

Withdrawal/Redaction Sheet

Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. memo	Carol Rasco to POTUS re: Liver Transplants (2 pages)	12/18/96	P5
002. fax	Attendees, 12/2/96 Meeting with Rasco and Jennings Social Security numbers redacted (1 page)	11/19/96	P6/b(6)
003. memo	Memo with attachment re: Liver Transplants (3 pages)	12/6/96	P6/b(6)

COLLECTION:

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

FOLDER TITLE:

Organ Donations

gf44

RESTRICTION CODES

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

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

C. Closed in accordance with restrictions contained in donor's deed of gift.

PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).

RR. Document will be reviewed upon request.

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

- b(1) National security classified information [(b)(1) of the FOIA]
- b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
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- b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
- b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
- b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

Withdrawal/Redaction Marker

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HRSA GRANTS: MODEL PROGRAMS TO INCREASE ORGAN DONATIONS

Applicant: Education Development Center & New England Organ Bank, Boston, MA

Project: Increasing Organ Donation by Enhancing End-of-Life Care: A Family-Centered, Quality Improvement Program

Empirical research has established that families are more likely to consent to organ donation if they are satisfied with the care that their loved ones received at the end of life. The New England Organ Bank and the Education Development Center of Boston will collaborate with hospitals in Massachusetts, Rhode Island, and New Hampshire to enhance end-of-life care and improve the donation request process. The study aims to increase health professionals' comfort and skill discussing death and dying and to build a hospital's capacity to support families through the end-of-life period.

Total Funding: \$937,892

Applicant: The National Kidney Foundation, New York, NY

Project: Take Time to Talk: A Family Discussion Guide

The National Kidney Foundation will study the feasibility of incorporating a donation education program into funeral pre-planning activities. The goal of this program is to provide individuals the opportunity to conduct family discussions about donation at the time they are making other end-of-life arrangements. If successful, this program could introduce an untapped source for donation education.

Total Funding: \$439,413

Applicant: The South-Eastern Organ Procurement Foundation, Richmond, VA and the University of Rhode Island, Providence, RI

Project: Stage-Based Curriculum Training for Procurement Coordinators to Increase Family Consent for Organ and Tissue Donation

The aim of this project is to improve family donation consent rates by training procurement coordinators to match their donation requests to reflect the family's readiness to donate. This project, involving staff from 16 of the Nation's 61 organ procurement organizations, represents the first multi-center study of requester training program effectiveness.

Total Funding: \$1,212,883

Applicant: The California Transplant Donor Network, San Francisco, CA

Project: Proposal to Increase Organ Donation-Consent Rates Involving Targeted Minority Populations

The California Transplant Donor Network has achieved notable success in capturing Hispanic community support for organ donation. This grant award will facilitate the development of cultural diversity and request training programs to garner donation support among African Americans and Asians in Northern California.

Total Funding: \$1,374,620

Applicant: The Regional Organ Bank of Illinois, Chicago, IL

Project: Impact of Educational Interventions Regarding Organ Donation on Declaration of Intention to Donate and on Family Discussion in the African American Community

This project seeks to increase the number of African-Americans who are willing to join the state organ donor registry and talk to their families about their decision by assessing the effectiveness of two separate strategies to encourage registry participation and by conducting and evaluating an ethnically sensitive media campaign.

Total Funding: \$366,584

Applicant: Kentucky Organ Donor Affiliates, Louisville, KY

Project: Increasing Commitment to Organ and Tissue Donation Through a Work-Site Intervention

Kentucky Organ Donor Affiliates proposes to collaborate with United Parcel Service (UPS) to study the effect of a work-place donor education program. This program could potentially serve as a model for corporate education programs throughout the country.

Total Funding: \$137,349

Applicant: The Johns Hopkins School of Medicine and Johns Hopkins University, Baltimore, MD

Project: Interdisciplinary Experiential Training for End-of-Life Care and Organ Donation

This project will implement and evaluate a family-centered program focusing on end-of-life decision making and organ donation discussions with the goal of increasing the frequency of donation consent. The proposed program will utilize a multi-disciplinary approach involving such health care professionals as physicians, nurses, hospital clergy, and organ procurement coordinators who play consistent, important, and inter-dependent roles in caring for patients and families when organ donation is possible.

Total Funding: \$929,044

Applicant: Emory University and LifeLink of Georgia, Atlanta, GA

Project: The Renaissance State-Wide Initiative to Increase Organ Donation in the State of Georgia

The purpose of this project is to replicate a successful donation-enhancing program launched at Emory University Hospital in Atlanta known as the "Renaissance Project." This end-of-life care model will be expanded to four additional Georgia hospitals with the goal of enhancing family support practices and increasing the number of organ donors at each institution.

Total Funding: \$606,716

Applicant: LifeGift Organ Donation Center, Houston, Texas

Project: Project to Increase Organ Recovery From Level I Trauma Centers

This project proposes to replicate a successful pilot program which significantly increased organ donation by placing "in house procurement coordinators" in two Level I Trauma Centers. This proposal will disseminate the concept to hospitals demonstrating significant untapped donor potential in Detroit, Chicago, Seattle, and Houston.

Total Funding: \$606,270

Applicant: Golden State Donor Services, Sacramento, CA

Project: Increasing Donation in the Hispanic Community Through Mass Media

This project aims to reverse the declining rate of donation consent among Hispanic families in the Sacramento area by implementing and evaluating an ethnically sensitive media campaign. This undertaking is especially critical in California due to the disproportionate rate at which Hispanics are placed on the transplant waiting list due to end-stage organ failure.

Total Funding: \$444,510

Applicant: Oklahoma Organ Sharing Network

Project: Project Team Life

This proposal seeks to increase commitment to donate by implementing a curriculum designed to introduce organ and tissue donation and transplantation to elementary and secondary school students. This project could potentially serve as a collaborative working model for donor education programs and public school systems.

Total Funding: \$770,644

Applicant: LifeGift Organ Donation Center, Houston, TX

Project: African-American Community Outreach Project

This program aims to increase family donation discussions and minority community support by implementing and evaluating an intensive education and training program targeting African American religious and spiritual leaders in Harris County, TX. The project will prepare clergy to develop and implement effective donation education and support programs for each of their congregations.

Total Funding: \$595,342

Applicant: The Center for Donation and Transplant, Albany, NY

Project: Testing and Replication of a Model Volunteer Program

This project proposes to increase donation consent rates by evaluating and replicating a volunteer program teaching mothers of organ donors to counsel potential donor families about the option of donation. This program represents the first formalized program assessing the effectiveness of a former donor family member's role in the donation decision process.

Total Funding: \$783,882

Applicant: Louisiana Organ Procurement Agency, Metairie, LA

Project: The Kiosk Learning Center: A Community Outreach Approach to Increase Donor Consent Rates, Public Access, and Overall Awareness

This project will attempt to improve driver's license renewal efficiency and enhance donor education and registry access by placing ATM-like kiosks in public venues. This program will promote a convenient one-stop system as a means to enhance public commitment to donation.

Total Funding: \$1,049,759

Applicant: Upstate New York Transplant Services, Buffalo, NY

Project: Decision for Life: An Intervention to Increase Organ Donation in the African American Community

This program seeks to increase the number of African Americans in the Buffalo urban community who have signed donor cards and discussed donation with their families. It aims to achieve this goal by increasing medical student and resident awareness of the importance of approaching families in a culturally sensitive manner and by training African American community educators to implement public education programs.

Total Funding: \$810,330

Applicant: Donor Network of Arizona, Phoenix, AZ

Project: Comprehensive Approach to Raising Organ and Tissue Donation Consent in the Hispanic Population

This project proposes to increase donation consent rates among Hispanic families through a comprehensive approach to increase donor awareness and family discussions. Implementation will include community, media, and requester outreach.

Total Funding: \$880,937

Applicant: Minority Organ and Tissue Transplant Education Program (MOTTEP) Howard University, Washington, D.C.

Project: "Say YES!" to Organ and Tissue Donation; Implementation and Evaluation of a Promising Youth Intervention

This project seeks to increase the number of youth registering to become donors when obtaining a driver's license by encouraging family discussions and promoting an informed donation decision. This program will enhance existing school-age driver curriculum with materials that will measurably increase family discussion on organ and tissue donations, raise positive consent rates, and increase youth awareness of organ donation needs.

Total Funding: \$464,163

Applicant: The Transplantation Society of Michigan and TransWeb

Project: Measuring the Effectiveness of a Multimedia Internet-Based Approach to Increasing Donor Registry Participation

This project aims to expand a previously existing transplant education Internet site by creating a new path focusing on the donor family's view of organ donation. The project's intent is to encourage participants to join the donor registry and will provide specially-designed electronic greeting cards to notify family members of the registrant's desire to donate.

Total Funding: \$895,699

SPEAKERS AT ORGAN DONATION EVENT

Tim Thompson, a 42 year old telecommunications expert for United Postal Service, lost his wife Harriet, aged 32, to a brain aneurysm three years ago. Because of the recent death of a close relative, Tim and his wife had discussed organ donation and he knew that she wanted to be a donor. Because he was overwhelmed trying to cope with the reality of his wife's sudden death and the impact it would have on their two children, Anne-Hamilton (aged 11) and David (aged 7), he doesn't think that he would have remembered that Harriet wanted to be an organ donor. Even if he had remembered, Tim thinks that he would have had an extremely difficult time bringing it up with hospital staff. When a nurse asked him about the possibility of donation, he remembers feeling "pure relief" at the idea that someone was there to help him carry out his wife's wishes. Harriet's organs went to seven different people, all of whom are doing well. Tim, who now serves on the Kentucky Organ Donation Affiliates' Board of Directors, is working with UPS to develop a workplace donation education initiative. His project has been selected as one of the first HHS Model Programs to Increase Organ Donation, and will receive almost \$140,000 of the \$5 million in grant funds that the Vice President is releasing today.

Oscar Robertson (the Big O) is generally considered the greatest all-around player in basketball history and international ambassador for the game 24 years after retirement. He has been an all-time all-star at every level- high school, college, the Olympics and the National Basketball Association, which recently named him one of the greatest players of all time. One of Mr. Robertson's proudest achievements was his 1997 donation of a kidney to his daughter, Tia, who had suffered a kidney failure as a result of lupus. He has since become active with the National Kidney Foundation, serving as an ambassador for organ donation and as Honorary Spokesperson for the 1998 U.S. Transplant Games, where Tia participated with fellow transplant athletes and won a gold medal in doubles tennis.

Jose Torres received his donated liver in July of 1997. A few months before that, he developed debilitating pains in his abdomen. He thought that it was food poisoning, and his wife Maria rushed him to the hospital – where he ended up staying for almost a month. Jose was diagnosed with a rare liver disease, and he and his family learned that without a transplant, he had less than a year to live. Those months were stressful ones for the family; Jose was forced to leave his job as a homicide detective and stay at home. Maria was forced to work extra hours and worried about the family's financial future; their six children all spent more time at home to try and help as much as they could instead of playing sports after school and taking up extracurricular activities. Jose calls his transplant a "gift from God" – he and his family now appreciate every day they have together. He speaks whenever he can about the importance of organ donation.

