WRITTEN TESTIMONY:
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Transplant Surgeon
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Chairman Wyden, Ranking Member Crapo, and Members of the Committee, my name is Dr. Jayme Locke, and I am the Director of the Division of Transplantation Surgery at the University of Alabama at Birmingham (UAB), where I also serve as the Director of the Comprehensive Transplant Institute. I have dedicated my career to serving vulnerable populations with the goal of eliminating or at least mitigating health disparities. I believe that patients should be the focus of everything we do.

At UAB, we currently have 1,022 patients waitlisted for kidneys, the majority self-identified as African American / Black. We have performed more than 10,000 kidney transplants and have performed the most living donor kidney transplants among African American / Black persons than any other program in the country. Our center is located in the southeastern United States, an area known to have one of the highest end-stage kidney disease burdens as well as communities with extreme social vulnerability – characteristics that drive demand for transplantation and reflect a limited supply.

Transplantation was always supposed to be about the patient, but the system we operate now has almost a complete lack of ownership and responsibility - whether it is an OPO failing to show up at donor hospitals and engage families, or UNOS failing at the most basic responsibilities of getting recovered organs matched and safely to the recipients at the other side. These are the government's own contractors.

My patients, your constituents, need your help.

We know that thousands of kidneys are recovered and discarded every year, and that thousands more are never recovered at all. Discards have increased steadily and transportation errors are frequent particularly since the most recent allocation change, as the new system increased complexity, and to date UNOS has shown no ability to manage even simple logistics.

The most powerful thing to know about this is that every organ represents a life. You could argue it represents more than one life; it has a profound impact on the patient, their family, and their community. We can never forget that. Imagine having a medication you need to live being thrown away simply because someone took too long to get it to you. Your life quite literally in a trash can. Organs are no different. They, too, have shelf lives, and they are measured in hours.

Discarded kidneys and transportation errors may sound abstract. Let me make this negligence real for you - and please remember the disregarded donors whose families trusted us with the most sacred of gifts, and the sick and dying patients waiting for these transplants. Think of the young girl looking forward to not having to miss the prom for dialysis, the mom who wants to live long enough to see her children grow-up, the parent who needs to be able to hold down a job to provide for his/her family. The

things we take for granted are the things that end-organ disease robs our patients of. Transplant is the cure – that is if the organ ever makes it to the patient.

In 2014, I received a kidney that arrived frozen. It was hard as a rock, like an ice cube you could put in your drink. The intended recipient was highly sensitized - meaning difficult to match. The only thing we could do was tell the waiting patient that, due to the lack of safeguards regarding transportation of organs, the kidney had to be thrown in the trash - the final, generous act of a donor in Maryland.

In 2017, I received a kidney that arrived in a box with tire marks on it. The box was squished, and the container inside had been ruptured (Image 1). We were "lucky" and were able to salvage the kidney for transplant. Why should luck even play a role?

