

Withdrawal/Redaction Sheet

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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. letter	letter to Chris Jennings from Walter K. Graham re: liver allocation policy (3 pages)	12/3/96	P6/b(6)

COLLECTION:

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

FOLDER TITLE:

Organ Donations [5]

gf45

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

Transplant Surgeons at Odds Over Liver Access Procedures

By Rick Weiss
Washington Post Staff Writer

A divisive debate about which patients should have access to liver transplants spilled into the open yesterday with surgeons accusing each other at a government hearing of misleading the public to further their center's interests.

The unusual airing of medical and political differences before a Health and Human Services panel focused on the United Network for Organ Sharing, a Richmond-based nonprofit agency that for the past decade has coordinated the collection and allocation of organs for transplantation. The organization, which answers to HHS, has recently come under fire from some transplant centers and patient groups who believe the network's patient priority system is unfair.

In a surprise conciliatory announcement at the hearing's opening, UNOS President James F. Burdick announced the organization would modify a controversial policy change it made earlier this month that would have removed scores of critically ill patients from the top of the liver waiting list.

Capitol Hill also got involved yesterday, as a bipartisan group of more than 25 members of the House and Senate signed a letter to HHS Secretary Donna E. Shalala, encouraging her to reconsider her plans to impose federal rules on liver allocation for the first time.

With no resolution in sight, however, several doctors and patient representatives expressed fear that the acrimony over the issue might undermine public confidence in the organ transplant system and cause a decline in donations. That would be tragic, all agreed, since a shortage of donor organs is at the heart of the problem; only about 4,000 livers are available each year for the more than 7,000 patients who need them.

"This is a matter of life and death," said Burdick, a Johns Hopkins University transplant surgeon. "It must not become a political football or a business strategy for market share."

The hearings, which will continue through Thursday at the National Institutes of Health in Bethesda, were called by Shalala after a friend of President Clinton voiced concern that the allocation system leaves some patients dying unnecessarily on waiting lists. That system offers organs preferentially to patients living in the same community where organs become available. Some centers would like to see a more open system in which organs are shared nationwide.

The current policy is "unconscionable," said Carolyn Dutton, of New York whose boyfriend died waiting for a liver in Pittsburgh while, she said, a relatively healthy patient in Alabama was called in from a golf course to get a liver that had become available there.

Others, however, said that the vast majority of patients most desperately in need do get a liver before it is too late.

Dismantling the UNOS network, "could encourage all transplant centers to act in their own self-interest instead of compromising for the national good," said Margaret Allen, a University of Washington heart transplant surgeon and past president of UNOS.

The best way to equalize and shorten waiting times, Allen and others said, is to increase the number of donations. Several

"This is a matter of life and death. It must not become a political football or a business strategy for market share."

— James F. Burdick,
head of United Network for Organ Sharing

states have significantly increased donation rates with modest educational efforts.

The four-person HHS panel, which includes officials from several government health agencies, will make recommendations to Shalala after the hearings and input from medical ethicists. Shalala has said she will formally propose the federal liver allocation policy within three months.

According to the letter signed by several influential members of Congress, HHS ought to focus on increasing donations and not "formulate and impose" organ allocation policies. The federal regulatory system is too cumbersome to deal with the quickly changing field of organ transplantation, the letter argued.

The letter, which was largely initiated by Sen. Mike DeWine (R-Ohio), whose daughter became an organ donor after she was killed in an auto accident three years ago, was signed by Senate Majority Leader Trent Lott (R-Miss.), Majority Whip Dan Nickles (R-Okla.), Sen. John Glenn (D-Ohio), Sen. Ernest F. Hollings (D-S.C.) and the House and Senate chairs of the health-related appropriations and authorization committees, among others.

In the policy change announced by UNOS, patients in the highest priority status for a transplant will not be downgrade when new, more strict criteria for that status are inaugurated in January. Rather they will be "grandfathered in," Burdick said.

The Washington Post

WEDNESDAY, DECEMBER 11, 1996

LIVER TRANSPLANTS

Q. Did you use undo influence to direct the Department of Health and Human Services to change liver allocation policy in this nation and micromanage the decisions made by the private/public body known as the United Network of Organ Sharing (UNOS)?

A. Of course not. I believe that decisions about the allocation of human livers should be based on medical and ethical considerations, and that politics should have absolutely no role in them. And that is exactly how this issue is being handled. The Department has been holding open and fair hearings to collect testimony on the controversial issue of liver allocation policy. This is part of a regulatory process that began in 1994.

As anyone who has been following these hearings knows, serious and legitimate concerns have been raised on all sides of this issue. I believe the airing of these issues has been constructive. But any changes on current policy will be made collaboratively with UNOS and all others in the transplant community. Our common goal is to serve transplant patients in the best way possible.

Q. Isn't true that you directed HHS to move quickly on changing current UNOS policy on liver transplant allocation after you received a letter from a politically-influential and long-time friend of yours (David Matter)?

A. Absolutely not. I received a letter from Mr. Matter and appropriately forwarded it over to the Department to review it. I did not direct HHS to take any action on this issue. I have been pleased to see that HHS held three days of public hearings on this issue last week and heard from over 100 patients and doctors, representing all sides of this complex and controversial issue. As I have said, decisions about this difficult issue should and will be made on the basis of medical and ethical considerations.

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 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 liver organs are allocated for transplantation. Last week, HHS held 3 days of public hearings on the rule at NIH in Bethesda, MD. Over 100 patients and doctors testified.

On December 11, 1996, The Washington Post 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. The President appropriately referred the letter to HHS and they responded. Both letters have been made public.

to Corp A programmers regarding program specifications. Corp H agrees to pay Corp A a fixed monthly sum during development of the program. If Corp H is dissatisfied with the development of the program it may cancel the contract at the end of any month. In the event of termination, Corp A will retain all payments, while any procedures, techniques or copyrightable interests will be the property of Corp H. All of the payments are labelled royalties. There is no provision in the agreement for any continuing relationship between Corp A and Corp H, such as the furnishing of updates of the program, after completion of the modification work.

(ii) *Analysis.* Taking into account all of the facts and circumstances, Corp A is treated as providing services to Corp H. Under paragraph (d) of this section, Corp A is treated as providing services to Corp H because Corp H bears all of the risks of loss associated with the development of modified Program X and is the owner of all copyright rights in modified Program X. Under paragraph (g)(1) of this section, the fact that the agreement is labelled a license is not controlling (nor is the fact that Corp A receives a sum labelled a royalty).