Sarah Lee Beck and her husband Mark donated their three year old daughter Anna's heart valves, corneas, liver, and kidneys after she died of a brain aneurysm in February 1998. Sarah said that the decision to donate Anna's organs was not a difficult one; although the day her daughter died was the worst one of her life, there was never any question about what they would do. She and her husband Mark have both pledged to donate their organs, and she speaks with pride of the people Anna helped. Sarah is extremely thankful for the support and guidance her local transplant organization provided her when they made their decision. Sarah and Mark have two children, David (aged 6 months) and Lily (aged 3).

SCRIPT FOR VICE-PRESIDENTIAL EVENT ON ORGAN DONATION

TIM THOMPSON

- My wife Harriet donated her organs three years ago. You don't usually think much about organ donation when you're in your early 30s, but Harriet and I had actually discussed it before she died, because a cousin of ours died of cancer.
- When Harriet died suddenly, I was really glad I knew what her wishes were. She was a pediatric nurse who spent her whole life helping people, and it was just natural that she would want to help others even after she was gone.
- But even more important was the fact that the hospital staff asked me if I knew what Harriet's views on donation were. I was so overwhelmed by her death and the impact that would have on our two children, I wouldn't have thought to ask about it. When the nurse wanted to talk to me about donation, I was so relieved that there was someone to help me carry out her wishes.
- Now, I work to educate others about the importance of organ donation, and to help them talk about this difficult subject with their loved ones. Because Harriet helped me realize how important this issue is to millions of families across America, I represent organ donor families on the Board of Directors of Kentucky Organ Donor Affiliates. Mr. Vice President, I work every day to represent the interests of donor families. The millions of dollars that you are releasing to communities all over the country will help me and people just like me continue this very important work. Thank you for longstanding commitment to this issue.

OSCAR ROBINSON

- When my daughter Tia developed lupus three years ago, she went into kidney failure pretty quickly. We were terrified – she was only in her late twenties when she got sick, and you just don't anticipate having to deal with that kind of debilitating illness in a young woman. It was heartbreaking to see my daughter so sick and so frightened, and it was killing us not to be able to do anything about it. That's the worst with your kids – that they sometimes have problems that you can't fix.
- The doctors told us that in order to live a normal life, she would need a new kidney. My whole family got tested, but I was the only one who was a match. There was never any question about what I would do. This was my baby girl we were talking about – and there's nothing I wouldn't do for her. There was really no other choice for me.
- Thanks to the transplant (which has worked well for the past two years), I now have weeks, and months, and years more to spend with my daughter. And, Mr. Vice President, because of your efforts, there are thousands of families around the country who now have more time with their children and your loved ones, and I want to thank you for that.

SARAH BECK

- When our daughter Anna died, it was the worst day of my life. One second we were watching the Olympics; then we were watching her struggle for her life in a hospital bed. It was horrifying. There is no way to describe the impact of the death of a child.
- Once we realized there was nothing we could do for her, we never had any questions about whether we should donate Anna's organs. My husband and I have made that decision for ourselves, and it seemed like the right decision for her as well.
- Anna donated her kidneys, liver, heart valves, and corneas. Thanks to my little girl, six people have been able to see better and live longer lives. Every time my husband and I look at our two children – my daughter is three and my little boy is 6 months old – we think of Anna and remember her. And I know that there are six people out there, who – when their parents look at them – think of my little girl as well and thank her for the days and months and years that they have to spend with their children. And I'm so grateful for that.
- Mr. Vice President, I know that you are a father, and I learned recently that you became a grandfather. You can understand the pain of losing a child. And so – when I can – I work to help other families in danger of losing their children by talking about the importance of this issue to everyone I can.

JOSE TORRES

- When I first got sick, I didn't think too much of it – I thought that it was something I ate, and that it would go away. I ended up spending almost a month in the hospital. The doctors told me I needed a new liver – and that if I didn't get one, I would die within the next 12 months.
- They sent me home to rest and wait. Those were the hardest months of my life – to sit and wait while the time I had left to spend with my wife and my children was slipping away. Before I got sick, I was a homicide detective. I protected people. Now, I sat by and watched my wife grow thinner and lose sleep – she spent three days at my bedside without sleeping. I watched my kids grow quieter. I worried about who would take care of my family if something happened to me. I worried that my children were missing out on being kids because they were worried about me. You don't expect to worry about these things in your thirties. You don't expect to have six kids and then just leave them.
- When we got the call that a liver was available, it was one of the happiest days of our lives. I've had my new liver for 3 years and 2 months now, and we're doing just fine. Each day, I thank God for being able to play sports with my kids, spend time with my wife, and work at a job that I love.

- Mr. Vice President, without your efforts and the good work that goes on all around the country on this issue, I wouldn't be here today. It's not often that you get to speak in front of a crowd like this, and I want to take this opportunity to thank you for your leadership.

STATEMENT BY THE PRESIDENT

Today, I am pleased to sign into law H.R. 457, the "Organ Donor Leave Act," which would enhance the Federal Government's leadership role in encouraging organ donations by making it easier for Federal employees to become donors.

Currently, more than 65,000 Americans are awaiting an organ transplant. Last year, almost 5,000 Americans died while waiting for an organ to become available. This amounts to an average of 13 citizens each day. Many of these deaths could have been prevented if there were a sufficient supply of donor organs. H.R. 457 is a valuable tool to help address the needs of Americans waiting for organs by encouraging donations by Federal employees.

In 1997, my Administration launched the National Organ and Tissue Donation Initiative, which included new efforts by the Federal Government to increase awareness among Federal employees of the need for organ and tissue donation. The Department of Health and Human Services, in partnership with the Office of Personnel Management, has implemented a Government-wide campaign to encourage Federal employees to consider organ donation and, as the country's largest employer, to set the example for the private sector as well as other public organizations.

H.R. 457 builds on my Administration's long-standing commitment to increasing organ donations nationwide. Under current law, a Federal employee may use up to 7 days of paid leave each year, other than sick leave or annual leave, to serve as a ~~bone marrow or organ~~ donor. Recent surveys of doctors and hospitals indicate that the current 7-day limit, ~~while adequate for bone marrow donation~~, is clearly insufficient for recovery from organ donation surgery. This bill ~~quadruples~~^{increases} the amount of paid leave available to Federal employees who donate organs for transplants, providing up to 30 days of paid leave, in addition to annual and sick leave, for organ donation.

In addition to our current efforts, my Administration ~~has called for~~ an organ allocation system that will serve patients *will go forward in the coming weeks with the framework for*

better. Our approach, which has been validated by the Institute of Medicine, calls for improved allocation policies to be designed by transplant professionals, not by the Government, and would ensure better and fairer treatment for patients. We need an organ allocation system that is as good as our transplant technology, and it is time for sound allocation policies to go into effect.

It gives me great pleasure to sign H.R. 457 into law. I welcome the opportunity to help Federal employees participate in this life-saving effort.

THE WHITE HOUSE,

THE WHITE HOUSE

WASHINGTON

February 21, 1997

RECOMMENDED TELEPHONE CALL

TO: Watson Bell, Chairman of the Patient Affairs Committee of the United Network for Organ Sharing (UNOS), (501) 268-4111 at work or [REDACTED] at home.

DATE: During the week of February 24.

RECOMMENDED BY: Chris Jennings (and Carol Rasco)

PURPOSE: To assure Watson Bell that any decisions about the allocation of human livers will be based on medical and ethical considerations, not on politics.

BACKGROUND: Watson Bell, whose wife had a liver transplant, was concerned that the Administration was biased against his position on liver allocation. As Carol mentioned in a previous note to you, we assured him (during a meeting in December and subsequent to it) that this was not the case. While he greatly appreciated the assurance, he still requested a meeting with you because he knew you had talked with David Matter (and heard the Pittsburgh Transplant Center's side of the allocation issue). As you may recall, he had Jim Guy Tucker write a personal note to you in this regard.

As a follow-up to our last meeting, I spoke with Watson today. He said that he would still very much like to talk with you, but believes a phone call would be more than adequate. He is also very interested in working with you to highlight the need for organ donation during National Organ and Tissue Donation Awareness Week this April.

The latest news from the Department is that they do not expect to forward a final rule to OMB on the organ allocation issue until mid-March. Public hearings that were held on this subject in December raised a number of concerns about the system and the actual allocation of organs. For example, there were concerns raised about uninsured individuals being dropped from priority lists and recommendations made about an ethical need to rectify this situation.

In addition, we are pushing the Department to place at least as strong an emphasis on the importance of organ donation and on ways to increase the number of organs donated. In response, the Department is working to design a public awareness campaign to address this issue. I have encouraged them to have this campaign ready prior to, or at least concurrent with, the final OMB cleared rule on allocation issues (which will probably be sometime in April).

TOPICS OF DISCUSSION:

1. Our common goal is to serve transplant patients in the best way possible.
2. We need to increase organ donation across the nation. I have asked DHHS to develop and plan and emphasize its important role in this area.
3. Overall, I believe the public hearings did serve a constructive goal of airing concerns on all sides of this issue. My understanding is that a final rule on the allocation issue will be coming out sometime this spring. But, as you know, I have directed any decisions about allocation issues to be based on medical and ethical considerations, not on politics.
4. I can assure you that any suggested changes on current policy on allocation will be made thoughtfully and, to the extent possible, in collaboration with UNOS and all others in the transplant community.
5. Finally, I agree with you that we must get past this allocation issue and address the real problem -- the shortage of organs. I have asked the Department to make this a strong priority. I know you are interested in doing something in April around the National Organ and Tissue Awareness Week and I hope we can be helpful.

CONTACT PERSON AND
TELEPHONE NUMBER:

Chris Jennings, 456-5560

DATE OF SUBMISSION:

January 30, 1997

ACTION:

cc: Erskine Bowles

LIGHTLE, BEEBE, RANEY, BELL AND HUDGINS

ATTORNEYS AT LAW
211 WEST ARCH AVENUE
SEARCY, ARKANSAS 72143-5331
501-268-4111
501-268-5306 (FAX)

MIKE BEEBE
DONALD P. RANEY
A. WATSON BELL
ROBERT HUDGINS

J.E. LIGHTLE, Sr. (1932-45)
J.E. LIGHTLE, Jr. (1936-88)

JAMES A. SIMPSON, Jr.

FAX TRANSMITTAL

DATE: November 19, 1996 TIME: _____

RE: Confirmation of December 2, 1996, Meeting with Carol Rasco

TO: Ms. Carol Rasco - Attention Jill

FROM: A. Watson Bell

FAX NUMBER: (202) 456-2878

TOTAL NUMBER OF PAGES (INCLUDING COVER SHEET): 3

MESSAGE:



11/20

Chris:

Reminder that you will be staffing
this meeting with Carol on Mon, 12/2.
Carol will want paper on this - Mr.
Watson Notes The purpose of the
meeting. Paper is due 11/29 (or earlier
if you plan on being out this day!)

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MIKE BEEBE
DONALD P. RANEY
A. WATSON BELL
ROBERT HUDGINS

JAMES A. SIMPSON, Jr.

November 19, 1996

FAX TRANSMITTAL

Ms. Carol Rasco
Domestic Policy Advisory Council
The White House
1600 Pennsylvania Avenue, N. W.
Washington, D. C.

