Written Testimony:

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Chairman Wyden, Ranking Member Crapo, and Members of the Committee, my name is Calvin Henry and I serve on the OPTN Patient Affairs Committee as the Region 3 Representative for the Southeastern US and the US territory of Puerto Rico. I am also a double lung transplant recipient of nine and a half years and have spent much of that time as a dedicated patient advocate in direct support of organ transplant candidates and recipients, as a community advocate for organ donation, and as a strong proponent for systemwide improvements and transparency throughout the organ procurement and transplantation process. It is a privilege to be invited here today to share my thoughts regarding the current state of this system.

I would like to share with the Committee a bit of my experience navigating the transplant system in order to get waitlisted and then receive a transplant.

Fifteen years ago, I was diagnosed with a terminal lung disease that was later identified as scleroderma and informed that my only option for survival was to receive a double lung transplant. I was told, however, that I was unlikely to receive one and that I should just begin making end of life preparations. I quickly moved on to another practitioner who subsequently made the referral for me.

The several years after that initial diagnosis were perilous. On three separate occasions, I nearly lost my life due to the adverse effects of the disease. First, during the early progression of my disease, I traveled to a high elevation destination without the realization that my scarred lungs could not process oxygen at a sufficient rate in order for me to adequately breath. A local doctor who checked my symptoms found that I had a blood oxygen level of 53% and noted I likely would have suffered from a stroke within that same day without immediate care. Secondly, during year three of my five-year journey to transplant, I went into respiratory arrest primarily due to the weakened lungs during a medical procedure and had to be resuscitated. Finally, just a few months before the transplant, I was hospitalized with a lung infection so widespread that it required hospitalization for a period of time that was two weeks longer than my post-transplant stay. The medical team later informed me that clearing the infection may not have been possible if I had sought treatment 8-12 hours later than I did. I've also had more instances of a collapsed lung than I would care to remember.

During this period, I was also diagnosed with achalasia. This is a disorder characterized by the inability of the esophagus to properly move food and liquids into the stomach. I was told after going through the evaluation process that this disorder disqualified me from receiving a transplant at my state's only lung transplant program since the risks of my surgery outweighed the benefits of receiving donor lungs. The rejection I received from that program launched a solo effort, without transplant program assistance, to locate another program that would take me on as a patient. Over the next several months I reached out to one program after another, slowly losing hope as each new month brought a new letter of rejection in the mail until I eventually found a program by happenstance while traveling out of state for work.

Several things stood out to me during this experience: The absence of a basic standard of care from the specialty physician who did not give a referral to an appropriate transplant hospital so that I could receive follow up care, the void in guidance to an appropriate transplant hospital when my first-choice program disqualified me from theirs which left me ill-informed and on my own, and the lack of clarity as to which programs would automatically exclude me as a potential candidate based on my medical complications.

When finally waitlisted, patients also do not have the visibility to know which organ offers are declined on their behalf. This lack of visibility disenfranchises the patient from the decision-making process and deprives us of opportunities to receive a life-saving transplant. These gaps in care and guidance are opportunities for improvement. We need a system that works for patients, is easily navigable, and is unambiguous.

The specific circumstances of my own experience may be unique but the consistent difficulties in accessing transplant services are all too common. I was fortunate that I had the means, including access to good insurance, that allowed me to travel to another state to receive care. That is not always the case. Many studies highlight the disparities and inequitable access to transplant services that disproportionately harm Black people and people of color who do not have the resources to access transplant in these circumstances.

This committee has previously highlighted that organ donation system failures are an "urgent health equity issue". Consider the numbers for kidney failure - Hispanic Americans are 1.5 times more likely to experience kidney failure than white Americans; Black Americans are 3 times more likely, and Native Americans are 4 times more likely. Yet we also know Black people and people of color are less likely to receive transplants. One particularly troubling piece of data: organ procurement organizations (OPOs) have massive disparities amongst recovery rates of donors of color across the country. Axios highlighted a ten-fold disparity of Black recovery rates between OPOs across the country. Since same ethnicity matches are more likely, Axios was clear about "why [that] matters: Fewer Black donors correlates to fewer Black recipients, which has led to more Black dying on the organ transplant waitlist."

