

# Withdrawal/Redaction Sheet

## Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
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001. note	Bruce Lindsey to POTUS re: Letter from David Matter (1 page)	2/97	P5
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**COLLECTION:**

Clinton Presidential Records  
 Domestic Policy Council  
 Chris Jennings (Subject File)  
 OA/Box Number: 23753 Box 22

**FOLDER TITLE:**

Organ Donations [6]

gf46

### 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]

December 9, 1996

C Jennings - fyi  
POTUS shared this  
with me.

**MEMORANDUM TO SECRETARY DONNA SHALALA**

**FROM: Kelly Craighead**

**RE: Proposed Liver Allocation Policy**

Wendy Marx is a close friend of mine. She has hepatitis B (apparently contracted while having her wisdom teeth removed). She is currently on the waiting list to receive a liver transplant. Under the newly proposed policy by the United Network for Organ Sharing (UNOS) the chronic nature of her illness could very well prohibit her from reaching the status needed to receive a liver in time to save her life. She, along with her brother and Olympian Carl Lewis, formed an organ donor awareness foundation seven years ago and each of them plans to testify in the hearings to be chaired by Phil Lee this week.

It appears that, prior to formulating its policy, UNOS did very little to invite comment from those who might be most greatly affected by the proposed changes. Much of the controversy generated by the new policy seems to stem from several areas; one, the discrimination against chronic patients as opposed to the treatment given to those with acute illness; the other, regional versus national allocation practices.

Based on my own experiences, I support the current policy of assigning organs to those patients with the greatest need (i.e. the sickest people). I furthermore support the idea of having a truly national system of distribution instead of the current system that sets up artificial barriers by UNOS regions. It seems to me that a truly national system is the only way to ensue public confidence.

It is my understanding that based on the committee's findings, you will issue the final regulations concerning new liver allocation policy. I am appealing to you on a personal level rather than a professional one. Please do not allow a system that would unfairly favor one patient over another based on nothing more than geographic location. Likewise, please do not deny patients with chronic illnesses their equal rights to liver transplants. I am hopeful that during the hearing process you will reach the same conclusion -- that no policy should issue a death sentence to my friend Wendy Marx or anyone like her.

I would be happy to provide you with any supporting information you might request. Thank you in advance for your time and consideration.

December 6, 1996

Kelly Craighead  
Special Assistant to the President  
The White House  
Washington, D.C. 20500

Dear Kelly,

As you know, the board of the United Network for Organ Sharing (UNOS) recently approved a major change in the way patients needing liver transplants will be given priority on the waiting list. Effective January 20, 1997, it will no longer be possible for patients with chronic conditions, regardless of how urgent those conditions may be, to be given the highest priority for a liver donor. These chronic patients include people with hepatitis, cirrhosis, primary biliary cirrhosis, sclerosing cholangitis, autoimmune liver diseases and other inherited diseases of the liver.

As an active carrier of one of these "chronic conditions", hepatitis, this policy effectively issues me to a death sentence. It is the same for many others like me around the country, people who are suffering from illnesses we certainly did not choose to contract. Under the current policy, patients projected to die within seven days without a transplant get the highest priority (Status 1). Those who need constant hospital care are next (Status 2). Less critical candidates are assigned lower priorities. When a liver becomes available, someone with the highest priority (i.e. the sickest) receives the organ first. When all else is equal, the liver goes to the person who has been waiting the longest. It is a system based on taking care of the patients with the greatest medical need. Under the proposed policy, I and thousands of others will automatically be relegated to Status 2 regardless of how sick we become.

UNOS based this new policy on a rather dubious assumption that patients with acute liver failure have a "greater chance of survival" than patients with chronic liver failure in similar conditions. However, analysis of UNOS Liver Registry data shows that this survival rate increase between chronic and acute patients is negligible and does not reflect the thousands of lives that will be lost by patients who will never be allowed to reach Status 1.

It is extremely troubling that this new policy eliminates the ability for doctors to make any meaningful decisions on a case-by-case basis. The new UNOS policy does not allow for any individual evaluation whatsoever. Most importantly, it fails to address the real issue at hand: the desperate need for more organs. That is where we need to be dedicating our resources. Let's not keep fighting about how to split up the pie. Let's work toward increasing the size of it.

Kelly Craighead  
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As someone who has already received a liver transplant -- and someone with chronic liver disease -- I am extremely thankful and proud to say it has already been seven years since I first got ill. In that time I have joined with my family and Olympian Carl Lewis in establishing and directing the Wendy Marx Foundation for Organ Donor Awareness. The foundation has been responsible for:

-- National donor awareness projects including production and distribution of an educational video for teens and distribution of more than one million donor cards.

-- A variety of regional and local programs targeting corporate, school and community groups in more than a dozen states.

My work on behalf of the foundation and my active participation in the transplant community constantly remind me that the issue of liver allocation would be moot if the number of existing, viable organs were offered for use by a greater number of potential donor families. This is what UNOS should be focusing on, not finding ways to ration health care.

I do remain optimistic, as always. The UNOS policy announced in October was met with considerable public discussion. Thankfully, Secretary Shalala and the Department of Health and Human Services have intervened by calling hearings to take place December 10-12. It is my hope that these hearings will help to broaden public understanding of this important issue. It is also my hope that public scrutiny will enhance the credibility of the entire donation and allocation process.

I, along with my brother Jeff and Carl Lewis, will testify on December 11. Please be kind enough to let me know if there is anything else I might be able to do in order to support this process. Meanwhile, I greatly appreciate the time and effort you have committed to this issue.

Sincerely,

*Wendy Marx*  
WJM

Wendy Marx  
141 Vicksburg Street  
San Francisco, CA 94114

Douglas W. Hanto  
April 11, 1997  
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reaction to her plans to release the data "because she [the reporter] could get it if she filed a FOIA." However, in a letter to me dated March 11, 1996, Ms. Braslow stated for the first time, "I'm writing to let you know that we have released the data asked for under the FOIA by the *Cleveland Plain Dealer*." This March 11, 1996, letter explains that the FOIA Officer and the Department's FOIA Attorney had considered the matter and had concluded that the reasons for withholding the data described in Dr. Daily's February 28, 1996, letter would not "withstand an appeal." It is unclear what that statement means. Since we had not been informed of a FOIA request, we had not submitted any specific reasons for HHS to exempt the release of data under FOIA. The first we learned of a FOIA request was the March 11, 1996, letter informing us after the fact that the data had already been released.

Mrs. Braslow's March 11, 1996, letter demonstrates that HRSA obviously knew that the data in question was potentially confidential commercial information because she stated that Dr. Daily's letter did not present "persuasive evidence" that would support invoking the FOIA exemption from release for confidential commercial information. Of course, it had not even been possible for us to invoke that exemption yet, because we did not know a FOIA request had been made. But, given that HRSA raised the point in Ms. Braslow's March 11, 1996, letter about the possibility of the data being exempt from release as confidential commercial information, and she even went so far as to say that there was evidence of it, albeit not *persuasive* evidence, HRSA clearly was aware that the information *could be* confidential commercial information. HRSA was therefore bound by its own regulations to give UNOS the notice and opportunity to object to the release.

Ongoing Difficulties. HRSA submitted another request to UNOS for additional center-specific information about turndown data for 1995, but we declined to give it to them because they would not provide assurances to us that they would not release it to the news media. The UNOS Board of Directors considered this matter at its November, 1996 meeting and voted unanimously to not provide the requested data until proper assurances were given by HRSA. Mrs. Braslow threatened legal action against UNOS, and UNOS offered to put the data in the hands of a neutral third party who would act as an escrow agent and would release the data to HRSA once HRSA promised to not release the data to the news media.

At the March, 1997, Board meeting, Mrs. Braslow met with the UNOS Executive Committee and the UNOS Board and agreed to an approach to resolve the issue. However, we recently received a letter from her which appears to reverse the essence of that agreement. I am convinced that the only way to resolve this matter is by the Congress stating in the law itself that these data are to be afforded confidentiality status, and that HRSA is required to respect that status.

Changes in NOTA Are Needed. The UNOS Board unanimously endorsed proposed modifications to NOTA, which would make it clear that institution and patient-identified data may not be disclosed by either the OPTN or the Government without the permission of the institution or patient. We believe this approach is most appropriate for the OPTN. After all, the OPTN is a unique arrangement in which all institutions in the country are pooling highly confidential data for the purpose of operating a national network to share organs for transplantation. In today's highly

Douglas W. Hanto  
April 11, 1997  
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competitive health care environment, no institution would voluntarily release such confidential information otherwise. If steps are not taken immediately to prevent further harmful and misleading release, institutions will simply choose to stop submitting data to the OPTN and the Scientific Registry in order to protect the interests of the institutions and their patients and consumers.

The Senate Labor and Human Resources Committee Report that accompanied Senate Bill 1324, which was passed by the Senate last year, included language that indicated the Committee viewed OPTN data as being in the public domain. UNOS had objected strongly to that characterization, which we believe is the extreme opposite of what is proper for the confidential data the OPTN collects - - the data are highly personal and confidential patient medical records as well as confidential commercial information for the institutions. We believe placing such information in the public domain is a very serious mistake.

The stories published in the *Cleveland Plain Dealer*, which reported inaccurate information about many excellent heart transplant programs and drew erroneous conclusions from that information, which impugned dedicated transplant professionals is a clear example of the kind of damage that will continue if this situation is not rectified. HRSA's position regarding the confidentiality of the data has changed frequently, and it has been amply demonstrated that neither the clear language of our contracts with the Government nor even the protections promised in HHS's own Federal regulations can be relied upon in this matter. The only solution is a change of the law, but the Senate Labor and Human Relations Committee will first need to reassess its view of these data.

Please let me know whether I can provide any further information regarding this situation, and I will be happy to do so at once because this is so vitally important to the future of UNOS. I fear that unless this kind of damaging activity is not prevented, it could severely damage our ability to provide the life-saving organ sharing network that operates today on the foundation of accurate and timely data.

Sincerely,



Walter K. Graham  
Executive Director



United  
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for  
Organ  
Sharing

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# MEMO

**To:** House Commerce Committee Health Policy Staffers  
**From:** Donna R Henry, Patient Affairs Specialist  
United Network for Organ Sharing  
**Subject:** National Organ Transplant Act  
**Date:** April 1, 1997

The Organ and Bone Marrow Transplant Program Reauthorization Act of 1995 threatened to undermine one of the most successful public/private partnerships created by Congress.

The United Network for Organ Sharing (UNOS) hopes that the members of the House Commerce Committee will again work to reinforce the original Congressional mandate which has resulted in an Organ Procurement and Transplantation Network (OPTN) whose policies and programs to effect an equitable utilization of the scarce supply of organs have helped achieve a 44% increase in the number of transplants and 27% increase in the number of organ and tissue donors since 1988 with only about \$2 million in annual government funds.

The National Organ Transplant Act (NOTA), which passed in 1985, directs the Secretary of the Department of Health and Human Services (DHHS) to contract with an independent, private organization which is empowered to make organ allocation policies and to maintain the list of people who are waiting for an organ transplant. This contract has been competitively awarded to the United Network for Organ Sharing (UNOS) since the act passed. UNOS is the organization which, previous to enactment of NOTA, had been established by the transplant centers and OPOs to regulate their policies and to resolve their disputes. UNOS is comprised of representatives of transplant centers, OPOs, organ recipients and donors, ethicists, and other members of the transplant community who have collectively donated over one million hours of their time to increase the availability and the quality of transplantation for all who need it. Its performance has been uniformly strong, and, while not free of controversy, honest and independent.