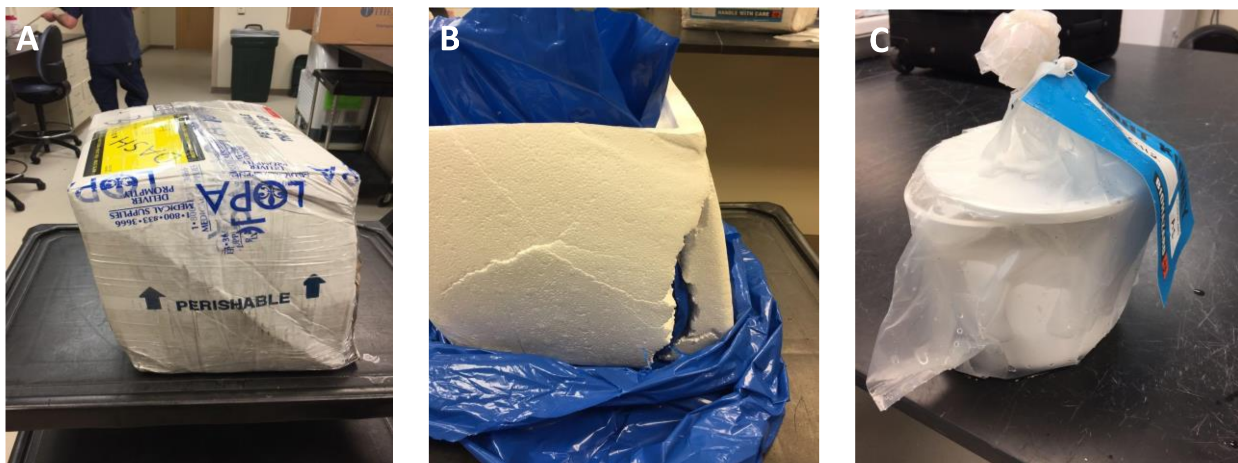

Image 1: Box as arrived to UAB. Tire marks - potentially from a luggage conveyor - were visible on the box; (B) Crushed styrofoam cooler housed inside box; and (C) Sterile bag inside white container intact but white container and external sterile bag disrupted. (Note: I understand these pictures were also shared with the Senate Finance Committee by the Louisiana Organ Procurement Agency, which similarly reported this issue at the time to UNOS.)

This is the level of care too many kidneys receive. How does UNOS allow this?

Once the kidney is packaged and leaves, no one really knows what happens, and that is as shocking as it is unacceptable.

Consider this: for our patients in Birmingham, most of our kidneys fly through Atlanta. When they were arriving on flights after 10pm, they were being taken down to sit in cargo hold like lost luggage, only to be taken out in the morning when flights restarted.

But Birmingham is only two hours away from Atlanta by car – and delays in transplanting organs literally mean life or death. Think of cold ischemia time this way: like shelf life. Each minute, each hour, that an organ is out of the donor's body, those cells are dying, which increases risk to the receiving patient. Increased cold ischemia time can mean delayed graft function – meaning the patient requires dialysis

after transplant. Delayed graft function is a known risk factor for acute rejection and reduced long-term graft survival.

When we realized what was happening with kidneys stuck in cargo hold at Atlanta airport, we called the airlines and dealt with it ourselves. I don't blame the airlines – their job is to move hundreds of thousands of people around the country each day. But where was UNOS? How did it ever let organs sit in cargo hold?

Another even simpler example: instances of UNOS saying that no flights are available, when my team has hopped on Expedia and found available flights themselves.

UNOS has failed at its responsibility for the efficient matching and distribution of organs. There are countless stories of inefficient algorithms and process that led to organs accruing unacceptably long cold ischemia times resulting in discard. In an era of same-day delivery of household goods from Amazon, the OPTN and its contractors have relied on outdated logistical systems akin to the Pony Express.

Moreover, UNOS has abdicated its duty to hold under-performing OPOs responsible for failing to convert eligible donors and manage organs on their end, and as such, have not optimized the number of organs available for transplant.

Since the frozen kidney, and the box with tire marks - I have received other kidneys that had to be discarded either due to surgical and OPO handling issues or UNOS transportation errors. But one week this May was particularly difficult.

In one week, I received four kidneys from four different OPOs - each with basic errors that led to the need to throw away those lifesaving organs (Images 4 & 5).

- One kidney had to be thrown away due to a botched biopsy into the kidney's collecting system, which means urine would have leaked from the kidney once transplanted;
- Another kidney had to be thrown away because the lower pole artery had been cut during procurement. That would have been fixable if someone involved in the procurement had assessed the kidney for damage and flushed it before packing, but that didn't happen;
- Two other kidneys arrived to me blue - meaning they hadn't been flushed.

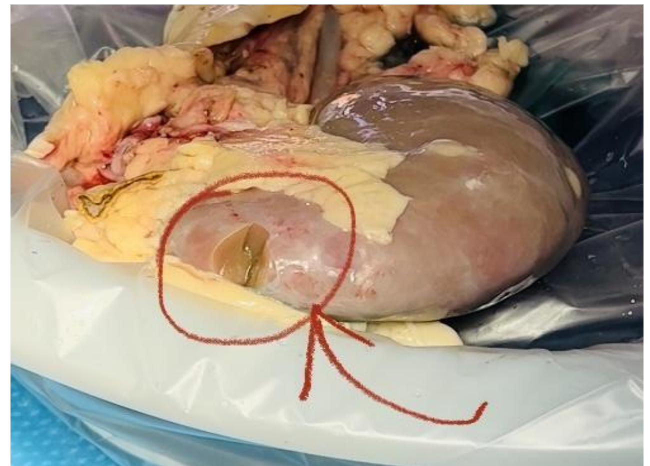

Image 4: Kidney with botched biopsy that cut into the kidney's collecting system. Collecting system injury could not be repaired. Urine would have leaked from biopsy site instead of flowing to bladder.
(see red circle/arrow)

