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United States Senate

COMMITTEE ON FINANCE

WASHINGTON, DC 20510–6200

November 29 2005

Elizabeth M. Duke, Ph.D
Health Resources and Services Administration
Parklawn Building
5600 Fishers Lane
Rockville, MD 20857

Dear Administrator Duke:

As Chairman of the Senate Committee on Finance (Committee), I would like to thank you for your prompt and thorough response to my October 19, 2005 letter requesting information on how the United Network for Organ Sharing (UNOS) handles allegations of "line jumping" and other violations of policies developed by UNOS pursuant to its contract with the Health Resources and Services Administration (HRSA) to administer the Organ Procurement and Transplantation Network (OPTN). The information you provided reassures me that violations of UNOS allocation policies, particularly "line jumping," are uncommon. Nonetheless, I have some remaining concerns about the ability of HRSA and UNOS to detect and prevent fraudulent and/or improper allocation of organs. In addition, I recently learned about serious problems at another transplant center, the University of California Irvine Medical Center (UCI) that make me wonder whether HRSA and UNOS are acting in the best interest of transplant candidates. I will discuss my concerns relating to St. Vincent and organ allocation and those relating to UCI separately.

<u>Concerns relating to St. Vincent Hospital:</u>

First, it is not clear that UNOS's June 15, 2005 audit of St. Vincent identified significant problems with the September 8, 2003 transplant that was later found to involve violations of OPTN policies. The audit report on St. Vincent does not indicate that UNOS had any concerns about possible violations of UNOS liver allocation policies or that it had any concerns about the September 8, 2003 transplant. The only finding relating to the September 8, 2003 transplant was a finding that St. Vincent had not removed two of 35 transplant candidates sampled, including the patient transplanted on September 8, 2003, from the OPTN liver waiting list immediately as required by OPTN policy. According to a supplementary timeline provided with the audit, UNOS did not become aware that St. Vincent transplanted a liver into a patient other than the designated recipient until September 20, 2005 when St. Vincent's liver program administrator notified UNOS that it was investigating the matter.

Second, I am concerned that the September 8, 2003 transplant did not trigger any investigation at the time of the actual transplant. The timeline submitted with the audit indicated that St. Vincent originally removed patient number 52, the actual transplant recipient, from the OPTN liver waiting list on September 9, the day after the transplant but subsequently asked UNOS to re-list the patient because he had been removed in error. According to the audit report, it was not until September 16, eight days after the transplant that St. Vincent removed patient number 2 from the waiting list. The OPTN Evaluation Plan you provided indicates that UNOS reviews daily all deceased donor liver match runs to determine if the organs were allocated according to the match run sequence and examines all instances where the match run was not followed to determine if the allocation was a violation of policy. Although St. Vincent subsequently re-listed patient number 52, given that there was a delay in de-listing the intended recipient, I would expect that the initial report that patient 52 had been transplanted would be cause for some further investigation.

Third, although I did not specifically request information regarding the relatively high rate of livers transplanted to foreign nationals at St. Vincent, I am concerned that this was not addressed in the June 15, 2005 audit of St. Vincent and HRSA did not address it in its response. According to newspaper accounts, approximately eight percent of the livers transplanted at St. Vincent went to foreign nationals. UNOS policy regarding transplantation of non-resident aliens states that "at centers where non-resident transplant recipients constitute more than 5 percent of recipients of any particular organ type, circumstances underlying the transplants for non-resident aliens will be reviewed by the [UNOS Ad Hoc International Relations Committee]." I would like to know if the UNOS Ad Hoc International Committee has reviewed liver transplants to non-resident aliens at St. Vincent and what it has found.

Concerns Related to the UCI Transplant Center:

Recent news reports described serious problems with UCI's transplant program that started more than three years ago. UCI's liver transplant program turned down a majority of liver offers received from the regional Organ Procurement Organization (OPO), most of which were accepted by other transplant centers. UCI's organ acceptance rate, 4 percent, was less than half the usual rate for the region and from August 2004 to July 2005, UCI rejected more than 100 of the 122 liver offers it received. Although UCI claimed that it refused most of the organs because they were of poor quality, it appears that the real reason may have been a lack of capacity to perform transplants due to personnel problems.

According to news reports, UCI has been operating for more than a year, since July 2004, without a full-time transplant surgeon. The former head of the transplant center, who left UCI in July 2004, reportedly alienated other transplant surgeons hired by UCI and was apparently focused more on building a practice involving other types of liver surgery than on performing transplants. As a result, for the last three years UCI failed to perform the minimum number of annual transplants, 12, required to maintain

active status. We need to know whether these factors contributed to the high organ refusal rate at UCI and also had an impact on patient outcomes – the percentage of transplant recipients at UCI who survived at least a year was well below the survival rate required for Federal certification.

It appears that patients almost certainly died, whether because an organ that could have been transplanted was refused, or because the transplant team was out of practice due to the low volume of transplants. Yet UCI was still aggressively recruiting new patients for its transplant center. I want to know if UNOS and/or HRSA did anything to ensure that those patients had the same chance to receive a liver transplant as other patients on the wait list.

It seems to me that UNOS, and by extension HRSA, should have been aware of at least some of these violations. The number of organ refusals was reported by the regional OPO and UNOS itself conducted an audit of UCI in 2003 and again in June 2005. Nonetheless, according to the information you provided in response to my last letter, this matter is still under review and no action has yet been taken against UCI. In addition, UNOS reaccredited UCI's transplant program in December 2004. I wonder how many other transplant programs are needlessly rejecting organs without the knowledge of patients desperately awaiting a transplant.