Example 16. (i) *Facts.* Corp A, a U.S. corporation, and Corp I, a Country Z corporation, agree that a development engineer employed by Corp A will travel to Country Z to provide know-how relating to certain techniques which are not generally known to computer programmers which will enable Corp I to more efficiently create computer programs. These techniques represent the product of experience gained by Corp A from working on many computer programming projects. Such information is not capable of being copyrighted, but it is subject to trade secret protection.

(ii) *Analysis.* This transaction contains the elements of know-how specified in paragraph (e) of this section. Therefore, this transaction will be classified as the provision of know-how.

(i) *Effective date.* This section applies to transactions occurring on or after the date that is sixty days after the date final regulations are published in the Federal Register.

Margaret Milner Richardson,

Commissioner of Internal Revenue.

[FR Doc. 96-29055 Filed 11-7-96; 3:11 pm]

BILLING CODE 4830-01-U

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 69

[AD-FRL-5645-2]

Proposed Conditional Special Exemption From Requirements of the Clean Air Act for the Territory of American Samoa, the Commonwealth of the Northern Mariana Islands, and the Territory of Guam

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: On September 13, 1995 (60 FR 47515), EPA proposed to grant the Territory of American Samoa (American Samoa) and the Commonwealth of the Northern Mariana Islands (CNMI) a conditional exemption from title V requirements and to grant the Territory of Guam (Guam) an extension of time in which to adopt a title V permit program. EPA proposed these conditional exemptions and this extension under the authority of section 325 of the Clean Air Act. EPA received comments during the public comment period requesting that EPA grant a permanent exemption to Guam. EPA also received a letter on December 18, 1995 from the Administrator of the Guam Environmental Protection Agency stating that Guam would develop an alternate local permitting program in exchange for a permanent exemption. In response to these comments and this commitment, EPA is proposing to conditionally exempt Guam, as well as American Samoa and CNMI, from title V of the Clean Air Act.

In a separate part of this Federal Register, EPA is promulgating this action as a direct final rule without a prior proposal because the public comments received to date support granting a permanent exemption. A detailed rationale and conditions for this approval are set forth in the direct final rule. If no adverse comments are received in response to this proposed rule, the direct final rule will take effect on January 13, 1997. If adverse comments are received during the comment period, EPA will publish timely notice in the Federal Register withdrawing the direct final rule for Guam, American Samoa and CNMI, and all public comments will be addressed in a subsequent final rule based on this proposal. The EPA will not institute an additional comment period on this action and any parties interested in commenting should do so at this time.

DATES: Comments on this proposed rule must be received in writing by December 13, 1996.

ADDRESSES: Written comments on this action should be addressed to: Norm Lovelace, Chief, Office of Pacific Islands and Native American Programs, US EPA-Region IX, 75 Hawthorne Street, San Francisco, California 94105. Supporting information used to develop the proposed conditional exemptions, including copies of the petitions, all comments received, and the response to comments document, are available for inspection during normal business hours at this location.

FOR FURTHER INFORMATION CONTACT: Norm Lovelace (telephone 415/744-1599, fax 415/744-1604), Chief, Office of Pacific Islands and Native American Programs or Sara Bartholomew (telephone 415/744-1250, fax 415/744-1076), Operating Permits Section, Air and Toxics Division, at the address above.

SUPPLEMENTARY INFORMATION: For additional information, please see the direct final rulemaking located in a separate part of this Federal Register.

Authority: 42 U.S.C. 7401-7671q.

List of Subjects in 40 CFR Part 69

Environmental protection, Administrative practice and procedure, Air pollution control, Hazardous air pollutants, Intergovernmental relations, Nitrogen oxides, Operating permits, Reporting and recordkeeping requirements, Sulfur dioxide, Volatile organic compounds.

Dated: October 28, 1996.

Carol M. Browner,
Administrator.

[FR Doc. 96-28431 Filed 11-12-96; 8:45 am]

BILLING CODE 6580-50-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

42 CFR Part 121

Organ Procurement and Transportation Network; Organ Allocation Policies

AGENCY: Health Resources and Services Administration, DHHS.

ACTION: Request for additional public comment on proposed rule; notice of public hearings.

SUMMARY: This document announces that the Secretary of Health and Human Services is formally inviting additional

public comment on the Notice of Proposed Rulemaking (NPRM) published on September 8, 1994, to establish rules governing the operation of the Organ Procurement and Transportation Network (OPTN). The Secretary is seeking additional comments on policies affecting the allocation of human livers for transplantation. In addition, this document announces that a public hearing will be held at which interested individuals may submit oral comments regarding such policies as well as regarding methods to increase organ donation.

DATES:

Hearing: The hearing will be held on December 10–11, 1996, beginning at 9 a.m. each day. Requests to testify must be submitted by December 2, 1996.

Comments: For those who choose to send written comments only, comments must be submitted by December 13, 1996 in order to ensure full consideration. Because the issue of organ donation is not part of the rulemaking process, we will accept comments and suggestions on this issue at any time.

ADDRESSES: Written requests to testify and written comments on allocation policies should be transmitted to: Ms. Judith Braslow, Director, HRSA Division of Transplantation, Room 7–29, 5600 Fishers Lane, Rockville, Maryland 20857.

In light of the short period for submitting requests to testify, such requests may also be submitted by telefax to Ms. Braslow at (301) 594–6095.

Comments will be available for public inspection three business days after their receipt in Room 7–29, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland, Monday through Friday of each week from 8:00 a.m. to 4:30 p.m. To view public comments in Washington, D.C., call (202) 690–7890 to make an appointment for inspection in Room 309 G of the Hubert Humphrey Building, 200 Independence Avenue, S.W.

The hearing will be held at the Natcher Center on the National Institutes of Health campus in Bethesda, Maryland.

FOR FURTHER INFORMATION CONTACT: Ms. Braslow at the address listed above. Telephone: (301) 443–7577.

SUPPLEMENTARY INFORMATION: Allocation of human livers for transplantation has been debated within the transplant community for several years. On September 8, 1994, the Department published an NPRM to establish rules

governing the operation of the OPTN (59 FR 46482–99). The public comment period expired on December 7, 1994, although additional comments were received and accepted after that date.