Attention: Jill Pizzuto

RE: Confirmation of December 2, 1996, Meeting With Carol Rasco

Jill:

This will confirm the meeting on December 2, 1996, at 3:30 p.m. at Carol's office with Carol, Chris Jennings, and the following individuals:

Mr. Walter K. Graham, Executive Director
United Network for Organ Sharing (UNOS)
DOB: P6/b(6) SSN: [REDACTED]

Arthur Watson Bell
Chairman, Patient Affairs Committee
United Network for Organ Sharing (UNOS)
DOB: P6/b(6) SSN: [REDACTED]

Jean Ann Bell
Liver Transplant Recipient
DOB: P6/b(6) SSN: [REDACTED]

501.268.4111
6pm

CLINTON LIBRARY
PHOTOCOPY

The purpose of this meeting will be to discuss proposed changes in the current national liver allocation policy and the administration's position thereon.

Thank you for your time and consideration in assisting me in scheduling this meeting. If you need

Ms. Carol Rasco

Page 2

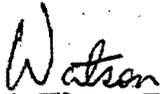
November 19, 1996

any additional information, please do not hesitate to get in touch.

My wife and I will be staying at the Willard Hotel on the evening of December 1, 1996, if you need to get in touch with us at that time.

Best personal regards.

Sincerely yours,


A. Watson Bell

AWB/fo

Withdrawal/Redaction Marker

Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
003. memo	Memo with attachment re: Liver Transplants (3 pages)	12/6/96	P6/b(6)

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For a complete list of items withdrawn from this folder, see the
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COLLECTION:

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

FOLDER TITLE:

Organ Donations

gf44

RESTRICTION CODES

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

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

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RR. Document will be reviewed upon request.

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

- b(1) National security classified information [(b)(1) of the FOIA]
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- b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
- b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
- b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
- b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
- b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

David M. Matter
501 UNDERCLIFF ROAD • PITTSBURGH, PENNSYLVANIA 15221

95 OCT 2 P3:12

September 30, 1996

*cc
Staff Secy
Can you get
answers asap
to these questions
RM*

President William J. Clinton
The White House
1600 Pennsylvania Avenue
Washington, D.C. 20500

Via Facsimile: 202.456.2983

Dear Mr. President:

As you know, I have always been very active and interested in issues that affect Pittsburgh and the State of Pennsylvania. The largest employer in Pittsburgh is the University of Pittsburgh and the related University of Pittsburgh Medical Center (UPMC). In my real estate and development business, UPMC has been a good client for a number of years. Although I have followed and supported the activities of UPMC for many years, I am not a lobbyist or paid consultant for it. Thus, I wish to bring to your attention an urgent matter that has been pending at the Department of Health and Human Services (DHHS) for over four years which affects UPMC, and more especially patients waiting for organ transplants at UPMC.

UPMC is one of the leading teaching and research hospitals in the country and is a world leader in the field of organ transplantation, especially liver transplantation. As a result of the passage of the National Organ Transplant Act in 1984, the control of donation, allocation and distribution of life-saving organs is placed in the Organ Procurement and Transplantation Network (OPTN) subject to supervision and review by DHHS. The OPTN is operated under contract with DHHS by the United Network for Organ Sharing (UNOS), a private entity. UNOS has 430 members, 276 of which are transplant centers, including UPMC. The other members of UNOS include organ procurement organizations, other medical organizations, 11 voluntary health organizations, and only 6 members of the general public. Decisions at UNOS are made on the "one-member, one-vote" rule. Thus, transplant centers (not the patients) control the decision making.

UNOS has adopted voluntary policies dealing with the operations of the OPTN (including how organs are allocated to waiting patients), but notwithstanding repeated Congressional criticism of foot dragging, DHHS has never adopted any binding regulations. DHHS began working on regulations in late 1989. In late 1990, UNOS, without DHHS's review or comment, eliminated the STAT priority for allocating livers to the sickest patients wherever located in favor of allocating most livers using the current geography-limited system. UPMC complained in writing to former DHHS Secretary Sullivan in March, 1991, to no avail. Shortly before you took office, DHHS was reportedly prepared to issue regulations adopting the then-existing system based on small geographic areas.

At the urging of Congress and others, your DHHS appointees began looking at the issues again in 1993. DHHS published proposed regulations in September, 1994, seeking comment from the transplant community. The preamble to those proposed regulations specifically asked for comment on the organ allocation policies of UNOS as in effect after the 1990 change and stated that "the present organ allocation policies ... raise difficult issues." UPMC and others submitted comments and proposed alternative allocation systems in December, 1994. Although DHHS stated in the preamble to the proposed regulation, "[t]he process is being initiated to allow the earliest possible adoption of final allocation policies ...", after two years DHHS has still not made any decisions on the issue. UPMC believes that DHHS must move quickly to change the current organ allocation policy because patients are dying while waiting for a liver transplant who would not otherwise die if the existing organ allocation system were changed.

The current liver allocation policy works as follows:

1. Patients are assigned to a Status depending upon their medical condition, as determined by the physician, with Status 1 being the sickest patients (in intensive care with a life expectancy of 7 days or less); Status 2 being patients who are continuously hospitalized. Status 3 are patients who are homebound, and Status 4 patients are the least sick.

2. Geographically, the United States is divided into 69 organ procurement organization (OPO) service areas which are aggregated into 11 UNOS regions.

3. Livers are allocated first to Status 1 through 4 patients in the OPO service area; if not accepted within the OPO service area, they are allocated to Status 1 through 4 patients in the UNOS region; and finally to Status 1 through 4 patients anywhere in the country outside the region.

The effect of the current policy is to allow a Status 3 or 4 (non-hospitalized) patient to receive a donated liver, instead of using that organ to transplant a Status 1 or 2 patient who, by definition, is near death, simply because the Status 3 or 4 patient is on the waiting list of a transplant center near where the liver is donated. After development of the University of Wisconsin solution almost 10 years ago, a donated liver can be preserved and shipped anywhere in the country by commercial airline (12 to 18 hours) and still be viable for transplantation.

Several viable alternatives to the current system have been proposed by UPMC and others. The proposal made by UPMC would allocate the livers first to a compatible Status 1 in the local OPO service area, then to a compatible Status 1 anywhere in the country; if there is no compatible Status 1 patient, the organ would be offered first to a compatible Status 2 patient in the OPO service area and then to a compatible Status 2 patient anywhere in the country, and so on for Status 3 and 4 patients. This proposal would allocate the livers to the sickest patients in the largest possible geographic area where the organ can be transported and remain in good condition to be transplanted.

Another proposal would allocate donated livers to compatible hospitalized patients (Status 1 and 2) first and then to compatible non-hospitalized patients ("In-Patient First system"). This proposal maintains the "local-region-national" geographic limits of the current system, but insures that patients who have the greatest risk of dying without a transplant, have the first opportunity to receive a compatible liver.

Consultants for UNOS and for UPMC have developed computer models for liver allocation and have published results from these models for various liver allocation proposals. All of those results have indicated that total deaths among liver transplant patients and recipients are less under the UPMC proposal than under the current system. The UNOS models have indicated that between 30 and 50 lives are saved each year under the UPMC proposal, while the modeling done by UPMC consultants indicates that in excess of 100 lives would be saved per year. The results for the In-Patient First proposal are very similar.

At the present time, there are significant disparities among waiting times for similar liver patients at different transplant centers around the country. The disparities are so great that some patients can wait 4 or 5 times longer for an available organ as similar patients in other parts of the country. The results from the UNOS model and from the UPMC model indicate that the disparity between the waiting times for similarly situated patients at different centers is reduced significantly under the UPMC allocation proposal, and under the In-Patient First system.

The current system has another consequence. The large disparity in waiting times for a liver transplant induces many patients to list at a small transplant center (35 or fewer transplants per year) in hopes of receiving a liver sooner. Approximately 65% of liver transplant centers are in this category. Unfortunately, a 1994 OPTN study showed that the risk of death for transplants at such small centers was 1.6 times greater than the risk of death at centers performing more than 35 liver transplants per year.

Personnel at DHHS are aware of these studies. Nevertheless, there appears to be a genuine reluctance to move forward with the formulation of an organ allocation policy. UNOS, as an organization made up mostly of small transplant centers, seems content to stay with the existing policy since it benefits a large number of the member centers. Although, the UNOS Board recently proposed for comment by its members some minor modifications to the current system, results from the UNOS and UPMC models suggest that such changes, which are now under final consideration by the UNOS Board, are not an improvement over the current system. However, the existing liver

allocation policy does not benefit patients waiting for liver transplants either. The results of all of the studies indicate that more patients die annually under the existing system than under the UPMC or In-Patient First alternatives, neither of which the UNOS Board is currently considering, and that there is greater disparity of waiting times among patients with similar medical conditions under the existing policy than under either of those proposed alternative allocation systems.

UPMC believes that DHHS should move forward immediately to develop and promulgate the actual organ allocation policy. If DHHS gives more weight to the interests of patients than transplant centers, the new liver allocation system will: (1) allow the patient to choose the transplant center; and, (2) direct the organs to the neediest patients wherever located. The current system is described in comments recently submitted by the University of Nebraska Medical Center at a UNOS forum:

“... the policy mandates that describe liver allocation are not patient-directed, but remain entitlement programs serving transplantation centers rather than patients in a direct and monitorable fashion.”

Does DHHS want to endorse this type of policy? DHHS must make the decision on liver allocation policy. UNOS has shown that it cannot, or will not. At present, everything is in limbo, with no reasonable prospects for change, and, by default, the existing system remains in place.

I recognize your tremendously busy schedule and the significant issues that you must face each day. I also know that you maintain a deep and abiding concern for the health and well-being of all of our citizens and are committed to the principles of fairness and a responsive and responsible government. I ask for your assistance in insuring that DHHS moves immediately to adopt regulations for the OPTN that will protect those patients facing imminent death while awaiting transplants and be fair and equitable to all patients.

I have taken the liberty of attaching to this letter a few questions, the answers to which will focus attention on the important

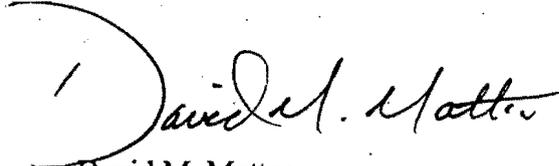
President William J. Clinton

September 30, 1996

Page 6

policy issues that need to be resolved. Thank you very much for your assistance, and I remain

Sincerely yours,

A handwritten signature in cursive script that reads "David M. Matter". The signature is written in dark ink and is positioned above the printed name.

