Chairperson Cardin, Ranking Member Young, and Members of the Committee, I'm grateful for the opportunity to testify today, and would like to thank you for your work to drive lifesaving, patient-centric reforms to the U.S. organ donation system through Senate bill 1668 to break up the national organ transplant monopoly.

My name is Molly McCarthy. I am a 3-time kidney recipient, having received my first 32 years ago. I'm one of the fortunate ones: I've made it despite the broken and corrupt organ donation system we have been saddled with, and I am all-too aware that many patients aren't as fortunate. I received two living donations, one from my mother and one from my father — an option that I know many patients do not have.

Then 11 years ago, I received one from a generous deceased donor. I am acutely aware that I may need a transplant again in the future. And whether that happens is dependent on what Congress does now. I'm here today to plead with you to pass Senate bill 1668.

The reason why is as simple as it is heartbreaking: the federal monopoly contractor managing the organ donation system — the United Network for Organ Sharing, or UNOS — is an unmitigated failure, and its leadership spends more time attacking critics than it does actually taking steps to fix the system.

I have seen this first-hand. As a passionate advocate for patients, I took on the volunteer role of Vice Chair of the Patient Affairs Committee, or PAC, for the Organ Procurement and Transplantation Network, the federal contractor that UNOS holds. I thought this would be a chance to ensure that the patient voice was included in national policy. Sadly, I couldn't have been more wrong.

What I learned is that UNOS, at best, treats patients as props; at worst, it outright lies to us, and then uses us as a shield against much-needed oversight and reform. UNOS knows enough not to lie to Congress, so it lies to patients instead, and then launders its lies through us.

For the last year, much of my work on PAC has consisted of writing to Congressional offices to fact-check UNOS misinformation, which I would like to take the opportunity to do here today.

For example, UNOS leadership has created a systematic effort to misrepresent the facts, regularly celebrating recent increases in organ donations as evidence of their success and a well-working system.

The reality, however, is that this growth is driven entirely by the opioid epidemic and skyrocketing gun deaths, as well as other increases in suicides and fatal car accidents. All UNOS is celebrating are national tragedies, not a well-run organ donation system.

Similarly, UNOS dramatically downplays the deadly toll of its failures by only publishing the number of deaths of patients who were already on the transplant waiting list. But most patients who need transplants are never even placed on the waiting list because of the severe organ shortage in UNOS's system.

And this is also where most of the inequity occurs, as UNOS does absolutely nothing to ensure that patients of color are added to the waiting list at the same rate as white patients.

For years, Black patients were even subject to a racist metric of kidney function; in fact, there is currently a class action lawsuit from 27,500 Black Americans alleging systematic racial discrimination against them in waiting list practices.

This is an issue that PAC had been raising for more than a year before UNOS took any action, and even then, the action wasn't enough to help many patients.

Worse than being ignored, however, is that people who speak out have been bullied, threatened, and retaliated against. This is well-documented, including in recent investigative journalism from the Richmond Times-Dispatch, UNOS's hometown paper.

I personally have been warned that the UNOS Board is unhappy with my advocacy, and that there will be consequences if I continue to speak out. Imagine saying that to a patient. Further, I've been called by a board member telling me to stop focusing on system outages of the UNOS system; he told me that having the system down for a few hours wasn't a big deal, that the donors are dead anyway.

UNOS has also failed to oversee organ procurement organizations (OPOs). As a patient, I don't understand why any tier 3 OPO is still allowed to operate. This is a life and death business, and the Centers for Medicare and Medicaid Services (CMS) must immediately replace failing OPOs with successful OPOS that are getting the job done. Now. It's costing taxpayer dollars and thousands of lives.

There is no shortage of evidence that the system is broken. But what I hope I can communicate to you is that the problems are far worse than what is publicly known, and the rot is far deeper.

UNOS behaves like mob bosses, and for every whistleblower who speaks out, there are another hundred who remain silent. It is no exaggeration that Forbes once called UNOS a "cartel."