As part of the preamble to the NPRM, the Department solicited comments on the organ-allocation policies used to distribute organs by the OPTN (59 FR 46487). Since that time, the OPTN has undertaken a major review of its policies governing the allocation of livers, and the Board of Directors of the OPTN has proposed a revised policy to allocate livers. The revisions proposed by the Board have generated considerable controversy within the transplant community. In view of sections 372–375 of the Public Health Service Act, 42 U.S.C. 274–274c, which vest responsibility in the Secretary of Health and Human Services for oversight of the OPTN, the Department has concluded that further public participation in the development of allocation policies related to livers is desirable. Accordingly, we have decided to seek additional comments on the NPRM and to accept oral testimony and written comments on liver allocation policies and the processes by which they may be developed.

In addition, we recognize that the difficult issues associated with establishing allocation policies stem from a central problem: the medical need for organs far exceeds organs donated. Accordingly, we have decided to use a public hearing as an opportunity to solicit public comments on methods to increase organ donation and general awareness of organ transplantation as a therapeutic alternative for end-stage organ disease.

Participants in the hearing will be limited to ten minutes per individual (or institution). Those requesting to testify should indicate whether their comments will address allocation policies, organ donation, or both. We are particularly interested in comments addressing the following issues:

1. Allocation of Human Livers for Transplantation

The Organ Procurement and Transplantation Network (OPTN) currently allocates human livers for transplantation in accordance with the following policy:

To local Status 1 patients first in descending point order; then to local Status 2 patients in descending point order; then to all other local patients in descending point order; then to Status 1 patients in the Host OPO's (organ procurement organization) region in descending point order; then to Status 2

patients in that region in descending point order; then to all other regional patients in descending point order; then to

Status 1 patients in all other regions in descending point order; then to Status 2 patients in all other regions in descending point order; and finally to all other patients in all other regions in descending point order.

The Status definitions, in pertinent part, are as follows:

A patient listed as Status 1 is in a hospital's Intensive Care Unit (ICU) due to acute or chronic liver failure with a life expectancy without a liver transplant of less than 7 days.

A patient listed as Status 2 is continuously hospitalized in an acute care bed for at least five days, or is ICU bound.

A patient listed as Status 3 requires continuous medical care.

A patient listed as Status 4 is at home and functioning normally.

A patient listed as Status 7 is temporarily inactive—patients who are temporarily unsuitable for transplant are listed as Status 7.

The OPTN Board's proposed policy would revise the definitions of several of the status groups and would revise the "local" area which constitutes the first allocation area. In seeking additional comment, the Secretary invites comments on the following questions:

a. Does the OPTN Board's policy achieve the best outcome that can reasonably be expected for the patients of America? If not, what revisions to the policy, alternative policy, or combination of policies would yield a superior result?

Please present data and other information that support your view; for example, success measures or factors mentioned in the NPRM which include (1) equitable distribution of organs; (2) improvement in graft and patient survival, and (3) enhanced patient choice among transplant programs. In particular, please indicate the measures you considered most important in assessing the relative efficacy of various policy options.

b. Would changes in other OPTN policies related to liver allocation, such as those noted below, yield a better outcome for the patients of America than the present system? Should such changes be implemented in addition to a change in the OPTN Board's allocation policy or phased in with a change?

- Criteria for entering patients on the waiting list for liver transplant.

- Definition of the status categories for patients on the waiting list for liver transplant.

- Procedures for ensuring compliance with OPTN policies affecting liver allocation.

- Use of performance measures, e.g., quality of transplant outcomes and annual number of transplants performed, in determining the eligibility of transplant centers to receive donor livers.

2. Donation of Organs for Transplantation

The medical need for livers and other human organs for transplantation continues to exceed the number of donor organs by a considerable margin. No organ allocation policies, no matter how well crafted or effectively implemented, can be expected to compensate for serious short-falls in the supply of organs relative to the demand.

a. What are the major impediments to organ donation?

b. How can the Department, organ procurement organizations, hospitals, and other entities improve current efforts to promote organ donation?

c. Where and to what extent are further initiatives necessary to ensure that members of racial and ethnic minority groups are appropriately apprised regarding such matters as the role of organ transplantation within the health-care system, the unique health benefits that can ensue from successful transplantation, the limitations associated with transplant procedures, and the challenges involved in recruiting organ donors?

Dated: November 6, 1996.

Ciro V. Sumaya,
Administrator.

Approved: November 7, 1996.

Donna E. Shalala,
Secretary.

[FR Doc. 96-29145 Filed 11-8-96; 10:52 am]

BILLING CODE 4160-15-M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

43 CFR Parts 1600, 1820, 1840, 1850, 1860, 1880, 2090, 2200, 2300, 2520, 2540, 2560, 2620, 2720, 2800, 2810, 2880, 2910, 2920, 3000, 3100, 3120, 3150, 3160, 3180, 3200, 3240, 3250, 3260, 3280, 3410, 3420, 3430, 3450, 3470, 3480, 3500, 3510, 3520, 3530, 3540, 3550, 3560, 3590, 3710, 3730, 3740, 3800, 3810, 3830, 3870, 4200, 4300, 4700, 5000, 5470, 5510, 8370, 9180 and 9230

[WO-130-1820-00 24 1A]

RIN 1004-AC99

Appeals Procedures; Hearings Procedures

AGENCY: Bureau of Land Management, Interior.

ACTION: Proposed regulations, extension of comment period.

SUMMARY: On October 17, 1996, the Bureau of Land Management (BLM) published a document in the Federal Register announcing a proposed rule to revise and consolidate existing procedures for hearings and appeals into a single, streamlined administrative review process covering most of BLM's decisions (61 FR 54120). The 30-day comment period for the proposed rule expires on November 18, 1996. BLM has received several requests from the public for additional time to comment and is extending the comment period for an additional 60 days.

DATES: Submit comments by January 17, 1997.

ADDRESSES: If you wish to comment, you may:

(a) Hand-deliver comments to the Bureau of Land Management, Administrative Record, Room 401, 1620 L St., NW., Washington, DC;

(b) Mail comments to the Bureau of Land Management, Administrative Record, Room 401LS, 1849 C Street, NW., Washington, DC 20240; or

(c) Send comments through the Internet to WOCComment@wo.blm.gov. Please include "attn: AC99", and your name and return address in your Internet message. If you do not receive a confirmation from the system that we have received your Internet message, please contact us directly at (202)452-5030.