Please consider the following amendments to NOTA which would serve to clarify the DHHS role in overseeing the OPTN, affirm the independent nature of

House Commerce Committee Health Policy Staffer

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the OPTN contractor with control of its private registration fees, increase efficiency through unification of the OPTN and Scientific Registry contracts, ensure the confidentiality of sensitive private medical data, and assure that increased funds are appropriated in accordance with contract required tasks and the need for increased public awareness, donation, procurement, and transplantation.

I have enclosed additional statistics and background information which should further elucidate the issues at hand. Please contact me at 703-413-5523 if you have any questions or desire any more information.

Thank you for your time and consideration of this matter.

**Sec. 274. Organ procurement and transplantation network**

(a)(1) Congress finds that -

(A) it is in the public interest to maintain and improve a durable system for promoting and supporting a central network to assist organ procurement organizations in the nationwide distribution of organs among transplant patients;

(B) it is desirable to continue the partnership between public and private enterprise, by continuing to provide Federal Government oversight and assistance for services performed by the OPTN; and

(C) the Federal Government should oversee OPTN activities to ensure that the policies and procedures of the OPTN for serving patient and donor families and procuring and distributing organs are fair, efficient and in compliance with all applicable legal rules and standards; however the initiative and primary responsibility for establishing medical criteria and standards for organ procurement and transplantation still resides with the OPTN.

(2) The Secretary shall by contract provide for the establishment and operation of an Organ Procurement and Transplantation Network (OPTN) which meets the requirements of subsection (b). The Secretary shall, upon determination that a new competitive contract solicitation is unlikely to result in a responsive bid other than that of the incumbent, be authorized to issue sole source extensions of a contract for the continuation of the OPTN including all functions and duties of the OPTN described in this section. The amount provided under the OPTN such contract in any fiscal year may not exceed \$2 4,000,000, and shall be sufficient to pay for all contract tasks required by the Secretary and for the Government's share of the costs of mutually agreed tasks in a cost-sharing contract. Funds for such contracts shall be made available from funds available to the Public Health Service from appropriations for fiscal years beginning after fiscal year 1984. No assets in the OPTN's possession or revenues collected by the OPTN, other than appropriated funds authorized under this part shall be considered Federal property or Federal revenues, nor shall such assets

or revenues be subject to control by the Secretary.

(b)(1) The Organ Procurement and Transplantation Network shall carry out the functions described in paragraph (2) and shall-

(A) be an independent private nonprofit corporation that has an expertise in organ procurement and transplantation, and

(B) have a board of directors-

(i) that includes representatives of organ procurement organizations that have received grants under section 371 [42 USCS Sec. 273], transplant centers, voluntary health associations, and the general public including a reasonable proportion of the members of the board who are patients awaiting a transplant or transplant recipients or individuals who have donated an organ or family members of patients, recipients or donors, and

(ii) that shall establish an executive committee and other committees, whose chairpersons shall be selected to ensure continuity of leadership for the board.

(2) The Organ Procurement and Transplantation Network shall-

(A) establish on one location or through regional centers-

(i) a national list of individuals who need organs, and

(ii) a national system, through the use of computers and in accordance with established medical criteria, to match organs and individuals included in the list, especially individuals whose immune system makes it difficult for them to receive organs, and

(iii) a national list of persons registering to be organ donors.

(B) have responsibility to establish OPTN membership criteria and, medical criteria for allocating organs and other OPTN policies and after providing to members of the public an opportunity to comment with respect to such criteria policies, provided that the Secretary may by promulgating a final rule, veto any OPTN policy that is determined.

based upon evidence gathered at a public hearing, to be detrimental to the public health

(C) maintain a twenty-four-hour telephone service to facilitate matching organs with individuals included in the list,

(D) assist organ procurement organizations in the nationwide distribution of organs equitably among transplant patients,

(E) adopt and use standards of quality for the acquisition and transportation of donated organs, including standards for preventing the acquisition of organs that are infected with the etiologic agent for acquired immune deficiency syndrome,

(F) prepare and distribute, on a regionalized basis (and, to the extent practicable, among regions or on a national basis), samples of blood sera from individuals who are included on the list and whose immune system makes it difficult for them to receive organs, in order to facilitate matching the compatibility of such individuals with organ donors

(G) coordinate, as appropriate, the transportation of organs from organ procurement organizations to transplant centers,

(H) provide information to physicians and other health professional regarding organ donation,

(I) collect, analyze, and publish data concerning organ donation and transplants;

provided that, except in the course of interactive organ sharing operations or as authorized

in paragraph (2)(L), neither the OPTN nor the Secretary shall release data permitting

direct or indirect identification of patients who have waited or are waiting for a transplant;

organ transplant recipients, potential or actual organ donors, or the institution submitting

the data without the written permission of those whose identity is to be revealed

(J) carry out studies and demonstration projects for the purpose of increasing organ donation and improving procedures for organ procurement and allocation,

(K) work actively to increase the supply of donated organs, and

(L) provide the public with information, including institution-identified data authorized for

release by the OPTN Board, designed to assist patients and referring physicians in choosing a transplant center including the triennial publication of a submit to the Secretary an annual report containing information on the comparative costs and patient outcomes at each transplant center affiliated with the organ procurement and transplantation network, and an annual report on the overall status of organ procurement and transplantation.

(M) maintain a scientific registry of patients awaiting organ transplantation, persons from whom organs are removed for transplantation, and organ transplant recipients for the ongoing evaluation of the scientific and clinical status of organ transplantation. The Secretary shall prepare for inclusion in the report under section 376 [42 USCS Sec. 274d] an analysis of information derived from the registry, and

(N) develop a peer review system for enforcement of OPTN policies, which may include penalties other than expulsion from OPTN membership, provided that except for public announcement of penalties imposed at the conclusion of OPTN peer review proceedings, neither the OPTN nor the Secretary shall release data or information relating to the proceedings without the written permission of all parties involved.

(O) Study the impact of possible transplantation of animal organs (xenotransplantation) and cloning to determine the impact upon, and prevent negative effects on, the fair and effective use of human allograft organs.

(c) The Secretary shall establish procedures for-

(1) receiving from interested persons critical comments relating to the manner in which the Organ Procurement and Transplantation Network is carrying out the duties of the Network under subsection (b); and

(2) the consideration by the Secretary of such critical comments.

~~Sec. 274a. Scientific registry~~

~~The Secretary shall, by grant or include under terms of the OPTN contract required in Sec. 274(a) contract, develop and maintain a scientific registry of the recipients of organ~~

~~transplants. The registry shall include such information respecting patients and transplant procedures as the Secretary deems necessary to an ongoing evaluation of the scientific and clinical status of organ transplantation. The Secretary shall prepare for inclusion in the report under section 376 [42 USCS Sec. 274d] an analysis of information derived from the registry.~~

**Sec. 274b a. General provisions respecting grants and contracts**

(a) No grant may be made under this part [42 USCS Secs. 273 et seq.] or contract entered into under section 372 or 373 [42 USCS Sec. 274 or 274a] unless an application therefor has been submitted to, and approved by, the Secretary. Such an application shall be in such form and shall be submitted in such manner as the Secretary shall by regulation prescribe.

(b)(1) A grant for planning under section 371(a)(2) [42 USCS Sec. 273 (a)(1)] may be made for one year with respect to any organ procurement organization and may not exceed \$100,000.

(2) Grants under section 371(a)(2) [42 USCS Sec. 273(a)(2)] may be made for two years. No such grant may exceed \$500,000 for any year and no organ procurement organization may receive more than \$800,000 for initial operation or expansion.

(3) Grants or contracts under section 371(a)(3) [42 USCS Sec. 273(a)(3)] may be made for not more than 3 years.

(c)(1) The Secretary shall determine the amount of a grant or contract made under section 371 or 373 [42 USCS Sec. 273 or 274a]. Payments under such grants and contracts may be made in advance on the basis of estimates or by the way of reimbursement, with necessary adjustments on account of underpayments or overpayments, and in such installments and on such terms and conditions as the Secretary finds necessary to carry out the purposes of such grants and contracts.

(2)(A) Each recipient of a grant or contract under section 372 or 373 [42 USCS Sec. 273 or 274a] shall keep such records as the Secretary shall prescribe, including records which fully

disclose the amount and disposition by such recipient of the proceeds of such grant or contract, the total cost of the undertaking in connection with which such grant or contract was made, and the amount of that portion of the cost of the undertaking supplied by other sources, and such other records as will facilitate an effective audit.

(B) The Secretary and the Comptroller General of the United States, or any of their duly authorized representatives, shall have access for the purpose of audit and examination of any books, documents, papers, and records of the recipient of a grant or contract under section 371 or 373 [42 USCS Sec. 273 or 274a] that are pertinent to such grant or contract.

(d) For purposes of this part [42 USCS Secs. 273 et seq]:

(1) The term "transplant center" means a health care facility in which transplants of organs are performed.

(2) The term "organ" means the human kidney, liver, heart, lung, pancreas, and any other human organ (other than corneas and eyes) specified by the Secretary by regulation and for purposes of Sec. 373 [42 USCS Sec. 274a], such term includes bone marrow.

#### **Sec. 274e b. Administration**

The Secretary shall designate and maintain an identifiable administrative unit in the Public Health Service to-

- (1) administer this ~~part~~ section 274b and coordinate with the organ procurement activities under title XVIII of the Social Security Act,
- (2) conduct a program of public information to inform the public of the need for organ donations,
- (3) provide the technical assistance to organ procurement organizations, the Organ Procurement and Transplantation Network established under section 372 [42 USCS Sec. 274], and other entities in the health care system involved in organ donations, procurement, and transplants, and

(4) provide information-

- (i) to patients, their families, and their physicians about transplantation; and
- (ii) to patients and their families about the resources available nationally and in each State, and the comparative costs and patient outcomes at each transplant center affiliated with the organ procurement and transplantation network, in order to assist the patients and families with the costs associated with transplantation.

**Sec. 274d c. Report**

Not later than February 10 of 1991 and of each second year thereafter, the Secretary shall publish, and submit to the Committee on ~~Energy and~~ Commerce of the House or Representatives and the Committee on Labor and Human Resources of the Senate a report on the scientific and clinical status of organ transplantation. The Secretary shall consult with the Director of the National Institutes of Health and the Commissioner of the Food and Drug Administration in the preparation of the report.

**Sec. 274e d. Prohibition of organ purchases**

- (a) It shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation if the transfer affects interstate commerce.
- (b) Any person who violates subsection (a) shall be fined not more than \$50,000 or imprisoned not more than five years, or both.
- (c) For purposes of subsection (a):
  - (1) The term "human organ" means the human (including fetal) kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, bone, and skin or any subpart thereof and any other human organ (or any subpart thereof, including that derived from a fetus) specified by the Secretary of Health and Human Services by regulation.

(2) The term "valuable consideration" does not include a benefit, the exchange of which is expressly contemplated by organ distribution policies or demonstration projects duly established by the OPTN Board of Directors, or the reasonable payments associated with the removal, transportation, implantation, processing, preservation, quality control, and storage of a human organ or the expenses of travel, housing, and lost wages incurred by the donor of a human organ in connection with the donation of the organ.

(3) The term "interstate commerce" has the meaning prescribed for it by section 201(b) of the Federal Food, Drug and Cosmetic Act [21 USCS Sec. 321(b)].

~~Sec. 274f. Study by the General Accounting Office.~~

~~(a) In general. The Comptroller General of the United States shall conduct a study for the purpose of determining-~~

- ~~(1) the extent to which the procurement and allocation of organs have been equitable, efficient, and effective;~~
- ~~(2) the problems encountered in the procurement and allocation; and~~
- ~~(3) the effect of State required request laws.~~

~~(b) Report. Not later than January 7, 1992, the Comptroller General of the United States shall complete the study required in subsection (a) and submit to the Committee on Energy and Commerce of the House of Representatives and to the Committee on Labor and Human Resources of the Senate, a report describing the findings made as a result of the study.~~

**Sec. 274g e. Authorization of Appropriation**

For the purpose of carrying out this part [42 USCS Secs. 273 et seq], there are authorized to be appropriated \$8 4,000,000 for fiscal year ~~1994~~ 1998 and such sums as may be necessary for each of the fiscal years ~~1992 and 1993~~ 1999 through 2003.