Other Concerns:

I am concerned that UNOS is not taking adequate corrective action when it determines that a UNOS member violates OPTN policy. In response to our request for information on allegations received and investigated by UNOS in the last 5 years, you submitted information on 24 allegations from 2003 through 2005. No information was submitted for 2000 through 2002. It appears that resolution of three of these allegations involved continuous monitoring, which is still ongoing. I would like to know what this monitoring entails and how UNOS ensures that transplant candidates at monitored centers are safely and fairly treated. In addition, according to the information provided, UNOS found that two OPOs violated OPTN Policy 3.3.6, Center Acceptance of Organ Offers. One of these OPOs was informed of the decision and it was indicated that the other OPO would be notified that the issue had been taken under consideration. I don't understand how informing an OPO that it has violated policy prevents such a violation from occurring again.

You also submitted information on facilities that had been considered for "member not in good standing" status. In response to our request for information on all members that UNOS has considered for "member not in good standing" status since 1986, you submitted information on 17 members, including seven OPOs and 10 transplant programs that had been recommended for "member not in good standing" status by the Membership Professional Standards Committee (MPSC) from 2002 through 2005. You did not submit information on recommendations for "member not in good standing" status prior to 2002. Although you report that most of these members satisfied the MPSC's concerns, you reported that one member transplant center was still on

probation and a second center had until October 31, 2005 to provide information relating to its compliance with OPTN bylaws. For all members recommended for "member not in good standing" status, but particularly for the two members mentioned above, I am concerned that potential transplant recipients did not know of potential problems with these centers.

Finally, I am concerned that HRSA may not be playing an active role in overseeing the OPTN contract with UNOS. UNOS is required to report to HRSA the results of any reviews and evaluations which indicate noncompliance with applicable Federal regulations or OPTN policies or indicate a risk to the health of patients. Although my initial request for information was directed to HRSA, there is no evidence in the information provided of HRSA's role in evaluating potential instances of non-compliance identified by UNOS. In addition, I am concerned that only if a policy is designated by HRSA as mandatory, does UNOS have authority to suspend member privileges for violation of the policy, yet HRSA did not designate a single UNOS policy as mandatory.

Accordingly, I am requesting that HRSA arrange to brief my staff on its role in overseeing the OPTN contract, specifically its role in evaluating allegations against UNOS members and possible instances of non-compliance with UNOS policies or Federal regulations. In addition, please provide following additional information by no later than December 12, 2005:

1. Please indicate whether UNOS was aware of any possible impropriety at St. Vincent with respect to the September 8, 2003 liver transplant of patient number 52 on the match list prior to September 20, 2005 when the liver program administrator at St. Vincent notified UNOS that falsified records relating to this transplant had been intentionally submitted to UNOS beginning in 2003 and continuing to the present.

2. Please describe any actions UNOS took to investigate St. Vincent's initial listing of patient 52 and/or the subsequent de-listing of patient number 2, the intended recipient, immediately subsequent to the transplant. In addition, please indicate how frequently de-listing errors are reported to UNOS (e.g., how many times each year) and UNOS's usual procedure for investigating such an incident.

3. State whether HRSA or UNOS recently reviewed/plans to review the Organ Procurement Organization (OPO) that serves St. Vincent to determine whether the OPO met its responsibility to report inaccuracies or transfers that appeared to be inappropriate to the UNOS regional review board staff?

4. The OPTN evaluation plan that you provided indicates that UNOS generates a report for every meeting of the Ad Hoc International Relations Committee to review centers that go above the five percent threshold. Please provide:

a. copies of all of these listings from January 1, 2000 through June 30, 2005;

b. a list of all centers during that time period that were referred to the MPSC because they either did not provide justification for going over the five percent threshold, or repeatedly went over the five percent threshold;

c. a summary of the actions taken by the MPSC for those centers referred to them during this period; and

d. a summary of the actions taken with respect to those facilities referred to the Ad Hoc International Relations Committee that were not further referred to the MPSC.

5. Please provide a copy of the 2003 UNOS audit of UCI Medical Center's transplant program and describe any follow-up actions taken by UNOS or HRSA to resolve issues identified in the audit.

6. Please provide a copy of the 2005 UNOS audit of UCI Medical Center's transplant program.

7. For each transplant center, please provide the following information by year and by organ type for January 2000 through June 2005:

   a. the number of organ offers received;

   b. the number of offers accepted;

   c. for each refusal please indicate the reason for the refusal and whether the organ was accepted by another center.

8. Information in your original response indicates that UNOS continues to monitor several organizations that were either investigated based on an allegation and found to be out of compliance with UNOS policies, or that were considered for listing as members not in good standing. Please explain the monitoring process referred to.

9. Please provide the number of on-site reviews conducted by UNOS each calendar year from 2000 through 2005 and approximately how often UNOS performs an on-site review of each institutional member?

10. Please verify that UNOS did not receive or investigate any allegations in calendar years 2000-2002. If UNOS did receive or investigate any allegations during that time period, please provide information on those allegations in the same format used to provide information on allegations from 2003 through 2005.

11. Please verify that the UNOS Membership Professional Standards Committee did not recommend any members for "member not in good standing" status prior to 2002. If any members were recommended for "member not in good standing" status prior to 2002, please provide information on the evaluation of those members in the same format used to provide information on members evaluated between 1986 and 2005.

12. Please explain why HRSA has not designated any of the OPTN policies as mandatory.

Thank you in advance for having your staff coordinate with my staff about this letter by December 5, 2005. Responses to questions 1 through 12 should be provided no later than December 12, 2005.

Sincerely,

Charles E. Grassley
Chairman

cc: Walter K. Graham
United Network for Organ Sharing