public and private, including federal, state, and local governmental organizations; social, educational, and religious institutions; professional and lay fraternities and clubs; medical professionals and organizations; media and entertainment industries; businesses; and community groups. HHS has begun collaborating with leadership groups in these areas and will explore partnerships with other federal agencies.

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INTERAGENCY COOPERATION

Lead Agency: Due to the variety of responsibilities required for this initiative, separate lead agencies are identified for each of the goals. A steering committee composed of representatives from HHS and other public and private organizations will oversee the progress on the National Initiative. An HHS interagency work group will continue to identify opportunities for collaboration. In addition, task forces will guide components of the Initiative, including minority organ donation and involvement of religious institutions.

Goal I: The lead agency is the Health Resources and Services Administration (HRSA). As the HHS agency responsible for managing the provisions of the 1984 National Organ Transplant Act, HRSA oversees the national organ transplant system and develops initiatives to increase the supply of donated organs. The President's fiscal year 1998 budget includes \$1.6 million for initiatives to increase organ donation, a substantial increase over HRSA's present budget. HCFA, through its financing, oversight, and statutory authorities, is a critical partner in this initiative. HCFA has the potential to increase organ donation by modifying conditions for hospital participation in the Medicare program and standards for certification of organ procurement organizations (OPOs).

Goal II: [TENTATIVE - STILL BEING EXPLORED]

*CDC is conducting a
literature review and
an issues analysis.*

Goal III: ~~LEAD AGENCIES TO BE DETERMINED~~

NIH is lead agency

Participating Agencies: To ensure that all avenues within the Department's reach were included in this Initiative, most of HHS' agencies, offices, and regions are identified as active participants. These agencies will play a significant role in developing communications strategies and in expanding information dissemination channels by incorporating organ donation messages into their programs, networks, grant announcements, speeches, and communications to HHS employees. These agencies also will be instrumental in developing partnerships with public and private organizations in support of the Initiative.

In addition, the National Institute of Allergy and Infectious Disease (NIAID) and the National Institute of Diabetes and Digestive and Kidney Disorders (NIDDK) at the National Institutes of Health will continue to conduct and sponsor research on issues related to organ donation and transplantation. NIAID supports basic, pre-clinical, and clinical research on immune system functioning, graft acceptance and rejection, avoiding the need for re-transplantation, organ matching in diverse populations, and improving the quality of life for transplant recipients. The NIDDK conducts and supports research on kidney, urologic, hematologic, digestive, metabolic and endocrine diseases, as well as on diabetes and nutrition. Research conducted by NIAID and NIDDK is used to improve clinical practice as well as health promotion and disease prevention efforts. Also, FDA will continue to oversee human tissue products, evaluate new drugs to inhibit graft rejection with fewer side effects, and conduct gene therapy research to treat diseases that can lead to organ failure; AHCPR will support research on organ donation and allocation, including factors related to consent; and OCR will provide policy guidance as needed to ensure that donor and allocation procedures comply with the anti-discrimination provisions of Title VI

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of the Civil Rights Act of 1964. Finally, the regional offices will help coordinate the Initiative in various states, including convening key organizations, ensuring the participation of minority communities, and communicating with HHS employees.

Participating agencies include the Administration for Children and Families (ACF), the Administration on Aging (AoA), the Agency for Health Care Policy and Research (AHCPR), the Centers for Disease Control and Prevention (Division of Diabetes Translation), the Food and Drug Administration (FDA), the Indian Health Service (IHS), the National Institutes of Health (the National Institute of Allergy and Infectious Disease and the National Institute of Diabetes and Digestive and Kidney Disorders) and the Substance Abuse and Mental Health Services Administration (SAMHSA). Within the Office of the Secretary, participating offices include the Office of Intergovernmental Affairs (IGA); the Office of the Assistant Secretary for Public Affairs (ASPA); the Office of the Assistant Secretary for Planning and Evaluation (ASPE); the Office for Civil Rights; and the Office of Public Health and Science (OPHS), including the Office of the Surgeon General (SG), the Office on Women's Health (OWH), and the Office on Minority Health (OMH). The regional offices are also participating in the Initiative, with representation from Regions IV (Atlanta), V (Chicago), VI (Dallas), VII (Kansas City), and X (Seattle). These regions are in regular communication with the other five regions on the progress of the Initiative. The Office of the Assistant Secretary for Management and Budget provided technical assistance on the development of the Initiative's goals and objectives and the Office of Inspector General provided information.

Cooperation: An interagency work group (Organ Donation Work Group) including representatives from each agency listed above will meet every four to six weeks in person and via conference call. Over time, meetings may be adjusted to quarterly. Agency representatives will identify additional opportunities for interagency cooperation and coordination to implement the action framework and provide suggestions on the role of the Secretary in these efforts. As needed, task forces will implement specific components of the Initiative. The regional health administrators will coordinate the efforts of the various HHS agencies in the field. (Members of the Organ Donation Work Group and the Task Force on Minority Organ Donation are listed in Appendix II). ← 10-page list of workgroup members omitted

ACTION FRAMEWORK

This Initiative focuses on cross-cutting interagency action steps as part of a multi-pronged strategy to increase organ and tissue donation. (A detailed summary of action steps is provided in Appendix III: Implementation Plan and performance measures for tracking progress on the Initiative are in Appendix IV). This approach is based on the findings of the following: (1) Report to the Secretary from the Assistant Secretary for Health on the December 10-12, 1996 hearings on the Notice of Proposed Rulemaking for OPTN policy, (2) testimony from the December 10-12, 1996 hearings, (2) proceedings and background papers from the 1991 Surgeon General's Workshop on Increasing Organ Donation, (3) the 1996 UNOS Annual Report (4) *Organ Transplantation: Issues and Recommendations, Report of the Task Force on Organ Transplantation*, April 1986, and (5) personal communications with the leadership of key organizations, including UNOS (Council on Organ Availability and Minority Affairs

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Committee), the Coalition on Donation, the American Society of Minority Health and Transplant Professionals, and the Minority Organ Tissue Transplant Education Program (MOTTEP).

The broad participation of HHS agencies in this Initiative will enable HHS to reach tens of thousands more Americans with organ donation messages, including seniors and minority and tribal populations. These efforts will contribute to the creation of an environment supportive of organ donation. For example, the Initiative proposes to conduct an education campaign in 3,000 federally-supported community and migrant health center sites, including dissemination of materials and training of health center personnel by local OPOs. Community health centers served nine million patients in FY 1996, two-thirds of whom were members of minority communities. Additional outreach will be conducted through ACF's programs, AoA's aging network, CDC's state Diabetes Control Programs, the *FDA Medical Bulletin* (distributed to 750,000 health professionals), HRSA's National Health Service Corps, tribal organizations and IHS' councils, PHS-OWH and OMH clearinghouses, minority-serving higher educational institutions (Historically Black Colleges and Universities, Hispanic-Serving Institutions, and Tribal Colleges and Universities), and other agency venues.

Because most activities to increase organ donation occur at the community or regional level through OPOs, local coalitions, and other groups, the HHS regions will play an essential role in stimulating community and professional education activities and in involving minority communities. Regional activities will include: forums for collaboration among HHS agency field offices, HHS programs, and local and regional groups (OPOs; hospitals; HMOs; local coalitions on donation; blood, eye, and tissue banks, local chapters of national health organizations such as the American Heart Association and the National Kidney Foundation; state health departments; state minority health offices; medical and public health schools; medical and legal societies; Department of Motor Vehicles; fraternities and sororities; churches; etc.); federal employee education; public speaking; and media outreach.

The success of this Initiative depends on our ability to develop strong partnerships with community, religious, educational, minority, and professional organizations. Collaboration with national or umbrella groups is essential for reaching target audiences with organ donation messages and for enhancing the credibility of those messages. Commitments to date include: major religious and minority organizations (the Congress of National Black Churches, the Union of American Hebrew Congregations), managed care organizations (Blue Cross/Blue Shield, Kaiser), donor family groups (the National Kidney Foundation's National Donor Family Council), the National Highway Traffic Safety Administration, and the American College Health Association, whose membership consists of 900 colleges and universities. Additional organizations in the donation and transplant field have expressed a willingness to work with HHS to refine and implement the Initiative.

Finally, improving organ donation and transplantation over the longer term will depend on our continued investment in research and evaluation. These research results will be used to replicate best practices in increasing organ donation, to expand the donor pool, to improve transplant outcomes, and to provide alternatives to transplantation.

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Regulatory Activities: Hospitals are not consistently carrying out their donation functions. Many hospitals have donor potential but fail to produce donors. One study, for example, found that of approximately 850 hospitals – 500 with more than 150 beds – with donor capability, none produced an organ donor from 1991 to 1993. Federal and state laws requiring hospitals to have policies in place for offering families the option of donation have been little enforced and largely ineffective. Therefore, the Work Group recommends that the Secretary support a notice of proposed rulemaking to modify conditions for hospital participation in the Medicare program that would require Medicare-participating hospitals to refer ~~patients~~ ^{potential donors} to the designated organ procurement organizations, subject to the determination of the legal authority to do so. The rule would allow each OPO to establish its own criteria for ~~death~~ ^{donor} referrals from hospitals. It is anticipated that this rule will have a substantial impact on the number of organ and tissue donors.

A Final Rule for FDA regulation of “banked human tissues” intended for administration to other humans and not currently regulated as a human drug, biological product, or medical device has been cleared by FDA and the Department and is currently at OMB awaiting sign off. FDA currently regulates some human tissue as medical devices (e.g., heart valve allografts).