## Numbers of U.S. Transplants – 1988-November 30, 1996

by Organ and Donor Type \*

Organ	Donor Type	Year								
		1988	1989	1990	1991	1992	1993	1994	1995	1996
Kidney *	Cadaveric	7231	7087	7784	7732	7697	8170	8383	8601	7833
	Living	1811	1902	2094	2390	2534	2850	3007	3217	2966
	Total	9042	8989	9878	10122	10231	11020	11390	11818	10799
Liver	Cadaveric	1713	2199	2676	2931	3031	3405	3592	3879	3677
	Living	0	2	14	22	33	36	60	44	38
	Total	1713	2201	2690	2953	3064	3441	3652	3923	3715
Pancreas*	Cadaveric	244	413	526	530	554	772	840	1021	909
	Living	5	4	2	1	3	2	2	6	9
	Total	249	417	528	531	557	774	842	1027	918
Heart	Cadaveric	1669	1696	2096	2121	2170	2295	2338	2360	2138
	Living	7	9	12	4	1	2	3	0	2
	Total	1676	1705	2108	2125	2171	2297	2341	2360	2140
Lung	Cadaveric	33	93	202	401	535	660	708	848	727
	Living	0	0	1	4	0	7	15	23	7
	Total	33	93	203	405	535	667	723	871	734
Heart-Lung	Cadaveric	74	67	52	51	48	60	70	69	38
	Living	0	0	0	0	0	0	0	0	0
	Total	74	67	52	51	48	60	70	69	38
Total*	Cadaveric	10964	11555	13336	13766	14035	15362	15931	16779	15322
	Living	1823	1917	2123	2421	2571	2897	3087	3290	3022
	Total	12787	13472	15459	16187	16606	18259	19018	20069	18344

\* In this table, Simultaneous Kidney-Pancreas transplants are counted *twice*, both in Kidney Transplants and in Pancreas Transplants. The number of Simultaneous Kidney Pancreas transplants performed in each year were: 1988-170, 1989-334, 1990-459, 1991-452, 1992-493, 1993-661, 1994-747, 1995-914

Number of U.S. Transplants

Page 2

Note: Double kidney, double lung, and heart-lung transplants are counted as one transplant. All other multi-organ transplants are being included in the total for each individual organ transplanted.

Based on UNOS Scientific Registry data as of March 2, 1997  
Data subject to change based on future data submission or correction.

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UNOS

[Home](#)

Use browser "Back" to return to previous page.

### REGIONAL WAITING TIME DIFFERENCES: A UNOS STUDY OF THE LIVER WAITING LIST

Geographic variability in pretransplant waiting times continues to be an area of debate in transplantation. The underlying reasons for variability are complex, however contributing factors include regional organ recovery rates, waiting list sizes and candidate characteristics such as first or repeat transplant, medical urgency status, blood type, race and age. In order to examine variability in liver waiting times, all primary registrations added to the waiting list between 1993 and 1995 (N=18,993) were analyzed. For each UNOS region, and for the U.S. overall, a ratio (R/T) of the number of registrations to the number of organs recovered and subsequently transplanted was calculated. R/Ts were compared with regional median waiting times (MWT), stratified according to UNOS medical urgency status at listing and at time of transplant (status at listing/status at transplant) as shown below. Status 3 and 4 patients were combined into one group.

Region	R/T	1/1	2/1	2/2	3,4/1	3,4/2	3,4/3,4	Overall
A	1.14	4	8	5	61	57	82	64
B	1.51	4	7	11	56	70	103	71
C	1.58	3	**	8	**	88	144	113
D	2.15	4	10	17	89	126	321	238
E	2.28	4	22	27	80	128	172	139
F	2.29	4	14	18	82	100	202	162
U.S.	2.64	4	12	15	95	127	243	164
G	3.05	3	11	13	77	125	323	182
H	3.18	5	10	20	136	112	279	193
I	3.50	2	10	13	91	158	+	278
J	4.19	6	13	53	235	215	580	423
K	4.72	5	17	56	122	182	862	290

+ median is not estimable; \*\* <10 registrations in stratum

Waiting times across regions for the most medically urgent patients were relatively uniform. Regional MWTs were longest and variability was largest when patients were both listed and transplanted as status 3 or 4. For such patients, MWTs were particularly long in two UNOS regions, where corresponding R/Ts were also very high. This suggests that waiting times for those patients and regional R/Ts could be reduced through increased organ recovery, increased interregional organ sharing, and/or redistribution of waiting list sizes to be more in proportion to local organ availability.

Maureen A. McBride, Mary D. Ellison, Charles F. Shield, Leah E. Bennett, H. Myron Kauffman, United Network for Organ Sharing, Richmond, Virginia

*Call Bruce -*

*Need to meet w/  
someone from operating side*

March 25, 1997

*to,*

*Call Toby re  
Tuesday meeting*

MEMORANDUM TO BRUCE REED  
CHRIS JENNINGS

FROM: BRUCE R. LINDSEY *br*

SUBJECT: LIVER ALLOCATION POLICY

As you may know, David Matter has written the President on several occasions about UNOS liver allocation policy. His first letter (copy attached) was the impetus for Secretary Shalala's decision to hold hearings on the liver allocation procedures. In response to his most recent letter (copy also attached), President Clinton has asked "What is right on the merits? Should we give to Chris Jennings to review?"

It is my understanding that in December 1996, Carol Rasco and Chris met with Watson Bell, his wife Jean Ann, and Walter Graham to discuss UNOS' position. David Matter would like to meet with the two of you to make the case for a wider geographic sharing proposal. Besides the two of you, the persons attending the meeting would include:

David Matter  
John Tisdale  
Liz Dunst  
Nancy Granese, and  
Charles Fiske

Time is of the essence because H.H.S. is currently reviewing this matter. Are the two of you available next week? If so, when. Jennifer Dudley will follow up.

Thanks.

# Withdrawal/Redaction Marker

## Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. note	Bruce Lindsey to POTUS re: Letter from David Matter (1 page)	2/97	P5

**This marker identifies the original location of the withdrawn item listed above.  
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 Box 22

---

**FOLDER TITLE:**

Organ Donations [6]

gf46

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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]

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]
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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]

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.

Rec'd 2-10-97  
10:00am

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

THE PRESIDENT  
2-19-97

February 7, 1997

**Via Facsimile: 202.456.6703  
and Federal Express**

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

Dear Mr. President:

I'm terribly sorry to add to your unbelievably crowded agenda, but we're at a critical point in the liver transplantation debate within HHS and I'm afraid if we don't act now we may forever lose the opportunity.

As you know, my letter to you on this subject last fall eventually led to three days of public hearings conducted by HHS in December. Donna Shalala promised in her response to me on your behalf to determine on the basis of the public hearings which liver allocation policies promised the best results for the patients of America and to embody that decision in a final rule for submission to OMB.

Simply stated, my fear is that because there are many more small transplant centers than large and each of them has lobbied their Congressmen and Senators in opposition to a policy change and even to HHS's intervention, the Department is beginning to get "cold feet."

After having studied this issue in great detail over the past year, there is absolutely no doubt in my mind that the position of the University of Pittsburgh Medical Center (and several other large transplant hospitals) is the correct one. Allocating livers to the sickest patients first on the widest geographic basis possible is what our national policy should be with respect to the allocation and distribution of human livers.

President William J. Clinton

February 7, 1997

Page 2

The private contractor, the United Network on Organ Sharing (UNOS), hired by HHS to operate the organ procurement and transplantation network, is by any other name a trade association controlled by small transplant centers (one center, one vote) operating largely on the basis of self-interest. If they were steel producers or communications executives sitting around the table carving-up the market, the federal government would intervene in a heartbeat. Because they are "medical professionals" HHS seems reluctant to intervene. But if it doesn't no one will, and patients will continue to suffer the consequences.

The facts, as I see them, are pretty clear. HHS has in the past essentially relinquished its oversight and regulatory responsibility with respect to organ procurement, allocation and transplantation to an industry trade group incapable of making a decision without an inherent conflict of interest. UNOS has established liver allocation rules that literally trap organs within artificial geographic boundaries, which has had two profound effects: 1) patients with liver disease who are not hospitalized and are in relatively better health often receive livers in one region when just an hour away by plane a patient lies dying in intensive care; and 2) the number of liver transplant programs has nearly doubled to 119 today, i.e. new programs can start because they know they will have a reliable and predictable supply of organs. It doesn't matter how proficient they are at transplantation or whether having such a large number of centers is an efficient and effective way to deliver health care.

Each of these centers, no matter how few transplants they do or how awful their success rates may be, have the same voice and vote in UNOS as does a major, highly proficient center that does 100 or more transplants a year. Decisions are made by majority vote, so the system will never be changed by a trade association the majority of whose memberships may be disadvantaged by a change. Meanwhile, 50-100 people die unnecessarily each year from liver disease; 2,000 patient life years are lost; and, horrifically unequal waiting times for transplant will continue.

I have enclosed copies of the five part series on organ transplantation published earlier this week in the Cleveland Plain Dealer. They are extraordinarily well-researched and a very important

President William J. Clinton

February 7, 1997

Page 3

contribution to the national debate. After reading them, I believe, any fair-minded person would conclude that the system is broken, UNOS does not represent the interests of patients very well, and the federal government has not properly performed its regulatory and oversight role. Although the articles are quite lengthy, I've included them in their entirety and have highlighted several relevant paragraphs in each for easy reference (the first such notation appears on page 11).

I don't want in any way to abuse our friendship over a substantive policy issue, but I feel so strongly about this that I just had to bring it to your attention again with a personal letter. Initially I was dragged into this debate quite reluctantly, but as time has gone on I have come to realize that it may be the most important thing I've done in my life. I'm sorry for the length of this letter and for imposing on you again, but I don't know where else to turn.

Regards,

A handwritten signature in cursive script, appearing to read "Bill Clinton", is written next to a large, hand-drawn oval that encloses the first few letters of the name.



February 21, 1997

Department of Surgery  
Division of Transplantation

Kevin L. Thurm  
Deputy Secretary  
Department of Health and Human Services  
200 Independence Avenue, S.W., Room 615-G  
Washington, DC 20201

Dear Mr. Secretary:

I understand that your Department is now in the process of formulating policies related to the allocation of human livers for transplantation. As you know, I participated in the December 10-12, 1996, public hearings on this subject, and I would like to share with you some concerns about a presentation by a witness associated with those centers seeking substantial policy changes.

I am referring to Dr. Mark A. Joensen, Ph.D., of the CONSAD Research Corp., an analytic firm under contract with the University of Pittsburgh (UPMC). Dr. Joensen indicated that the CONSAD analysis had identified an allocation methodology that was superior to current procedures. I disagree strongly with this characterization. Rather, it is my view that CONSAD shaped their results by adopting certain underlying assumptions that Dr. Joensen did not fully explicate during his presentation. Further, I believe that once these assumptions are fully understood, an accurate view of the CONSAD analysis is that it does not differ materially from the computer modeling conducted by UNOS.