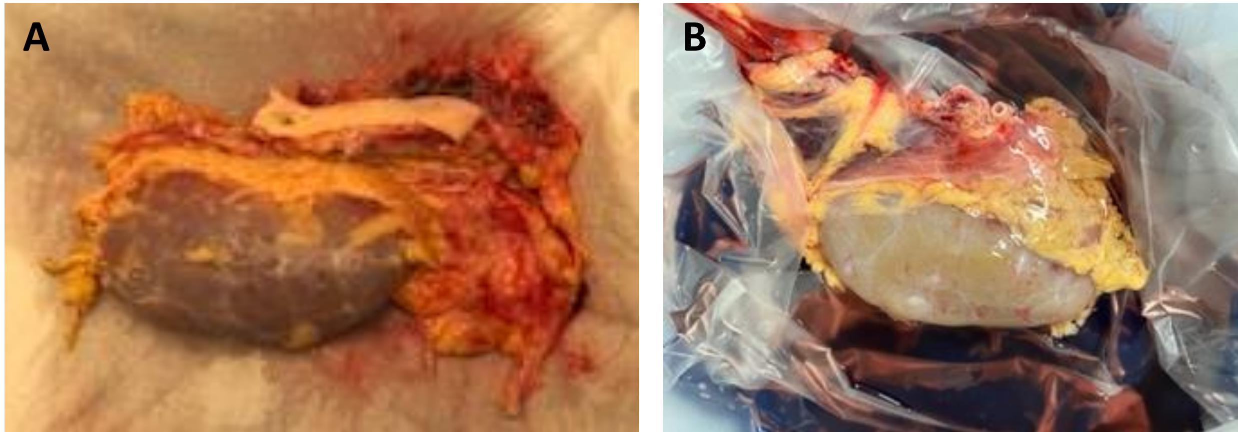

Image 5: (A) Blue kidney – unflushed; arrived from outside OPO; (B) Same kidney after having been flushed on the backtable more than 20hrs after initial procurement. Kidney was discarded secondary to high risk of primary non-function.

Errors happen. We all understand that. However, opacity at UNOS means that we have no idea how often basic mistakes happen across the country, nor can we have confidence that anything is being done to redress such errors so they don't keep happening.

All I know is that in one week I received four kidneys - two from donors in Tennessee, one from a donor in Florida, and one from a donor in Georgia - that had to be thrown away.

What was particularly heartbreaking was that two of these kidneys were for highly sensitized African American / Black women - meaning they were the proverbial needle-in-a-haystack kidneys for patients that are hard to match. Our patients become sensitized through prior exposure to foreign tissue – previous transplant, blood transfusion, and/or pregnancy.

Women who have been pregnant - especially multiple times - are more sensitized/harder to match, and pregnancy related sensitization contributes to both gender and racial disparities in access to kidney transplantation. So when we talk about the system being inequitable, this is a very real example of how a constrained pool of organs for transplant, and high discards, are failures that disproportionately hurt women, and women of color who are more likely to have multiple pregnancies.

Somewhere along the way we forgot why we're here - saving people's lives. We have to do better, and that includes transplant centers, too.

I know others in my field have spoken up, and more still who want to speak up. But, Senators, please know that every person I have talked to who has spoken up about system failures has told me they have been punished in some way through both micro and macroaggressions. The very highest levels of leadership within UNOS is an insular club that has turned its back on the very patients they purport to support by ignoring their own unconscious biases, and even impugning patients behind closed doors.

For example, a UNOS board member in an email to the UNOS CEO, labelled patients from the southeastern United States as "dumb f*$#". This is not who we are as medical professionals. We are here to serve all people and in particular those who are the most vulnerable among us. We need reform now.

The solutions are clear and I am asking for your urgent help on behalf of my patients and all the other patients waiting around the country:

- Immediately separate the OPTN board from any of the boards of any contractors;
- Bring in the real experts to ensure our patients are served by the best-of-the-best in each field, separating out key functions of the OPTN: for example, policy, technology/matching, and logistics; and
- Ensure that patients are safer by holding all contractors accountable, including through public adverse event reporting and immediate redressing of problems.

One final and critical point. I can't tell you how disturbing it was to read recent reporting of the way UNOS has allegedly held the U.S. transplant system hostage. According to the Washington Post: *"UNOS also 'has at times even threatened to walk away and continue operating the [transplant network] without a contract, despite the fact that it would be illegal.'"*

Doing anything to jeopardize patients - including even threatening to walk away - violates a basic principle of healthcare. It's called patient abandonment. You simply can't do that - or even threaten to do that. I would lose my medical license for walking away from a patient.

