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Grassley follows up on violation of rules governing organ transplants, asks questions of federal watchdogs

WASHINGTON — Sen. Chuck Grassley is asking federal officials about the reasons behind a large organ transplant center suspending its liver program.

He based his inquiry on the September announcement by the St. Vincent Medical Center in Los Angeles that a patient who was low on the waiting list for a liver transplant was bumped ahead to receive an organ intended for someone else.

While this type of situation is uncommon, Grassley said he's concerned that two years went by before an audit discovered what had happened. Transplant centers are overseen by the Organ Procurement and Transplantation Network, which is operated by the United Network for Organ Sharing under contract with the Health Resources and Services Administration within the U.S. Department of Health and Human Services.

The text of Grassley's letter to the Health Resources and Services Administration follows this news release. Grassley is chairman of the Senate Committee on Finance, which has legislative and oversight jurisdiction over the Medicare and Medicaid programs.

October 18, 2005

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

Dear Administrator Duke:

The Senate Committee on Finance (Committee) has jurisdiction over the Medicare and Medicaid programs, and, accordingly, a responsibility to the more than 80 million Americans who receive health care coverage, including organ transplants, under those programs. This coverage includes payments for liver transplants at transplant centers overseen by the Organ Procurement and Transplantation Network (OPTN), which is operated by the United Network for Organ Sharing (UNOS) under contract with the Health Resources and Services Administration (HRSA).

I was concerned to read recently about the alleged violations of organ transplant rules at the St. Vincent Medical Center in Los Angeles California which allegedly resulted in a foreign national, who was 52nd on the list of eligible recipients, receiving a liver transplant before other eligible patients on the list. I fully support efforts to encourage organ donation, but I believe such efforts are easily undermined by events such as those alleged to have taken place at St. Vincent. As UNOS's president, Francis L. Delmonico, stated in a recent press release, "The national transplant system is dependent upon the public's trust in the equity of that system."

According to the Los Angeles Times, St. Vincent was notified on September 8, 2003 that a liver was available to transplant into a St. Vincent patient who was first on the regional transplant waiting list. That patient was home in Saudi Arabia on the advice of the then director of St. Vincent's liver transplant program. St. Vincent bypassed the second candidate on the waiting list, who was located at another hospital, and nine of its own patients before transplanting the organ into another Saudi national who was 52nd on the list and whose costs were paid for by the Royal Embassy of Saudi Arabia. Hospital staff subsequently altered records to make it look like the donor liver had been transplanted into the first patient, who died within the year, on the waiting list and that the liver removed from the actual transplant recipient had come from the first patient on the waiting list. St. Vincent first discovered problems with the transplant only last month after conducting an internal investigation prompted by a routine UNOS audit.

I am glad that the problems at St. Vincent have been brought to light, but it should not have taken two years to discover that there was a problem, especially when about 8 percent of liver transplants at St. Vincent were to foreign nationals. That is significantly higher than the 1 percent of organ transplants that go to foreign nationals nationwide, and higher than the 5 percent guideline established by the OPTN. I wonder how many Saudi nationals received liver transplants at St. Vincent while Americans awaiting a liver died.

Let me be clear, I am not against foreign nationals receiving organ transplants in this country, but I want to be sure they do not receive priority over United States Citizens and Permanent Residents. I am also sorry that the patient designated to receive the organ in question, also a Saudi resident, died and I would like to be sure such a tragedy does not occur again.

Accordingly, I am requesting that you provide me with the following information:

- 1. A copy of the two most recent OPTN contracts with UNOS, including the recently awarded contract.
- 2. A copy of the standards a transplant center must meet to remain in good standing, and, if separate, a list of violations that will cause a transplant center to lose good standing.
- 3. A list of all transplant centers, since 1986, that have been placed on bad standing or been warned that they may lose their good standing and the violations that resulted in the loss of good standing or warning.
- 4. A list of any allegations received by HRSA or UNOS in the past five years involving the possible provision of an organ to a patient "out of line" or otherwise inequitable distribution of organs and a brief description of how HRSA and/or UNOS investigated and resolved each allegation.

- 5. A copy of the UNOS audit of St. Vincent.
- 6. A list of those actions HRSA and/or UNOS identify as a result of the audit of St. Vincent and any corresponding investigation into the alleged violation of transplant rules at St. Vincent.
- 7. A plan and detailed timetable for implementing actions listed in response to number 6. I also intend to request that the Department of Health and Human Service, Office of Inspector General and the Department of Justice to conduct an investigation into the alleged violations of transplant rules and possible violation of 42 U.S.C. 274e, which prohibits any purchase or sale of human organs that affects interstate commerce.

Thank you in advance for having your staff coordinate with my staff about this letter by October 28, 2005. At that time I would like you to provide an estimated response date for items 5 through 7. Responses to questions 1 through 4 should be provided no later than November 4, 2005.

Sincerely, Charles E. Grassley Chairman

cc: Walter K. Graham United Network for Organ Sharing Inspector General Daniel R. Levinson Department of Health and Human Services Attorney General Alberto R. Gonzales Department of Justice