Let me explain. In discussions held at the law firm of Hogan and Hartson, during the winter of 1996, Dr. Mark A. Joensen, Ph.D., admitted the Pritsker/UNOS computer model and CONSAD's model are equivalent, (using the same inputs and assumptions about donors and patients, the outputs would be the same). Therefore, why is there a difference between the two models? The reason lies in assumptions made about both pre-transplant and post transplant patients. CONSAD's model places high value on 1.) life years saved 2.) Pre/post transplant deaths 3.) equalizing waiting times for patients, whereas the Pritsker/UNOS places value on 1.) total patients transplanted 2.) percent patients surviving 2 years post transplant 3.) post transplant life years saved.

I believe the assumptions made by CONSAD/UPMC in their model are flawed. Unfortunately, UPMC believes all patients who are status 3 (at home, not continually hospitalized) do not need a transplant. If this is so, how do we account for both the mortality and number of patients in this group which move up to a higher status to be transplanted? Data presented by UPMC at the Consensus Conference on Indications of Liver Transplantation, Paris, France, June 1993 clearly shows that 60% of patients initially listed at the lowest priorities (at home, elective transplant, at home requiring sporadic care) become more ill and were transplanted at a higher status. In addition, in their own data, 17% of patients not continuously hospitalized died while waiting. While 56% of patients in the lowest priority were alive without transplantation, a large portion (36%) required transplantation to ensure survival. Comparing patient survival, without transplantation, in the lowest priority group to patient and graft survival post transplant, in the same groups, UPMC concluded that transplantation was not beneficial. I believe that it is important to realize that all patients within a group are not equal. It is incorrect and inappropriate to compare survival between those patients who are felt to require transplantation, to ensure survival, and those who do not require transplantation for survival.

The University of Alabama at Birmingham  
748 Lyons-Harrison Research Building • 701 South 19th Street  
Birmingham, Alabama 35294-0007 • (205) 934-7714 • FAX (205) 934-8378



Feb. 21, 1997

Page 2

UPMC also states that many of these patients could be treated by other means, avoiding transplantation. It is impossible to compare patients involved in the studies, cited by UPMC, to patients on the waiting list due to the different natures and degrees of disease. It is hoped that consideration would be given to other treatment modalities, avoiding transplantation if possible, before listing a patient for transplantation - this is the process that is used at our center and at other centers.

UPMC places an extremely high value on transplanting the sickest patient first and "life years saved" by transplanting these patients. For instance, UPMC believes that the "life years" of a patient with 100% chance of dying within 30 days without a transplant are more valuable than a patient with only a 50% chance of dying within 360 days. This would be true if all of the variables were equal, but unfortunately they are not. Most specifically, survival post transplant and the need for retransplant are quite different for the patients described above. These variables, do and should, play an important role in a physician's decision about the appropriateness of transplantation in each of these patients.

I believe UNOS has taken the most logical course, attempting to maximize utilization, in light of the current shortage of organs. If the shortage of organs did not exist, then we could transplant any and all patients, within our financial means, without respect for risk factors/post transplant survival. Unfortunately, this is not the case and we are left with difficult decisions about who will have the chance to be transplanted and who will not.

The most important information which was released at the hearings, by UNOS, was that which showed the results of increasing donors per million by only a few over the present rate. This is where the real answer lies to this problem, but unfortunately is lost over arguing how to divide the pie, rather than working to increase the overall size of the pie.

While at the public hearings on December 10, I also heard a number of other instances where I felt witnesses reached conclusions that were not fully supported by the substantive content of their presentations. However, I thought the CONSAD example was of particular concern because several of the DHHS panel members seemed, during the question period, to have accorded it considerable significance. I hope this information is helpful. Please give me a call if you would like to discuss this or other subjects in more detail.

Sincerely,



J. Stevenson Bynon, Jr., M.D., FACS  
Assistant Professor of Surgery  
Director, Liver Transplant Program

## **LETTERS OF SUPPORT FROM CONGRESS**

**Representative Henry A. Waxman (D-CA-29)**

**and Representative John D. Dingell (D-MI-16)**

**Senator Edward M. Kennedy (D-MA)**

**and Representative Joseph M. Moakley (D-MA-9)**

**Representative Mike Doyle (D-PA-18)**

**Representative Phil English (R-PA-21)**

**Representative Martin Frost (D-TX-24)**

**Representative James C. Greenwood (R-PA-8)**

**Representative Frank Mascara (D-PA-20)**

**Representative John P. Murtha (D-PA-12)**

**Representative William J. Coyne (D-PA-14)**

**Representative Alan B. Mollohan (D-WV-1)**

**Senator John D. Rockefeller IV (D-WV)**

**Senator Rick Santorum (R-PA)**

**Senator Arlen Specter (R-PA)**

**Congress of the United States**  
**House of Representatives**  
**Washington, D.C. 20515**

January 13, 1997

The Honorable Donna E. Shalala  
Secretary of Health and Human Services  
Department of Health and Human Services  
200 Independence Avenue, S.W.  
Washington, D.C. 20202

Dear Secretary Shalala:

We want to commend you, and the Administration, for the approach you have taken recently toward implementing a national policy for allocation of human organs that is consistent with the requirements and goals of the National Organ Transplant Act of 1984. The public meetings convened by the Department of Health and Human Services last month provided an essential opportunity for participation by a broad spectrum of interested parties in the process of setting this critically important policy.

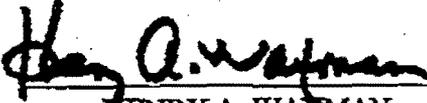
Both public input and a significant leadership role for the National Organ Procurement and Transplantation Network contractor are envisioned by the statute. However, the statute also clearly provides the Secretary of Health and Human Services with the authority to use an appropriate public process, including rulemaking, to secure consensus among patients and families, physicians and transplant centers, organ procurement organizations, the national network, and others directly affected by this policy and to ensure uniform and equitable enforcement, which protects the interests of the public, across the country. Your public meetings are a first step in assuring that the national policy will accomplish its most important objective -- availability of organs to patients whose lives depend on it.

We urge you to proceed toward conclusion of this process as expeditiously as possible, keeping in mind both the importance of the national network in policy development and implementation of the public's need and right to be involved.

The Honorable Donna E. Stalala  
Page 2

Thank you for your good work.

Sincerely,



---

HENRY A. WAXMAN  
RANKING MEMBER  
COMMITTEE ON GOVERNMENT  
REFORM AND OVERSIGHT



---

JOHN D. DINGELL  
RANKING MEMBER  
COMMITTEE ON COMMERCE

PHIL ENGLISH  
21ST DISTRICT, PENNSYLVANIA

WAYS AND MEANS  
COMMITTEE

SUBCOMMITTEES:  
HUMAN RESOURCES  
SOCIAL SECURITY



## Congress of the United States

House of Representatives

Washington, DC 20515-3821

January 2, 1997

The Honorable Philip R. Lee, M.D.  
Assistant Secretary for Health  
U.S. Department of Health and Human Services  
200 Independence Avenue, S.W.  
Washington, DC 20201

PLEASE REPLY TO:

- 1721 LONGWORTH BUILDING  
WASHINGTON, DC 20515-3821  
(202) 225-5408
- MODERN TOOL SQUARE  
310 FRENCH STREET, SUITE 107  
ERIE, PA 16507-1543  
(814) 456-2038
- CITY ANNEX BUILDING  
900 N. HERMITAGE ROAD, SUITE 6  
HERMITAGE, PA 16148-3243  
(412) 342-6132
- 305 CHESTNUT STREET  
MEADVILLE, PA 16335-3207  
(814) 724-8414
- 327 N. MAIN STREET  
BUTLER, PA 16001-4918  
(412) 285-7005

Dear Dr. Lee,

I wanted to contact you to share my views on the issue of medical criteria for liver allocation. I realize the deadline for comment was December 13, however, I was unable to address this issue until now. I hope you will accept my views however outdated.

As you know, recent changes in the medical criteria for liver allocation passed by the United Network for Organ Sharing (UNOS), the government transplant contractor, have intensified the national debate over to whom a scarce national resource should be given and who should determine the policy. I believe that patient needs and benefit should be the standards for a national allocation policy. Patients who are critically ill in need of a transplant pray the policy will work for them.

The National Organ Transplant Act of 1984 (NOTA) stated the intention of Congress to create a national list and national system to ensure equity and fairness for the patients of America needing organ transplants. The legislative history at the time the law was passed, a General Notice from the Department in the December 18, 1989, *Federal Register*, the Notice of Proposed Rulemaking in the September 8, 1994, *Federal Register*, and the various House and Senate NOTA Reauthorization bills specifically or implicitly refer to the regulatory and oversight roles of the Department of Health and Human Services over transplantation policy.

I support the public-private partnership between the federal government and the professional transplant community set forth in NOTA as the appropriate mechanism for developing transplant policy.

The Board of UNOS recently provided its collective judgement on the medical criteria for allocation. I agree with the plan of the Department of Health and Human Services to conduct public hearings and to issue an allocation rule incorporating these medical criteria according to the Department's view of what would most benefit the patients of America.

I urge the Department to select an allocation policy that will save as many patient lives as possible, equalizing their waiting times, and transplant sicker patients before less ill patients. Thank you for your consideration of these views.

Sincerely,



Phil English  
Member of Congress

**MARTIN FROST**  
24th District, Texas

RULES COMMITTEE

**Congress of the United States**  
**House of Representatives**  
Washington, DC 20515

WASHINGTON OFFICE:  
2458 Rayburn House Office Building  
Washington, DC 20515  
(202) 225-3605

March 13, 1997

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

Dear Madame Secretary:

I am writing to urge you to exercise your authority to establish an equitable national system for the allocation and distribution of human organs for transplantation which will best serve this nation's citizens, based on medical necessity.

As I understand it, the current allocation policy, established by the HHS contractor, United Network for Organ Sharing (UNOS) gives primacy to location regionally and then finally nationally. This policy does not guarantee that the patients with the greatest medical need receive organs. Instead, an individual who is in less need may receive an organ, while others, in more dire medical need, wait, simply because of geography.

According to a recent series of articles in the Cleveland Plain Dealer, the median waiting times for a liver transplant can vary from as 18 to as many as 648 days, depending on which transplant center waiting list a patient is on. This appears to run contrary to the mandate in the National Organ Transplant Act of 1984 which directed that a system be established to assure that all citizens have equal access to transplants, regardless of where they live or where they choose to be transplanted.

Of equal concern are the nation's servicemen and veterans. Active servicemen are limited to San Antonio, Texas and Washington D.C. for transplants. Veterans are limited to Portland, Oregon and Pittsburgh, Pennsylvania for transplants. Because of the current geographic based system, they are thus severely disadvantaged in their waiting times.

Please reply to office checked

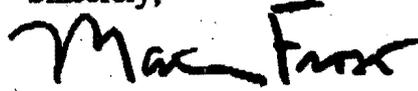
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1-800-848-8213

Dallas, TX 75208  
 400 S. Zang Blvd., Suite 506  
(214) 948-3401  
1-800-937-2056

Corsicana, TX 75110  
 100 N. Main, Suite 594  
(903) 874-0780  
1-800-292-4423

I encourage HHS should adopt a system to mandate the broadest possible sharing of livers, with as equitable distribution of waiting times as possible. The organ allocation system should serve the needs of patients rather than the dictates of geography.

Sincerely,

A handwritten signature in black ink that reads "Martin Frost". The signature is written in a cursive, slightly slanted style.

MARTIN FROST  
Member of Congress

MF:jmk

JAMES C. GREENWOOD  
8TH DISTRICT, PENNSYLVANIA

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LANGHORNE, PA 19047  
(215) 752-7711

February 11, 1997

The Honorable Philip R. Lee, M.D.  
Assistant Secretary for Health  
U.S. Department of Health and Human Services  
200 Independence Avenue, SW  
Washington, DC 20201

Dear Dr. Lee:

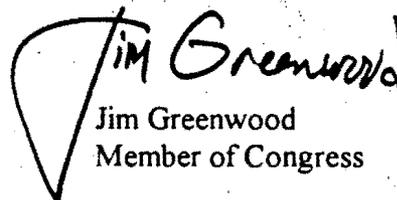
As a Member of the Pennsylvania Congressional delegation, I join with many of my colleagues who have already expressed their views with you regarding recent changes in the medical criteria for liver allocation. I realize the deadline for comment was December 13, and hope that you will accept my views however outdated.