Legislative Activities: Many transplant centers receive accreditation from the Joint Commission on the Accreditation of Health Organizations (JCAHO). To ensure that these hospitals meet the same requirements as those hospitals certified by HCFA, the Work Group recommends that the Secretary endorse legislation to require hospitals accredited by JCAHO to meet Medicare standards. This language is included in the President’s FY 1998 budget request and has ~~been included~~ ^{created} ~~from both JCAHO and hospitals.~~ ^{no significant opposition from either JCAHO or hospitals.}

To recognize the contributions of living donors and donor families and to help all Americans realize the importance of organ and tissue donation, the Work Group recommends that the Secretary encourage the Congressional Task Force on Organ Donation to persuade the U.S. Postmaster General to support adoption of a postage stamp or stamp booklet cover to honor organ donors. The Congressional Task Force successfully championed the “Organ Donation Insert Card Act” passed by the 104th Congress as part of the Health Insurance Portability and Accountability Act of 1996. This Act will enable about 70 million Americans to receive organ donation cards with their tax refunds this year.

Public Affairs Activities: Public affairs activities will include opportunities for the Secretary to be a visible spokesperson on organ donation, including speeches, site visits, radio and television interviews, op-eds or letters to the editor, public service announcements, and communications with HHS employees. Regional health administrators and regional directors will also engage in local and regional public affairs activities. Finally, senior HHS officials who are members of minority communities will be recruited to serve as credible spokespersons on minority organ donation. ^{and other senior officials}

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Budgetary Resources: Successful implementation of this Initiative will require a sustained increase in the budget for organ donation activities, including the \$1.6 million proposed in President Clinton's FY 1998 budget. In addition to the basic, pre-clinical, and clinical research on organ donation and transplantation currently supported through NIH, FDA, and AHCPR, resources will be needed to fund demonstration projects to identify best practices for increasing organ donation (e.g., donor registries, behavioral change models, educational approaches for minority communities, support for living donation, etc.) and to evaluate the impact of policy changes (e.g., the effect on organ donation of OPTN policy changes, changes in Medicare conditions of participation and JCAHO accreditation standards, etc.)

Agencies will need to identify resources necessary to enhance continuing efforts, as well as to carry out proposed new activities. This commitment may require the use of available FY 1997 funding. ~~Other increases anticipated in FY 1998 budgets (note: agency FY 1998 budget submissions are due to ASMB by June 13, 1997).~~ Other increases anticipated by HHS agencies will be proposed in FY 1999 budgets (note: agency FY 1999 budget submissions are due to ASMB by June 13, 1997).

IMPLEMENTATION PLAN/ACCOUNTABILITY

A detailed summary of action steps with agencies identified for OS accountability is provided in Appendix III: Implementation Plan. Performance measures for tracking progress on the Initiative are in Appendix IV.

SECRETARY'S ROLE

The Secretary can be a strong spokesperson for organ donation through speeches and media interviews, supporting a legislative or regulatory agenda, meeting with health care organizations and professional associations to encourage action, and promoting the adoption of model programs by the private sector and all levels of government. The Secretary can also endorse the steering committee for the Initiative.

Specific Events:

- o Use the National Organ and Tissue Donor Awareness Week (April) to recognize donors and donor families; reinforce the message about the importance of organ donation, and educate HHS employees about organ donation through the HHS Scoop, employee earnings and leave statements, and other means. Use this opportunity to involve the White House and major public and private sector organizations in national education initiatives.
- o Meet with managed care organizations (MCOs) to encourage industry-wide campaigns promoting organ and tissue donation by their beneficiaries and donation interventions by their facilities and health professionals. Build on the commitment of Blue Cross/Blue Shield and Kaiser to demonstrate potential strategies. Speak at HRSA's proposed meeting with MCOs about the important role they can play in increasing donation.

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- o Hold an Organ Donation Summit for health professionals, hospital administrators, medical school deans, business leaders, and state health care policymakers to encourage organ donation programs and activities to meet the critical need for organ donation.
- o Participate in the 4th Annual Southwest Transplant Foundation Golf Tournament in Dallas, Texas in September, 1997. The Foundation provides funds for transplant patients who are financially burdened with costs associated with waiting for and receiving an organ donation. Future funds raised also will be used to promote organ donation, including an education program in schools.
- o Engage in organ donation activities as part of ongoing awareness-raising events, e.g., National Liver Awareness Month (October), National Diabetes Month (November), National Kidney Month (March), Hispanic Heritage Month (mid-September through mid-October, Black History Month (February), Asian Pacific American Heritage Month (May), [Native American Heritage Month? Week?, date?].

Media and Entertainment Industry Outreach:

- o When traveling, participate in media briefings and editorial boards to communicate the critical need for organ donation.
- o Visit transplant centers while on travel to highlight the critical need for donated organs and the scientific achievements of transplantation.
- o Participate in radio and television public service announcements and web site messages to communicate organ donation message.
- o Highlight the need for organ donation when meeting with entertainment industry leaders.

Speaking Opportunities:

- o Association of Organ Procurement Organizations (AOPO) Annual Meeting (June 18-20, 1997, Chicago, IL) The AOPO meeting is attended by approximately 300 transplant professionals working primarily in organ procurement organizations. Illinois has been a leader in implementing initiatives to increase donation. Following implementation by Illinois' Secretary of State of a Department of Motor Vehicles-linked donor registry and additional public education efforts, the donation rate at the Regional Organ Bank of Illinois increased 9 percent between 1995 and 1996.
- o American Medical Association (AMA) Annual Meeting, (June 22-26, 1997, Chicago, IL). To be attended by approximately 4,000 physicians.

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- o Fourth International Society for Organ Sharing Congress (July 10-12, 1997, Washington Hilton Hotel). An international meeting that focuses almost entirely on organ donation. Attendance is expected to be approximately 500.
- o National Association of Counties (NACo) Annual Meeting, (July 11-15, 1997, Baltimore, MD).
- o American Public Welfare Association (APWA), (July 20-23, 1997, Washington, D.C.)
- o 12th International Interdisciplinary Conference on Blacks and Hypertension (July 20-24, 1997, London, England). Society headquarters is located in Atlanta, Georgia.
- o National Governors' Association (July 27-30, 1997, Las Vegas, NV).
- o North American Transplant Coordinators Organization (NATCO) Annual Meeting, (July 29 - August 3, 1997, Minneapolis, MN). The NATCO meeting is attended by approximately 800 procurement and clinical transplant coordinators from the United States and Canada.
- o National Medical Association Annual Meeting, (August 2-7, 1997, Honolulu, HI). Association of minority, primarily African American physicians. To be attended by approximately 2,500 physicians.
- o The National Black Nurse Conference (August 16-19, 1997, New York)
- o American Association of Motor Vehicle Administrators (AAMVA) Annual International Meeting, (September 7-10, 1997, Little Rock, AK). This meeting of motor vehicle agencies in the United States and Canada is attended by approximately 1,500 individuals.
- o The American Society of Minority Health and Transplant Professionals Annual Meeting (September 10-12, 1997, Atlanta, GA, J.W. Marriott). Possible presenters include Les Brown, Dexter King, and Dr. Kenneth Moritsugu, Medical Director, Federal Bureau of Prisons (his wife and daughter were both organ donors).
- o The Association of State and Territorial Health Officials Annual Meeting, (September 24-26, 1997, Sunburst Resort, Scottsdale, AZ).
- o American Public Health Association: The 125th Anniversary Meeting, (November 9-13, 1997, Indianapolis, IN).
- o National League of Cities (NLC), (December 3-6, 1997, Philadelphia, PA).

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- o The 12th National Conference on Chronic Disease Prevention and Health Promotion, "Opportunities for the 21st Century," (December 3-7, 1997, Washington Hilton and Towers). Sponsored by the CDC and the Association of State and Territorial Chronic Disease Program Directors. Topics include cancer, diabetes, heart disease, nutrition, oral health, physical activity, and tobacco. Emphasis on interaction among federal, state, and local health departments, voluntary health agencies, professional organizations, and other groups.

- o National Council on the Aging Annual Meeting (March 29 - April 2, 1998, Washington, D.C.) Approximately 2,000 people concerned with gerontology are expected to attend.

APPENDIX I National Organ and Tissue Donation Initiative Goals and Objectives

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INTRODUCTION: This initiative lays the foundation for a focused, long-term commitment to addressing the critical need for increased organ and tissue donation in the United States. Government cannot accomplish this task alone. Success will require collaboration among all sectors of society, both public and private, including federal, state, and local governmental organizations; social, educational, and religious institutions; professional and lay fraternities and clubs; medical professionals and organizations; media and entertainment industries; businesses; and community groups. HHS will seek collaboration with leadership groups in these areas.

GOAL I. INCREASE ORGAN AND TISSUE DONATION.

A. Increase the donor pool.

1. Create an environment supportive of donation.

- a. Increase exposure to donation messages and opportunities to express donation commitments.
 - i. Increase exposure in national and local media.
 - ii. Increase community interventions (at schools, churches, etc.)
 - iii. Increase promotion of organ donation through health promotion and disease prevention efforts.
 - iv. Disseminate and replicate best practices identified through research and evaluation.
- b. Evaluate the impact of increased support for living organ donation (e.g., provisions to cover child care, travel, and other expenses for living donors).

