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United States Senate

COMMITTEE ON FINANCE

WASHINGTON, DC 20510-6200

KOLAN DAVIS, STAFF DIRECTOR AND CHIEF COUNSEL
JOSHUA SHEINKMAN, DEMOCRATIC STAFF DIRECTOR

January 22, 2019

VIA ELECTRONIC TRANSMISSION

The Honorable Alex Azar
Secretary
U.S. Department of Health & Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Azar:

We are writing to voice concern about a national policy change that could lead to prolonged waiting periods for many Americans seeking liver transplants.

The changes made on December 3, 2018, by the Organ Procurement and Transplantation Network (OPTN) to the national liver distribution policy could adversely impact many Americans seeking liver transplants. In particular, we are concerned that the negative effects of this new policy could be most severe for rural, low-income populations. It appears that the Department of Health and Human Services (HHS) interceded and directed the OPTN to develop a proposal that does not include donation service areas (DSA) and region when determining liver allocation in response to a lawsuit that was filed. Therefore, the Department only asked the OPTN to address the concerns specifically laid out in the suit – the justification for OPTN geographic regions. We are concerned that this intervention tipped the scales toward one outcome, and did not set up a process to address all the issues and factors that should be considered for fair liver distribution. In particular, both the Department and the OPTN ignored the impact of socio-economic factors and local organ procurement efforts that help ensure successful liver transplants.

Specifically, this policy change does not appear to give any weight to locations that have been successful in reducing their waitlists through aggressive organ procurement or through adopting innovative transplant techniques. Instead, the OPTN rewards locations that underutilize existing organ resources and have historically had troubled organ procurement organizations (OPOs) by completely ignoring these factors during their deliberation. The policy change did not incorporate the performance of OPOs, which vary widely from state-to-state and is linked to significant regional disparities in liver donation rates. As reported last month by the *Washington Post*, for example, the Centers for Medicare and Medicaid Services has “repeatedly found that many [OPOs] do a poor job of recovering enough organs to meet the need.”^[1]

^[1] Kimberly Kindy and Lenny Bernstein, “A human heart was left on a plane, revealing how organs move around the country,” *The Washington Post*, Dec. 14, 2018.

Finally, the manner by which the OPTN's decision was reached calls into question the process by which decisions are made. The December 3rd policy change both conflicts with the 2017 OPTN decision and ignores the recommendation of the Liver and Intestine Transplantation Committee, whose members include some of the nation's leading transplant experts. Further, as the CEO of OPTN acknowledged to a transplant hospital in email, not all public comments were considered during deliberations. This outcome makes us question the directive OPTN received from HHS, the process undertaken and the OPTN decision.

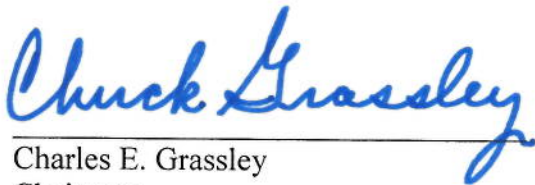
Therefore, we request responses to the following questions no later than February 15, 2019:

1. The OPTN Board decision represents a marked departure from the 2017 national liver distribution policy. To what extent did the OPTN Board account for regional variations in liver donation rates and regional disparities in OPOs' performance in considering this change?
2. Did the filing of litigation last year play any part in the policy decision? If so, what was communicated from the Department, the Health Resources and Services Administration and the Office of the Secretary, to the OPTN regarding organ allocation? Please explain.
3. Is the Department aware of the process used to consider public comments, and whether all of the public comments were considered? Please explain.
4. To what extent did the OPTN Board consider the 2018 recommendation of the Liver and Intestine Transplantation Committee in making this policy change? Please explain.
5. A new allocation proposal had been developed by the Liver and Intestine Transplantation Committee in accordance with new instructions issued by the OPTN Board in August at the request of the Administrator of the Health Resources and Services Administration. The Committee met weekly from July until the end of November developing the proposal. However, on December 3rd, the OPTN Board overruled this recommendation and voted to advance a proposal that had been defeated in the Committee earlier in the fall.
 - a. Did the Department question why the Liver and Intestine Transplantation Committee's recommendation was overruled?
 - b. How often does the OPTN board overrule the recommendation of the expert committee?
6. What data did the OPTN Board use to support this decision, and to what extent did the Board consider the potential adverse effects of its policy change on low-income populations and residents of rural communities?
 - a. What effect will this change have on the following respective regions and populations: Midwestern and Southern states, and low-income patients?