As a transplant recipient, I am committed to taking the best care of my organ as possible. Not only is it a necessity for my health, safety, and best long-term outcome success, but I also consider it an almost sacred duty. It is the bare minimum for me to be the best steward possible to show the proper respect and honor for my donor. Patients resoundingly agree on this point.

It is troubling to see, then, that we as Americans are asked to donate our organs but our OPOs do not appear to be the best stewards of the organs that we are donating. It is heartbreaking that thousands of recovered organs each year are not used while thousands more are not recovered at all. In addition, twenty-three percent of kidneys are wasted that could have made a significant dent in our transplant waitlist and saved lives.

Here is some additional data that is equally troubling:

33 Americans die every day for lack of a transplant, while thousands of organs go unrecovered and not transplanted every year. That number includes both patients dying on the waitlist and the removal from the waitlist of those who have died from being too sick to transplant.

The federally-funded deceased donor potential study showed the U.S. may be recovering as few as one in five potential organ donors.

To make this shocking status quo real: 28,000 organs go unrecovered each year, including: 17,000 kidneys; 8,000 livers; 1,500 hearts; and 1,500 lungs.

For scale, according to the Chief of Transplant at Vanderbilt who testified at the House Oversight hearing last year, if the system were fully functioning, there would be no waiting list for livers, hearts, or lungs within three years, and the kidney waitlist would be dramatically reduced.

According to data released by the Centers for Medicare and Medicaid Services this April, the majority of organ procurement organizations are failing to miss performance standards; again, which translates into thousands of organs unrecovered each year.

Research has documented that often Black families receive differential treatment from OPOs. As former Surgeon General Dr. Ken Moritsugu noted: “Often, misallocation of OPO resources means OPOs do not respond to all donation cases, or do not properly train and support their frontline staff. The impact of this, unsurprisingly, falls disproportionately on families of color.” When I have personally spoken at donor remembrance ceremonies or other events in my community these same anecdotes supporting Dr. Moritsugu’s research have been shared with me. Similar anecdotes have been shared with me by mainly Spanish-speaking families who have had the hurdle of language barriers that are difficult to clear.

Senators, the leaders and several of my colleagues on the OPTN Patient Affairs Committee asked me to submit a letter (Appendix A) for the record. I have joined them. Among their messages to you:

“Antiquated technology and an apathetic culture cause patients to languish with incomplete and often incorrect information, and leave people to die every day on the list. OPTN PAC members have raised these points often with UNOS leadership, and have seen our calls for reform ignored. We have been aghast at the absolute failure of UNOS to operate the practice and business of transplant, and to acknowledge - much less effectively serve - patients who are waiting and dying on the organ waitlist…

“The alarming revelations in the Washington Post… [including] covering for failures of organ procurement organizations; and lack of cooperation with the government, even devolving to UNOS having ‘threatened to walk away’, lead us to believe that UNOS has proven itself incapable of functioning as the OPTN.

“We ask that you ensure that the federal government makes the fast-approaching contracting OPTN cycle competitive for the first time since the original OPTN contract was awarded in 1986, opening critical functions up to best-in-class innovators across the country; and we implore you to ensure that UNOS does not hold patients hostage in the process.”

Senators, I urge you all to act to ensure that we make better use of the organs that are donated, to ensure that health equity issues with Black people and people of color are addressed, and that the glaring technology issues causing patients harm are quickly remedied. I thank you for your time.

Calvin Henry
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Organ Procurement and Transplantation Network (OPTN)
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Appendix A: UNOS Hearing PAC Letter, August 2, 2022

August 2, 2022

Dear Members of the Senate Finance Committee,

As the leaders of the OPTN Patients Affairs Committee (PAC), we are reaching out to share our experiences on the committee that we believe indicate a systemic failure of UNOS to serve patients as the OPTN. This is all the more urgent in light of investigative reporting from the Washington Post.