While we may never know the true toll of the gross negligence and abuse of the government's own organ contractors, we do at least know the solutions.

- CMS needs to move urgently to open data for organ procurement organizations; replace failing OPOs without caving to industry pressure to weaken standards; and close the dangerous pancreas loophole that allows OPOs to pad their numbers and jeopardize patients' lives; and
- Congress needs to break up UNOS's monopoly by passing S 1668, ensuring that the Department of Health and Human Services uses its authorities to replace UNOS as its contractor.

Before my last transplant, I waited 6 agonizing years. Watching the Senate Finance hearing last August, I realized that potentially years of that wait were unnecessary. Patients deserve an effective, safe, transparent, and equitable organ donation system. Speaking as a patient of this system, I have no zero confidence that we will ever have it if UNOS has any role in the transplant system.

Thank you.

Appendices Below

- *Appendix A: "Fact Check of AOPO Misinformation" posted on Medium, February 2023*
- *Appendix B: Fact Check of then-UNOS President Dr. Jerry McCauley sent to various Congressional offices, October 2022*
- *Appendix C: OPTN Patient Affairs Committee Statement For the Record for Senate Finance Committee August 2022 Hearing*

Appendix A: "Fact Check of AOPO Misinformation" posted on Medium, February 2023

On January 28th, the New York Times ran a heartbreaking guest essay about Tonya Ingram, a 31-year-old woman who died in need of a kidney transplant. Tonya had tirelessly advocated for reforms to the organ donation system, including the government's monopoly contractors charged with organ recovery, called organ procurement organizations (OPOs).

Tonya even testified before the House Oversight Committee in May 2021 that absent such reforms, she would die. No reforms came, and she was ultimately proven right: she died on December 30, 2022. Tonya was full of joy, and her life was cut way too short.

In response, the Association of Organ Procurement Organizations (AOPO), which is currently the subject of a Congressional investigation for various abuses, including misinformation and anti-patient lobbying, issued an absolutely wild statement in which they spread falsehoods and deflected blame, and, implicitly, disparaged Tonya's work and dishonored her legacy.

Below is a fact-check of AOPO's statement, which I post with the hope that facts will prevail, and the reforms that Tonya fought so vigorously for may ultimately be finalized, saving the lives of tens of thousands of other future patients.

Molly McCarthy
3-time Kidney Transplant Recipient
Vice Chair of the Organ Procurement Transplantation Network Patient Affairs Committee

AOPO wrote: *Sadly, 17 people die each day waiting for a lifesaving transplant. There is no question that Americans, especially those suffering from acute kidney disease, deserve greater access to organs for transplant.*
Fact-check: The number of people who die every day is much higher than 17. Inclusive of patients who die every day after having been removed from the waiting list for becoming "too sick to transplant," the current number is 32. (The OPTN database is quite difficult to use, however, if you run a report for "waiting list removals by reasons by year" and then add the columns for "died" and "Too Sick to Transplant" for 2022 and then divide by 365, the number is 31 deaths per day. In 2021, when Tonya Ingram testified before House Oversight, it was 33 — see Washington Post.)

Of course, inclusive of patients who never even reach the waiting list — disproportionately patients of color because of racial bias in waiting list practices — the number is much, much higher than that. Using the number 17 erases their deaths and suffering from the story and is simply a function of UNOS's "accounting practices" in waitlist management to downplay the scale of the system's failures.

AOPO wrote: *Recent data released by the Organ Procurement and Transplantation Network (OPTN) shows how these efforts have resulted in an increase in the number of deceased organ*

donors year over year for the last 12 consecutive years. Since 2010, the data represents an 87% increase overall in deceased organ donors. Notably, in 2022, OPOs recovered a record number of kidneys from deceased donors resulting in over 25,000 kidney transplants.