David M. Matter

Questions

1. What projections or data has DHHS prepared or compiled which compare patient lives saved by Status, pre- and post-transplant, for the current liver allocation system, the UNOS Board proposed changes, the UPMC proposal and the In-Patient First proposal?
2. What projections or data has DHHS prepared or compiled which compare total patient life years saved by Status, pre-and post-transplant, for the current liver allocation system, the UNOS Board proposed changes, the UPMC proposal and the In-Patient First proposal?
3. What projections or data has DHHS prepared or compiled which compare disparities in waiting times by Status by UNOS region, pre- and post-transplant, for the current liver allocation system, the UNOS Board proposed changes, the UPMC proposal and the In-Patient First proposal?
4. If the In-Patient First proposal will save more patient lives, increase total patient life years, and equalize waiting times for patients in a similar medical status across the country when compared to the current system, are there demonstrated negative effects to patients of such proposal which outweigh the benefits?
5. If the UPMC proposal will save more patient lives, increase total patient life years, and equalize waiting times for patients in a similar medical status across the country when compared to the current system, are there demonstrated negative effects to patients of such proposal which outweigh the benefits?
6. DHHS has data which indicate significant differences in risk of mortality for liver patients, pre- and post-transplant, between centers performing more than 35 transplants per year and those performing fewer than 12 transplants. Are there demonstrated medical benefits to patients to encourage patients to choose to be transplanted at high risk centers?

→ Where we are:

7. Of those centers performing fewer than 35 liver transplants per year, how many are approved for participation in Medicare, Medicaid, VA or other federal government programs for reimbursement for liver transplants?
8. How many centers are performing fewer than 12 liver transplants per year, and are any of those centers approved for participation in Medicare, Medicaid, VA or other federal government programs for reimbursement for liver transplants?
9. Has DHHS established any criteria for determining when the mortality rate at a liver transplant center is unacceptable so that the center may not participate in government reimbursement programs or receive livers for transplant?

2 weeks ago
can you write

Partially claims in brief

UNOS

Allocation

Liz Dorset Flynn & Hobbs

John Tisdale is what represents Linda, courses

Met w/ David

690-7755

→ when are we

Phalena

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Lisa

Proven

→ next steps

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Press Guidance
December 19, 1996

Liver Transplantation

Background: There is a politically charged debate underway in the transplant community around the allocation of liver donations. There are moral and public health questions at stake as well as financial interests. Under the current system, livers are allocated by the Organ Procurement Transplantation Network using a grading system which favors recipients in high donor areas (basically, local recipients are given top priority for donated livers). This system has been criticized by many as unfair. In September of 1994, HHS published a proposed rule to provide for federal oversight of the processes by which OPTN allocates organs for transplantation. December 10-12, HHS will hold public hearings on the rule at NIH in Bethesda.

The Washington Post today implied that a letter on the issue written by one of the President's close friends, David Matter, may have influenced the Administration's decision to make a move on this issue.

- This process was begun in September of 1994. It is one of intense interest for many parties. Hundreds of people from across the country on all sides of this issue have asked to testify.
- The President appropriately referred the letter to HHS and they responded. Both letters have been made public.

Did the President influence the decision by HHS to hold hearings?

He forwarded the letter to HHS appropriately. Those letters are available to you. In addition, it is our understanding that hearings were one of the options already under serious consideration prior to HHS' receipt of the letter.

FYI -- As a courtesy, Chris Jennings and Carol Rasco met within the last week or two with the opponents of the views of Pittsburgh Medical Center.

Drafted: Amellody
Approved: CJennings, KWallman

Why is HHS holding these hearings?

These hearings are part of a process that began in 1994, when the Health Resources and Services Administration (HRSA) published a notice in the Federal Register stating its intention to develop federal regulations on organ transplantation and donation policy. During the public comment period that followed the publication of that notice, a number of serious concerns were raised in the specific area of liver allocation and donation policies. Secretary Shalala thought those concerns were serious enough to warrant public hearings to make sure that U.S. policies are serving transplant patients in the most effective, efficient, and equitable way possible.

Are these hearings being held because of a letter to the President from David Matter?

The Matter letter was just one piece of input among a great many pieces of input that HHS has received on these issues. The fact that more than 100 people from across the country on all sides of these issues have asked to testify at these hearings proves that the hearings are of interest to more than any one person or organization.

Who is David Matter and what did he say in his letter to the President?

David Matter [is a former college classmate of the President] * who is now a developer in the Pittsburgh area. The letter, which has been publicly released, merely restates concerns that have been voiced publicly by a number of people in the transplant community.

Is this process an attempt to derail or override recent policy changes made by UNOS?

No, the HHS regulatory process that resulted in these hearings began in 1994, long before UNOS made its policy changes in November 1996. The HHS process and the UNOS policy changes have been moving along two separate tracks.

What happens if the HHS Secretary decides to issue a regulation that runs contrary to UNOS policies?

Our common goal is to serve transplant patients in the best way possible. We will seek to work with UNOS and all others in the transplant community toward achieving this goal.

* According to
Business Week



SHIMABUKUR_L @ A1
02/03/97 12:25:00 PM

Record Type: Record

To: Sandra L. Bublick Max

cc:

Subject: REPORT: SOME TRANSPLANT CENTERS REFUSE ORGANS FOR ...

Date: 02/03/97 Time: 12:00

OReport: Some transplant centers refuse organs for nonmedical

CLEVELAND (AP) Patients awaiting new organs should be told how often transplant centers turn away potential donor organs for nonmedical reasons, such as the unavailability of surgeons, medical ethics leaders say.

Twenty-eight of the nation's 167 heart-transplant centers refused donor hearts for nonmedical reasons 20 percent of the time or more during a seven-month period in 1994, The Plain Dealer reported today. The period is the only one in which complete data are available.

Of those hearts rejected for nonmedical reasons, 97 percent eventually were transplanted by other hospitals, the newspaper said in the second part of a series on the organ transplant industry.

Patients should be given such information while they are deciding where to have a transplant, not after they are hospitalized, said Jeffrey M. Prottas, an ethics committee member of the government's organ allocation contractor, United Network for Organ Sharing.

"Whenever I have my say on this issue, I say that UNOS ought to be publishing all of this," said Prottas, who teaches health politics at Brandeis University in Waltham, Mass. "It's really unfair. Everybody should know these sorts of things."

"I'm surprised that the numbers are that high," said Thomas H. Murray, director of the Center of Biomedical Ethics at Case Western Reserve University and one of several ethicists and doctors who said they were unaware of the practice. "You'd like to know what the circumstances were ... but if they can't give good reasons, it's troubling."

Every transplant center turns down some donor organs for nonmedical reasons, said Dr. John R. Wilson of Vanderbilt University.

"There is no program in this country that can guarantee that every organ that's acceptable is taken," Wilson said.

Judith B. Braslow, who heads the U.S. Department of Health and Human Services' Division of Organ Transplantation, said the number of hospitals that regularly refuse donor organs for nonmedical reasons is small.

"We do 19,000 to 20,000 transplants a year. We're talking about very small numbers," she said.

But when it comes to withholding such data from patients, "That's not to say patients should have been treated this way," she said.

The Plain Dealer said a high rate of rejecting organs for nonmedical reasons sometimes reflects the size of a hospital's program and the resources and staff available for transplants.

The number of people nationwide awaiting an organ transplant has tripled to more than 50,000 since 1988, with more than 3,700 waiting for heart transplants. During 1994, a total of 2,361 received heart transplants and 770 people died waiting, the newspaper said.

APNP-02-03-97 1206EST

THE WHITE HOUSE
WASHINGTON

MEMORANDUM

December 6, 1996

TO: Kevin Thurm

FROM: Chris Jennings

RE: Liver Transplants



Enclosed please find a note from Mr. Walter K. Graham, executive director of the United Network for Organ Sharing, sharing his perspective on developments surrounding the liver donation issue. In a conversation I had with Mr. Graham this morning, he indicated he would appreciate my sharing his letter with you.

It is unclear to me whether this letter needs a response. However, it might be nice to acknowledge the letter without revisiting the issue.

I appreciate your assistance in this matter. I will talk with you soon. Thanks.

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET

Route Slip

=====

TO: Sally Katzen
Nancy-Ann Min
Chris Jennings

cc: Don Arbuckle
John Morrall
Barry Clendenin
Richard Turman
Greg White
Randy Lutter
Virginia Huth

<input type="checkbox"/>	Take Necessary Action
<input type="checkbox"/>	Approval or Signature
<input type="checkbox"/>	Comment
<input type="checkbox"/>	Prepare Reply
<input type="checkbox"/>	Discuss with me
<input checked="" type="checkbox"/>	For Your Information
<input type="checkbox"/>	See Remarks Below

FROM: Allison Herron Eydt *ANE*

Date: 12/12/96

=====

I have attached the following preliminary materials from the Health Resources and Services Administration (HRSA)/ HHS three day hearing on liver allocation and donation policies. More will be forthcoming when the testimony transcripts are available:

- Washington Post articles discussing the context for HRSA's public hearing and some of the early proceedings;
- Federal panel members and agenda for the HRSA hearings on 12/10 - 12/12;
- Summary materials describing the UNOS computer model (ULAM) and the University of Pittsburgh's model developed by CONSAD;
- Letter to Secretary Shalala dated December 10, 1996 from various Senate members expressing concern regarding the Federal oversight role over UNOS' allocation policy.

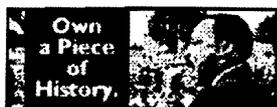
With few exceptions, the substance of public hearing testimony fell along the lines of the following distinct interest groups: 1) several established transplant centers (University of Pittsburgh, Baylor University, Mount Sinai Medical Center, and University of California at San Francisco); 2) medium to small transplant centers

(e.g. The University of Chicago, Mayo Clinic, The University of Texas at Houston, etc.); and 3) the Organ Procurement Organizations (OPOs). National organizations and patients, recipients, and families varied in their positions.

The University of Pittsburgh and other large centers argued for a national allocation policy and were opposed to the stricter definition of Status 1 sick patients excluding patients with chronic conditions. These groups argued that a national wait list system with a broader Status 1 definition would lead to fewer patient deaths over time, and would enhance patient choice, equity, and the credibility of the Federal transplantation system.

The smaller transplant centers, including Vanderbilt University, argued for preservation of the existing local, regional, and national hierarchy and UNOS' recent incremental expansion of local sharing parameters for Status 1 patients. They argued that complete elimination of local primacy in organ sharing would result in reduced incentives for and performance in organ donation. They also argued that local primacy was necessary to ensure access to transplantation services for minority, indigent, and vulnerable populations. In addition, they made arguments to discredit the University of Pittsburgh's CONSAD model. Finally, Vanderbilt University vehemently urged Federal restraint in UNOS oversight, consistent with their interpretation of congressional intent. Vanderbilt was concerned that organ donation policy has become more political since the Federal government has exerted more oversight over UNOS. Vanderbilt believed that the public hearing was politically motivated.

The Organ Procurement Organization arguments were similar to the smaller transplant centers, with a particular focus on policies that would improve donation rates and a call for national leadership in this area. In addition, the OPOs generally endorsed the use of performance measures in evaluating transplant centers.

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Who Should Get Liver Transplants?

As Demand Far Outpaces Donors, Federal Officials May Revamp Rules

By Rick Weiss

Washington Post Staff Writer

Monday, December 9 1996; Page A01

The Washington Post

An unusually politicized and rancorous debate has broken out over the nation's system for deciding which critically ill patients should have access to potentially life-saving liver transplants.

At the heart of the dispute is a fundamental disparity in which only 4,300 livers a year are available for the approximately 7,000 liver failure patients -- and a 1990 rule that makes the organs available preferentially to people who live near the hospitals where they are retrieved.