2. Increase minority cadaveric and living organ donation.

3. Increase donation from non-traditional donors (older donors, living donors, etc.)

B. Increase donation through improved donor identification, referral, and request.

1. Reduce the number of lower-performing OPOs.

- a. Identify and resolve barriers to OPO performance.
 - i. Identify and replicate best practices of higher-performing OPOs.
 - ii. Maximize the number and type of organs procured per donor.
 - iii. Establish partnerships with representative organizations (AOPO, ACORD, etc.) to enhance overall OPO capacity and effectiveness.

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2. Increase the number of hospitals that identify at least 90 percent of their potential donors.
 - a. Institute mandatory referral of in-hospital deaths.
 - i. Ensure that mandatory referrals of in-hospital deaths are a condition of participation for Medicare-participating hospitals.
 - ii. Endorse legislation to require JCAHO to meet Medicare standards, including Medicare conditions of participation.
 - b. Decrease the number of the largest hospitals with no donors by 30 percent by the year 2000.
 - i. Ensure that non-donor hospitals have access to appropriate equipment and staffing (e.g., life support equipment, neurologist).
 - c. Establish partnerships with relevant organizations to encourage hospital referrals (e.g., American Hospital Association, Association of American Medical Colleges, National Association of Public Hospitals, National Association of Children's Hospitals, JCAHO).
 - d. Require OPOs to evaluate hospital donor referral performance through death record reviews and other means.
3. Augment hospital capacity to successfully increase organ donation.
 - a. Increase the number of health professions schools incorporating curricula on organ donation and transplantation.
 - b. Increase adoption of best practices through education, training, and technical assistance for relevant hospital personnel (boards of directors, administrators, staff, and medical personnel) on all aspects of organ donation process, including medical and ethical guidelines.
 - i. Identify through research and evaluation models that work and characteristics of effective interventions (e.g., impact of hospital chaplains, same-race requesters, de-coupling, familiarity with grieving process, etc.)
 - c. Ensure that hospitals identify an individual or a team to be accountable for hospital organ donation efforts.
4. Improve determination of death, including brain death.
 - a. Disseminate guidelines about determining death, including brain death.
 - b. Provide professional education and training on guidelines to appropriate medical personnel.

DRAFT 3**5. Increase timely communication of donor preference at time of death.**

- a. Evaluate donor registries as a method for increasing organ donation.
- b. Improve communication of donor preference (from driver's license, donor registry, insurance ID card, medical file, etc.) to appropriate hospital/OPO personnel.

GOAL II. DECREASE THE PERCENT OF POPULATION NEEDING TRANSPLANTS. [Tentative -is still being explored]

- A. Increase efforts to prevent contributing diseases and conditions.

GOAL III. INCREASE TRANSPLANTATION OPTIONS [To be revised and developed by the appropriate agencies]

- A. Develop alternatives to living and cadaveric donors.
- B. Increase organ usage (e.g., older donors, split organs, extended ischemic time).
- C. Reduce the proportion of transplant recipients who require re-transplantation.
- D. Identify factors that lead to more successful transplantation for diverse populations (e.g., antigen-matching and graft failure for African American kidney recipients).
- E. Apply research results to practice (e.g., SIDS "Back to Sleep" Campaign).

PROCESS OBJECTIVES

- A. Conduct consultation process (public hearings, one-on-one meetings, etc.) with external organizations and individuals to solicit input into, and support of, the National Initiative.
- B. Create a steering committee to oversee the progress on the National Initiative.
- C. Create task forces to guide components of the National Initiative, including minority organ donation and involvement of religious institutions.
- D. Hold regular status updates with Secretary and Deputy Secretary.

DRAFT**APPENDIX III****IMPLEMENTATION**

Dates indicated below are anticipated start dates, with the exception of those in parentheses, which are expected completion dates. "Ongoing" indicates continuous efforts over time. Some activities are repeated annually. In these cases, the pertinent months and years are indicated.

GOAL I: INCREASE ORGAN AND TISSUE DONATION**A. Increase the donor pool.****1. Create an environment supportive of donation**

- | | |
|-------------------------------|---|
| Fall 1997 | Convene workshop or hearings on strategies to improve organ donation, as recommended in the Lee Report. (HRSA) |
| Ongoing | Continue support for the Coalition on Donation's "Share your life. Share your decision." national media campaign. (HRSA) |
| Ongoing | Conduct annual National Donor Recognition Ceremony (NDRC) to honor the Nation's donors and expand recognition of donors and donor families through churches, civic associations, etc. using NDRC model and Surgeon General certificates of appreciation. (HRSA, SG, RHAs/RDs) |
| Ongoing | Recognize successful organ donation education programs through HRSA's Models That Work Campaign. (HRSA) |
| November - April
1998-2000 | Expand National Organ and Tissue Donor Awareness Week (3rd full week of April) activities by coordinating with regional organ procurement organizations and other partners. (HRSA, RHAs/RDs) |
| Winter/Spring
1998 - 2000 | Conduct annual "Education Forum" to disseminate information about effective pro-donation initiatives to transplant professionals. (HRSA) |
| June 1997 | Stimulate nationwide replication of HRSA's college campus donation education campaign and associated web site in partnership with the American College Health Association with assistance from the University of Rhode Island which served as the demonstration site. (HRSA) |
| (September 1997) | In conjunction with TransWeb University, develop interactive activities to teach children, teens, adults, medical and transplant-related professionals and others about organ and tissue donation and transplantation. (HRSA) |

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- June 1997 Develop a web site, in partnership with the National Kidney Foundation's National Donor Family Council to provide donation information and bereavement support by and for donor families. (HRSA)
- June 1997 Develop nationwide education efforts with national religious leadership organizations and increase their involvement and their members' involvement in the National Donor Sabbath (NDS) observed annually in November. Develop and provide materials to OPOs to assist them in promoting NDS in the religious institutions in their areas. (HRSA)
- Ongoing Expand reach of organ and tissue donation messages through HHS agency spokespersons, networks, programs, grant announcements, and mailings. (HHS-wide)
- Ongoing Increase public and professional education activities in each HHS region. (RHAs/RDs, HRSA [HQ and field offices], IGA, HCFA, ACF, AoA, FDA, CDC)
- Ongoing Promote organ and tissue donation awareness through diabetes control efforts in each state in collaboration with Diabetes Control Programs in state health departments, the American Diabetes Association, the Juvenile Diabetes Foundation, and the American Association of Diabetic Educators. (CDC [HQ and field offices], RHAs/RDs)
- June 1998 Develop educational campaigns to increase organ donation among women, especially minority women and mothers. (PHS-OWH, HRSA, HHS women's health coordinators)
- (add date) Sponsor local or regional Healthy Women 2000 conference on organ failure as a consequence of disease for women and the need for increased organ donation. (PHS-OWH, HHS women's health coordinators)
- Fall 1997 Include organ donor and transplant information in HHS clearinghouses and web sites, including the upcoming National Women's Health Information Center Directory and toll-free number and the Office of Minority Health Clearinghouse. (PHS-OWH, OMH)
- Summer 1997 Secure commitments from national professional associations (e.g., medical associations and the American Bar Association) to engage their members in pro-donation activities. (HRSA)

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- Summer 1997 Encourage the Congressional Task Force on Organ Donation to support adoption of a postage stamp and stamp booklet cover to encourage organ and tissue donation. (OS)
- Ongoing Educate HHS employees throughout the country about the need for organ and tissue donation. (HRSA, RHAs/RDs)
- Summer 1997 Include organ donation information in Combined Federal Campaign literature. (HRSA)
- Summer/Fall 1997 Implement demonstration project with Blue Cross/Blue Shield and Kaiser managed care organizations to promote organ and tissue donation among their staff and beneficiaries, followed by a national initiative to conduct similar programs with other MCOs. (HRSA, SAMHSA?)
- Ongoing *tentative* (Study the impact of OPTN policy changes on donation rates. ~~(HRSA, HCFA, AHCPR)~~)
- TBD¹ *tentative* (Support research to apply behavioral change theories and models to donation behavior. ~~(NIH, AHCPR)~~)
- Fall/Winter 1997/1998 Analyze and report results of National Mortality FollowBack Data that surveyed donor and non-donor families' about their actual hospital donation-related experiences and other donation-relevant issues. (HRSA, CDC/NCHS)

2. Increase minority cadaveric and living organ donation.

- Ongoing Facilitate collaboration among local/regional OPOs, hospitals, minority health and community organizations, state minority health officers, NIDDK's 15-city Minority Organ and Tissue Transplantation Education Project (MOTTEP), etc. (HRSA, HCFA, OMH, RHAs/RDs, NIDDK)
- Winter 1997 Tailor existing organ donation materials specifically to minority groups. (HRSA, OMH, IHS)
- Spring 1998 Conduct an education campaign in 3,000 community and migrant health center sites and develop a partnership with the National Association of Community Health Centers. (HRSA)

¹To be determined

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Fall 1997

Promote organ and tissue donation among American Indians and Alaska Natives by engaging IHS local health boards, clinics, and hospitals in education and outreach efforts; by modifying existing materials; and by encouraging Indian donors and donor families to become spokespersons in their communities. (IHS, HRSA, CDC, NIDDK, NIAID, OMH)

Winter 1997

Promote dialogue among and education of minority physicians in organ donation and transplantation, in collaboration with the American Society of Minority Health and Transplant Professionals, minority-serving medical schools, and the National Medical Association, etc. (HRSA, RHAs/RDs, NIH, OMH)

Ongoing

Conduct media outreach to minority-serving outlets using credible spokespersons. (HRSA, OMH)