Fact-check: These statistics are wildly devoid of context, as has been pointed out repeatedly in response to misleading UNOS lobbying. As former United States Chief Data Scientist DJ Patil has published, *"To deflect criticism, OPOs and UNOS have lobbied aggressively to confuse the recent increases in organ donors from opioid and other external causes (i.e., non-medical deaths like trauma, substance use, and suicide) with improved performance overall. If donation numbers are increasing, their argument goes, then the system must be performing well, and so the push for reform must be misguided. This is a cynical attempt to politically profit from the opioid scourge and other second-order effects of the deadly pandemic, mischaracterizing the data to evade accountability."*

In fact, peer-reviewed data published in JAMA has found that, after controlling for increases in donation outside of OPO control (e.g., public health trends), donation rates in recent years have not even kept pace with simple population growth (see data visualization — here).
If a baseball player had 5 hits in 10 at-bats his rookie year, and then 10 hits in 100 at-bats during his second season, we would all find it risible if his agent argued that he deserved a huge new contract because he doubled his number of hits. Only in this case, what AOPO is shamefully claiming credit for are terrible American public health tragedies, including spikes in opioids overdoses, gun deaths, suicides, and fatal car accidents, including as second-order effects of the Covid pandemic.

The fact that AOPO does not seem to understand the drivers of donation, or even how to describe procurement practice in the U.S., calls into question its ability to identify and rectify system failures. In case anyone has not seen it, here is a video of AOPO CEO Steve Miller testifying before Congress that he does not have a deep understanding of the OPO regulatory system. Based on his comments, I believe him.

AOPO wrote: *These numbers show improvement and support that the U.S. is the world's most successful organ donation and transplantation system, yet there is more to do.*
Fact-check: As alluded to above, these numbers do not actually show system improvement. In fact, as a relative matter, the system has gotten worse over this period.
Likewise, these numbers absolutely do not show that the U.S. has the "world's most successful organ donation and transplantation system." As DJ Patil wrote in the editorial I referenced above:

"Similarly, a common OPO and UNOS refrain is that the U.S. now has the highest number of organ donors per capita of any country, which they use to characterize the American organ donation system as the "best in the world." But context is critical. The higher organ donation rates in the U.S. actually reflect higher levels of societal ills, rather than superiority of the organ procurement system.

"More plainly: We have more organ donors in America not because we have a strong — or even remotely adequate — organ procurement system, but because on a per capita basis among wealthy nations, we have many times more deaths in those subsets of deaths that allow for organ donation to occur. This includes 20 to 30 times more opioid deaths, 25 times as many gun deaths, the highest suicides rates, and more than twice as many fatal car accidents — a number that spiked again precipitously last year."

To give an even more plain speak analogy, imagine that 100 Americans were in one room, and in another room, there were 100 Canadians. In the American room, let's say 15 of them die in organ donation eligible ways, and our system successfully converts 2 of them into organ donors. In the Canadian room, 2 people die in such ways, and their system converts 1 of them into an organ donor. It is simply not statistically reasonable — or intellectually honest — to suggest that this means the U.S. system is twice as good as the Canadian system simply because it had 2 donors per capita instead of 1.

Obviously, the numbers used in the example above are for simplicity, but it is to make the point that using a per capita comparison across different countries is nonsensical. That the U.S. has more organ donation eligible deaths than other countries (e.g., from opioids, gun deaths, suicides, and car accidents) is one tragedy; when we fail to recover potential organ donors, that's another, and the two compound.