The high-stakes battle is pitting large, established transplant centers against fledgling ones, major metropolitan areas against rural regions and, inevitably -- because of the huge shortage of donor organs -- extremely ill patients against others who are only marginally less ill. The conflict could result in the biggest revamping of organ transplant policy since Congress last addressed the emotional issue in 1984.

Now, the Department of Health and Human Services will step in to decide the issue, with three days of public hearings that begin Tuesday in Bethesda. HHS Secretary Donna E. Shalala ordered the hearings after a friend of President Clinton's voiced

concerns about the current system of organ allocation. On the basis of the hearings, Shalala plans to propose the first federal mandate on how livers should be allocated.

That promise alone has angered many patients, surgeons and transplant center officials, who see the action as an unprecedented federal takeover of transplant policy that for 10 years has been handled by the Richmond-based United Network for Organ Sharing, a congressionally designated nonprofit agency that coordinates organ donation and allocation nationwide.

But the particulars of the changes that Shalala may impose are equally contentious, with different factions offering dueling computer projections of how many patients will die unnecessarily if the system is either changed or left as it is.

Leading the charge for change is the University of Pittsburgh Medical Center, a pioneering transplant hospital that has lost business steadily since the 1990 UNOS rule fostered the growth of competing transplant centers around the country. Pittsburgh and others complain that the current system of organ allocation allows moderately ill patients to get local livers while patients who are more desperate elsewhere must wait, and often die, on waiting lists.

"We've spent six years looking at a system that we predicted in 1990 would increase inequities, and that's what's happened," said John Fung, chief of transplantation at Pittsburgh.

But others warn that governmental intrusion could easily destabilize the nation's fragile network of donors and recipients.

"There is plenty of good reason to be concerned about a major perturbation in a system that is basically working very well," said James F. Burdick, a transplant surgeon at Johns Hopkins University and president of UNOS. "I sincerely hope that this unfortunate politicization can be defused."

Politics entered the debate in the person of David Matter,

president of a Pittsburgh real estate company and an undergraduate classmate of Clinton's at Georgetown University. Matter has maintained a friendship with Clinton for more than 30 years and has contributed to the Democratic National Committee and to Clinton's campaign.

"Patients are dying while waiting for a liver transplant who would not otherwise die if the existing organ allocation system were changed," Matter wrote in a Sept. 30 letter to Clinton.

Matter told Clinton that the president of the University of Pittsburgh Medical Center, Jeffrey Romoff, had asked for his help in advocating a change to the liver policy. Matter became convinced that change was indeed needed, he said, after looking at data supplied by the university, with whom he has real estate and property management dealings.

For years, Matter explained, Pittsburgh and other institutions had petitioned HHS, which oversees UNOS, to change the local-first rule. HHS was aware of the controversy, Matter wrote, but had shown "a genuine reluctance" to get involved.

Clinton apparently was not so reluctant. He spoke to Shalala, who in November wrote Matter that the department would hold hearings to look into the situation.

"I've never seen the government move so quickly," said Timothy Shaver, director of abdominal transplantation at Fairfax Hospital and a UNOS board member. "All of a sudden HHS has decided that maybe they can make a better decision. But these are the kinds of decisions best made by the transplant community."

Pittsburgh and other opponents of the current system say that because livers, unlike some other organs, can survive for 18 hours or more -- long enough to be shipped anywhere in the country -- they ought to be offered nationwide to the most severely ill patients. Now, they say, waiting times for livers are grossly unequal because of the differing number of organs donated in different regions, and the varying densities of

transplant centers around the country.

In Kansas, for example, where donors are plentiful and transplant centers and needy patients are few, the average waiting time for a liver is 12 days, compared with about 18 months in Massachusetts.

Moreover, wealthier patients can take advantage of that inequity. People who can afford a flight to Kansas, for example, can get evaluated there and be placed on that region's list, boosting their odds of getting a liver before they die.

Centers such as Pittsburgh have suffered under the local-first plan as the number of transplant centers around the country has increased from 70 in 1988 to 119 today. While the number of liver transplants has risen steadily in the past decade, Pittsburgh's count has fallen from a peak of 571 in 1990 to 266 in 1995. At hundreds of thousands of dollars per case, that's a big drop in income.

"We used to export 40 to 50 livers a year outside the area, mostly to Pittsburgh," said Lori Brigham, executive director of the Washington Regional Transplant Consortium, which coordinates organ retrieval in the Washington metropolitan area. But with Howard University and Fairfax Hospital now doing liver transplants, she said, "it is very rare for me to send a liver out of this city. That's happening all over the United States. So many centers are getting very nervous about their source of organs as additional centers open up."

University of Pittsburgh officials say it is patient care, not money, that is at stake. In addition to the problem of wait-list disparities, they said, death rates from liver transplants are about 2.5 times higher in centers that do fewer than 12 transplants a year than in the busiest centers, such as Pittsburgh.

They also note that the local-first system is already breaking down as large insurance companies and health maintenance organizations increasingly cut deals with one or a few medical centers to do all their transplant work. Patients in the

Washington area covered by Kaiser Permanente, for example, must go to Birmingham if they need a liver transplant. For people in Alabama, that means the number of patients in need is increasing while the number of available organs remains flat, unless wider organ sharing is allowed.

But experts who oppose dismantling the local-first system are just as vehement in their arguments.

"The data that supports higher mortality in small centers is very weak," said Johns Hopkins surgeon Andrew Klein, who chairs the UNOS liver and intestine allocation committee. Klein said most centers have very similar survival rates, and some of the smallest centers have the best.

"If there is local expertise and good results locally then you have to ask why we should export these things," Klein said. "These livers start flying across the country at enormous expense."

Of even greater concern is that people may be less willing to donate organs if the organs are not going to be used locally. No study has proven such a link, but many experts believe it is real, as shown by the increase in donations typically seen in cities when a transplant center opens.

"A national list does not foster local donor activity," said Clive Callender, director of the Howard University transplant center. "Anything that's going to negatively impact on donation, I'm opposed to."

Perhaps the most serious drawback to nationwide liver sharing, however, is the lack of consistency in how doctors in various parts of the country classify how desperate their patients are, Klein said. Until there are clear-cut rules for determining which patients need organs most urgently, any nationwide system will preferentially benefit regions with the most liberal definitions of "critically ill."

UNOS earlier this month started codifying those rules to begin moving gradually toward a system that would equitably allow

for wider sharing of livers. But that action was overshadowed by a more controversial decision by the UNOS board to place all chronically ill liver patients, no matter how close to death, into a priority tier below acutely ill patients whose livers had suddenly failed as a result of infection, toxic reaction or transplant failure.

UNOS justified that decision with computer models showing that the change would make 200 more livers available to patients over the next three years, in part because transplants into acutely ill patients are among the most successful and tend not to consume multiple livers from repeated attempts. The change affected only about 4 percent of recipients, but it angered some who claimed the model was faulty and that the plan would leave scores of chronically ill patients unfairly dying on the waiting list.

It is ironic, said Burdick, the UNOS president, that institutions such as Pittsburgh criticized that change, since it represented UNOS's first effort to create strict definitions for at least one stage of disease severity. Over time, the same clarity will be imposed for lower tiers, he said, and it would be wrong to initiate widespread sharing until that is complete.

"I think we need to walk before we run here, and not think later, 'Gee, I wish we did this with a little more forethought,'" said Klein of Johns Hopkins. "The important thing is to engender trust and collegiality, and to reinforce the faith of the public, upon whom the entire system relies."

Others said such conflicts are bound to persist as long as the number of dying patients exceeds the number of organs available, and expressed hope that Shalala will focus on that part of the equation.

"The thing that really needs to be addressed is what we're going to do to increase organ donation in this country," said Antonio Benedi, president of Transplant Recipients International Organization, an advocacy group in Fairfax.

U.S. organ donations have remained essentially flat during the past decade, while the number of patients waiting for organs increased from 15,000 in 1988 to 49,000 last year. The problem is especially acute for livers because there are no medical alternatives to keep a patient in liver failure alive.

"There will never be a fair and equitable system," Benedi said, "when there is such a short supply of organs."

WAITING FOR A TRANSPLANT

The number of people waiting for livers is increasing much faster than the number of people donating them.

Advocates of a new policy for allocating livers complain that the wait for a transplant depends too much on where a patient lives.

Median wait for a liver transplant, in days*

Kansas 12

Iowa 28

Alabama 33

Wisconsin 36

Kentucky 40

Georgia 41

Connecticut 42

Virginia 50

Colorado 55

Washington 55

Tennessee 57

Florida 62

Louisiana 67

South

Carolina 69

New Jersey 78

Oklahoma 95

Missouri 109

Utah 114

D.C. 115

Minnesota 132

California 136

North

Carolina 143

U.S.

average 146

Ohio 148

Nebraska 162

Oregon 164

Hawaii 173

Texas 183

Indiana 226

Pennsylvania 237

Michigan 269

New York 296

Illinois 349

Maryland 351

Massachusetts 569

* As of 1995. States without transplant programs are not listed.

SOURCE: United Network for Organ Sharing

@CAPTION: Transplant recipient Antonio Benedi, playing basketball with son Tony, says increasing organ donations is paramount.

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Department of Health and Human Services
Public Hearings on Liver Allocation and Organ Donation

December 10-12, 1996
Natcher Center, National Institutes of Health
Bethesda, Maryland

Chair

Philip R. Lee, MD
Assistant Secretary for Health
Department of Health and Human Services

Panelists

Ciro V. Sumaya, MD, MPHTM
Administrator
Health Resources and Services Administration

Bruce C. Vladeck, Jr. (morning first day)
Administrator Kathy Bulo (Day 2 and 3)
Health Care Financing Administration

Phillip Gordon, MD
Director
National Institute of Diabetes and Digestive and Kidney Disease

Consultants to the Panel Chair

Ann Mongoven, PhD
Department of Religious Studies
Indiana University

Nancy N. Dubler, LLB
Director, Division of Bioethics
Montefiore Medical Center

Daniel Wikler, PhD
Program in Medical Ethics
University of Wisconsin

December 10, 1996

Department of Health and Human Services
PUBLIC HEARING
LIVER ALLOCATION AND ORGAN DONATION

-- AGENDA --

Tuesday, December 10, 1996
Natcher Center, National Institutes of Health
Bethesda, Maryland

- 8:00 Registration Open
- 9:00 - 9:15 Introduction of Panelists and Consultants to Panel Chair
Philip R. Lee, MD
Assistant Secretary for Health
Hearing Chairman
- 9:15 - 9:45 Overview of OPTN and Policy Formulation
James F. Burdick, MD
President, United Network for Organ Sharing
- 9:45 - 10:45 Group #1 - Transplant Professionals/Centers
1. Charles Miller, MD (*Mount Sinai Medical Center, NY*)
 2. Anthony D'Alessandro, MD (*University of Wisconsin-Madison*)
 3. Lewis Teperman, MD (*New York University Medical Center*)
 4. John Fung, MD (*University of Pittsburgh Medical Center*)
 5. Mitchell Shiffman, MD (*Medical College of Virginia, Richmond, VA*)
- 10:45 - 11:00 Break
- 11:00 - 12:00 Group #2 - National Organizations
1. Hans Sollinger, MD (*American Society of Transplant Surgeons*)
 2. Frances Hoffman, RN (*North American Transplant Coordinators Org.*)
 3. Thelma King Thiel (*Hepatitis Foundation International*)
 4. Alan P. Brownstein (*American Liver Foundation, Cedar Grove, NJ*)
 5. Howard Nathan, (*Coalition on Donation*)
 6. Leslie Miller, MD (*American Society of Transplant Physicians*)
- 12:00 - 1:00 Group #3 - Transplant Patients and Related Organizations
1. Robert W. Beidler (*West Chester, PA*)
 2. Charles Fiske (*The Family Inn, Brookline, MA*)
 3. Karen Kamisar (*Issaquah, WA*)
 4. Sylvia Aiken (*Walterboro, SC*)
 5. Antonio Bendi (*Transplant Recipients International Organization, Inc.*)
 6. Carolyn Dutton (*General public-New York*)