Fall 98

tentative (Evaluate extent of OPO efforts to facilitate minority organ donation, including outreach. (~~OIG, AHCPR, HRSA~~))

Winter 1998

Adapt and replicate college campus demonstration project at Historically Black Colleges and Universities, Hispanic-Serving Institutions, and Tribal Colleges and Universities. (HRSA, OMH)

TBD

Include organ donation in development of an HHS Asian/Pacific Islander Health Initiative. (OMH, HRSA)

(add date)

Conduct pilot project at the University of Washington to explore approaches to educate the Alaska Native American Population about organ and tissue donation. (NIAID)

3. Increase donations from non-traditional donors (older donors, living donors, etc.)

Fall 1997

Educate seniors and state and local professionals in the aging network through community seminars, newsletters, etc. (AoA, HRSA)

Spring 1998

tentative (Implement a demonstration project to evaluate the impact of increased support for living organ donation (e.g., provisions to cover child care, travel, and other expenses for living donors). (~~OIG, HC, ID regions, HRSA, HRSA~~))

TBD

tentative (Conduct assessment of new laparoscopic removal of kidneys as an alternative procedure to reduce recovery time for living donors (e.g., from 3 months to 3 weeks). (~~HRSA, NIH, OPHS~~))

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B. Increase donation through improved donor identification, referral, and request.**1. Reduce the number of lower-performing OPOs.**

Fall ~~(HRSA)~~ Review literature related to high and low performing OPOs

(June 1997) Conduct study to characterize determinants' of families' willingness to donate, assess the effectiveness of requesting approaches, and recommend improvements for the procurement process. (ACHPR)

Summer 1998 *tentative* (Evaluate the extent of OPO community education activities and involvement and make recommendations for improvement.)
~~(HRSA)~~

2. Increase the number of hospitals that identify at least 90 percent of their potential donors.

September 1997 *Require hospitals to refer potential donors to OPOs as using condition of participation for Medicare-participating hospitals. Referrals defined by the OPO*
~~Require mandatory referrals in hospital death as~~ (HCFA) ~~to OPOs~~

September 1997 Endorse legislation to require JCAHO to meet Medicare standards, including Medicare conditions of participation. (HCFA)

Summer 1998 Implement project to decrease by 30 percent the number of the largest hospitals that do not produce donors through adoption of Medicare rules and JCAHO legislation (if enacted), training and education by OPOs, and partnerships with relevant organizations, e.g., American Hospital Association, American Association of Medical Colleges, National Association of Public Hospitals, and National Association of Children's Hospitals. (HCFA, HRSA)

Fall 1998 *Encourage* ~~Require~~ OPOs to evaluate hospital donor referral performance through death record reviews and other means. (HCFA)

3. Augment hospital capacity to successfully increase organ donation.

Winter 1997/1998 Implement project to encourage health professions schools, including HRSA's health professions training programs, to incorporate curricula on organ donation and transplantation. (HRSA, RHAs/RDs)

Fall 1998 Conduct pilot test in several sites to confirm efficacy of condensed four-hour training model for hospital nurses developed by the Arizona Donor Network. (~~HRSA, RHAs/RDs~~)

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Winter 1998 Implement project to increase adoption of best practices through education, training, and technical assistance for relevant hospital personnel on all aspects of organ donation process, including medical and ethical guidelines. (HRSA)

Fall 1997 *Encourage*
~~Ensure~~ hospitals identify an individual or team to be accountable for hospital organ and tissue donation efforts. (HCFA, HRSA)

Summer 1998 *Encourage*
~~Ensure that~~ non-donor hospitals have access to appropriate equipment and staffing for dealing with donation. (HCFA)

4. Improve determination of death, including brain death.

Fall 1998 Disseminate guidelines about determining death, including brain death. (HRSA)

Winter 1998/1999 Provide education and training on declaration of death guidelines to appropriate medical personnel. (HRSA)

5. Increase timely communication of donor preference at time of death.

(Fall 2000) Support a demonstration project by the Louisiana Organ Procurement Agency to design, implement, and evaluate the effectiveness of an organ donor registry and community education programs as a model for increasing organ donation, particularly among minorities. (NIAID)

Summer 1997 Develop partnership with the National Highway Traffic Safety Administration to expand public education at Department of Motor Vehicle licensing sites; to assure that law enforcement personnel communicate donor preference from driver's licenses to appropriate medical personnel; and to identify and disseminate information on model programs. (HRSA)

GOAL II. DECREASE THE PERCENT OF POPULATION NEEDING TRANSPLANTS.

A. Increase efforts to prevent contributing diseases and conditions.

Winter 1997/1998 Create an early intervention campaign to detect and treat hypertension and kidney disease in community health center clients. (HRSA)

DRAFT**GOAL III. INCREASE TRANSPLANTATION OPTIONS**A. Develop alternatives to living and cadaveric donors. ~~(NIDDK)~~

B. Increase organ usage. (e.g., older donors, split organs, extended ischemic time)

(TBD) Support research to examine the long-term effectiveness of organs from older and other non-traditional donors. ~~(NIDDK)~~C. Reduce the proportion of transplant recipients who require re-transplantation. ~~(NIH, HCEA)~~Winter 1997/1998 *initative* (Implement study to determine the number of recipients requiring re-transplantation due to inability to afford the cost of immunosuppressive drugs or noncompliance with drug regimen. ~~(HRSA)~~)

Ongoing Conduct basic, pre-clinical, and clinical research on transplantation immunobiology to define factors involved in graft rejection and to develop regimens to modulate the immune response and facilitate engraftment of organs, tissues, and cells. (NIAID)

(Winter 1998/1999) Conduct clinical trials in adult and pediatric kidney transplantation to evaluate various therapies and approaches to immune modulation to increase graft acceptance, avoid re-transplantations, and improve quality of life. (NIAID)

Ongoing Conduct basic research to enhance understanding of the immune system. (NIAID)

D. Identify factors that lead to more successful transplantation for diverse populations

(August 1997) Conduct project to study equity of access to kidney transplant waiting lists by age, sex, race, and income for cadaver kidney transplantation for Medicare patients with end-stage renal disease. (AHCPR)

Winter 1998/1999 Conduct research to improve the ability to match donors and recipients in minority populations, including differences in transplantation antigens among minorities. (NIAID)

Ongoing Apply research results to practice (e.g., SIDS "Back to Sleep" Campaign).

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PROCESS OBJECTIVES

- June 1997** Conduct consultation process (public hearings, one-on-one meetings, etc.) with external organizations and individuals to solicit input into, and support of, the national initiative. (HRSA, HCFA, OS)

- Summer 1997** Create a steering committee to oversee the progress on the national initiative. (HRSA, OS)

- Ongoing** Create task forces to guide components of initiative, including minority organ donation and involvement of religious institutions. (HRSA, HCFA, OMH)

- Ongoing** Hold regular status updates with Secretary and Deputy Secretary. (HRSA, TBD)

DRAFT**APPENDIX IV****GOAL I: INCREASE THE NUMBER OF ORGAN AND TISSUE DONATIONS**

OBJECTIVE	SUBOBJECTIVE	SUB-SUB-OBJECTIVE	MEASURES
			<ul style="list-style-type: none"> - Change in number of living organ donors - Change in number of cadaveric organ donors - Change in reported deaths on waiting list - Change in cadaveric and living transplant recipients
Increase the donor pool.	Create an environment supportive of donation.	Increase exposure to donation messages and opportunities to express donation commitments: <ul style="list-style-type: none"> - National/local media - Community interventions - Link w/ health promotion - Disseminate best practices 	<ul style="list-style-type: none"> - Number of individuals exposed to messages through media and community interventions (e.g., BPHC-funded health centers, college education campaign, Donor Sabbath, donor family web site, etc.) - Placement and reach of op-eds, radio/TV interviews, etc. - Percent of Americans who have signed an organ donor card and, especially, how many have talked with their families about the decision to donate (baseline and change) - Change in number of people in donor registries where appropriate - Analysis and report on hospital experience for surviving and donor families (NCHS National Mortality Followback Survey) - Analysis and report on managed care demonstrations <p>NOTE: Changes in above should be linked wherever possible to specific interventions.</p>
		Evaluate the impact of increased support for living organ donation (e.g., child care, travel expenses).	<ul style="list-style-type: none"> - Implementation of demonstration project - Completion of analysis and report on demonstration project

GOAL I: INCREASE THE NUMBER OF ORGAN AND TISSUE DONATIONS

OBJECTIVE	SUBOBJECTIVE	SUB-SUB-OBJECTIVE	MEASURES
	Increase minority cadaveric and living organ donation.		<ul style="list-style-type: none"> - Change in number of minorities exposed to organ donation messages by racial/ethnic category (e.g., churches) - Change in number of minority donors by racial/ethnic category. - Increase in joint initiatives with minority and tribal organizations - Adoption of curricula at minority-serving institutions - Increase in tailored materials for minorities
	Increase donation from non-traditional donors.	<ul style="list-style-type: none"> - Older donors - Living donors 	<ul style="list-style-type: none"> - Number of seniors reached with organ donation messages (through aging network) - Change in number of donors ages 50-64 and ages 65+ - Change in number of living donors by various categories - Analysis and report on laparoscopic kidney removal
Increase donation through improved donor identification, referral, and request.	Reduce the number of lower-performing OPOs.	Identify and resolve barriers to OPO performance: <ul style="list-style-type: none"> - Best practices - Maximize number and type of organs procured per donor - Partnerships 	<ul style="list-style-type: none"> - Change in number of donors procured per million population - Change in number of OPO agreements with hospitals - Change in number of MOUs or informal arrangements with other procurement programs, e.g., eye and tissue banks - Change in number and type of organs procured per donor
	Increase the number of hospitals that identify at least 90 percent of their potential donors.	Institute mandatory ^{(selective) referrals to OPOs} referral of in-hospital deaths ^{potential donors to OPOs} <ul style="list-style-type: none"> - Medicare conditions of hospital participation rule - JCAHO legislation 	<ul style="list-style-type: none"> - Adoption of Medicare conditions of participation rule. - Adoption of legislation to require JCAHO to meet Medicare standards (including Medicare conditions of participation) - Change in number of hospitals that report deaths to OPOs (before and after regulatory and legislative changes) - Change in number of donors identified at each hospital (before and after regulatory and legislative changes) - Number of hospitals that identify at least 90 percent of their potential donors.