I am concerned with the recent changes in the medical criteria for liver allocation passed by the United Network for Organ Sharing (UNOS). While the UNOS Board has submitted its plan, it is the Department of Health and Human Services which should set organ allocation policy. That policy should serve the interests and needs of the patients first. I urge the Department of Health and Human Services to exercise its role as the proper federal authority to set liver allocation policy over that of a private contractor.

The policy should be one that saves the most lives, most effectively equalizes waiting times for organs, and transplants sicker patients before less ill patients. Given that Pennsylvania is home to several notable transplant centers, I strongly urge the Department to select an allocation policy accordingly.

Thank you for your consideration of these views. Please keep me apprised of your intentions, as I have many constituents whose lives are riding on your decision to improve upon the "new" allocation process.

Sincerely,

  
Jim Greenwood  
Member of Congress

FRANK MASCARA  
20TH DISTRICT, PENNSYLVANIA1531 LONGWORTH HOUSE OFFICE BUILDING  
WASHINGTON, DC 20515  
(202) 225-4665

**Congress of the United States**  
**House of Representatives**  
Washington, DC 20515-3820

TRANSPORTATION AND  
INFRASTRUCTURE COMMITTEE  
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PUBLIC BUILDINGS  
AND ECONOMIC DEVELOPMENT

VETERANS' AFFAIRS COMMITTEE  
EDUCATION, TRAINING, EMPLOYMENT  
AND HOUSING

December 12, 1996

Philip R. Lee, M.D.  
Assistant Secretary For Health  
Health and Human Services  
Hubert H. Humphrey Building  
200 Independence Avenue S.W.  
Washington, D.C. 20201

Dear Doctor Lee:

As a Member of the Pennsylvania Congressional delegation, I wish to share my views with you regarding an issue of the greatest importance to the University of Pittsburgh Medical Center.

Recent changes in the medical criteria for liver allocation passed by the United Network for Organ Sharing (UNOS), the government transplant contractor, have intensified the national debate over to whom a scarce national resource should be given and who should determine the policy. I believe that patients needs and benefit should be the standards for a national allocation policy. Patients who are critically ill and in need of a transplant certainly pray the policy will work for them.

The National Organ Transplant Act of 1984 (NOTA) (Public Law 98-507) stated the intention of Congress to create a national list and national system to ensure equity and fairness for the patients of America needing organ transplants. The legislative history at the time the law was passed, a General Notice from the Department in the December 18, 1989 *Federal Register*, and Notice of Rule Proposed Rulemaking in the September 18, 1994 *Federal Register*, and the various House and Senate NOTA reauthorization bills specifically or implicitly refer to the regulatory and oversight roles of the Department of Health and Human Services over transplantation policy.

I support the public-private partnership between the Federal government and the professional transplant community set forth in NOTA as the appropriate mechanism for developing transplant policy.

DISTRICT OFFICES

(800) 213-5570

Greene Co. Ofc. Bldg.  
93 E. High St. Rm. 303  
Waynesburg, PA 15370  
(412) 852-2182

47 East Penn Street  
Uniontown, PA 15401  
(412) 437-5078

98 North Main Street  
Washington, PA 15301  
(412) 228-4328

3093 Washington Pike  
Bridgeville, PA 15017  
(412) 220-9046

Municipal Bldg. Room 103  
334 Fallowfield Avenue  
Charlottesville, PA 15022  
(412) 483-8016

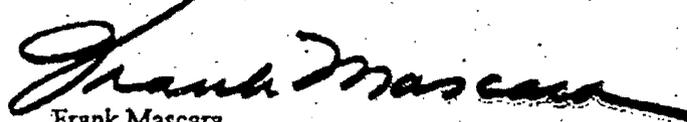
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Page 2

The Board of UNOS recently provided its collective judgment on the medical criteria for allocation. I agree with the plan of the Department of Health and Human Services to conduct public hearings and to issue an allocation rule incorporating these medical criteria according to the Department's view of what would benefit the patients of America.

I urge the Department to select an allocation policy which will save as many patients as possible, equalize their waiting times, and transplant sicker patients before less ill patients. Thank you for your consideration of my views.

Very truly yours,



Frank Mascara  
Member of Congress

FM:bml

**MARTIN FROST**

24th District, Texas

WASHINGTON OFFICE:

2459 Rayburn House Office Building

Washington, DC 20515

(202) 225-3605

**Congress of the United States****House of Representatives****Washington, DC 20515**

RULES COMMITTEE

March 13, 1997

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

Dear Madame Secretary:

I am writing to urge you to exercise your authority to establish an equitable national system for the allocation and distribution of human organs for transplantation which will best serve this nation's citizens, based on medical necessity.

As I understand it, the current allocation policy, established by the HHS contractor, United Network for Organ Sharing (UNOS) gives primacy to location regionally and then finally nationally. This policy does not guarantee that the patients with the greatest medical need receive organs. Instead, an individual who is in less need may receive an organ, while others, in more dire medical need, wait, simply because of geography.

According to a recent series of articles in the Cleveland Plain Dealer, the median waiting times for a liver transplant can vary from as 18 to as many as 648 days, depending on which transplant center waiting list a patient is on. This appears to run contrary to the mandate in the National Organ Transplant Act of 1984 which directed that a system be established to assure that all citizens have equal access to transplants, regardless of where they live or where they choose to be transplanted.

Of equal concern are the nation's servicemen and veterans. Active servicemen are limited to San Antonio, Texas and Washington D.C. for transplants. Veterans are limited to Portland, Oregon and Pittsburgh, Pennsylvania for transplants. Because of the current geographic based system, they are thus severely disadvantaged in their waiting times.

Please reply to office checked

Fort Worth, TX 76140  
 3020 S.E. Loop 820  
 (817) 293-8231  
 1-800-846-8213

Dallas, TX 75208  
 400 S. Zang Blvd., Suite 506  
 (214) 948-3401  
 1-800-937-2056

Corpusano, TX 75110  
 100 N. Main, Suite 534  
 (903) 874-0760  
 1-800-292-4423

I encourage HHS should adopt a system to mandate the broadest possible sharing of livers, with as equitable distribution of waiting times as possible. The organ allocation system should serve the needs of patients rather than the dictates of geography.

Sincerely,

A handwritten signature in black ink that reads "Martin Frost". The signature is written in a cursive, slightly slanted style.

MARTIN FROST  
Member of Congress

MF:jmk

Congress of the United States  
House of Representatives

Washington, DC 20515-3812

December 13, 1996

The Honorable Philip R. Lee, M.D.  
Assistant Secretary for Health  
U.S. Department Of Health and Human Services  
200 Independence Ave SW  
Washington, D.C. 20201

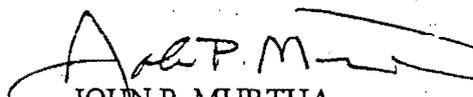
Dear Dr. Lee:

I am writing out of concern over the recent changes made in the criteria for liver transplant allocation by the United Network for Organ Sharing (UNOS) and the anticipated issuance of an allocation rule by the Department of Health and Human Services early next year.

While the UNOS Board has submitted its plan, it is the Department of Health and Human Services who should set organ allocation policy. That policy should serve the interests and needs of the patients first. I therefore urge the Department of Health and Human Services to exercise its role as the proper federal authority to set liver allocation policy over that of a private contractor. The policy should be one that saves the most lives, most effectively equalizes waiting times for transplants and allocates organs according to level of medical urgency of the patient's need for a transplant.

Thank you for your consideration in this matter.

Sincerely,

  
JOHN P. MURTHA  
YOUR CONGRESSMAN

JPM:dt

WILLIAM J. COYNE  
PENNSYLVANIA  
14TH DISTRICT

COMMITTEE ON  
WAYS AND MEANS

SUBCOMMITTEE:  
TRADE

COMMITTEE ON  
THE BUDGET

COLEMAN J. CONROY  
ADMINISTRATIVE ASSISTANT



Congress of the United States  
House of Representatives  
Washington, DC 20515-3814

WASHINGTON OFFICE:  
2455 RAYBURN HOUSE OFFICE BUILDING  
WASHINGTON, DC 20515-3814  
(202) 225-2301

DISTRICT OFFICE:  
2009 FEDERAL BUILDING  
1000 LIBERTY AVENUE  
PITTSBURGH, PA 15222  
(412) 644-2870

December 12, 1996

The Honorable Philip R. Lee, M.D.  
Assistant Secretary for Health  
U.S. Department of Health and Human Services  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

Dear Dr. Lee:

I wish to share my views with you regarding an issue of great importance. Recent changes in the medical criteria for liver allocation passed by the United Network for Organ Sharing (UNOS), the government transplant contractor, have intensified the national debate over to whom a scarce national resource should be given and who should determine the allocation policy. I believe that patient needs and benefit should be of paramount concern in our country's organ allocation policy.

The National Organ Transplant Act of 1984 (NOTA)(P.L. 98-507) set forth the intention of the Congress to create a national system to ensure equity and fairness for the patients of America needing organ transplants. The legislative history at the time the law was passed, including a General Notice from the Department in the December 18, 1989 *Federal Register*, the Notice of Proposed Rulemaking in the September 8, 1994 *Federal Register*, and the various House and Senate NOTA Reauthorization bills specifically or implicitly refer to the regulatory and oversight roles of the Department of Health and Human Services over transplantation policy.

I support the public-private partnership between the federal government and the professional transplant community set forth in NOTA as the appropriate mechanism for developing transplant policy. Further, I agree with the Department of Health and Human Services' plan to conduct public hearings and then to issue an allocation regulation that incorporates UNOS' medical criteria for allocation along with the Department's view of what will most benefit the patients of America.

The Honorable Philip R. Lee, M.D.  
December 12, 1996  
Page Two

I strongly urge the Department to select an allocation policy that will save as many patient lives as possible, equalize their waiting times for organs, and transplant sicker patients before less ill patients. Thank you for your consideration of these views.

With all best wishes, I am

Sincerely,

A handwritten signature in cursive script that reads "William J. Coyne".

William J. Coyne  
Member of Congress

WJC:ar

03/18/97 TUE 08:13 FAX 4123852000

D E A W

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APPROPRIATIONS  
COMMITTEE  
SUBCOMMITTEE ON COMMERCE, JUSTICE,  
STATE & FOREIGN AFFAIRS  
SUBCOMMITTEE ON VA, HUD &  
INDEPENDENT AGENCIES  
BUDGET COMMITTEE  
CONGRESSIONAL STEEL CAUCUS  
EXECUTIVE COMMITTEE

ALAN D. MOLLOHAN  
1ST DISTRICT, WEST VIRGINIA

Congress of the United States  
House of Representatives

March 17, 1997

2427 RAYBURN HOB  
WASHINGTON, D.C. 20513-8001  
(202) 225-2172  
FAX (202) 225-7284

DISTRICT OFFICES:  
ROOM 208, POST OFFICE BUILDING  
P.O. BOX 1400  
CLARKSBURG, WV 26303-1400  
(304) 823-4444

ROOM 12, OLD CITY HALL BUILDING  
300 SPRUCE STREET  
MORGANTOWN, WV 26502-3803  
(304) 252-3018

ROOM 4311, FEDERAL BUILDING  
P.O. BOX 148  
PARKERSBURG, WV 26102-0148  
(304) 424-6403

ROOM 315, FEDERAL BUILDING  
1125 CHARLIE STREET  
WHEELING, WV 26003-2900  
(304) 232-5330

The Honorable Donna E. Shalala  
Secretary  
Department of Health and Human Services  
200 Independence Avenue, Sw  
Room 615 F  
Washington, DC 20201

Dear Secretary Shalala:

I want to take this opportunity to express my concern with the policy recently adopted by the United Network for Organ Sharing (UNOS) regarding national liver allocation. As a member of the House Veterans Affairs Appropriations Subcommittee, I am particularly concerned with how this policy affects Veterans.