You will be able to review comments at BLM's Regulatory Affairs Group office, Room 401, 1620 L Street, N.W., Washington, D.C., during regular business hours (7:45 a.m. to 4:15 p.m.) Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Jeff Holdren 202-452-7779, or Bernie Hyde 202-452-5057.

Dated: November 6, 1996.

Annetta Cheek,

Regulatory Affairs Group Manager.

[FR Doc. 96-29028 Filed 11-12-96; 8:45 am]

BILLING CODE 4310-84-M

FEDERAL MARITIME COMMISSION

46 CFR Part 586

[Docket No. 96-20]

Port Restrictions and Requirements In the United States/Japan Trade

AGENCY: Federal Maritime Commission.
ACTION: Notice of proposed rulemaking.

SUMMARY: The Federal Maritime Commission, in response to apparent unfavorable conditions in the foreign oceanborne trade between the United States and Japan, proposes the imposition of fees on liner vessels operated by Japanese carriers calling at United States ports. The effect of the rule will be to adjust or meet unfavorable conditions caused by Japanese port restrictions and requirements by imposing countervailing burdens on Japanese carriers.

DATES: Comments due on or before January 13, 1997.

ADDRESSES: Send comments (original and 15 copies) to: Joseph C. Polking, Secretary, Federal Maritime Commission, 800 North Capitol Street, N.W., Washington, D.C. 20573, (202) 523-5725.

FOR FURTHER INFORMATION CONTACT: Robert D. Bourgoin, General Counsel, Federal Maritime Commission, 800 North Capitol Street, N.W., Washington, D.C. 20573, (202) 523-5740.

SUPPLEMENTARY INFORMATION:

Background

Information Demand Orders

On September 12, 1995, the Federal Maritime Commission ("Commission" or "FMC") issued information demand orders to carriers in the U.S./Japan trade,¹ inquiring about certain restrictions and requirements for the use

¹ NYK Line (North America) Inc.; Mitsui O.S.K. Lines (America), Inc.; K Line America Inc.; Sea-Land Service, Inc.; American President Line; Westwood Shipping Lines; Evergreen Line; Hanjin Shipping Co. Ltd.; Maersk Inc.; China Ocean Shipping Co.; Hyundai Merchant Marine; Orient Overseas Container Line ("OOCL"); Yangming Marine Line; Neptune Orient Lines; Senator Line (USA) Inc.; Mexican Line (TMM); Hapag-Lloyd (America) Inc.; Zim Container; and Cho Yang Line.

THE PRESIDENT HAS SEEN USE

10-3-96

Mr. President:

You were going
to write a note
to Donna Shalala
asking for a
response to David's
questions and a
status report on
this matter.

Ben

Jim asked Jeff
Secretary to get some
answers —

BC

~~TH~~

I also sent Mark's memo
to Shalala — BC



THE WHITE HOUSE
WASHINGTON

60/2

Dear Donna

This man has been a
friend of mine for over 30 years,
He's a straight shooter -

Please advise me as to
the status of this issue

Burke

Send to
Secy Shalle -
wade sur sur
See - BK

David M. Matter

P6/b(6)

95 OCT 2 P3:12

September 30, 1996

*cc Jeff Seely -
Can you get answers asap?
to these questions?
M*

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.

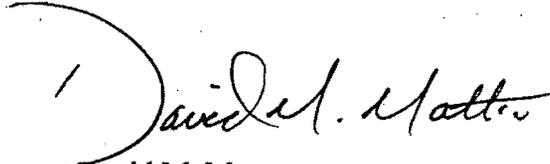
I recognize your tremendously busy schedule and the significant issues that you must face each day. I also know that you maintain a deep and abiding concern for the health and well-being of all of our citizens and are committed to the principles of fairness and a responsive and responsible government. 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,



David M. Matter

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?

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?

11/4/96

- HHS Reg. Transit Network

- Draft Revised Reg - 8/93

- Little comment from everyone

- Dept. has a framework rule - Network relationship w/ Dept.

- See could come back w/ their allocation rules

→ Spring '96 - Allocation policies of lines reviewed by private sector Orga Transit Network

HHS - has a \$2 million contract

- Annual fee from private companies - yield a lot more money

- Categories

4 = ① Local ~~has~~ has priority - seeked to least size if no match, then

4 = ② Regional - if no match, then

4 = ③ National

(4 = 4 categories)

- Pittsburgh says:

• With Quaker allocation, contention in the more time would be small, like you would be great.

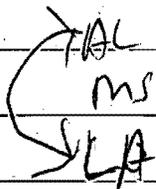
• In terms of death before transplant, some lived + some die while waiting

• Senior patients are less likely to fare better than less sick. If so, another time transplant is necessary

• Pittsburgh says if you go there risk, you take care of 75% of cases, even if healthy have to wait longer.

→ Only 200 out of 600 hospitals are harvesting organs.

→ Southeast is the best harvestor



→ Need increase in organ donation. Proposed ~~by~~
how best we can do this.

→ Conditions of partnership with Medical - all
delegated to JCAH

Proposal for Mary Forward

1 inscription / 1 vote

15th - Margaret Shaw Friday

20/20?

Also - Sally / Mary Ann

↓
Jackie

Letter to Mr. for Secretary

President ask me to resign



THE DEPUTY SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

NOV 1 1996

NOTE TO CHRIS JENNINGS:

SUBJECT: Organ Allocation Issue

I want to provide you with the attached background materials for our meeting on Monday, November 4 at 5:30 p.m.

A handwritten signature in black ink, appearing to read "Kevin Thurm", is written above the printed name.

Kevin Thurm

ISSUES FOR DISCUSSION

o Resolution of Liver Allocation Issue

HHS is proposing to re-open the public comment period on selective provisions of the NPRM which establishes rules governing the operation of the Organ Procurement and Transplantation Network. We propose to hold a public hearing December 10 and 11 to accept oral and written comments on liver allocation policies and the processes by which they may be developed. We will also solicit comments on methods to increase organ donation.

o Composition of the Hearing Panel

Five to seven members are proposed: Federal members would include Assistant Secretary for Health Philip Lee (chair), HCFA Administrator Bruce Vladeck, National Institute of Diabetes and Digestive and Kidney Diseases Director Phillip Gorden and HRSA Administrator Ciro Sumaya. Two private sector members would be ethicists.

o Location

NIH's Natcher Center in Bethesda

o Timetable

November 8, 1996	Federal Register Notice Letter to transplant community	- Friday
December 10 and 11	Public Hearing	
January	Hearing Report and HHS Decision making	
January/February	Final Rule to OMB and draft of plan to increase organ donation	

Thank you for sharing with me the letter from David M. Matter of Pittsburgh, Pennsylvania regarding human organ transplants. Mr. Matter has cogently and succinctly summarized several of the issues with which the organ-transplantation community has been struggling for several years. In particular, I share his desire for a prompt and fair resolution to controversy over allocation of human livers and am committed to achieving such a resolution.