Antiquated technology and an apathetic culture cause patients to languish with incomplete and often incorrect information, and leave people to die every day on the list. OPTN PAC members have raised these points often with UNOS leadership, and have seen our calls for reform ignored. We have been aghast at the absolute failure of UNOS to operate the practice and business of transplant, and to acknowledge - much less effectively serve - patients who are waiting and dying on the organ waitlist.

On July 28th, in preparation for the upcoming August 3rd Senate Finance Committee hearing into UNOS, PAC leaders received an email from UNOS CEO, Brain Shepard, referring to your investigation, in which he makes four assertions that UNOS has shared with the Committee.

We wish to correct the record for your urgent consideration.

> *Shepard: "Our IT system remains safe, secure and routinely meets and surpasses federal standards"*

The Washington Post reported *"The system for getting donated kidneys, livers and hearts to desperately ill patients relies on out-of-date technology that has crashed for hours at a time and has never been audited by federal officials for security weaknesses or other serious flaws."*

We hope the Committee asks UNOS how many patients have died due to the inability to match organs during downtime, as well as other technological inefficiencies such as data error due to manual entry, as well as how many patient life-years have been lost due to delays in organ transportation. That said, given the lack of transparency in the UNOS tech system, it is difficult to imagine anyone at UNOS could answer this question with any confidence.

> *Shepard: "We have worked together as a community to improve the transport of organs with innovative, evidence-based products"*

The UNOS transportation record on organs is woefully - and fatally - inadequate, as outlined by investigative reporting from Kaiser Health News - as well as cases brought before the Senate Finance Committee. Put simply, UNOS operates as an antiquated, closed system that keeps out external innovators that could help patients with better tools and services.

> Shepard: "*Our committees and staff are proud to work collaboratively with all members to serve as partners in improvement"*

PAC members have often sought - and not received - clarity on how patient input is used. When PAC takes clear positions (such as the need to fast-track proposed changes to using eGFR results to list people of color), UNOS has refused to act. Compare this to a recent UNOS fast track process that addressed a hardware defect in a mechanical heart that went through in less than a month. Black patients deserved this kind of speedy remedy when eGFR was proven to have racial bias. We also note Washington Post reporting that UNOS's policy making processes have been so divisive that they have *"spark[ed] open conflict"* among OPTN members.

> Shepard: *"The system we are all so honored to be a part of just surpassed 41,000 transplants in 2021, while continuing to expand equitable access to transplant"*

UNOS obscures its underperforming record behind recent increases in organ donation rates that have resulted from tragic spikes in opioid overdoses, gun deaths, and car accidents, including as second-order effects of the COVID pandemic, not from UNOS's own performance. See the former U.S. Chief Data Scientist making this point in MedPage, and research in the Journal of the American Medical Association finding that, after controlling for public health trends and scientific advancements which have increased the size of the donor pool, organ donation rates have not even kept pace with population growth.

The alarming revelations in the Washington Post (antiquated technology; covering for failures of organ procurement organizations; and lack of cooperation with the government, even devolving to UNOS having *"threatened to walk away"*) lead us to believe that UNOS has proven itself incapable of functioning as the OPTN.

We ask that you ensure that the federal government makes the fast-approaching contracting OPTN cycle competitive for the first time since the original OPTN contract was awarded in 1986, opening critical functions up to best-in-class innovators across the country; and we implore you to ensure that UNOS does not hold patients hostage in the process.

We urge you to continue with your oversight and institute urgent reforms that will literally result in lives saved.

Signed,

Garrett Erdle
Chair, OPTN PAC
Living Kidney Donor, Alexandria, VA

Molly J. McCarthy
Vice Chair, OPTN PAC
3-time Kidney Transplant Recipient, Redmond, WA

Chris Yanakos
Former Member of OPTN PAC
Living Liver Donor, Caregiver and Donor Family Member, Pittsburgh, PA

Steve Weitzen
Region 2 Representative, OPTN PAC
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Region 3 Representative, OPTN PAC
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Lorrinda Gray-Davis
Region 4 Representative, OPTN PAC
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Region 8 Representative, OPTN PAC
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