

United States Senate

WASHINGTON, DC 20510

December 11, 2018

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

Dear Secretary Azar,

We are writing to express our concerns regarding the December 3, 2018, decision by the Organ Procurement and Transplantation Network (OPTN) to change liver distribution policy. This decision disregards expert opinion, overturns the current policy adopted in December 2017, and calls into question the OPTN process and whether it can fairly determine a policy for distributing livers nationwide.

Last week's decision to ignore the Liver and Intestine Committee's recommendation is extremely concerning. The Liver and Intestine Committee is comprised of a panel of transplant experts from some of the most prestigious institutions in the country charged with considering the medical, scientific, and ethical aspects related to liver procurement. As such, the Committee's recommendations should be followed unless there are specific, vetted, and justifiable reasons to do otherwise. The OPTN Board's decision to overturn the Liver and Intestine Committee's decision does not meet this standard. Simply put, what is the value of having liver transplant experts deliberate for months when the OPTN Board disregards their advice?

When we met in October with Dr. George Sigounas, the Administrator of the Health Resources and Services Administration, we raised concerns about the Department of Health and Human Services interceding after last year's decision simply because a lawsuit was filed. The Department's decision to intercede due to a lawsuit makes us question whether the Department has faith in the outcome of OPTN decisions. It also makes us expect that the Department will weigh in should a lawsuit be filed now that a new OPTN decision was reached.

Last week's decision is fundamentally different from the outcome one year ago. How can a fair and equitable process radically change the outcome of a decision from one year to the next? If this decision were made next year, there is no indication based on past precedent that the same conclusion would be reached. That shows fundamental flaws in the process.

The OPTN process needs to be open, transparent, and one that takes into consideration both the expertise of the Liver and Intestine Committee and the public comments submitted by the current liver distribution regions. It is particularly concerning that OPTN has recognized that comments from major transplant stakeholders were not considered prior to the Liver and


Intestine Committee's November 2 deliberations. Last week's decision undermines the entire process and calls into question why the Department has ceded control.

We look forward to hearing from you soon regarding our concerns and the change in liver distribution policy.

Sincerely,



Roy Blunt



Jerry Moran

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