GOAL I: INCREASE THE NUMBER OF ORGAN AND TISSUE DONATIONS

OBJECTIVE	SUBJECTIVE	SUB-SUB-OBJECTIVE	MEASURES
		Decrease the number of the largest hospitals with no donors by 30 percent by the year 2000.	<ul style="list-style-type: none"> - Change in number of largest non-donor hospitals that report deaths - Change in number of largest non-donor hospitals that produce donors - Change in number of non-donor hospitals with access to appropriate equipment/staff
		Establish partnerships with relevant organizations.	<ul style="list-style-type: none"> - Number of MOUs and joint initiatives with organizations.
		Provide evaluations of hospitals by OPOs.	<ul style="list-style-type: none"> - Publication of report and/or feedback to hospitals on hospital performance
	Augment hospital capacity to successfully increase organ donations.	Increase the number of health professions schools adopting curricula.	<ul style="list-style-type: none"> - Change in number of schools adopting curricula
		Increase adoption of best practices.	<ul style="list-style-type: none"> - Change in number of hospitals incorporating professional education and training on organ donation - Frequency of professional education/training (re: staff turnover)
		Ensure that hospitals identify an individual or team.	<ul style="list-style-type: none"> - Number of hospitals with identified individuals/teams
	Improve determination of death, including brain death.	Disseminate guidelines; provide education/training	<ul style="list-style-type: none"> - Number of professionals exposed to guidelines (through publications, conferences, training, etc.) - Changes in policies by hospitals, professional societies, etc.
	Increase timely communication of donor preference at time of death.	Evaluate donor registries.	<ul style="list-style-type: none"> - Proportion of families who consent pre and post implementation of donor registry - Number of times registry is used
		Improve communication of donor preference.	<ul style="list-style-type: none"> - Number of DMV licensing sites engaging in public education activities - Change in practice (e.g., providing on-site medical personnel with donor preference information) and/or number of law enforcement officers receiving education

GOAL II: DECREASE THE PERCENT OF POPULATION NEEDING TRANSPLANTS

OBJECTIVE	SUBOBJECTIVE	SUB-SUB-OBJECTIVE	MEASURES
Increase efforts to prevent contributing diseases and conditions.		Create an early intervention campaign to detect and treat hypertension and kidney disease in BPHC-funded health centers.	<ul style="list-style-type: none"> - Number of centers participating in intervention campaign - Change in identification of hypertension and kidney disease among BPHC-funded health center patients. - Change in incidence of hypertension and kidney disease among BPHC-funded health center patients.

GOAL III: INCREASE TRANSPLANTATION OPTIONS (To be revised and developed by the appropriate agencies)

OBJECTIVE	SUBOBJECTIVE	SUB-SUB-OBJECTIVE	MEASURES
Develop alternatives to living and cadaveric donors.			
Increase organ usage.			
Reduce the proportion of transplant recipients who require re-transplantation.			
Identify factors that lead to more successful transplantation for diverse populations.			
Apply research results to practice.			

File: OREGON H/Th.
Case

TO: Hillary Rodham Clinton
FROM: Pauline Abernathy
cc: Chris Jennings, Jen Klein, Jeanne Lambrew
DATE: April 22, 1997
RE: Your request for information on the Oregon Health Plan

After reading the attached *Newsweek* article by Jonathan Alter, you asked me what exactly Oregon has done to expand health insurance coverage.

What Oregon Has Done: The Oregon Health Plan, the collective name for a series of laws enacted between 1989 and 1995, includes expanded Medicaid to cover everyone under 100% of the federal poverty line, insurance reforms and insurance-purchasing pools for small employers, and state-run insurance pools to cover people denied coverage in the private market because of pre-existing conditions. Oregon received a federal Medicaid waiver in 1993 to expand Medicaid to everyone -- including men without children -- under 100% of poverty. It pays for the expansion through savings from limiting coverage to services on a "priority list," extensive use of managed care, and additional State appropriations. About 120,000 people have gained coverage under the Medicaid expansion, 35,000 under the small business insurance-purchasing pools, and 5,000 through the state high-risk insurance pool.

Reaction: The Oregon Health Plan is widely perceived as successful, as evidenced by the award it won from the Ford Foundation's Innovations in American Government program. (See attached.) Although many people had initially been concerned that the Plan would lead to unacceptable rationing of services for people with low-incomes and disabilities, these fears have not been realized. This is in part because to date the State has appropriated enough funding to cover an extensive list of services -- more expansive than under the traditional Medicaid program -- so few services of consequence have been denied. In addition, some providers have continued to provide uncovered services for free. Thus, the priority list has not yet tested the public's and providers' willingness to accept tough choices between covering more people and fewer services, and covering fewer people and more services.

Replication: The *Newsweek* article talks about the need to replicate successful programs such as the Oregon Health Plan. Florida's Healthy Kids program to expand health insurance for children is being successfully replicated in others States (see attachment), but it may indeed be difficult to replicate the Oregon Health Plan in other States. The Oregon Plan required years of extensive public deliberation of the priority services list under the Governor's personal leadership and may be the product of Oregon's somewhat unique political culture. In addition, Oregon already used managed care extensively. By contrast, some of the problems with TennCare in Tennessee may stem from its not having had widespread use of managed care

prior to adopting TennCare.

Attachments:

- Newsweek article by Jonathan Alter which mentions the Oregon Health Plan
- Ford Foundation descriptions of the Oregon Health Plan and the Florida Healthy Kids Corporation

David M. Matter

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April 15, 1997

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Assistant to the President and
Deputy White House Counsel
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Washington, D.C. 20500

Mr. Christopher C. Jennings
Special Assistant to the President
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Washington, D. C. 20502

Mr. Bruce Reed
Assistant to the President
for Domestic Policy
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Gentlemen:

On behalf of the representatives of the University of Pittsburgh Medical Center, Mr. Charles Fiske of the Family Inn located in Brookline, Massachusetts, and myself, I wish to thank each of you for taking the time from your busy schedules to visit with us on the issue of allocation of livers donated for transplantation. It was obvious from your questions and comments that you were already well informed regarding many of the issues and arguments involved in this important public policy decision. However, we wanted to provide you with further comments and clarification with respect to three of the issues discussed in our meeting and to bring one additional item of interest to your attention.

First, Mr. Jennings is correct that a significant increase in organ donation, for all organs not just livers, would correct many of the problems and ease much of the anxiety in the transplantation community. Increasing donation is a goal of most of the professionals and institutions involved with organ transplantation. Many procurement organizations and transplant centers across the country have started innovative new programs to increase donor awareness, have pursued state legislative efforts to increase donation rates, and have committed significant time and money to donor education programs. A significant increase in organ donation, however, is a long-term, rather than an immediate solution to the current problem of patients dying while waiting for a liver transplant. It has become obvious from the

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experiences over the last ten years that it will take a prolonged and enhanced effort at education, trust building and, in some cases, cultural modification before we can hope to see any significant increase in donation rates. In the interim, the Department and this Administration can, with the stroke of a pen, implement programs which will save the lives of nearly 300 patients over the next three years. We are not in an "either/or" situation; rather, there is a "both/and" response to this problem. The Department can require broader geographic sharing of donated livers, resulting in saving the lives of approximately 100 patients per year, while also putting in place initiatives which, hopefully, will increase organ donation significantly.

Second, we committed to attempt to provide you with information relating to donation rates for livers at organ procurement organizations which are not associated with a liver transplant program compared to those that have such programs. In checking with CONSAD Research Corporation, we determined that UNOS has failed to make such data available either to the public or to CONSAD despite repeated requests. There is some UNOS data available which describes the composite procurement rates for organ procurement organizations for all organs (including both solid organs and tissue, bone etc.). That data indicates a very significant variation between OPO's but without data about procurement rates for specific organs, which UNOS refuses to make public, any more detailed analysis of the factors that relate to the differences is impossible.