- 1:00 - 2:00 Lunch (On Your Own)
- 2:00 - 3:00 Group #4 - Transplant Professionals/Centers
1. Richard Howard, MD (*University of Florida, Gainesville*)
 2. Richard J. Rohrer, MD (*New England Medical Center, Boston*)
 3. Goran B. Klintmalm, MD (*Baylor University Medical Center, Dallas*)
 4. Douglas Hanto, MD (*University of Cincinnati Medical Center*)
 5. J. Steve Bynon, MD (*The University of Alabama at Birmingham*)
- 3:00 - 3:10 Break
- 3:10 - 4:10 Group #5 - Social Scientists/Public Interest Groups
1. Roger Evans, PhD (*Economist, Mayo Clinic, Rochester, MN*)
 2. Mark A. Joensen, PhD (*CONRAD Research Corporation, Pittsburgh*)
 3. Emanuel D. Thorne, PhD (*Economist, Brooklyn College, NY*)
 4. Craig Irwin (*National Transplant Action Committee, Brookline, MA*)
 5. Brenda Gleason (*Policy Analyst, Silver Spring, MD*)
- 4:10 - 5:00 Group #6 - Patients/General Public
1. Robert Peelle (*Oak Ridge, TN*)
 2. Julie Damon (*Brentwood, TN*)
 3. Craig Staples (*Scranton, PA*)
 4. Marian Moyer (*Bellevue, OH*)
 5. Phil Boxwell (*Pittsburgh, PA*)
- 5:00 Adjourn

Wednesday, December 11, 1996
Natcher Center, National Institutes of Health
Bethesda, Maryland

- 8:00 Registration Open
- 9:00 - 10:00 Group #7 - Organ Procurement Organizations
1. Mary Ann Lunde (*Transplant Foundation of So. Florida*)
 2. J.C. Rosenberg, MD (*Transplantation Society of Michigan*)
 3. Louise Jacobbi (*Louisiana Organ Procurement Agency*)
 4. Brian Broznick (*Center for Organ Recovery & Education, Pittsburgh*)
 5. Richard Luskin (*New England Organ Bank, Newton, MA*)
- 10:00 - 11:00 Group #8 - Transplant Professionals/Centers
1. Todd Howard, MD (*Barnes-Jewish Hospital, St. Louis*)
 2. Jeffrey C. Reese, MD (*Fletcher Allen Health Care, Burlington, VT*)
 3. R. Patrick Wood, MD (*The University of Texas at Houston*)
 4. Alan Langnas, MD (*University of Nebraska Medical Center, Omaha*)
 5. Prabhakar Baliga, MD (*Medical University of South Carolina, Charleston*)
- 11:00 - 11:10 Break
- 11:10 - 12:10 Group #9 - National Organizations
1. Jarold Anderson (*Association of Organ Procurement Organizations*)
 2. Hector Ramos, MD (*LifeLink Transplantation Institute, Tampa*)
 3. Bruce Bowden (*National Kidney Foundation*)
 4. Stanley Finger, PhD (*American Autoimmunity Related Disease Assoc.*)
 5. Michael Reed (*National Transplant Society*)
- 12:10 - 1:00 Lunch (On Your Own)
- 1:00 - 2:00 Group #10 - Patients/General Public and Related Organizations
1. Carl Lewis (*Santa Monica, CA*)
 2. Wendy Marx (*San Francisco, CA*)
 3. Jeffrey Marx (*Washington, DC*)
 4. A. Watson Bell (*Searcy, AR*)
 5. Donna Heil (*Pittsburgh, PA*) (by telephone)
- 2:00 - 3:00 Group #11 - Transplant Professionals/Centers
1. J. Michael Millis, MD (*The University of Chicago*)X
 2. Robert Fisher, MD (*Medical College of Virginia, Richmond*)
 3. Ruud Krom, MD (*Mayo Clinic, Rochester, MN*)X
 4. John Roberts, MD (*University of California at San Francisco*)
 5. Baburao Koneru, MD (*University of Medicine & Dentistry of NJ*)
 6. Jameson Forster, MD (*University of Kansas*)

3:00 - 3:10

Break

3:10 - 4:00

Group #12 - National Organizations/Organ Procurement Organizations (OPOs)

1. Carol Beasley (*The Partnership for Organ Donation*)
2. Teresa Shafer (*LifeGift Organ Donation Center*)
3. William O. Ritchie, Jr., PhD (*Washington Hospital Center*)
4. Jim Springer (*Colorado Organ Recovery Systems, Inc.*)
5. Vicki Crosier (*National Donor Family Council*)

4:00 - 5:00

Group #13 - Transplant Professionals/Centers

1. Clive Callender, MD (*Howard University Medical School, DC*)
2. Marsha Morien (*University of Nebraska Medical Center, Omaha*)
3. J. Michael Henderson, MD (*Ohio Solid Organ Trans. Consortium*)
4. Oscar Bronsther, MD (*Strong Memorial Hospital, Rochester, NY*)
5. Robert Sade, MD (*Charleston Health Care Colloquium*)

5:00

Adjourn

Thursday, December 12, 1996
Natcher Center, National Institutes of Health
Bethesda, Maryland

- 8:00 Registration Open
- 9:00 - 10:00 Group #14 - Patients/Recipients
1. Dale Middleton (*Westminster, MD*)
 2. Jennifer Herrick (*South Amboy, NJ*)
 3. Miriam Wrenn (*Temple Hills, MD*)
 4. Todd Tomasic (*Pittsburgh, PA*)
 5. Joy Horne (*Tampa, FL*)
 6. Lisa Busher (*Westminster, MD*)
- 10:00 - 11:00 Group #15 - Transplant Professionals/Centers
1. Gregory Everson, MD/Igal Kam, MD (*University of Colorado Health Sciences Center*)
 2. Dinesh Ranjan, MD (*University of Kentucky Transplant Center*)
 3. C. Wright Pinson, MD (*Vanderbilt University, TN*)
 4. Geraldo Mendez-Picon, MD (*Virginia Transplant Center, Richmond*)
 5. Frederick Bentley, MD (*University of Louisville*)
- 11:00 - 11:10 Break
- 11:10 - 12:10 Group #16 - General Public/Patients and Families
1. Sandra Walker (*Germantown, MD*)
 2. Marilyn J. Leonard (*Englewood, CO*)
 3. Brian A. Trainor (*Ithaca, NY*)
 4. Corey Washington (*May Day Hepatitis Action Committee*)
 5. Jon Zeschin (*Denver, CO*)
- 12:10 - 1:00 Lunch (On Your Own)
- 1:00 - 2:00 Group #17 - Transplant Professionals/OPOs
1. Abraham Shaked, MD (*Delaware Valley Transplant Program*)
 2. Steven Rudich, MD (*University of California at Davis*)
 3. W. Ben Vernon, MD (*Porter Care Adventist Hospital, Denver*)
 4. Les Olson (*Miami OPO*)
 5. Bruce Lucas, MD (*Kentucky Organ Donor Affiliates*)

- 2:00 - 3:00 Group #18 - Patients/Families
1. Barbara J. Pfisterer (*Pittsburgh, PA*)
 2. Martha Patton (*Pittsburgh, PA*)
 3. Donald Critchfield (*Washington, DC*)
 4. Hans VanNes Hall, Jr. (*Lafayette, LA*)
 5. Doris Francis (*Lexington, KY*)
 6. Tom Korten (*Richmond, VA*)
- 3:00 - 3:10 Break
- 3:10 - 4:10 Group #19 - Patients/Recipients
1. Blaine Miller (*New Kensington, PA*)
 2. Jackie Miller (*New Kensington, PA*)
 3. Patricia Amer (*Long Beach, NY*)
 4. Nathaniel Semple (*Washington, DC*)
 5. Peggy Brown (*West Homestead, PA*)
- 4:10 - 5:00 Group #20 - Patients/Recipients and General Public
1. Deborah Anne Thomas (*Colwyn, PA*)
 2. Mary Ellen Lannon (*Rockville, MD*)
 3. Cleonard D. Gilmore, Jr. (*PA*)
 4. Kenneth Vargo (*Homestead, PA*)
 5. Rhoda L. Blicht (*Greater NY American Liver Foundation, Commack, NY*)
- 5:00 - 5:10 Closing Comments - OPTN Perspective
- 5:10 Adjourn

Brief Synopsis of UNOS Liver Allocation Modeling, 1994-1996

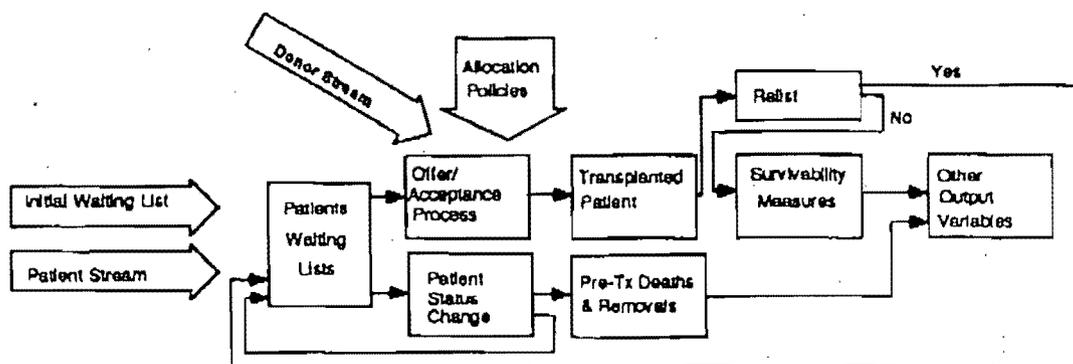
UNOS

Simulation modeling for policy comparison and evaluation.

In 1994, UNOS began compiling the data necessary to construct a computer simulation model for use in comparing alternative liver allocation policies. In November 1994, UNOS President Margaret Allen placed computer modeling at the top of her list of priorities for her 1994-1995 tenure. In December 1994, UNOS began to search for an outside expert in the field of computer simulation and modeling. In January 1995, UNOS contracted with the Pritsker Corporation to develop a computer simulation model for liver allocation to be used in evaluating alternative policy scenarios. An *ad hoc* Modeling Oversight Committee provided medical and scientific direction for development of the UNOS Liver Allocation Model (ULAM). The model specification was approved in March of 1995, and a phase I model was developed by June, 1995. The ULAM was demonstrated at the June 1995 Board of Directors meeting, and results for 8 initial policy alternatives were presented.