Liver allocation is of special concern for three reasons. First, the number of patients in need of a liver transplant far exceeds the number of livers available. Second, on any given day, many of these patients are at a stage where they face imminent death if a transplant is not performed immediately; and many others are substantially more ill than they were when their names were entered on the waiting list. Third, while excellent working relationships between organ-procurement organizations and organ-transplant centers generally are easiest to build and maintain when the centers are geographically close to one another, finding a proper match between donor organ and recipient requires some organ sharing on a regional or national basis.

The challenge is to define sharing and allocation policies that are effective, efficient, and equitable. However, we must recognize from the outset that, so long as demand significantly exceeds supply, any policy for sharing and allocating livers will mean that some patients awaiting liver transplants--determined by transplant "status," geography, or other factors--will have a greater chance of a life-saving transplant than others and any policy will also create other trade-offs in areas such as quality of life and graft survival rates. Some patients and some transplant facilities will be winners and some losers. And any decision, whether it be a new policy or a reaffirmation of the current one, is certain to draw intense public and Congressional interest. In fact, the Conference Report for the FY 1997 Omnibus Spending Bill (H.R. 3610) specifies factors that the Congress expects to be considered in a revised liver allocation mechanism and states that no organ allocation changes are to be adopted until the Congress can be assured that these specified priorities are addressed.

My staff and I have paid close attention to the deliberations within the Organ Procurement and Transplantation Network (OPTN) regarding liver allocation. I am pleased that the OPTN Board and its associated committees have recognized the need to improve upon current policies and have proposed some promising initiatives related to standardizing wait list criteria. At the same time, I am disappointed that the allocation policies to date have provoked considerable unresolved controversy within the transplant community and still do not address many serious concerns. In addition, Mr. Matter believes that the decision-making processes of the OPTN are not well attuned to making these kinds of choices, i.e., that OPTN members may be perceived as hard-pressed to endorse any policy option that portends disadvantage for their own institutions and patients. I want to ensure that any federal decision regarding this issue is free from that perception.

Therefore, I intend to take three actions related to these issues. First, I will consult with experts who are not affiliated with the OPTN to help me assess the issues associated with allocation of human livers for transplant; the experts will review the OPTN policy and the principal alternatives and advise me on their relative merits. Second, on the basis of these consultations and the other public comments we have received, I will determine by the end of January which of the liver allocation policies promises the best result for the patients of America. Third, I then will submit to OMB the proposed text for a final rule that codifies the structure and basic operating principles of the OPTN (and enables DHHS and the general public to have greater input into significant OPTN policies such as liver allocation) and embodies my decision with respect to liver allocation. I wish that this process could be accomplished more rapidly, but I do not believe we can ensure a high-quality, credible outcome within a shorter time frame.

While these actions are underway, DHHS will intensify its efforts to increase organ donation. Currently more than 7,000 individuals are awaiting a liver transplant; yet, in the next 12 months, only about half the required number of donor livers is likely to become available. A similarly severe disparity between demand and supply exists for other organs such as hearts and kidneys. Therefore, I will send you soon a plan for a Government-wide initiative, led by DHHS, to increase organ donation.

I hope the comments above and the enclosure, which provides the answers to the set of questions that Mr. Matter appended to his letter, are helpful for your consideration of the important issues he described and our plans for addressing them.

Enclosure

RESPONSES TO QUESTIONS OF DAVID M. MATTER

Transmitted to President Clinton by letter dated September 30, 1996

INTRODUCTION

Over the last several years, the United Network for Organ Sharing (UNOS), the DHHS contractor for the Organ Procurement and Transplantation Network (OPTN), and the University of Pittsburgh, an advocate for an alternative to the current OPTN liver-allocation policy, have commissioned substantial computer modeling efforts to determine possible effects of different allocation policies. The modeling for UNOS has been performed by the Pritsker Corporation of Indianapolis, Indiana; and the modeling for the University of Pittsburgh Medical Center (UPMC) has been performed by the CONSAD Research Corporation of Pittsburgh, Pennsylvania.

The most recent modeling efforts include projections for (1) the current liver-allocation policy, (2) an alternative policy proposed by the UNOS Board of Directors (which functions as the OPTN policy board), (3) several policies proposed by OPTN committees, (4) a proposal for national allocation offered by UPMC among others, and (5) a policy called "In-Patient First". Pritsker has modeled approximately 30 alternative policies but was not asked to model the "In-Patient First" Policy. The projections available from these models include information on pre- and post-transplant deaths, days to transplant for waiting list patients, patient life years pre- and post-transplant, the number of different patients transplanted, graft (transplant) survival rates, and other factors.

In the answers that follow, both Pritsker and CONSAD projections are included wherever applicable numbers are available. They are the results of computer simulation models that take into account varying probabilities of dying with, or without, a liver transplant. Projections generated by such models are extremely sensitive to assumptions and formulae used. Moreover, the technology of transplantation is improving rapidly -- making projections necessarily uncertain; and neither of the models considers the possibility that either an increase or decrease in organ donation could result from a change in policy.

In addition to differences in the detailed structures for the models and the starting assumptions used for particular simulations, the models' projections often are presented in different ways. For example, Pritsker presents projections covering years 2 through 4 after each postulated policy change (recognizing that estimates for Year 1 will be heavily influenced by the phase out of the old policy and thus not be reasonably representative of the new policy); whereas CONSAD presents projections covering years 1 through 3. Notwithstanding the differences in the models and how their results may be presented, expert reviewers have found both models sufficiently credible for use as aids to policy-making.