Third, in response to Mr. Reed's question about the comparison of life expectancies between a Status 1 patient who receives a transplant and a Status 3 patient, we discussed both life expectancy and survival rates. Because a Status 3 patient is not nearly as sick as a Status 1 patient at the time of transplant, a Status 3 patient has a predictably higher survival rate (80.9% 1 year graft survival rate) than a Status 1 patient (60.1% 1 year graft survival). However, it is important to note that after one year the proportion of patients alive remains essentially the same for all statuses. For example, approximately 5% of liver transplant patients who have survived one year have died by the second year regardless of status; an additional 2%-3% have died, again regardless of status, after surviving 2 years but before the third year, and so on. The survival rates for all liver transplant patients, even those within seven days of death at the time they receive a transplant, are quite good, especially when you consider that transplantation is a life saving operation. As we mentioned in the meeting, if the goal were to transplant those patients with the best chance of survival, the medical priorities

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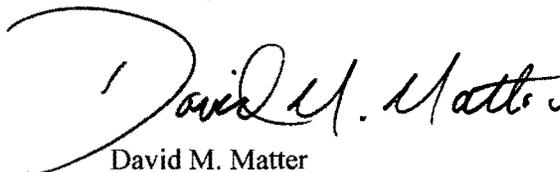
established by the transplant community would be completely reversed, and those patients least in need of a transplant would receive the first priority. The goal of liver transplantation, however, is to save the lives of those patients who have no other alternative. Thus, the medical priority of transplanting the sickest patients first is appropriate.

And finally, allow me to draw your attention to the attached Code of Medical Ethics, published by the American Medical Association, Council on Ethical and Judicial Affairs, 1996-1997 Edition, Section 2.16(6): "Organs should be considered a national, rather than a local or regional resource. Geographical priorities in the allocation of organs should be prohibited except when transportation of organs would threaten their suitability for transplantation." (Emphasis added). With a cold ischemic time of from 12-18 hours for donated livers, there is literally no part of the United States from/to which a donated liver cannot be transported for transplantation. The current UNOS system of organ allocation, which traps livers in 70 small geographic areas, is, at the very least, ethically questionable and, quite simply, bad public policy.

Again, we thank you very much for your questions, comments, and observations during our meeting and for your attention to this very important issue. As Mr. Fiske said in the meeting, and as other patient advocates have said in other forums, UNOS and the transplant centers who are its members, are fully capable of being involved in this discussion and looking out for their own self-interests. Someone else must protect the interests of the patients in making sure that the system is fair. That "someone" is the Department and this Administration.

If there is other information or data which we can provide to you, please do not hesitate to contact me.

Sincerely,

A handwritten signature in black ink that reads "David M. Matter". The signature is written in a cursive style with a large, sweeping initial "D".

David M. Matter

DMM:tn



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Deputy Secretary

Washington, D.C. 20201

FACSIMILE

DATE April 8, 1997

TO: (NAME, ORGANIZATION, CITY/STATE AND PHONE NUMBER):

*Ms. Sarah Bianchi
DPC*

FROM: (NAME, ORGANIZATION, CITY/STATE AND PHONE NUMBER):

*Lisa Gilmore
Special Assistant to the
Deputy Secretary
DHHS*

*202/690-6133
202/690-7755 (Fax)*

RECIPIENT'S FAX NUMBER *(202) 456-5557*

NUMBER OF PAGES TO SEND (INCLUDING COVER SHEET): 4

COMMENTS:

This should be more readable.

Lisa

THE Mitzvah

of ORGAN DONATION

Rabbi Joseph H. Prouser

THE DONOR CARD

Please detach and give this portion of the card to your family. You may wish to provide copies of this document to various family members.

This is to inform you that I want to be an organ and tissue donor if the occasion ever arises. Please see that my wishes are carried out by informing attending medical personnel that I am a donor. In so doing, you will be acting as my partner and agent in the Mitzvah of *Pikuah Nefesh*, saving lives.

In keeping with the Jewish belief that the human body is God's creation, and is thus to be accorded sanctity even after death, please see that all appropriate steps are taken on my behalf to maintain *K'vod ha-Met* (honor to the deceased). As soon as organs or tissues are retrieved in accordance with my instructions, see that the rest of my remains are buried in a Jewish cemetery, in accordance with Jewish law and custom.

Thank You.

Signature _____

Date _____

The Rabbinical Assembly • (212) 678-8060

The United Synagogue of Conservative Judaism • (212) 533-7800

In keeping with the moral and religious teachings of Jewish law, and in an effort to help others, I hereby make this anatomical gift, if medically acceptable, to take effect upon my death.

For Purposes of Transplantation Only, I donate:

a) Any needed organs or tissues

b) only the following organs or tissues

(specify which organs or tissues): _____

Limitations or special wishes, if any: _____

Signature of donor: _____

Birthdate: _____

City & State where signed: _____

Date: _____

Witness: _____

Witness: _____

Must be signed by donor and two witnesses in the presence of each other.

The inestimable value of human life is a cardinal principle of Jewish law. This principle includes an obligation for maintenance of our own health and for self-preservation. This obligation, known as *pikuah nefesh*, also includes the duty to save the life of one's fellow human being, should he or she be in mortal danger. This is the significance of the Commandment: "You shall not stand idly by the blood of your neighbor" (Lev. 19:16). Codifying this *mitzvah* in his *Mishneh Torah*, Maimonides emphasizes how broadly its obligation devolves, holding that anyone who is able to save a life, but fails to do so, violates this commandment.

These sources provide the halakhic basis for the decision by the Rabbinical Assembly's Committee on Jewish Law and Standards that "the preservation of human life is obligatory, not optional. When needed for life-saving transplantation, withholding consent for post-mortem tissue donation must be considered forbidden." This decision is the conclusion of my responsum "The Obligation to Preserve Life and the Question of Post-Mortem Organ Donation," which the Committee recently adopted. Based on this responsum, the Committee has also unanimously approved a Conservative Movement Organ Donor Card, published and distributed in a joint effort with The United Synagogue of Conservative Judaism.

The actions of the Conservative Movement to urge its members to register as organ donors reflect the compelling urgency and the massive need for organ transplants. Well over 40,000 people are on the waiting list of the United Network for Organ Sharing. Every thirty minutes, a name is added to this national waiting list. Due directly to the shortage of willing donors, thousands of adults and children die each year. The cost in human lives is staggering: According to one estimate, as many as nine people die each day for lack of available organs.

The life-saving impact of organ donation reaches far beyond the sizable number of potential recipients. Prospective living donors, as well as recipients, are needlessly placed at mortal risk by the shortage of cadaver organs. Desperate parents want to donate organs even when doctors are unwilling to do the operation because they think it would be futile, or would entail too great a risk to the donor. Dr. Thomas Starzl, the renowned surgeon who pioneered liver transplants, now refuses to perform transplants from living donors for this very reason. Nevertheless, medical reliance on living donors continues to mount. Such a trend in the field of transplantation places tremendous pressure on relatives of prospective organ recipients to imperil themselves by serving as donors. In 1994 alone, 2,980 kidney transplants were performed using living donors.

A specific aspect of this trend is particularly troubling. Spouses are increasingly being viewed as important sources for living organ donation. In cases where these spouses are also parents, as is common, spousal organ donation means that both parents (donor and recipient) — and, therefore, their children's well-being — are placed at mortal risk.

Even a minute risk to the living is a significant religious and halakhic datum. Former British Chief Rabbi Immanuel Jakobovits thus rules that donation of organs by living donors (even blood donation), while commendable, may not be viewed as obligatory because it may entail a measure of risk for the donor. This risk is, by definition, completely absent in post-mortem donation.

To be sure, post-mortem donation of human tissue is not without difficulties from the perspective of Jewish law. Objections to this practice include the prohibitions against *nivul ha-met* (disgracing the dead body, as by disfigurement), *hanu'ah min ha-met* (deriving benefit from a dead body), and *halanat ha-met* (delaying burial). In discussing these issues (collectively termed *kevod ha-met*), the Committee on Jewish Law and Standards concluded that just as the religious mandate to preserve life takes precedence over all other religious obligations, it also must be given precedence over *kevod ha-met*. It thus affirmed the statement of Rabbi Isaac Klein in his *Guide to Jewish Religious Practice* that "there is no greater *kevod ha-met* than to bring healing to the living."

Continued on next page

THE MITZVAH OF ORGAN DONATION continued from previous page

Based on the precedence of *pikuah nefesh*, the seriously ill are required to eat on Yom Kippur and it is forbidden to circumcise a sick or weakened infant if this would further compromise his health. The circumcision must be delayed, for, as the *Shulhan Arukh* observes, "preservation of life overrides all other considerations." (The prohibitions against murder, sexual immorality, and idolatry are, under normal circumstances, the only exceptions.) In other words, it is not merely permissible to delay what would be a life-threatening *brit milah*. Indeed, it would be sinful to perform the circumcision under such circumstances.

Similarly, it would be sinful to impair one's health by fasting while seriously ill, or to wait until the conclusion of *Shabbat* or Festivals to drive a sick or injured party to the hospital. Indeed, according to the *Shulhan Arukh*, "One who is zealous (and eagerly violates the Sabbath in such a case) is praiseworthy."

Sadly, many members of the Jewish community have been reluctant to register as organ donors. This is due in part to the misperception that Jewish law forbids organ donation. Perhaps the most decisive factor in this reluctance, however, has simply been the widespread aversion to any interference with the dead among most Jews. In general, this aversion reflects entirely appropriate devotion to venerable religious principles, and should be commended.

Kevod ha-met, the dignity and honor of the dead, is a weighty and cherished religious imperative. This is indicated by the designation given those charged with the religious task of attending the dead and preparing them for burial: *Hevra Kadisha*, the "Holy Society." Judaism teaches the sanctity of the human body as a reflection of the "Image of God," which is in every human being. This sanctity adheres to the body even after mortal life has ended.