ULAM was designed to simulate the liver allocation process in the United States. Thus, it must include all the elements that are present in the existing system, such as donors, recipients, an offer/acceptance process, and so forth. The seven major components of the model are:

1. Initial Waiting List
2. Recipient Stream
3. Patient Medical Urgency Status Change Process
4. Donor Stream
5. Allocation Policy
6. Liver Offer/Acceptance Process
7. Post-transplant Relisting/Mortality



Schematic of UNOS Liver Allocation Model (ULAM)

Brief Synopsis of UNOS Liver Allocation Modeling, 1994-1996

UNOS

ULAM (Cont'd)

- The ULAM is *modular*, consisting of these components. Each component may be modified to accommodate new data or to reflect changes in the technology of transplantation. For example, new data may suggest that post-transplant mortality is a function of waiting time to transplant. Alternatively, a new immunosuppressive drug may emerge that promises a dramatic increase in post-transplant survival rates. In either case, model components may be modified to reflect estimated or hypothetical changes in the field of liver transplantation.
- ULAM uses either *historical data* or *generated data* for policy simulation. Historical donor and recipient data streams use actual OPTN data collected during 1992-1995. The generated donor and recipient data streams are modeled based on the patterns found in the historical data, and can be used to model the 1992-1995 time period or to forecast the effects of the policy over the 1996-1998 time period.

Brief Synopsis of UNOS Liver Allocation Modeling, 1994-1996

UNOS

Model Verification/Validation

The ULAM was validated extensively by comparing the output of each component model as well as the overall model output to actual results from the 1992-1995 time period. The component models were developed and validated using data from the same period. Particular effort was directed to the validation of the patient status change probabilities, which determine each patient's movement between medical urgency status codes or to death or removal. Estimates of these transition probabilities were obtained for the period 1992-1995. Three-year survival and relist rates were calculated using data from patients transplanted in 1991-1993; these components required analysis of this cohort due to the need for sufficient post-transplant follow-up. Using input data from 1992-1995, the model simulation should produce results that are similar to the actual results from the same period.

In general, the ULAM predictions are extremely close to the actual 1992-1995 results. For those output measures that are absolute values (e.g., number of transplants, number of removals), no measure was more than 12%; several measures were within 1% of the actual value. For those measures expressed as percentages (e.g., percent of transplants by status), no measures were more than 5% from the actual percentage. Due to the lag time in patient follow-up, it was not possible to validate post-transplant death or survival measures.

Validation of the model using historical donor and recipient streams was performed by comparing results from the model to actual data for the period from 1992-1995. Validation of the generated data is done prospectively. For example, donor procurement data from 1991-1994 were used to project 1995 donor arrivals, which were compared to 1995 actual data once it had been collected and verified. The projected number of 1995 donors was similar to the actual number of donors with only a 5.6% discrepancy between actual and predicted.

A comparison of the predicted versus actual numbers of registrations by transplant center revealed that the estimation technique used was a strong predictor of patient registrations at the center level. The very few deviations between actual and predicted patient registrations by transplant center were easily explained by key personnel changes at those centers, or, in one case, closure of a transplant center.

A complete description of the ULAM components and methodology can be found in Organ Transplantation Policy Evaluation (Pritsker, et al) in: *Proceedings of the 1995 Winter Simulation Conference*, ed. C. Alexopoulos, K. Kang, W.R. Lilegdon, and D. Goldsman, p. 1314-1323.

Brief Synopsis of UNOS Liver Allocation Modeling, 1994-1996

UNOS

POLICY EVALUATION***Policy Types Evaluated***

- Variants of the current distribution system; examples:
 - Redefinitions of local (i.e., state) or region (i.e., "Super-Region")
 - Single National List/Modified Single National List
 - Residence-based distribution
- Population-Grouped Distribution System: distribution unit based on size (percentage) of waiting list rather than geographic boundaries
 - Local = 5%, Regional = 20%
- Combinations of current/PGDS:
 - Local = OPO, Region = 20% circle

Over 30 policy proposals were formally evaluated by UNOS' Committees and Board during this process

- In general, the same sequence of allocation of liver within the distribution unit remained the same: Status 1s, Status 2s, Status 3/4s.
- 9 Policy types presented to the UNOS Liver and Intestinal Transplantation Committee in May, 1996, including: Current policy, UPMC proposal, several PGDS variations. Each policy was modeled with the current status codes and the proposed status codes (preference to acutes/primary non-function).

Final Policies Considered

- Liver Committee proposal (5-96)
- Allocation Advisory Committee proposal (6-96)
- UNOS Board Proposal (6-96)
- Final Board-approved Policy (approved by Liver Committee, 9-96, accepted by Board 11-96)

Brief Synopsis of UNOS Liver Allocation Modeling, 1994-1996

UNOS

ULAM MODELING OUTPUT

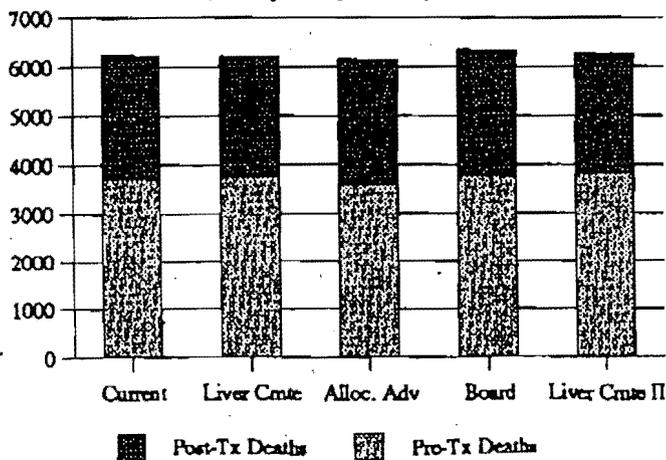
The "most pertinent data" is in the eye of the beholder: better survival, fewer retransplants, fewer pre- or post-transplant deaths, higher pre- or post-transplant life-years, less variation in regional waiting times, etc.

The ULAM produces a wide array of outcome measures for policy comparison: 10 pages of output are produced for each individual policy, and an 8-page spreadsheet is created for policy comparison. A sample of ULAM's policy comparison capability is shown below.

Measure	Current Policy	Liver Cmte (5-96)	Alloc. Adv. Cmte (6-96)	Board Proposal (6-96)	Final Board-Approved Policy (11-96)
Total Patients Transplanted	10992	11147	10998	11141	11194
Retransplants	1663	1509	1659	1516	1463
3-year Survival (%)	74.9	75.8	74.8	75.9	76.0
Distribution of Transplants					
Local	77.5	74.8	44.1	74.4	77.9
Regional	80.0	8.0	27.7	18.4	17.9
National	4.0	17.1	28.2	7.2	.2
Relists	2297	2211	2254	2213	2191
End Waiting List	11534	11500	11789	11463	11308

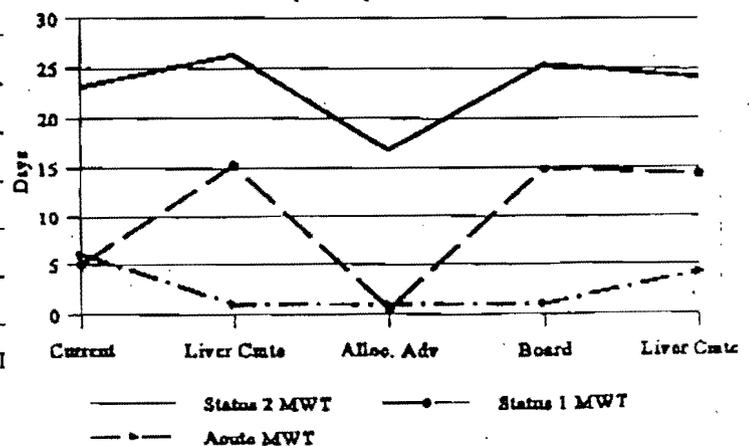
Pre- and Post-Transplant Deaths

ULAM Policy Comparisons, 1996-1996



Median Waiting Times to Liver Transplant

ULAM Policy Comparisons, 1996-1998



An Assessment of Liver Allocation Options:
Results from the CONSAD Liver Allocation Simulation Model

CONSAD Research Corporation
121 North Highland Avenue
Pittsburgh, Pennsylvania 15206

December 5, 1996

The attached table contains a summary of the results produced by the CONSAD liver allocation simulation model in six analyses. The analyses evaluate the consequences for patients from applying three alternative liver allocation policies within the context of two different specifications of health status categories.

In the table, the specifications are labeled "Original Health Status Categories" and "Revised Health Status Categories". The original categories correspond to the set of categories that UNOS currently uses in liver allocation, and the revised categories correspond to the set recently approved for use by the UNOS Board of Directors. In the two specifications, the categories are numbered from 1 to 3 or 4, in decreasing order of medical severity. In the original category specification, chronically ill patients with short life expectancies are included in health status 1; in the revised category specification, such patients are included in health status 2.

The alternative allocation policies are labeled "Current UNOS Policy", "Priority to Inpatient Proposal", and "Local-first National Proposal". The policies differ in the way that geographic restrictions affect the allocation of donor livers among patients in the specified health status categories. Allocation may be restricted to a **local** area consisting of the service area of the Organ Procurement Organization (OPO) in which the liver was donated, or to a **regional** area consisting of the UNOS Region containing that OPO. Otherwise, allocation is **national**. The order in which each alternative policy offers donor livers to transplant candidates is summarized below:

Current UNOS Policy		Priority to Inpatient Proposal		Local-first National Proposal	
Health Status	Area	Health Status	Area	Health Status	Area
1	Local	1	Local	1	Local
2	Local	2	Local	1	National
3,4	Local	1	Regional	2	Local
1	Regional	2	Regional	2	National
2	Regional	1	National	3,4	Local
3,4	Regional	2	National	3,4	National
1	National	3,4	Local		
2	National	3,4	Regional		
3,4	National	3,4	National		

In the Current UNOS Policy, geographic considerations outweigh health status in the allocation of donor livers among patients; whereas in the Local-first National Proposal, health status outweighs geography. In the Priority to Inpatient Proposal, health status outweighs geography in the allocation of livers to inpatients (patients in health status 1 or 2) rather than outpatients (patients in health status 3 or 4), but geographic considerations outweighs health status in the allocation of livers among inpatients.

The Simulation Model

To evaluate the differences among alternative liver allocation policies, CONSAD has developed a computer model that uses a Monte Carlo (probabilistic) simulation approach to estimate organ donations, patient registrations, waiting lists, and outcomes for any allocation policy. The patient outcomes of primary concern are deaths of transplant candidates while on the waiting list, deaths of patients after transplantation, years of life that patients experience, and the time patients wait between registration and transplantation. The model contains representations of the flows of donor livers to transplant centers, the flows of candidates to transplant centers, the progressive degradation of health status for patients as they wait for transplantation, the deaths of some candidates while waiting, the matching of donor livers with candidates on waiting lists, the transplantation of livers into patients, and the subsequent survival, relisting, or death of the patients who receive liver transplants.

