

NLWJC - Kagan

DPC - Box 029 - Folder 008

**Health - Liver Allocations
Policy**

Health-Liver Allocation Policy

March 25, 1997

CM -
Ask EK if it's appropriate
for us to have such a mtg.
If so, I'm happy to do it.
BR

MEMORANDUM TO BRUCE REED
CHRIS JENNINGS
FROM: BRUCE R. LINDSEY
SUBJECT: LIVER ALLOCATION POLICY

Bruce
As long as council's
office has approved -
which council's
office clearly has -
it's
OK.
EK

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.

CM -
Ok, let's do it.
BR



THE WHITE HOUSE
WASHINGTON

Mr. President,

You should know that this is in formal rule-making process and any substantive comments you may have must be on the record. Bruce

THE WHITE HOUSE
WASHINGTON

February 12, 1997
THE PRESIDENT AND SENATE
1-11-97

Mr. President:

The attached letter from [redacted] Matter concerns the liver transplant issue.

Bruce Lindsey advises that this is in the formal rulemaking process. You should know that any comments -- written or oral -- to HHS would have to be made a part of the record of the proceeding.

Phil Caplan

PHL

*Bruce L
What is right
on the record?
Should you give to
Lindsay's letter?
BS*

You should not make any written or oral comments because it is in the rulemaking process. There is not supposed

to be any political pressure.

Presidents usually do not get involved in rulemaking processes.

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

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

THE PRESIDENT
2-18-97

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

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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.

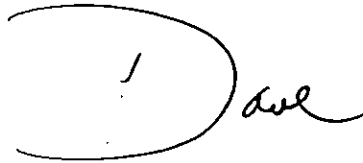
I have enclosed copies of the five part series on organ transplantation published earlier this week in the Cleveland Plain Dealer. They are extraordinarily well-researched and a very important

President William J. Clinton
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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". The signature is written in dark ink on a white background.