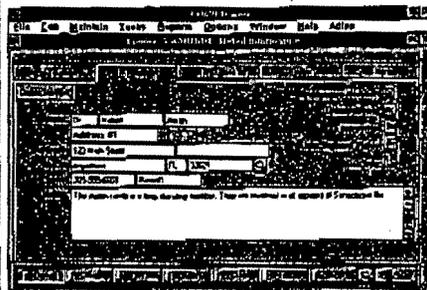
It is precisely a sensitivity to such well-intentioned sentiments which characterizes the educational campaign undertaken jointly by The United Synagogue of Conservative Judaism and the Rabbinical Assembly to register Conservative Jews as organ donors. Framing this teaching in terms of persuasion rather than coercion does not imply that this life-saving action is elective. Rabbis and Jewish communal leaders frequently engage in educational endeavors and persuasive techniques aimed at generating compliance with clear religious obligations. Persuading a Jew to comply with the laws of *Shabbat* or *kashrut*, or to engage in Jewish study, does not suggest that such observances are optional — just as The

Continued on page 16

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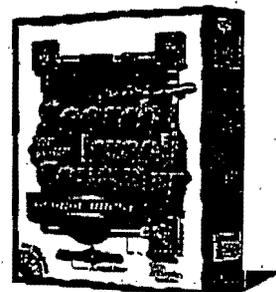
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THE MITZVAH OF ORGAN DONATION *continued from 9*

United Synagogue's campaign Jewish Living Now is a wise and welcome reminder of Jewish religious obligations.

Consenting to post-mortem organ donation may be emotionally difficult; that difficulty may in part reflect appropriate religious sentiments. However, we are obligated to preserve life. We ought not, as our final act, glorify strictly subjective aversions, aesthetic objections, and personal preference at the expense of human life.

It is essential that one undertaking persuasive outreach in regard to the *mitzvah* of *pikuah nefesh* sensitively place organ donation into a constructive context in communicating with prospective donors or responsible next of kin. Referring to life-saving transplant procedures as the "harvesting" of organs, for example, evokes a sense of violence and disregard for the humanity of the deceased. "Recover" or "retrieve" are more appropriate terms to describe the donation process. It is similarly imperative that a ventilator not be referred to as "life-support," as this seems to imply that the patient is not yet dead. (The ventilator is used following death to maintain circulation of oxygenated blood to viable organs.)

Those contemplating organ donation should also be made aware that studies show that donation of one's organs helps to shorten the time needed by bereaved family members to recover from their loss. Serving as an organ donor thus not only saves lives but also provides comfort and healing to one's own loved ones. It does not remove the pain or loss, but organ donation allows something good and uplifting to be salvaged from an otherwise horrible occurrence. Families of donors know their loved one will never be forgotten by those whose lives they save and report a sense of extended family and community with other donors and recipients.

Given the increasing sophistication and success of transplant technology, and the increased

confidence regarding determination of death, the post-mortem donation of vital organs clearly constitutes *pikuah nefesh* — the saving of human lives. Indeed, one individual can save as many as eight or more lives by consenting to donation. The demand for organs far outweighs the supply, creating thousands of desperate, specific, life-threatening situations. Jewish law, therefore, requires us to grant our consent for post-mortem organ donation when requested by doctors or hospitals for use in life-saving transplant procedures.

This religious obligation can be fulfilled by personally registering as a donor by, for example, properly completing the Rabbinical Assembly/United Synagogue of Conservative Judaism donor card, and carrying it on one's person. The donor card additionally provides a form for use in informing family members of one's intention in this matter. It is most advisable to include written documentation of one's donor status as part of a more general "living will."

The preservation of human life is obligatory, not optional. Thus, withholding consent for post-mortem organ donation when needed for life-saving transplant procedures is prohibited by Jewish law. This applies to the individual in anticipation of his or her own death, as well as to health care proxies or next of kin, whenever they are legally empowered to make such decisions on behalf of the deceased. The identity and, certainly, the religious status of the recipient are irrelevant. A bereaved family member who grants consent for organ donation acts as an agent and partner of the deceased in observance of the *mitzvah* of *pikuah nefesh*, in saving human lives. By so doing, he or she renders only profound and genuine honor to the deceased, while simultaneously bringing comfort to those who mourn. □

Rabbi Joseph H. Prouser is the spiritual leader of Congregation B'nai Shalom in Newington, Connecticut. He also serves on the United Synagogue's National Youth Commission, as well as on its National Commission on Jewish Education.



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DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Deputy Secretary

Washington, D.C. 20201

FACSIMILEDATE April 8, 1997

TO: (NAME, ORGANIZATION, CITY/STATE AND PHONE NUMBER):

Ms. Toby Damerfeld
 Vice President's office
 202-456-6265

FROM: (NAME, ORGANIZATION, CITY/STATE AND PHONE NUMBER):

Lisa Gilmore
 Special Assistant to the
 Deputy Secretary
 DHHS

202/690-6133
 202/690-7755 (Fax)

RECIPIENT'S FAX NUMBER (202) 456-6231NUMBER OF PAGES TO SEND (INCLUDING COVER SHEET): 6

COMMENTS:

Judy Broslow just gave me the attached 2 pages on commitments the Vice President could announce. Also attached is an update on Transweb University which could be announced. It's a HRSA grant but doesn't look fully cooked yet. Please call with questions.

Lisa

Commitments that can be made by Vice President Gore

1. The Union of American Hebrew Congregations (UAHC) has launched a major effort to educate the members of its 850 reform Jewish temples across the United States on issues surrounding organ donation and transplantation. The UAHC has mailed over 30,000 brochures to members within the last few months, is developing a study guide for its member congregations to teach about organ donation and transplantation, and is encouraging its members to rabbis to give sermons, workshops and symposiums on donation and transplantation. UAHC has also developed a religious ceremony focused on honoring donors, not unlike what you would do to honor the birth of the baby or a prayer for the recovery of an individual. UAHC has made this a priority for its committees on older adults and its bioethics committee. UAHC member congregations will be encouraged to participate in National Donor Sabbath and honoring donors within their own congregations. We are proud that we have been part of this effort and look forward to replicating this model with other religious organization. (Toby-- What I would do with religious organizations is highlight the UAHC and then announce how pleased we are that the CNBC and the Catholic Health Association have agreed to partner with us on a similar effort)
2. The Congress of National Black Churches has committed itself to a partnership in this area as well. Since the diseases for which organ transplantation is a viable treatment modality disproportionately affects African-Americans we are delighted with the willingness of the CNBC to participate with us in a national educational effort on the importance of minority organ donation. Member denominations will be offered a range of participatory options related to the educational campaign, including participation in National Donor Sabbath and ceremonies honoring donors within their own member churches. Material for church newsletters, brochures, sermons and development of new liturgy are all among the options that will be presented to member churches and denominations within this very large umbrella organization. We will be meeting with the health committee of the CNBC in the coming months to help launch this initiative and bring African-Americans on the waiting list one step closer to a transplant.
3. The National Kidney Foundation, the principal co-sponsor of the ceremony today, has agreed to partner with us in making additional resource materials available to donor families. Because of the very great and wonderful gift that those of you we are honoring today have given, we feel it is important and our obligation to make the grieving period as easy on donor family members as possible. Thus I am pleased to announce that NKF in partnership with us will be launching a web site geared to the needs and assistance donor families want and deserve. This website will have a 24 hour "write-" system, where donor families can write in and be directed to resources and scheduled open chats with trained facilitators.

4. One of the most successful programs we have launched in the past several years has been a donor awareness program at the University of Rhode Island. URI has developed brochures, materials for Freshman Orientation, trailers for movies shown on campus, health education class materials and even donor designation on the back of student ID cards. The URI program has reached thousands of students over the last several years. I am so pleased to announce that the American College Health Association has agreed to partner with us to replicate this program at other colleges and Universities across the country. The URI program is a program that can be adapted at large and small institutions and materials developed at one institution can be easily modified. We are pleased with this program because it gives us an opportunity to educate the college population about donation, but the implicit message about safe behaviors will also be carried to this population.

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Subject: Re: help
Author: "Eleanor Jones"
<Eleanor_Jones.TRANSPLANT@mailgw.surg.med.umich.edu>
at
INTERNET
Date: 4/8/97 1:54 PM

Reply to: RE>help

Hi Gwen!

Here's the current status of TransWeb University:

If you want to put it in terms of our Revised Work Plan, we have accomplished the first five items, and have made progress towards the 6th, 7th, 8th and 9th. I realize that our mid-year report was due April 1, so I will be getting that to you ASAP.

Existing educational materials (booklets, curriculum guides, videos, handouts, etc.) about transplantation and donation for teens and children were collected from all over the country; we found some very useful ideas in them. Several of the high school students working on TransWeb University have evaluated each item in terms of content, effectiveness, and appeal. The students' impressions have been a good guide for us in the design process.

We continue to scout out and review other educational web sites, for ideas on how to structure and present our content. Also, there are many exciting technical developments (like the recent launch of RealVideo) and multimedia opportunities (like Shockwave) that we've been learning about, so as to see if they could be applied to TWU.

We are in the midst of developing the content of one level (cadaveric kidney transplant), as the basis for the content that should be covered in all transplant process modules. (The transplant process, as we define it, includes all that happens from diagnosis of organ failure, the transplant evaluation & decision, the waiting list, the surgery, post-surgery recovery, rejection & other complications, to taking care of yourself after transplant, etc.) Content-gathering has consisted largely of interviews with transplant staff, as well as review of existing educational materials (above).

We continue to work with local high school and elementary school students and teachers, whose insight into the teaching & learning processes is key to the success of TWU. Transplant recipients and their families will also be involved.

The first phase of the design process was the overall structure and navigational strategy for TWU as a whole, and we've made good progress in that phase. We are now starting to address the graphic design features.

