

January 24, 2022

VIA ELECTRONIC TRANSMISSION

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Secretary Becerra,

For many years, Members of the Senate have expressed serious concerns about the Department of Health and Human Services' contractor-driven organ allocation policy. These concerns have included issues with the Department ceding control to a contractor to determine all organ allocation decisions; limited oversight by the Department of the Organ Procurement and Transplantation Network (OPTN) policymaking process, run by the United Network for Organ Sharing (UNOS); the UNOS Board's orchestrated overruling of their expert Liver and Intestine Committee's recommendations; and the Board's failure to include all public comments in its consideration.

Congressional action with regard to these concerns has ranged from letters to the Secretary and the Health Resources and Services Administration (HRSA) Administrator, questions at Committee hearings, language included in several appropriations bills, requests to the Government Accountability Office and National Academy of Sciences to evaluate the process, and letters to the Department's contractor, UNOS. In addition to the concerns raised by Members of Congress, more than a dozen transplant hospitals have taken the Department to federal court to overturn the allocation changes for three different organs – lungs, livers, and kidneys. These actions clearly show that there is not unanimous, or even a majority, agreement on the radical changes underway on organ allocation policy.

A significant issue is that the Department has ceded authority to ensure a fair and equitable organ distribution process to a private contractor, with virtually no oversight from HHS or HRSA. Specifically, the Department has used the argument that its contractor, UNOS, is in charge of determining policy. In a February 2020 letter, the HRSA Administrator stated that "The OPTN is responsible for organ allocation policy and Health Resources and Services Administration (HRSA) is charged with the oversight of the OPTN." In a January 2019 letter by UNOS President Sue Dunn, she states that the "OPTN board of directors retains ultimate authority and responsibility...including policies for the equitable allocation of organs." Finally, Secretary Azar gave the following testimony to the Senate Finance Committee on February 25, 2020, reflecting a fundamental misunderstanding of the relationship between the Department and the OPTN as defined by the applicable statute and implementing regulations:

“As you know, HHS does not make decisions on organ allocation policy. The Organ Procurement Transplant Network is responsible for organ allocation policy. While we’re charged with oversight of the OPTN, and I do not have the ability to change those decisions. We continue to look for authorities that might do that, and we certainly look forward to working with you if there were legislative proposals that might give me authority, but those have actually been walled off from the Secretary.”

This arrangement raises two important questions. First, which entity, HHS or the OPTN contractor, is ultimately accountable for these policy changes and their implementation? And second, how does Congress provide oversight of a life-or-death policy change when a federal department dodges responsibility for the decisions made?

Finally, in December 2021, our biggest fear was confirmed when emails UNOS fought vigorously for years to keep sealed and out of the public domain were ordered released by two federal courts. The previously hidden communications clearly demonstrate that UNOS colluded against certain regions when it issued a new liver allocation policy in December 2018. We knew, based on the actions outlined above, that the process was fundamentally unfair. But what we learned with the release of these emails was far worse. The process was not simply flawed — it was designed to deliberately deny patients in certain parts of the country their fair chance at a lifesaving liver transplant based upon despicable manifestations of bias.

There are hundreds of pages of emails that show clear collusion between UNOS, and in particular its CEO, a New England-area organ procurement organization, and others prior to the changes in the liver allocation policy. These favored organ procurement organizations were sent UNOS documents to edit and reports to comment upon, including letters to HHS. They were asked to weigh in on policy prior to actions taken by the UNOS board of directors, and wrote arguments for its CEO to use. All of these actions benefited certain states at the expense of others and led to the adoption of an organ allocation policy that has already resulted in a substantial decrease in organ availability in certain parts of the country, specifically the Midwest and South.

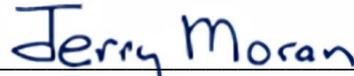
Further, dozens of the emails use profane language and disparage Americans living in the South. One, authored by the president and CEO of the New England organ procurement organization and sent to the UNOS CEO, says, “You’re a dumb (expletive) for living” in the South. The emails show a clear regional bias against those who UNOS and their favored associates do not consider worthy. Yet these emails ignore the fact that it is Midwesterners and Southerners who donate organs at a higher rate than those in the Northeast.

Mr. Secretary, these emails show, without a shadow of a doubt, that the liver allocation decision was fundamentally flawed, and the body charged with carrying it out is systematically broken. In particular, the adoption of the allocation policy for livers has been fraught with inconsistency, a lack of transparency, and clear violations by UNOS in determining the policy. Yet, in every instance that these concerns have been brought to the Department, they have been disregarded. It is time for the Department to reverse this biased, partial, and unjust allocation policy. We would appreciate hearing back from you in 30 days, outlining your plan to address this urgent matter.

Sincerely,



Roy Blunt
United States Senator



Jerry Moran
United States Senator



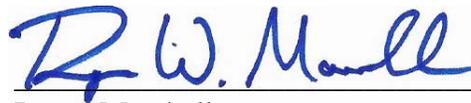
Mitch McConnell
Senate Minority Leader



Richard Shelby
United States Senator



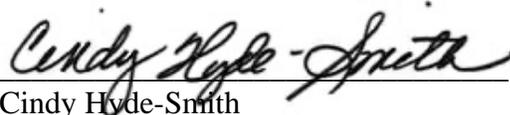
Lindsay O. Graham
United States Senator



Roger Marshall
United States Senator



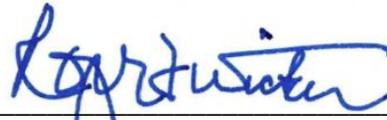
John Boozman
United States Senator



Cindy Hyde-Smith
United States Senator



Marsha Blackburn
United States Senator



Roger F. Wicker
United States Senator



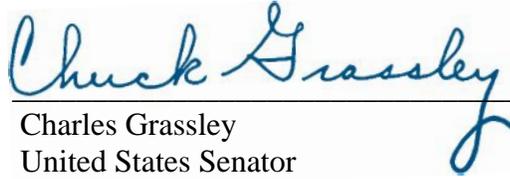
Josh Hawley
United States Senator



Todd Young
United States Senator



Mike Braun
United States Senator



Charles Grassley
United States Senator



Tommy Tuberville
United States Senator



Tom Cotton
United States Senator