The model operates with a daily time increment. On each simulated day, transition probabilities are consulted to determine the types of events (e.g., registrations, changes in health status, transplantations, and deaths) that occur that day. The model can be used to simulate any year, or group of years, for which data exist to describe registrants, candidates on waiting lists, and donor livers. All data used in the computer model have been obtained from UNOS sources.

Consequence Measures

For each of the six combinations of an alternative allocation policy and a specification of health status categories, the attached table contains estimates for eight measures that we believe are most important to patients. The first four measures relate to the medical efficacy of the option in achieving specific goals, and the last four relate to its equity or fairness to patients. The measures of medical efficacy are:

- (1) the percentage of donor livers allocated to patients in each health status category. This measure describes how well the option distributes livers in accord with the medical priorities established by the specified health status categories.

- (2) the percentages of donor livers that are allocated to patients at transplant centers in different proficiency classes. Statistical studies conducted by UNOS have consistently found that, in general, risk-adjusted post-transplant survival rates are significantly higher in centers that have large annual volumes of liver transplants than in centers that have small annual volumes.
- (3) the number of patients who die during the simulation. Separate estimates are provided for the number who die while waiting for transplants, the number who die after transplantation, and the sum of those values.
- (4) the number of years of life realized by patients in the aggregate. Separate estimates are reported for years experienced before transplantation, years experienced up to two years after transplantation, and the sum of those values.

The measures of equity or fairness include two that relate to a patients who obtain transplants and two that relate to candidates who die while waiting for transplantation. They are:

- (5) the average amounts of time patients wait, between the time they register as candidates and the time they obtain transplants, at centers that have different annual volumes of liver transplants.
- (6) the average amounts of time patients wait at centers in different UNOS regions.
- (7) the percentages of patients at centers that have different annual volumes of liver transplants who die while waiting for donor livers.
- (8) the percentages of patients at centers in different UNOS regions who die while waiting for transplantation.

For each of the last four measures, the equity or fairness of the option is indicated by the standard deviation of the set of values produced for the measure. Total equity or fairness would be realized if all values in the set were equal, and hence the standard deviation was zero. Larger standard deviations indicate lower degrees of equity.

Results

Comparing the results obtained for all three alternative liver allocation policies in combination with the original and the revised health status categories reveals that the recent revision of health status categories approved by the UNOS Board of Directors will have the following effects:

- Fewer livers will be allocated to chronically ill patients with short life expectancies, and more will be allocated to healthier inpatients.
- Pre-transplant deaths will increase, and post-transplant deaths will decrease by roughly the same amount. The net effect on the mortality of patients will be small.
- The total number of years that patients live will increase, primarily as a result of allocating more livers to healthier inpatients.
- Equity will stay the same or decrease slightly (as indicated by the comparative values of the standard deviations).

Thus, the aggregate effect of the recent revision of health status categories on medical efficacy will be small, and the effect on equity will be negligible or slightly adverse.

In marked contrast, comparing the results obtained for the three alternative policies in combination with either of the specifications of health status categories reveals that relaxing the geographic restrictions on the allocation of livers among patients yields:

- Greater achievement of the medical priorities established by the specification of health categories.
- Decreases in pre-transplant deaths that substantially exceed the corresponding increases in post-transplant deaths, resulting in sizable decreases in total mortality.
- Increases in the total number of years that patients live, consisting primarily of substantial increases in life-years before transplantation, with small changes in life-years after transplantation.
- Substantial improvements in all equity measures (as indicated by the uniformly large decreases in their standard deviations).
- Performance of more transplants by the centers in the most proficient class, and fewer transplants by centers in the less proficient classes.

In summary, the results clearly show that, using either the existing health status categories or the recently revised categories, broad geographic sharing of donor livers both saves and extends lives and improves fairness, when compared with the current liver allocation policy.

Summary of Estimated Consequences of Alternative Policies for Allocating Donor Livers Among Registrants on the Basis on the Original and Revised Health Status Categorizations for the Period from 1996 to 1998

Health Status Categorization		Original Health Status Categories			Revised Health Status Categories		
		Current UNOS Policy	Priority to Inpatient Proposal	Local-First National Proposal	Current UNOS Policy	Priority to Inpatient Proposal	Local-First National Proposal
Percent of All Transplants*	Health Status 1 (1)	0.7%	1.0%	2.3%	0.8%	1.3%	1.8%
	Health Status 2 (1)	22.5%	34.3%	65.6%	9.3%	13.2%	12.1%
	Health Status 2 (2)	42.9%	64.8%	32.0%	55.3%	85.5%	86.1%
	Health Status 3 (3)	31.7%	0.0%	0.0%	32.3%	0.0%	0.0%
	Health Status 3 (4)	2.3%	0.0%	0.0%	2.2%	0.0%	0.0%
Percent of All Transplants**	Small-volume Centers	24.4%	19.3%	17.9%	24.1%	19.3%	18.9%
	Medium-volume Centers	37.1%	31.8%	29.6%	37.1%	31.8%	30.0%
	Large-volume Centers	38.6%	48.9%	52.5%	38.8%	48.9%	51.0%
Deaths**	Pre-transplant	4,443	4,060	3,664	4,571	4,196	4,216
	Post-transplant	2,612	2,734	3,067	2,468	2,549	2,527
	Total	7,055	6,794	6,731	7,039	6,745	6,743
Patient Life-years**	Pre-transplant	16,032	17,861	18,556	17,093	17,312	18,683
	Post-transplant	35,742	35,520	35,134	36,107	36,270	36,465
	Total	51,774	53,381	53,690	53,200	53,582	55,148
Average Waiting Time Until Transplant***	Small-volume Centers	52.68	94.09	115.10	52.24	97.87	110.37
	Medium-volume Centers	61.59	95.54	115.42	62.70	99.64	114.13
	Large-volume Centers	128.71	119.00	115.61	140.88	124.60	126.04
	Overall	90.50	109.57	115.26	97.63	114.60	121.61
	Standard Deviation	41.56	13.98	0.26	48.44	14.95	8.18
Average Waiting Time Until Transplant***	UNOS Region 1	107.12	110.31	110.96	102.41	108.48	105.36
	UNOS Region 2	104.36	121.15	112.91	126.43	133.58	123.94
	UNOS Region 3	23.74	80.78	114.79	23.03	80.87	109.16
	UNOS Region 4	89.38	99.72	111.82	91.26	102.13	112.76
	UNOS Region 5	112.36	108.77	111.55	120.72	115.28	119.34
	UNOS Region 6	56.81	93.57	111.03	55.98	94.85	106.84
	UNOS Region 7	114.33	104.76	110.59	118.13	112.04	109.97
	UNOS Region 8	103.19	106.41	112.59	110.29	113.91	122.50
	UNOS Region 9	113.01	107.34	110.48	118.59	111.96	114.79
	UNOS Region 10	89.45	92.78	113.29	87.59	96.04	109.70
	UNOS Region 11	73.91	88.15	109.04	69.90	89.95	122.87
Standard Deviation	28.36	11.55	1.59	32.24	14.53	6.81	
Percent Dying Pre-Transplant***	Small-volume Centers	12.17%	13.92%	13.66%	12.30%	14.33%	14.62%
	Medium-volume Centers	12.48%	13.78%	13.29%	12.82%	13.79%	14.91%
	Large-volume Centers	19.66%	15.97%	13.35%	20.24%	16.63%	15.92%
Standard Deviation	4.24%	1.23%	0.20%	4.44%	1.51%	0.68%	
Percent Dying Pre-Transplant***	UNOS Region 1	15.71%	15.41%	14.45%	15.77%	16.68%	13.66%
	UNOS Region 2	20.51%	17.48%	13.26%	21.16%	18.34%	16.35%
	UNOS Region 3	4.67%	10.29%	14.01%	4.91%	9.73%	14.85%
	UNOS Region 4	16.67%	13.79%	13.36%	16.06%	14.87%	14.91%
	UNOS Region 5	16.84%	14.75%	13.71%	17.64%	15.81%	16.08%
	UNOS Region 6	10.34%	14.58%	13.89%	11.89%	14.29%	14.92%
	UNOS Region 7	18.06%	15.33%	12.95%	18.30%	15.70%	14.39%
	UNOS Region 8	19.76%	16.15%	13.48%	20.09%	15.91%	15.76%
	UNOS Region 9	16.04%	16.08%	13.00%	17.09%	15.33%	15.22%
	UNOS Region 10	14.52%	13.64%	13.14%	14.25%	13.62%	14.45%
	UNOS Region 11	10.92%	12.94%	12.65%	11.56%	13.08%	15.79%
Standard Deviation	4.64%	1.92%	0.53%	4.59%	2.23%	0.81%	

* 1996-1998, revised (original) health status categories.

** 1996-1998.

*** 1998.

United States Senate

WASHINGTON, DC 20510

December 10, 1996

The Honorable Donna Shalala
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington D.C. 20201

Dear Secretary Shalala,

While we applaud the Department of Health and Human Services' (HHS) decision to hold public hearings to assess the issues associated with liver allocation, we note with serious concern that you intend to then formulate and impose a national liver allocation policy.

Under P.L. 98-507, the National Organ Transplant Act (NOTA), Congress directed HHS to contract with a private non-profit entity to establish and coordinate national organ transplant policy. The Department has repeatedly awarded this contract to the United Network for Organ Sharing (UNOS), which consults with a broad cross-section of the transplant community and provides an impartial forum for consideration of important policies affecting patient prioritization and regional organ sharing.

This process allows for development of new policies and continual improvement of existing policies -- whether they are on procurement or allocation, on livers or any other organs. This process should be left intact. We strongly caution against usurping UNOS' traditional role.

In the past ten years, liver allocation policy has continually changed to accommodate new discoveries in medicine or to make the existing body of policies fairer. These changes could not have been implemented on such a timely basis if each proposed change had to endure the protracted administrative requirements inherent in amendment of federal regulations, which can exceed several years in each instance. This is a principal reason that Congress placed this responsibility in the private sector rather than in the Department.

These are complex and difficult issues, where honest differences must be expected. The best way to deal with them is through a democratic process that is fair, open, and representative -- as UNOS' process currently remains. Preemptive federal action would undermine UNOS and require similar action on other organs in short supply. We do not believe that HHS should proceed in such a direction.

Very respectfully yours,

Trent Lott
Trent Lott
Mike DeWine
Mike DeWine
James M. Jeffords
James Jeffords

Bill Frist
Bill Frist
Wendell Ford
Wendell Ford
John Warner
John Warner

Strom Thurmond
Strom Thurmond
John Glenn
John Glenn
Herb Kohl
Herb Kohl

James Inhofe
James Inhofe
Carl Levin
Carl Levin
Ernest Hollings
Ernest Hollings

Tom Campbell
Tom Campbell
Cass Ballenger
Cass Ballenger
Richard Burr
Richard Burr

J. C. Watts
J. C. Watts
Judd Gregg
Judd Gregg
Don Nickles
Don Nickles

John Braux
John Braux
Floyd Spence
Floyd Spence
Kay Bailey Hutchison
Kay Bailey Hutchison

Bob Livingston
Bob Livingston
Jim McCrery
Jim McCrery
Billy Tauzin
Billy Tauzin

cc: Phil Lee, MD, Assistant Secretary for Health
Judy Braslow, Division of Transplantation