As you may know, Veterans are particularly impacted by the current policy, as those in need of a liver transplant are limited to only two transplant facilities, one located in Pittsburgh, Pennsylvania and the other in Portland, Oregon. They have no other options. With the proliferation of more than 100 small, regional transplant centers, this means that there are fewer organs available for Veterans in need of transplants. Many Veterans are among the sickest patients, and under the current UNOS policy, many Veterans will needlessly continue to die while waiting for a liver.

In 1984, Congress passed the National Organ Transplant Act (NOTA) in order to create a national list and national system that was fair and equitable to those in need of organ transplants. Under NOTA, the Department of Health and Human Services was to have an integral role in developing a national transplant policy as well as corresponding regulations.

The present UNOS policy is unfair and misdirected and consequently should be reexamined. The policy places regional and local interests over the needs of the nation's sick. For these reasons, I urge the Department of Health and Human Services to issue final rule on liver allocation incorporating the medical criteria established by the Organ Procurement and Transplantation Network (OPTN).

An allocation policy that emphasizes saving patients' lives by equalizing patient waiting times, and allowing sicker patients

03/18/97 TUE 08:13 FAX 4123552608

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The Honorable Donna E. Shalala  
March 17, 1997  
Page 2

to receive transplants before less ill patients, is far superior to a policy based solely on geographic considerations.

Thank you for your attention to this matter, and please do not hesitate to contact me if I can provide additional information in this regard.

Most sincerely,



Alan B. Molichan

ABM:cl

JOHN D. ROCKEFELLER IV  
WEST VIRGINIA

## United States Senate

WASHINGTON, DC 20510-4802

March 12, 1997

Dear Secretary *Donna* Shalala,

As ranking minority member of the Subcommittee on Health Care of the Senate Finance Committee and the Senate Veterans Affairs Committee, I am writing in support of your decision to conduct a review of our current policy governing the allocation of human organs under the National Organ Transplant Act (NOTA) of 1984.

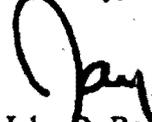
The 1984 Transplant Act recognized uniform federal regulation was the best way to eliminate the potential for bias and favoritism in the allocation of scarce life saving organs. To that end, national policy is supposed to ensure equal access to transplants to all citizens of similar health status, regardless of where they live. The current geographic based allocation system does not appear to meet that test. As I understand it, the median waiting time for liver transplants can vary from as few as 18 to as many as 648 days, depending on which transplant waiting list a patient is on. Some difference in waiting periods based on location is probably unavoidable, but a disparity of this magnitude obviously raises basic questions of fundamental fairness.

Moreover, since veterans are currently limited to only two transplant centers, they are particularly disadvantaged by the current geographic based system and do not have the ability to "center shop."

The statute gives you the authority to employ rulemaking to ensure uniform and equitable application of the policy.

I urge you to proceed as expeditiously as possible and look forward to working with you on this matter.

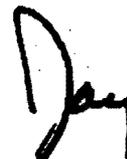
Sincerely,



John D. Rockefeller IV

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

*Interesting policy involved  
in this.*



# United States Senate

WASHINGTON, DC 20510-3804

202-224-6324

January 30, 1997

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

Dear Secretary Shalala:

In a letter dated December 13, 1996, I wrote to Ms. Judith Braslow of the Health Resources and Services Administration expressing my strong interest in being kept informed about the liver allocation regulatory process underway in the Department of Health and Human Services.

I write as a follow up to reiterate my support for the oversight roles of the Department in setting national transplant policy, based on the public-private partnership of HHS and the OPTN. Once medical criteria for allocation have been established by the OPTN--as authorized in the National Organ Transplant Act--and with input from transplant patients, I believe the Department should take a much greater role in liver allocation policy making.

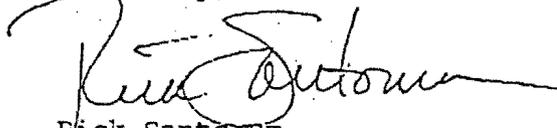
For some time, I have been concerned with the allocation policy UNOS established in 1991--where livers are first distributed downward through the Status structure locally, second regionally, and finally on a national basis. This policy has failed to ensure an adequate supply of livers to patients with the greatest medical need, regardless of where they are located. I understand that waiting times vary greatly, from 21 days in Kansas, to 200 in Pennsylvania, to 600 days in Massachusetts. Very few policies directly control the life and death of American citizens, as does the allocation policy. The current policy, developed by a private organization, literally determines which patients will live and die. Human organs are too precious and scarce a human

resource to be allocated by a private contractor without government oversight of the policy.

I also am concerned with decisions the UNOS Board made in November 1996. Specifically, UNOS announced plans to transfer patients with long-standing, chronic liver problems from Status One to Status Two, effective January 20. The rationale behind this policy is reportedly to allocate available livers to those patients with the best chance for long-term survival, based on the assumption that acute patients enjoy significantly better survival rates from transplant, versus chronic patients. I understand, however, that acute patients have only a 10 percent higher survival rate than chronic patients. I believe that a 10 percent difference in survival rates may not justify a policy restricting access to livers for those most in need. Nor is the 10 percent threshold consistent with other UNOS policies: to cite just one example, female heart-lung transplant patients have a 15 percent better survival rate than males, yet UNOS does not allocate organs accordingly.

The reports I have received regarding the patient and family testimony at the recent HHS hearings reinforced the concerns expressed above. I hope that the Department will strongly consider their testimony when deciding on a liver allocation policy. Thank you for your consideration.

Sincerely,

A handwritten signature in black ink, appearing to read "Rick Santorum", with a long horizontal flourish extending to the right.

Rick Santorum  
United States Senate

cc: Ms. Judith Braslow  
HHS/Social Security Liaison Office

United States Senate

WASHINGTON, DC 20510-3804

202-224-6324

December 13, 1996

Ms. Judith Braslow  
Director of Transplant Division  
U.S. Department of Health and Human Services  
200 Independence Ave. SW  
Washington, DC 20201

Dear Ms. Braslow,

I understand the Department of Health and Human Services is currently conducting public hearings and accepting public comments regarding liver allocation policy as established by the United Network of Organ Sharing (UNOS).

The National Organ Transplant Act of 1984 (NOTA) created a system to ensure equity in allocation for patients needing organ transplants. I recognize that the regulatory and oversight roles of the Department of Health and Human Services over transplantation policy has been referenced in past legislative actions, such as NOTA reauthorization bills. I support the public-private partnership between HHS and UNOS set forth in NOTA as the appropriate mechanism for developing transplant policy.

Given that Pennsylvania is home to several notable transplant centers, I would like to stay abreast of the situation. Please keep me apprised of these proceedings and any policy adjustments that may result. Additionally, in light of my ongoing interest in this issue, I look forward to actively participating in future NOTA reauthorization and congressional oversight.

Thank you for keeping me informed on the progress of the hearings and any policy determinations regarding liver allocation.

Sincerely,



Rick Santorum  
United States Senate

cc: HHS/Social Security  
Liaison Office

TED STEVENS, ALASKA, CHAIRMAN

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STEVEN J. CORTESE, STAFF DIRECTOR  
 JAMES H. ENGLISH, MINORITY STAFF DIRECTOR

## United States Senate

COMMITTEE ON APPROPRIATIONS  
 WASHINGTON, DC 20510-6025

February 7, 1997

Philip R. Lee, M.D.  
 Assistant Secretary for Health and Science  
 U.S. Department of Health and Human Services  
 200 Independence Avenue, SW  
 Washington, DC 20201

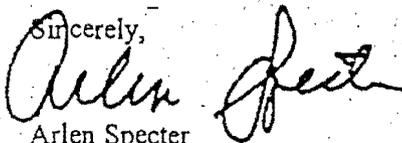
Dear Dr. Lee:

The University of Pittsburgh Medical Center remains deeply concerned about current policies on liver transplant allocation. UPMC believes that the new policy implemented January 20, 1997, by the United Network for Organ Sharing significantly reduces the opportunity for a wider distribution of organs. I understand that you, prior to your departure from the department, are weighing the medical evidence and other major factors to determine whether the current policy ought to be changed. I strongly urge you to carefully weigh the points that UPMC have raised in the department's public hearing at NIH. Because of the utmost importance of saving as many lives as feasible, I believe UPMC's concerns deserve a comprehensive consideration.

I wish you well as you return to private life.

My best.

Sincerely,



Arlen Specter

Chairman, Subcommittee on Labor, Health and  
 Human Services, Education and Related Agencies

**LETTERS OF SUPPORT**

**Baylor Health Care System  
Howard University Hospital  
University of Nebraska Medical Center**



BAYLOR HEALTH CARE SYSTEM

February 20, 1997

Boone Powell, Jr., F.A.C.H.E.  
President

Secretary Donna Shalala  
Department of Health and Human Resources  
200 Independence Ave., S.W.  
Suite 615 F  
Washington, D.C. 20201

Dear Secretary Shalala:

I am forwarding to you a copy of an opinion editorial on the need for change in the current organ allocation system written by Goran B. Klintmalm, M. D., the director of the Baylor Institute of Transplantation Sciences. The opinion editorial is to be published in the Austin American Statesman in the next few days. I wanted you to have this because Dr. Klintmalm has clearly articulated an issue that desperately needs your attention and support for change.

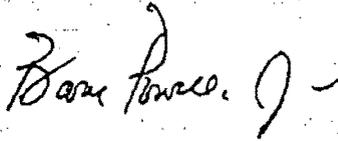
I know your staff has been working on developing new guidelines for allocating livers in the United States and on what the role of the United Network for Organ Sharing will be in setting future policies. I wanted to take this opportunity to go on record with you as a strong proponent for change in the current system and to urge you and your staff to remain steadfast in pursuing what is right for patients.

Organs are a national resource and should be distributed as such. Patients in need of a liver, or any organ, should have an equal chance of receiving that organ no matter where they chose to go for care. The current allocation system is directly opposed to this principle and had been promulgated by a group of individuals whose self-interest should automatically eliminate them from participating in such a decision.

I don't want to belabor this issue because I know you have been inundated by opinions on the organ allocation system and I am in total agreement with the enclosed editorial. I hope you will have time to review it. It is important to me that you know where I stand personally and that you be aware that Baylor is firmly in support of your decision to intervene and correct what is fundamentally flawed. Yours is not an easy task in the face of the pressure being placed on HHS to maintain the status quo, but I am confident that you and your staff will see through the rhetoric and posturing to the real issue of how to distribute organs to those in most need.

We are all appreciative of your attention to this problem and admire your courageousness in bringing resolution to the controversy.

Sincerely,

A handwritten signature in cursive script that reads "Boone Powell, Jr." followed by a flourish.