The tables presented in answers to Questions 1-3 below include codes and abbreviations defined as follows:

Patient Status:

- A/PNF - Acute/Primary NonFunction;
patient is in intensive care unit (ICU).
- 1 - Patient is chronically ill and in ICU.
 - 2 - Patient is continuously hospitalized in an acute care bed for at least five days or is ICU bound.
 - 3 - Patient requires continuous medical care but not continuous hospitalization.
 - 4 - Patient is at home and functioning normally.
 - 7 - Patient is considered temporarily unsuitable for transplant.

Question 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?

Neither Pritsker nor CONSAD presents results in terms of "lives saved"; rather, they project deaths over time. Therefore, in the tables below, differences in the number of projected deaths for each policy option when compared with the current policy are presented as "lives saved." Pritsker projections are "by status". CONSAD projections are for all patient groups in the aggregate.

LIVES SAVED PRE-TRANSPLANT

PRITSKER PROJECTIONS:

Patient Status	Current Policy # deaths	Board Proposal # deaths	Lives Saved (Board)1	UPMC Proposal # deaths	Lives Saved (UPMC)2	IP 1st Proposal # deaths	Lives Saved (IP 1st)
A/PNF	98	32	+ 66	87	+ 11	NA	NA
1	511	640	-129	79	+432	NA	NA
2	485	469	+ 16	399	+ 86	NA	NA
3	897	913	- 16	1067	-170	NA	NA
4	318	306	+ 12	328	- 10	NA	NA
7	1395	1411	- 16	1003	+392	NA	NA
Total	3704	3771	- 67	2963	+741	NA	NA

CONSAD PROJECTIONS:

All Status Groups	Current Policy # deaths	Board Proposal # deaths	Lives Saved (Board)1	UPMC Proposal # deaths	Lives Saved (UPMC)2	IP 1st Proposal # deaths	Lives Saved (IP 1st)3
Total	4571	4556	+ 15	4216	+355	4060	+511

1. column 2 - column 3 2. column 2 - column 5 3. column 2 - column 7

LIVES SAVED POST-TRANSPLANT

PRITSKER PROJECTIONS:

Patient Status	Current Policy # deaths	Board Proposal # deaths	Lives Saved (Board)1	UPMC Proposal # deaths	Lives Saved (UPMC)2	IP 1st Proposal # deaths	Lives Saved (IP 1st)
A/PNF	114	198	- 84	143	- 29	NA	NA
1	781	424	+ 357	1826	- 1045	NA	NA
2	902	1127	- 225	1124	- 222	NA	NA
3	712	633	+ 79	50	+ 662	NA	NA
4	30	69	- 39	1	+ 29	NA	NA
Total	2539	2451	+ 88	3144	- 605	NA	NA

CONSAD PROJECTIONS:

All Status Groups	Current Policy # deaths	Board Proposal # deaths	Lives Saved (Board)1	UPMC Proposal # deaths	Lives Saved (UPMC)2	IP 1st Proposal # deaths	Lives Saved (IP 1st)3
Total	2468	2498	- 30	2527	- 59	2734	- 226

LIVES SAVED TOTAL (PRE-TRANSPLANT PLUS POST-TRANSPLANT)

Model	Current Policy # deaths	Board Proposal # deaths	Lives Saved (Board)1	UPMC Proposal # deaths	Lives Saved (UPMC)2	IP 1st Proposal # deaths	Lives Saved (IP 1st)3
Pritsk. pre:	3704	3771	- 67	2963	+741		
post:	2539	2451	+ 88	3144	-605	NA	NA
total	6243	6222	+ 21	6107	+136		
CONSAD pre:	4571	4556	+ 15	4216	+355	4060	+511
post:	2468	2498	- 30	2527	- 59	2734	-266
total	7039	7054	- 15	6743	+296	6794	+245

1. column 2 - column 3 2. column 2 - column 5 3. column 2 - column 7

Question 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?

"Life-years" is an alternative measure of life-saving effects. It is particularly appropriate when, as in the case of liver transplants, very few patients achieve normal life expectancies even if they receive treatment. Neither Pritsker nor CONSAD present results in terms of patient life years "saved." Instead, they show total life years for patients over a three-year period.

PATIENT LIFE-YEARS PRE-TRANSPLANT

PRITSKER PROJECTIONS:

Patient Status	Current Policy life-yrs	Board Proposal life-yrs	diff. (Board) life-yrs1	UPMC Proposal life-yrs	diff. (UPMC) life-yrs2	IP 1st Proposal life-yrs	diff. (IP 1st) life-yrs
A/PNF	32	7	- 25	31	- 1	NA	NA
1	90	117	+ 27	10	- 80	NA	NA
2	507	487	- 20	417	- 90	NA	NA
3	13904	14138	+ 234	16830	+ 2926	NA	NA
4	9184	8858	- 326	9628	+ 444	NA	NA
7	2883	2885	+ 2	2998	+ 115	NA	NA
Total	26600	26492	- 108	29914	+ 3314	NA	NA

CONSAD PROJECTIONS:

All Status Groups	Current Policy life-yrs	Board Proposal life-yrs	diff. (Board) life-yrs1	UPMC Proposal life-yrs	diff. (UPMC) life-yrs2	IP 1st Proposal life-yrs	diff. (IP 1st) life-yrs3
Total	15093	17105	+ 2012	18683	+ 3590	19580	+ 4487

1. column 3 - column 2 2. column 5 - column 2 3. column 7 - column 2

PATIENT LIFE-YEARS POST-TRANSPLANT

PRITSKER PROJECTIONS:

Patient Status	Current Policy life-yrs	Board Proposal life-yrs	diff. (Board)1 life-yrs	UPMC Proposal life-yrs	diff. (UPMC)2 life-yrs	IP 1st Proposal life-yrs	diff. (IP 1st) life-yrs
A/PNF	653	1276	+ 623	811	+ 158	NA	NA
1	3812	2077	- 1735	8755	+ 4943	NA	NA
2	8629	10817	+ 2188	11300	+ 2671	NA	NA
3	11199	9983	- 1216	882	- 10317	NA	NA
4	419	1101	+ 682	17	- 402	NA	NA
Total	24712	25254	+ 542	21765	- 2947	NA	NA

CONSAD PROJECTIONS

All Status Groups	Current Policy life-yrs	Board Proposal life-yrs	diff. (Board)1 life-yrs	UPMC Proposal life-yrs	diff. (UPMC)2 life-yrs	IP 1st Proposal life-yrs	diff. (IP 1st)3 life-yrs
Total	36107	36074	- 33	36465	+ 358	35537	- 570

PATIENT LIFE-YEARS TOTAL (PRE-TRANSPLANT PLUS POST-TRANSPLANT)

Model	Current Policy life-yrs	Board Proposal life-yrs	diff. (Board)1 life-yrs	UPMC Proposal life-yrs	diff. (UPMC)2 life-yrs	IP 1st Proposal life-yrs	diff. (IP 1st)3 life-yrs
Pritsk. pre:	26600	26492	- 108	29914	+ 3314	NA	NA
post:	24712	25254	+ 542	21765	- 2947		
total	51312	51746	+ 434	51679	+ 367		
CONSAD pre:	15093	17105	+ 2012	18683	+ 3590	19580	+ 4487
post:	36107	36074	- 33	36465	+ 358	35537	- 570
total	51200	53179	+ 1979	55148	+ 3948	55117	+ 3917

1. column 3 - column 2

2. column 5 - column 2

3. column 7 - column 2

Question 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 proposal?