If it is true that in any way UNOS has suggested that it might walk away, or in any way not cooperate with a transition to new OPTN contractors, that would make it an organization that cannot be responsible for taking care of lives.

There is very little in healthcare that has the immediate life and death stakes as organ transplantation. Please realize that every day that passes with these failing systems in place means more of our neighbors will die. My patients need the Senate to act.

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See attachment for OPTN Region 3 letter, February 23, 2022

Attachment: OPTN Region 3 letter, February 23, 2022

February 23, 2022

Dear Chairman Wyden, Senator Grassley, Senator Young, and Senator Cardin,

We are writing to you as Region 3 members of the Organ Procurement Transplantation Network (OPTN) about grave concerns we have about the leadership of the OPTN (current contractor, UNOS) and to express our strongest possible objection to the content of recently published email communications among OPTN leaders.

At the February 1st, 2022 OPTN Region 3 meeting, several members sought to raise the issue of leadership, as a Federal judge recently unsealed deeply concerning emails from the UNOS CEO (Brian Shepard) and a then-OPTN/UNOS board member (Alexandra Glazier).

In policymaking deliberations, we note the following exchanges:

Glazier to Shepard: *"The fact that some states do better than others in preventing preventable deaths and providing health care insurance coverage and access means you're a dumb fuck for living there."*

Shepard to Glazier: *"Only people who have means can get a transplant. So this isn't a 'give txs to poor people argument; its a 'give txs to those of us who have to live near poor people' argument."*

These exchanges are only a fraction of the concerning transgressions found in the unsealed emails, representing a serious failure of leadership and breach of trust. Irrespective of positions on any given policy, these comments are disqualifying for positions of public service. It does not represent who we are as leaders of the organ donation and transplantation community. It is equally concerning that the OPTN/UNOS Board of Directors has failed to apologize or publicly denounce these disparaging opinions voiced by Shepard and Glazier, suggesting that these views are truly those of the OPTN. UNOS speaks often of the importance of "maintaining public trust" in the organ donation system; it is unfortunate that its executives have so flagrantly flaunted it, and, as such, must be held accountable.

At the most recent meeting, Region 3 member representatives wished to raise that (1) we believe Shepard should resign as the CEO of UNOS; and (2) that Glazier should no longer be permitted the privilege of OPTN/UNOS policymaking positions. However, we were told we could not raise this issue at the OPTN meeting as it was intended only for OPTN policy development purposes, not other matters pertaining to the OPTN or UNOS. Unfortunately, UNOS has offered no other public venues to discuss our concerns.

Having been denied the opportunity to vote on our concerns for patient welfare, we and others in the community were further stifled in our discussion by repeated statements that we should discuss our

opinions 'offline' with OPTN/UNOS board president Dr. Matthew Cooper. During the public meeting, Mr. Shepard and Dr. Cooper misrepresented the OPTN/UNOS board's discussions of the emails and actions we have outlined above. The continued attempts to suppress conversations about vulnerable patients and avoid accountability for reprehensible views and actions has broken our faith in UNOS's ability to self-regulate its leaders, so, instead, we are writing to you.

As you are aware, OPTN board members concurrently serve as the board members of UNOS. This creates a serious conflict of interest as, too often, the principal goal of UNOS is maintaining its status as the monopoly OPTN contractor, rather than focusing on issues that will actually help more patients and steward the use of precious donated organs. In fact, in 2018, the Government Accountability Office agreed with a directive from HRSA that the OPTN and the OPTN contractor (currently UNOS) must maintain separate boards, though, nearly 4 years later, UNOS still has not done so.

It was more than 20 years ago that Forbes called UNOS the *"cartel"* that's *"chilling the supply of transplantable organs and letting Americans who need them die needlessly"*, and - in the absence of structural reform to the OPTN - this dynamic remains today.

The quashing of dissenting voices within the OPTN is both ongoing and deeply damaging to the patients we serve. If the OPTN/UNOS had proper governance, not only do we believe there would be clear leadership changes, we trust that there would be more attention - and action - on issues that cost patients their lives, rather than a primary focus on UNOS continually maintaining its monopoly hold on the U.S. organ donation system.

33 Americans die every day for lack of an available organ transplant. Please ensure that proper governance is in place to help change this.

Yours sincerely,

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