Boone Powell, Jr.  
President and CEO

**BAYLOR INSTITUTE OF TRANSPLANTATION SCIENCES**  
BAYLOR UNIVERSITY MEDICAL CENTER

BLOOD &amp; MARROW

• CARDIOTHORACIC

• KIDNEY

• LIVER

• PANCREAS

• SMALL BOWEL

February 26, 1997

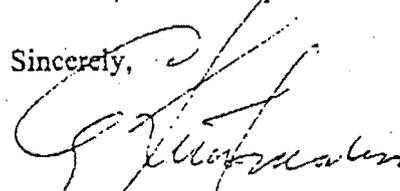
Dear Transplant Recipient:

As a liver transplant patient you should know that the Department of Health and Human Services held public hearings in December to discuss the issue of organ allocation in the United States. I testified at those hearings advocating a more fair and equitable allocation system for transplant patients on the waiting list.

Today, the system of allocating organs in the United States ignores patients' needs. Every transplant patient on the waiting list deserves a fair chance at receiving an organ regardless of where medical care is sought. Unfortunately, because of the current system, patients inevitably have to choose between a transplant center such as Baylor, a transplant center with extensive experience, expertise and excellent results, and a transplant center where organs are quickly available but medical care less well delivered.

Enclosed is an editorial I submitted to the *Austin American-Statesman* explaining my opinion on the currently allocation system and an explanation of how it can be fixed. An opinion from the Department of Health and Human Services is expected in mid-March 1997. If you would like to voice your opinions or concerns regarding the organ allocation system, please write to Secretary Donna Shalala, Department of Health and Human Services, at 200 Independence Ave., SW, Suite 615F, Washington, DC, 20201.

Sincerely,

  
Gojan Klintmalm, M.D., Ph.D.  
Chairman, Baylor Institute for Transplantation Sciences

Enclosure

## **THE ORGAN ALLOCATION SYSTEM . . . IN NEED OF CHANGE**

*by Goran Klintmalm, M.D., Ph. D.*

Transplant patients are dying needlessly due to the current way organs are allocated in the United States. I have patients needing liver transplants who have been on the waiting list for more than one year. They could have sought treatment in Shreveport or Houston where their waiting times would have been substantially shorter according to published statistics, but instead they chose a transplant center with extensive experience, expertise and consistent, successful results. And because of the complex, unfair organ allocation system they continue waiting.

Why does this inequity exist, and why should we be concerned about it? The current system of allocating organs for transplantation ignores patients' needs; however this system is fixable. Currently, transplant organs are "owned" by transplant centers within self-serving geographical boundaries without considering where the patients go to be treated. In other words, the availability of these organs depends on where treatment is sought rather than how badly or where the organ is needed.

This controversial issue poses two difficult questions for the patient with a complex and deadly disease in need of a transplant: 1) Is my priority to choose a transplant center where organs are quickly available? or 2) do I choose a transplant center where the health care and transplant expertise is superior?

While receiving an organ quickly eases the anxiety of waiting, the issue of quality medical care and experience is a matter of life or death. Out of 113 liver transplant centers

FEB 24 '97 03:55PM BONE TRANSPLANT SERV

nationwide, 25 of the largest centers (less than one quarter) perform 60 percent of all liver transplants, while half perform fewer than 12 transplants a year. The death rate at these smaller centers is 2.4 times higher than at the 25 larger centers with experience.

The fact is patients should not have to choose between the availability of organs and quality medical care, yet they are forced to do so every day. For example, at Baylor, where I am the director of transplantation sciences, our waiting list for liver transplants makes up half of all the people in Texas and Oklahoma who wait for a liver. Yet under the current system, these patients have access to only one-third of the available organs. The remaining two-thirds of all the livers donated for transplants in Texas and Oklahoma first go to centers with fewer patients awaiting transplants.

The ideal solution would be to have enough organs for every patient in need; however, because this is not the current situation, changes must be made to revamp the organ allocation system to focus on patients. No matter how we structure the allocation system, patients will die due to lack of organs. In this situation we must demand equal waiting time for every patient. Every patient should have the same chance to receive a life-saving organ regardless of where they wait for transplant -- Dallas, Houston, Shreveport or Oklahoma City.

In December 1996, the Department of Health and Human Services held public hearings that addressed the problems of patient need and organ allocation. During those hearings, patients and public representatives asked for a change in the system. Several transplant surgeons, including myself, advocated a new regional system that would send a donated organ to the patient in the greatest need, within a reasonable distance from the donor hospital.

Such a system would eliminate the patient's agonizing choice between availability of organs and quality of medical care. What's more, it would provide for a more equitable distribution of organs, so that people whose lives depend on transplants don't die waiting, while in neighboring cities less acutely ill patients are receiving transplants within shorter periods of time.

An opinion from the Department of Health and Human Services is expected in mid-March 1997. It is within their power to restructure the system and/or make recommendations to Congress that legislators would be certain to heed.

*If you would like to voice opinions or concerns regarding the organ allocation system, please write to Secretary Donna Shalala, Department of Health and Human Services, at 200 Independence Ave., SW, Suite 615F, Washington, DC, 20201.*

Clive O. Callender, M.D., F.A.C.S.  
LaSalle D. Leffall, Jr., Professor of Surgery  
Chairman, Department of Surgery  
Director, Transplant Center

January 22, 1997



Surgeon-in-Chief  
Howard University Hospital  
Washington, D.C. 20060  
(202) 865-1441  
FAX: (202) 865-5396

The Honorable Donna Shalala  
Secretary  
U.S. Department of Health and Human Services  
615F Hubert H. Humphrey Building  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

Dear Secretary Shalala:

Although I have written to you recently on the issue of liver allocation (public testimony and written comments, December 11, 1996), I feel compelled to write to you again in light of the opposition to Department rule-making by some of my transplant colleagues.

Over the years, through my participation in the OPTN and in my efforts to promote transplant objectives in the minority community, I have long held the views that OPTN policies require input from several sources: the expertise of transplant professionals; the perspectives of candidates, recipients, and their families; and the significant involvement of the Department of Health and Human Services.

My transplant colleagues have already provided their professional judgment in the establishment of medical criteria as the law provides. Although contrary to the OPTN contractor's views, the members of the patient community expressed their strong support at the DHHS hearings for a different and fairer system that would allocate organs to the patients in greatest need, regardless of their location. A broader sharing of organs as was suggested in Part E on page 2 of my testimony is likely to result in a fairer allocation of organs and was echoed by many of the patient witnesses. Reasonably broader sharing can be achieved by allocating organs first to the local status 1 and 2 patients and then to Status 1 and 2 patients nationally, before going to less sick patients. This type of allocation would preserve and elevate the medical urgency of patients and not lose the local reward to local donors. As I said in my testimony at the hearing: "...the new policy which goes into effect January 20, disadvantages the largest segment of liver patients ... who have acute exacerbations of chronic liver disease which is remediable only by performing emergency or urgent liver transplant ... this new policy, also, affects the poverty stricken minority populations who see the doctor very late in their disease, and if they are referred for liver transplantation will likely be in the category of patients with acute exacerbation of chronic illnesses and an urgent need for transplantation." The fact that such a large proportion of candidates will be disadvantaged by the liver allocation changes approved in November by the UNOS Board, to me, is a clear indication that the process currently

Letter to The Honorable Shalala  
Page two

used by the OPTN can be improved upon. A different perspective is often desirable especially the perspective presented by our patients and other users or potential users of our services. Your office's oversight and participation in the final policy making in this allocation matter are critical.

I also mentioned in my testimony that the Department should "... assist UNOS in its policy making and ... help it make the fairest decision and when it needs help to provide it in a way that best meets our national needs". The needs of transplant candidates nationally will be best served by the department's modification of the liver allocation changes approved by the UNOS Board.

I, now therefore urge you and your Departmental staff to provide the leadership on the liver allocation policy that will protect the interests of all transplant candidates and meet their needs for a fair, accessible system.

I would be happy to discuss these issues further with you and your staff should you desire it.

Sincerely,



Clive O. Callender, M.D., F.A.C.S.  
LaSalle D. Leffall, Jr. Professor  
Chairman, Department of Surgery

COC/lsp

Enclosure: pg. 2-3 of Testimony

this is not evident. African Americans comprise 12% of the American population and 35% of ESRD transplant waiting lists because they have 2 - 4 times more ESRD than Caucasians. On liver transplant waiting lists African American rarely account for more than 10% it should be more than 20%. I believe this lower number is because of a "Green Screen" which means that if one does not have the fiscal resources one will never get on the transplant waiting list. The physician will not refer this patient for liver transplant because of a lack of resources and many hospitals cannot afford to transplant such patients. They therefore die without being given the option of transplantation. This accounts for why the celebrity appears to get "favored treatment" and why the minority communities do not believe the system is "fair". It is not the allocation scheme in this instance which is unfair but the global society, which opposes the raising of taxes to make health care a right for all. I request DHHS to look into this great inequity which we must strategize to overcome as vigorously as we attack all other obstacles to successful transplantation.

C - The new policy which goes into effect January 20, 1997 disadvantages the largest segment of liver patients - those like Morgan Wooten, Governor Casey, and many others who have acute exacerbations of chronic liver disease which is remediable only by performing emergency or urgent liver transplantation.

D - this new policy also affects the poverty stricken, minority populations who see the doctor very late in their disease and if they are referred for liver transplantation will likely be in the category of patients with acute exacerbations, of chronic illnesses and in urgent need for transplantation. This includes the substance abuse patients - who when rehabilitated want to live too!

E - I favor a modification of the University of Pittsburgh Medical Center's algorithm which would offer an available liver to patients on the local list, who are the old status 1 and 2 and then to status 1 and 2 nationally and then 3 and 4 locally and then to status 3 and 4 nationally. This presumes the old status 1 - 7 classification is preserved and elevates the importance of medical urgency for all categories of patients without losing the local reward to local donors which I believe is important to not inhibit the altruistic local donors. My community presentations and the feedback received suggests this is an important stimuli to local organ donation. Liver allocation has become a mediagenic issue and what is decided here will have a tremendous influence on the number one (1) problem in transplantation today - the shortage of donors. It is important therefore to emphasize that, which is fairest to all groups is that which must be done.

I welcome the DHHS calling these public hearing to help us all do the right thing. The right thing in the case of liver allocation is to assist UNOS in its policy making and to help it make the fairest decision and when it needs help to provide it in a way that best meets our national need. This should not be to bully UNOS but to give good and appropriate oversight!

Finally, the closer we get to an equitable allocation system the louder we can speak when we go into the community to educate and empower in order to maximize community participation in all aspects of transplantation especially organ and tissue donation.

## II - Donation of organs and tissues for transplantation.

### A. The major impediments to organ donation are:

1. Inequitable organ allocation
2. Suboptimal use of the community as a change agent for organ tissue donation and transplantation.
3. Lack of optimization of community input at all levels of problem resolution, research and resource allocation.
4. Lack of transplantation awareness.
5. Religious myths and misperceptions.
6. Distrust of the health care system and health care professionals.
7. Fears that signing donor cards will lead to premature declaration of death.
8. Inadequate emphasis on behavior modification towards health promotion and disease prevention along with increasing donor card signing, family discussions and giving organ/tissues in life and after death.
9. Lack of adequate use of recipients, donors, transplant candidates as community messengers.



University  
of Nebraska  
Medical Center  
Nebraska's Health Science Center  
March 18, 1997

Office of the Chancellor  
600 South 42nd Street  
Box 986605  
Omaha, NE 68198-6605  
(402) 559-4200  
Fax: (402) 559-4396

The Honorable Donna E. Shalala  
Secretary of Health and Human Services  
Department of Health and Human Services  
200 Independence Avenue, S.W.  
Washington, D.C. 20202

Dear Secretary Shalala:

This letter is to follow-up on your meeting of March 6, 1997, with Senator Robert Kerrey of Nebraska. At this meeting, the Senator expressed concerns regarding the current system of human donor liver distribution in the United States.