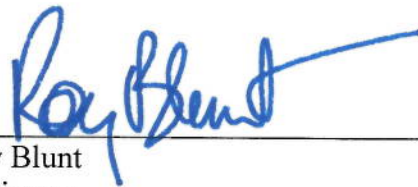
7. It has been estimated that the proposal will increase the amount of flying time for organ retrieval from 50-55 percent to 75 percent, which will increase the cost of liver transplantation dramatically, not only for the third-party payors, but also for Medicare and Medicaid. To what extent will this change increase transportation costs and impose logistical barriers for hospitals in different regions of the country?
8. The probability for a successful liver transplant is measured by the Cold Ischemia Time (CIT), which starts from the moment the blood vessels in the donor are tied off, until the reconstructed blood vessels in the recipient are opened up by reperfusion. Further complicating viability of liver transplants is the effect the health and age of the donor has on the CIT time. With most of the CIT time being consumed by transportation of the liver to the transplant hospital, what impact will OPTN's new distribution policy have on the viability of livers in transport?
 - a. What modeling was conducted on the effect of this change on individuals' willingness to donate organs?

We appreciate you looking into these areas of concern. We look forward to better understanding how the Department will assure Americans that livers are fairly distributed across the country.

Sincerely,



Charles E. Grassley
Chairman
Senate Finance Committee



Roy Blunt
Chairman
LHHS Appropriations Subcommittee




Mitch McConnell
Senate Majority Leader

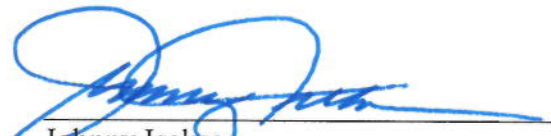


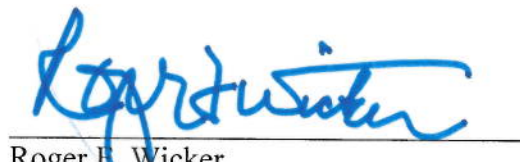
Richard C. Shelby
Chairman
Senate Committee on Appropriations


Debbie Stabenow
United States Senator

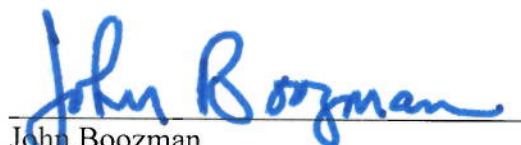

Jerry Moran
United States Senator

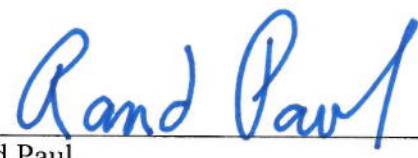

Lindsey Graham
United States Senator



Johnny Isakson
United States Senator



Roger F. Wicker
United States Senator


Pat Roberts
United States Senator


John Boozman
United States Senator

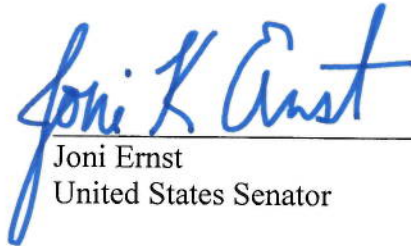

Rand Paul
United States Senator


Gary C. Peters
United States Senator


James Lankford
United States Senator



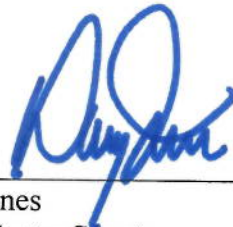
Tom Cotton
United States Senator



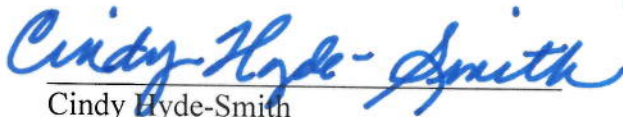
Joni Ernst
United States Senator



Todd Young
United States Senator



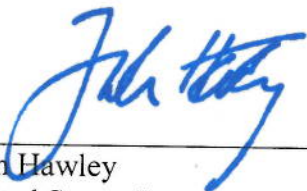
Doug Jones
United States Senator



Cindy Hyde-Smith
United States Senator



Marsha Blackburn
United States Senator



Josh Hawley
United States Senator



Tim Scott
United States Senator

CC: Dr. George Sigounas, Administrator, Health Resources and Services Administration
Ms. Sue Dunn, President and Chief Executive Officer, OPTN/UNOS Board of Directors