Is this the kind of information you needed? Please let me know if there's anything else you need. I'm also enclosing the "Comparision of TransWeb and TransWeb University." (see below)

--Ellie

TransWeb University

----- TransWeb University (TWU) will be a collection of age-appropriate teaching modules, each designed to convey a specific parcel of information relating to organ and tissue donation and/or transplantation. Each will be a multimedia, interactive unit that can be completed in a classroom or by an individual on his/her own via the World Wide Web. The age levels and subject areas under consideration are given below.

Modules introducing transplantation and organ and tissue donation to the general public:

- Preschool and lower elementary
- Upper elementary
- Junior high/middle school
- High school
- Adult

Modules for medical and transplant-related professionals:

- Medical school: an introduction to the field
 - Nursing & critical care staff: potential organ and tissue donor recognition
 - Procurement staff: approach to the donor family and donor management
- We are working closely with students and members of each intended target audience, so that each module benefits from the audience's suggestions, contributions, and criticism. We are also utilizing the guidance of teachers of each age level as well as that of medical/health educators, to make TWU as effective as possible.

The first module is scheduled for completion (including testing) in September 1997. The TWU project is supported by the Division of Transplantation, whose

\$25,000 grant has made the initial phase possible.

TransWeb University as compared to the TransWeb site

TransWeb (www.transweb.org) was created to be a collection of reliable transplant-related information, as well as a directory of valid transplant-related resources on the Internet. (See charter.) As such, TransWeb is largely a text-based reference, written for adults. Realizing that children and teens need a place to learn about transplantation and donation, we saw a need to create age-appropriate teaching modules for them, at their reading level and with graphics, sound, and activities (like puzzles or quizzes) appropriate for them. A grant from the Division of Transplantation has made it possible

The difference between TransWeb and TWU is that TransWeb is more of a passive reference or resource, while TWU takes the user through the transplantation and donation processes, actively teaching along the way.

Date: 4/8/97 11:58 AM

To: Eleanor Jones

From: Gwen Mayes

ellie,

if you're out there, I need some help, ASAP. I need the latest up date on TransWeb..any progress made, next steps, etc. We want to include this project in some educational ideas that are to be presented to the Secretary. I'll be back in this afternoon about 2 p.m. and need to have something around that time.

thanks

gwen

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April 11, 1997

Douglas W. Hanto, M.D.
Liver Transplant Program
University of Cincinnati Medical Center
231 Bethesda Avenue
Cincinnati, Ohio 45267-0558

Dear Doug,

This is in response to your request for an explanation of how unverified, inaccurate information about the number hearts offered for transplantation during 1994 came to be published in the *Cleveland Plain Dealer*. That newspaper's outrageous story about organ "turndowns" implied that several fine transplant institutions allowed their heart transplant candidates to languish on the waiting list by declining offers of hearts for transplantation, which otherwise would have been accepted and transplanted.

HRSA released this information to the *Plain Dealer* over our objections, and in so doing, failed to adhere to Federal regulations that protect the rights of those who submit data. As with other recent controversies over confidential data, this release represented a significant departure from the historic arrangement between HRSA and UNOS regarding OPTN and Scientific Registry data. I believe the only way to stop this kind of damaging activity is through a change in NOTA, patterned after the law establishing HHS's Agency for Health Care Planning and Research. That law prohibits the Government from releasing patient or institution-identifiable data, an approach that would serve the OPTN, its members, and the patients and public it serves, very well.

Background: The Release of Turndown Data. UNOS policies have long prohibited the public release of institution-specific data without permission. Those policies permit UNOS to provide HRSA with data required under the contracts for oversight. We had provided HRSA with a report of the number of organ offers and refusals for each transplant center following the public outcry over the situation at the University of Kansas heart transplant program. HRSA was fully aware of the preliminary and incomplete nature of the information, but requested the report as a "rough cut" analysis of the context in which to place the Kansas aberration.

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G. Melville Williams, M.D., 1984-85
Oscar Subitivities, Jr., M.D., 1985-86
John C. McDonald, M.D., 1986-88
H. Keith Johnson, M.D., 1988-89
Robert J. Curry, M.D., 1989-90
James S. Wolf, M.D., 1990-91
Robert Mendez, M.D., 1991-92
R. Randal Bollinger, M.D., Ph.D., 1992-93
Douglas J. Narman, M.D., 1993-94
Margaret D. Allen, M.D., 1994-95

Executive Director Emeritus
Gene A. Pierce

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When we learned that HRSA was contemplating releasing that report to the press, we warned them repeatedly that the information was grossly incomplete and unverified, and it therefore would be highly misleading and damaging if released to the public. Once the report had been released, we spent hours talking to no avail with the newspaper about the incompleteness of the information and the great disservice that would result from publishing the report.

An Earlier Instance of the Change in HRSA's Approach - Data Release to Pittsburgh. Until only recently, HRSA was in accord with UNOS's policies regarding data release. HRSA even attached those policies to its most recent Request for Proposals soliciting bids on the OPTN contract and added a new task to the OPTN contract requiring the contractor to adopt them. But, in May, 1995, HRSA began changing its position when it pressed us to release patient-identified and institution-identified data to the University of Pittsburgh's agents ostensibly for development of proposed new liver allocation policies. That request turned into a very heated dispute between UNOS and HHS (including an outpouring of mail from the transplant community opposing the release) as a result of a letter from Mrs. Judy Braslow, Director of the Division of Transplantation, to UNOS asking us to release patient and center-identified data to Pittsburgh's consultants. The controversy went all the way to Dr. Lee, who at the time was Assistant Secretary for Health, the highest ranking official in the Public Health Service. Despite a personal appeal from UNOS's General Counsel, Mrs. Braslow released the center and patient-identified liver transplant data to Pittsburgh's consultants herself after requiring UNOS to deliver a computer tape of the data to HRSA under the OPTN contract.

Mrs. Braslow's Testimony to Senator Frist. The foregoing background is important because it was only two months later that HRSA testified before Congress about its concern for protecting confidentiality of center-identified data. In light of that very recent controversy, which certainly had not been something that would have slipped anyone's mind, we were happily surprised at Mrs. Braslow's testimony before the U. S. Senate Labor and Human Resources Committee on July 20, 1995, about the NOTA reauthorization. We took her testimony as a reaffirmation of HRSA's historic position regarding this issue. Mrs. Braslow responded to questions from Senator Frist:

Senator Frist: "The data -- as a physician, I was very concerned giving all of my data about each transplant I did to the Federal Government. I did not trust the Federal Government and did not know what would be done with that data..."

... the doctor-patient relationship, which is sacred to those of us in the profession - all of a sudden, we have people coming in and wanting pieces of information which will be used for policy, disseminated broadly. What should we be telling the doctors?"

Mrs. Braslow: "In terms of the tone of your question and your concern about the confidentiality of the patient, I think we are very, very concerned about patient confidentiality, and any time we request that our contractor give out data to handle a specific data request, that is always couched in terms of scrambling or making certain that patient identifiers and institutional identifiers are not available to the

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requester. So we are concerned about precisely the same issues that you are concerned about.... " (emphasis added)

Of course, what she said about "always" telling us to make certain that "institutional identifiers are not available to the requester" was technically incorrect, since she had, only a few months earlier, requested specifically that we release patient and institution-identified data to Pittsburgh's consultants, which *she* herself ultimately gave to them over *our* objections. But, since that had been a rare occasion, and this was testimony before the United States Congress, we took it as a fundamental reaffirmation of HRSA's previous practice of honoring the confidentiality of OPTN data. However, only a few months later we were surprised to see that the policy had been apparently reversed again.

HRSA's Failure to Follow FOIA Regulations. In January 1996, we received an undated letter from Ms. Braslow addressed to Dr. Daily in which she described the request for data from the *Cleveland Plain Dealer* reporter. We understand that Mrs. Braslow had offered her master list of the data UNOS had provided DOT under the contract to this reporter to be used to request data to be released. In her undated letter, Ms. Braslow listed all of the data she had already given the reporter and described other data the reporter "could get if she filed a FOIA request. I think we should mail them to her because she would be able to get it through FOIA. If you think otherwise, let me know." The 1994 transplant center-specific heart turndown report we had previously given HRSA was specifically listed in that category.

We replied to Ms. Braslow's letter on February 28, 1996, and asked that HRSA not respond to the newspaper's request but refer it to UNOS as they had routinely done in the past as provided in the OPTN contract. We explained why the data were confidential and not subject to release by HRSA under FOIA. We pointed out that the release of unverified, misleading and competitively sensitive information that had been submitted to UNOS voluntarily under the terms of the data release policies in our by-laws, which protect center and patient identity, would be harmful and could destroy the system.

HHS's FOIA regulations state, "We have no discretion to release certain records, such as trade secrets and confidential commercial information. We will not disclose records whose information is 'commercial or financial,' . . . and is 'privileged or confidential.' We interpret this category broadly." An official notification with five business days to object to disclosure must be given to the submitters of "confidential commercial information" whenever HHS receives a request to release such data. Even if the information had not been labeled as confidential, the regulations require that the notice be given if HHS has substantial reason to believe that it *could be* considered as such. If HHS then decides to release the information, a second notice is required. It must explain why HHS did not sustain the submitter's objection and provide five business days to file suit in Federal District Court to prevent the data's release.

UNOS was never given any of the notifications required by the regulations. Ms. Braslow's undated letter makes it clear that a FOIA request had not been filed. Rather, she informally asks for our