Both Pritsker and CONSAD have modeled the expected effects of various liver-allocation policies on waiting times for a transplant. The Pritsker projections are both "by status" and "by UNOS region". CONSAD projections are "by UNOS region" only. These tables are presented on the following two pages.

Pritsker Projections:

AVERAGE WAITING TIME (DAYS) TO TRANSPLANT BY STATUS AT REGISTRATION
(UNOS Liver Allocation Simulation Models Summary)

UNOS REGION	Status A/PNF			Status 1			Status 2			Status 3			Status 4		
	Cur.	Brd	UP MC	Cur.	Brd	UP MC	Cur.	Brd	UP MC	Cur.	Brd	UP MC	Cur.	Brd	UP MC
Region 1	27	3	15	54	125	9	255	243	147	476	491	445	726	716	683
Region 2	25	5	14	132	228	61	214	251	172	417	445	434	796	822	810
Region 3	12	4	10	31	43	5	60	68	100	168	191	346	365	351	479
Region 4	19	2	21	43	66	5	93	104	91	241	253	356	594	554	704
Region 5	13	3	6	49	108	14	136	144	109	321	346	368	605	609	603
Region 6	41	10	24	59	81	5	132	161	96	283	303	352	419	517	516
Region 7	14	3	9	66	117	20	128	138	107	331	357	378	527	521	592
Region 8	28	1	13	60	100	8	144	149	114	290	294	364	452	424	517
Region 9	16	3	10	47	88	9	147	150	104	420	420	398	750	735	731
Region 10	19	4	13	54	76	7	132	127	110	316	319	382	523	538	636
Region 11	24	4	20	44	727	5	93	97	121	212	216	355	391	376	484
Total	19	4	12	63	107	20	134	145	123	301	319	383	577	577	639

AVERAGE WAITING TIMES (DAYS) TO TRANSPLANT FROM REGISTRATION
BY UNOS REGION

UNOS REGION	Current Policy		Board Proposal		UPMC Proposal		In-Patient First Proposal	
	Consad	Pritsker	Consad	Pritsker	Consad	Pritsker	Consad	Pritsker
Region 1	102	427	107	451	105	354	110	N.A.
Region 2	126	371	127	414	124	319	121	N.A.
Region 3	23	159	25	172	109	221	81	N.A.
Region 4	91	232	93	240	113	270	100	N.A.
Region 5	121	318	117	358	119	296	109	N.A.
Region 6	56	231	62	253	107	234	94	N.A.
Region 7	118	300	120	322	110	275	105	N.A.
Region 8	110	236	110	240	123	227	106	N.A.
Region 9	119	391	116	410	115	334	107	N.A.
Region 10	88	263	91	266	110	261	93	N.A.
Region 11	70	186	70	189	123	226	88	N.A.
Standard Deviation	32	N.A.	31	N.A.	7	N.A.	12	N.A.

Question 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?

Question 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?

The modeling results are not as straight-forward as presumed in Questions 4 and 5 for the three measures specified: lives saved, patient life-years, and waiting times. Moreover, for certain others measures (in particular, total patients transplanted and quality of life), neither the In-Patient First proposal nor the UPMC proposal appears to offer an improvement over the current policy.

As indicated by the tables provided in response to questions 1-3, Pritsker has modeled the current OPTN liver-allocation policy, the Board proposal, and the UPMC proposal but not the In-Patient First proposal. CONSAD has modeled all four. The models show similar results in some areas and divergent results in some other areas, as highlighted below.

1. Lives Saved

With respect to "lives saved total", the modeling results are similar. Pritsker projects that the Board proposal would yield an outcome almost identical to the outcome for the current policy (i.e., a 0.3% improvement) and that the outcome for the UPMC proposal would be better than both (i.e., about a 2% improvement). CONSAD also projects that the outcomes of the Board proposal and the current policy would be almost identical (i.e., a 0.2% increase in deaths with the Board proposal) and that the outcomes for both the UPMC proposal and the In-Patient First proposal would be better than those for the other two proposals (i.e., about 4% and 3.5% improvement, respectively).

However, the modeling results diverge somewhat when broken down by "lives saved pre-transplant" and "lives saved post-transplant". For example, Pritsker projects that the UPMC proposal, compared to the current policy, would produce about a 20% improvement in the pre-transplant category but an almost 24% decrement in the post-transplant category. CONSAD projects a similar pattern (albeit with changes of smaller magnitude) for both the UPMC proposal and the In-Patient First proposal when each is compared to the current policy. In particular, CONSAD projects improvements of about 8% (UPMC) and 11% (In-Patient First) in the pre-transplant category and decrements of about 2.5% (UPMC) and 11% (In-Patient First) in the post-transplant

category. These discrepancies probably stem from differences in the structures of the models, the assumptions used for particular simulations, and the way results are presented (see Introduction). For example, the CONSAD model seems to include more favorable assumptions regarding post-transplant mortality than does the Pritsker model.

2. Patient Life-Years

With respect to "patient life-years total", Pritsker projects that the outcomes for the Board proposal and the UPMC proposal would be almost identical to the outcome for the current policy (i.e., improvements of 0.8% and 0.7%, respectively). In contrast, CONSAD projects that all three proposals for a new policy would be superior to the current policy: i.e., a 3.9% improvement (Board), a 7.7% improvement (UPMC), and a 7.6% improvement (In-Patient First).