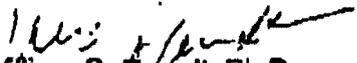
I would like to bring to your attention the letter of February 18, 1997, which was sent to you by Dr. Alan N. Langnas, Chief of Transplantation Surgery, and Marsha Morien, Associate Hospital Director of the University of Nebraska Medical Center. This letter clearly articulates our concern with regard to Section 3.0 of the Bylaws of the United Network for Organ Sharing (UNOS). This policy requires patients to be listed at the Organ Procurement Organization (OPO) contracted to the transplant center that has been selected by the patient, referring physician, or insurance company. This policy forces an OPO to deliver its primary service to the local transplantation center rather than to the population of residents in their local area who are candidates for transplantation.

I urge you and your staff to become leaders for change that will bring about a system that will be better for patients. I am in agreement with a new system that would allow a patient awaiting organ transplantation to be listed with their local OPO regardless of the transplantation center assigned to the patient. More information about how a new interpretation of existing UNOS Bylaws could make that happen is outlined in the attached letter.

I believe that the Department of Health and Human Services has the authority for oversight of the Organ Procurement Transplantation Network and has the authority to interpret UNOS Bylaws.

Your attention to this issue is greatly appreciated.

Sincerely,

  
William O. Berndt, Ph.D.  
Chancellor

enclosure

University of Nebraska - Lincoln University of Nebraska Medical Center University of Nebraska at Omaha University of Nebraska at Kearney

cc: Karen Davenport, Tabe Cohen, Alan Langnas, Marcia Morien, Bob Barlee



200  
P. 02

FAX NO: 6477852

UNMC KETC/BIONMED

03/20/97 THU 13:40 FAX 402 559 8220

MAR-25-97 TUE 11:39 AM LEGAL



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February 18, 1997

The Honorable Donna E. Shalala
Secretary of Health and Human Services
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20202

Dear Secretary Shalala:

The purpose of this letter is to request an interpretation by the Department of Health and Human Services of Section 3.0 of the Bylaws of the United Network for Organ Sharing. Section 3.0 policies apply to the allocation of organs for transplantation.

In this section of the bylaws, it states that it is the policy of UNOS to encourage cooperative working relationships within and among OPO's to serve the best interests of transplant patients. We believe that the current interpretation of this policy that requires patients to be listed at the OPO contracted to the transplant center forces an OPO to deliver its primary service to the local transplantation centers rather than to the population of residents in their local area who are candidates for transplantation.

We propose to your administration, an interpretation of existing UNOS Bylaws and policy that could allow for the direct linkage of waiting recipients to organs available regardless of their chosen or assigned transplantation center location. The definition of local would be defined by the origin or home of the waiting recipient. A patient awaiting organ transplantation would be listed with their local organ procurement organization regardless of the transplantation center assigned to or chosen by that patient. The patient would benefit from the element of service provided by the local OPO and yet have the ability to receive transplantation at any center based upon whatever reason(s) are important to the patient, his/her primary caregiver, payor, etc.

The OPO would be responsible for serving local recipients regardless of where those recipients might be listed for care. A local organ identified by the present allocation system as designated for a given locally-listed recipient would be recovered and moved to the designated transplantation center for that recipient. This would reinterpret the concept of 'local' by changing it from a geographic designator to one which identifies a group of patients for which an OPO would be responsible. This system of allocation would provide directly linked patient service regardless of the

University of Nebraska--Lincoln University of Nebraska Medical Center University of Nebraska at Omaha University of Nebraska at Kearney

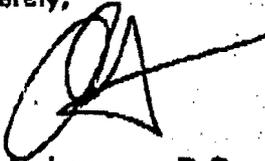
Letter to Secretary Shalala  
February 19, 1997  
Page 2

location of the transplantation center. This service would be provided by the patient's local OPO. This is a true patient-driven system of organ allocation. We already have the bylaws, ability, and technology to make this system work today.

A new interpretation of UNOS bylaws would allow the patients from other OPO's to have the option to list and be served by the OPO in their home location. We believe that the Department of Health and Human Services has authority for the oversight of the Organ Procurement Transplantation Network and has the authority to issue this interpretation. We are not aware of any HCFA regulations that would prevent this interpretation of the Bylaws.

We would welcome the opportunity to discuss this request with you. We look forward to hearing from you concerning the interpretation of UNOS policies in section 3.0 of the Bylaws.

Sincerely,



Alan N. Langnas, D.O.  
Chief of Transplantation Surgery



Marsha Morien  
Associate Hospital Director

cc: Judith Braslow, Division of Transplantation  
Bruce Vladek, Health Care Financing Administration  
Byers W. Shaw, Jr. M.D.  
Michael F. Sorrell, M.D.  
Senator J. Robert Kerrey

**Veterans of Foreign Wars of the United States  
National Coalition for Homeless Veterans**

# VETERANS OF FOREIGN WARS OF THE UNITED STATES



March 4, 1997

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

Dear Secretary Shalala:

As Commander-in-Chief of the Veterans of Foreign Wars of the United States (VFW) and on behalf of over 1.9 million members who are veterans, I am compelled to write this letter to express our concerns with recent policy changes in medical criteria for human liver allocations and ask that you promulgate final rules reversing this policy. The changes I speak of have been approved by the United Network for Organ Sharing (UNOS), the Government transplant contractor for the National Organ Procurement and Transplantation Network (OPTN). We feel these changes in policy fail to meet the needs of our nation's veterans, particularly if the veteran is considered the neediest and sickest patient.

Under the new policy which changed what type of patients are considered as status 1 for transplant purposes, only patients with life expectancies of seven days without transplant who have one of only four acute liver failure diagnoses would receive priority for transplantation. This leaves all other liver transplant candidates, regardless of their medical urgency and life expectancy, to be considered status 2 or 3 patients and may never receive a life sustaining liver transplant. What this means to the VFW is that some veterans, who may be service connected for conditions which should require liver transplants will never be offered transplantation as an option, especially those veterans who suffer from chronic conditions such as Hepatitis, liver cirrhosis due to self medication with alcohol, primary biliary cirrhosis or hereditary diseases. Veterans in these categories could be forced to go without liver transplants and, as a result, may die prematurely.

Further exacerbating this dilemma is the current policy which establishes geographical restrictions that further restrict veterans from equal access to available donor livers similar to liver transplant candidates in the private sector. The reason for this being, that veterans, particularly low income, medically indigent veterans, are limited to only two liver transplant facilities in the entire VA system - Pittsburgh, Pennsylvania and Portland, Oregon. Using this present transplant policy, veterans who need liver transplants are added to the local waiting lists in Pittsburgh and Portland with no special consideration given to the fact that these seriously ill veterans come from numerous cities and towns

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**The Honorable Donna Shalala**  
**Secretary, HHS**  
**March 4, 1997**  
**Page 2**

throughout the country. This causes the waiting lists in these two cities to become exceptionally long resulting in many veterans never receiving life saving liver transplants. Therefore, it is conceivable that many veterans on the VA waiting lists in Pittsburgh and Portland may never rise higher than status 2. Furthermore, due to present policy that local candidates are considered first, it may culminate in veterans being neglected and left to die unnecessarily.

This policy is patently unfair to everyone, but especially to veterans. It's obvious that something is wrong when a policy permits organs to be transplanted into less-sicker status 3 patients in local areas before being offered to status 1 and 2 patient who are needier and sicker throughout the country. Therefore, the VFW must go on record opposing these liver transplant policies and urge you as Secretary for Health and Human Services to use your authority and issue final rules on liver allocation using a National Liver Transplant Policy whereby the sickest and neediest have priority to donor livers regardless of their geographic location or where the organ was donated.

I ardently await your response to this matter and trust you will consider the well being of our nation's veterans in your decision.

Sincerely,

**JAMES E. NIER**  
**Commander-in-Chief**

cc: **Honorable Jesse Brown, Secretary of Veterans Affairs**  
**Honorable Arlen Specter, Chairman, Senate Veterans' Affairs Committee**  
**Honorable John D. Rockefeller, IV, Ranking Minority Member, SVAC**  
**Honorable Bob Stump, Chairman, House Veterans' Affairs Committee**  
**Honorable Lane Evans, Ranking Minority Member, HVAC**  
bc: **All Members, Senate & House Veterans' Affairs Committees**  
**Dave Gorman, Executive Director, DAV**  
**John Sommer, Executive Director, The American Legion (Harry Kelly)**  
**Gordon Mansfield, Executive Director, PVA**  
**Michael E. Naylor, Executive Director, AMVETS**  
**Carl F. Stout, Acting Executive Director, Vietnam Veterans of America**  
**Patricia Potter, Chairman, Hospital Committee, Pennsylvania**  
**Ken Steadman, Executive Director**  
**Bob Wallace, Deputy Executive Director**  
**All Directors, VFW Washington Office**  
**All Field Representatives**

The first sentence of the article reads: "According to the law firm of Doepken Keevican & Weiss, the United Network for Organ Sharing, the government contractor that oversees the national organ allocation system, has adopted a liver transplant policy that allocates livers not to the neediest and sickest patients, but to local transplant centers nearest the organ donor."



**LEGISLATIVE INFORMATION**

**National Organ Transplant Reauthorization Act - Health and Human Services Policy**  
 According to the law firm of Doepken Keevican & Weiss, the United Network for Organ Sharing, the government contractor that oversees the national organ allocation system, has adopted a liver transplant policy that allocates livers not to the neediest and sickest patients, but to local transplant centers nearest the organ donor. Proposed rules and regulations stemming from this Act have been making their way through HHS and will soon become final. A change in current policy could save the lives of up to 200 people each year, including veterans, who would benefit by the adoption of a fair, national liver transplant policy. Veterans' benefits limit the choice of veterans in need of a liver transplant to only two facilities, located in Pittsburgh and Portland, Oregon. This unfair and misdirected policy combined with the proliferation of over 100 small transplant centers nationwide has reduced the number of organs available for veterans and neediest patients. For more information and how you can impact policy

changes contact *Breat Fewell, at Doepken, Keevican & Weiss Attorneys at Law, 412 355-2600.*

**National Association of Housing Cooperatives.** In a recent letter advised that veterans who want to obtain VA home loan mortgage guarantees to purchase housing cooperative units, are unable to do so. This is because VA regulations do not allow mortgage guarantees for veterans to purchase a cooperative. Last year, Rep. Maloney (D-NY) introduced a bill (HR 1006) that would allow veterans to purchase housing cooperatives. She plans to reintroduce the measure this year. The VA has the belief that the potential demand for VA-guaranteed cooperative loans would not justify the VA in becoming familiar enough with the cooperatives to evaluate individual loan requests. For more information contact: *Jack Sullivan, at NAHC, 1614 King St., Alexandria, VA 22314-3719, 703 549-5201.*

**Isaak Amendment Reintroduced in the House, HR 233, Amendment to the Lobbying Disclosure Act of 1995** This bill takes the Simpson Amendment to its extreme. The Simpson Amendment prohibits 501c4's that receive federal grants from lobbying. However, the Simpson Amendment allows 501c4's that receive federal funds to affiliate with organizations that lobby. Specifically, Senator Simpson said on the floor of the Senate that organizations could bifurcate, creating an entity that receives federal funds and another that lobbies. This new bill would prevent this from occurring by prohibiting lobbying by any organization (such as 501c3's) affiliated with a 501c4 that receives federal funds. This bill has been referred to the House Judiciary Committee. At this point, it is not clear that this bill will move, particularly because it would have to be approved by the Judiciary Committee, which is less fertile ground for Isaak proposals. Watch for updates and progress on this bill.

**HR 168, Veterans' Entrepreneurship Promotion Act, introduced January 7, 1997 by Rep. Bob Filner (D-CA).** This bill is designed to assist the development of small businesses owned by disabled and other eligible veterans. Under this measure, a program would be established to help eligible veteran-owned small businesses compete for Federal government