As with "lives saved", the modeling results for "patient life-years total" diverge when broken down by "pre-transplant patient life-years" and "post-transplant patient life-years". For example, for the pre-transplant category, Pritsker projects a 12.4% improvement for the Board proposal over the current policy; whereas CONSAD projects improvements over the current policy of 23.8% (UPMC) and 29.7% (In-Patient First). Further, for the post-transplant category, Pritsker projects an almost 12% decrement for the UPMC proposal compared to the current policy; whereas CONSAD projects almost no change from the current policy for either the UPMC proposal (a 1% improvement) or the In-Patient First proposal (about a 1.5% decrement).

3. Waiting Time to Transplant

The substantial differences in the absolute values of the waiting times projected by Pritsker and CONSAD (see tables in response to Question 3) suggest some fundamental differences in their approaches to this aspect of the modeling -- possibly different definitions of waiting time. Even the rankings of Regions with respect to projected waiting times under the current policy are different. Direct comparisons of the modeling results therefore could be seriously misleading.

Nevertheless, the projections of both models are qualitatively consistent with the reduction in waiting-time disparity across Regions that one would expect for the UPMC proposal. For example, the CONSAD model projects that the UPMC proposal, in achieving a cross-Regions standard deviation of 7 days compared to 32 days for the current policy, reduce waiting time slightly in four Regions while increasing waiting times in seven Regions - in some cases substantially (e.g., greater than 4 times in Region 3).

4. Other Considerations

The UPMC and In-Patient First proposals seem certain to reduce the total number of individuals who receive a transplant. That is, by transplanting a higher percentage of sicker patients, one would expect an increase in the number of transplant failures and therefore an increase in the number of second (and even third) transplants. For every liver used for a repeat transplant, one fewer individual can receive a first transplant.

According to Pritsker projections, the current policy would enable 12,650 total transplants over three years; of these, 10,990 would be to first-time (non-repeat) patients and 1,660 would go to repeat transplants. For the UPMC proposal, Pritsker projects that first-time patients would receive only 10,230 transplants -- a reduction of 760.

In addition, the UNOS Liver Committee and the OPTN Board have considered a wide variety of other measures. One of the most important is quality of life. Any policy changes that were to increase waiting time for a transplant significantly could have an adverse effect on quality of life overall -- for, in general, post-transplant health for liver patients is better than pre-transplant health. In this regard, the Pritsker model projects that the UPMC proposal would increase the lower-quality pre-transplant life years from 26600 to 29914 while decreasing the higher-quality post-transplant life years from 24,712 to 21,765. The CONSAD model projects a similar increase in pre-transplant life-years (from 15093 to 18683) for the UPMC model but also projects a modest increase in post-transplant life-years (from 36107 to 36465).

Question 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?

There are data that would indicate that in the aggregate centers that do fewer than 12 transplants per year are higher risk centers, and that the centers with more than 35 transplants annually have the lowest mortality rates. However, not all low volume centers (i.e., fewer than 12 transplants per year) are higher risk centers. Some have high survival rates and some have low survival rates. In 1993, four out of 17 centers doing under twelve transplants per year had a survival rate above the national average and above the Medicare standard.

In other words, volume is an imperfect proxy for risk.

The reasons a patient may choose a low volume center or a higher risk center are that it may be closer to home and more convenient, and that the waiting time may be shorter at the low volume or higher risk center.

Question 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?

There were 73 liver transplant programs performing fewer than 35 transplants in 1995. Twenty-two of these were Medicare approved centers. Both VA approved programs did fewer than 35 transplants in 1995.

As of October 2, 1996, there are a total of 118 liver transplant programs in the U.S. Sixty of these are Medicare approved centers and two are VA approved programs.

David M. Matter

P6/b(6)

SEPT 2 P3: 12

September 30, 1996

*cc Jeff Seely
Can you get answers asap?
to these questions?
M*

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.

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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.

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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.

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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

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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.

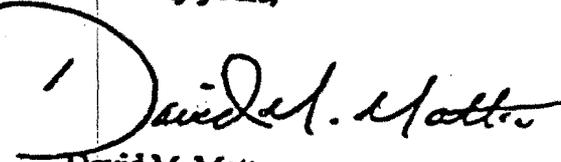
I recognize your tremendously busy schedule and the significant issues that you must face each day. I also know that you maintain a deep and abiding concern for the health and well-being of all of our citizens and are committed to the principles of fairness and a responsive and responsible government. 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

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

Sincerely yours,


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?

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?

Withdrawal/Redaction Marker

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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
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001. letter	letter to Chris Jennings from Walter K. Graham re: liver allocation policy (3 pages)	12/3/96	P6/b(6)
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RESTRICTION CODES

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

- P1 National Security Classified Information [(a)(1) of the PRA]
- P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
- P3 Release would violate a Federal statute [(a)(3) of the PRA]
- 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]
- b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
- b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
- b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
- b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
- b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
- b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

MEETING ON HEALTH CARE

DATE: December 2, 1996
TIME: 3:30 pm
LOCATION: CHR's Office
CONTACT: Chris Jennings

I. PURPOSE

To discuss the Administration's position on proposed changes in the current national liver allocation policy.

II. BACKGROUND

Secretary Shalala sent a letter on November 8, 1996 to Mr. David M. Matter regarding the Administration's position on organ transplants. In this letter, the Secretary stated her commitment to achieving a prompt and fair resolution to issues over allocation of human livers. (See attached letter)

In particular, the Secretary plans to take three actions related to these issues. First, she has asked Assistant Secretary for Health Phillip R. Lee, M.D., to chair a panel to hold public hearings on these issues. (On November 8, the Secretary forwarded to the Federal Register a notice announcing the public hearings, which are to be held December 10 and 11, 1996). Second, based on these consultations and other public comments, the Secretary will determine in the next three months which of the liver allocation policies promises the best result for the patients of America. Third, the Secretary will submit to OMB the text for a final rule that codifies the structure and basic operating principles of the Organ Procurement and Transplantation Network.

III. PARTICIPANTS

Participants will include:

Walter K. Graham
Executive Director
United Network for Organ Sharing

Arthur Watson Bell
Chairman, Patient Affairs Committee
United Network for Organ Sharing

Jean Ann Bell
Liver Transplant Recipient

IV. SEQUENCE OF EVENTS

This meeting will be led by you and Chris Jennings.

V. MEDIA

No media will be present.

VI. REMARKS

No formal remarks will be prepared.