AOPO wrote: *A key area of improvement is in the number of organs recovered by OPOs but refused by transplant centers and instead go to waste. That number is rising dramatically. In fact, 7,540 kidneys, amounting to 26% of all kidneys recovered and offered by OPOs for transplantation in the U.S., were turned down by transplant centers last year.*

Fact-check: Discards in the U.S. are too high and are rising. There is broad agreement on this. AOPO's framing of the problem as entirely a transplant center issue, however, is incorrect and overly reductive. There are many contributing factors, certainly including transplant center "weekend effect" and transplant center risk aversion, though also including:

- Differential effort and ability from OPOs in clinical management of donors and waitlist navigating, as evidenced by wildly different organ placement rates across OPOs for clinically similar organs;
- DonorNet inefficiencies and frictions, as identified by the United States Digital Service and reported on by the Washington Post, and testified before the Senate Finance Committee by Mid-America's Diane Brockmeier;
- Failures of organ logistics and transportation, including deeply unprofessional OPO practices of selecting and managing transportation vendors, as well as gross failures of the UNOS Organ Center, as reported on by Kaiser Health News and covered in the Senate Finance Committee hearing; and
- OPOs often recover kidneys they have no intention of placing for transplant, but, because of an arcane reimbursement system, OPOs are able to overbill Medicare through cost-shifting enabled by explanting more kidneys even if they are not transplanted. There is, honestly, likely an issue of systemic Medicare Fraud here.

The best way to inform solutions on this is to have more transparency into the system. Ironically, this is one of the solutions explicitly called for in the NYT piece — as well as Tonya's advocacy: to follow the Senate Finance Committee's recommendations for CMS to publish OPO process data. This is standard in every other mature transplant system in the world, including, of course, all systems with lower discard rates than ours.

AOPO wrote: *In Los Angeles, where Tonya Ingram lived, organ donation was up 10% last year — a two-decade upward trend. The local OPO recovered a record 2,143 organs in 2022 but also saw 520 organs rejected by transplant centers, up from 376 the year before. Moreover, 397 of the 520 rejected organs were kidneys, up from 273 the year before. One of these kidneys may have saved Tonya's life. This rise in rejection rates is disheartening to the OPOs that work*

each day to increase the number of organs they are recovering. But it is devastating to patients living — and often dying — on dialysis, waiting for an organ. OPOs have no control over whether organs are actually transplanted into patients. Our nation's transplant centers make this critical decision, determining whether to accept an organ offered from an OPO.

Fact-check: The "two-decade upward trend" framing is addressed above, as well as the organ discard issue. I will note here, though, that OneLegacy's OPO is Tier 3, failing according to CMS, as it has been for every year that CMS has published Tier ranking data. (In the most recently available data from 2020 released by CMS last year, OneLegacy's failure to reach Tier 1 standards by 328 transplants, or — in plain speak — 328 preventable deaths.) I would also note that OneLegacy is under investigation by the House Oversight Committee for "shocking mismanagement."

AOPO wrote: *The exclusion from this discussion of our nation's transplant centers and their regulators as important stakeholders involved in improving the system's ability to save more lives is a serious oversight. For the entire system to save more lives, we need to ensure that transplant centers have declared clear organ acceptance criteria, have the appropriate resources to process the influx of available organs, and utilize organs from more medically complex donors.*

Fact-check: While transplant centers (and UNOS) certainly have some responsibility related to discards, as further expounded on above, the NYT piece itself highlights that the Indiana OPO, in response to oversight pressures, increased organ donation rates by 44% in one year by simply approaching 57% more donors. Restated: the increase did not necessitate behavior changes at transplant centers, new OPTN technology, or any other changes; the major increase resulted through the single intervention of applying oversight pressure to the OPO to follow the existing legal mandate of approaching every donation referral it receives.

AOPO wrote: *The National Academy of Science, Engineering, and Medicine's (NASEM) report — "Realizing the Promise of Equity in the Organ Transplantation System" — which was developed in 2021 at the request of Congress and sponsored by the National Institutes of Health (NIH) is the only peer-reviewed, data-driven assessment of the entire organ donation and transplantation system, and it focuses specifically on kidneys. The report categorically states that the whole system — the Center for Medicare and Medicaid Services (CMS), the United Network for Organ Sharing (UNOS), transplant centers, OPOs, and donor hospitals — bears responsibility for increasing the number of transplants in the U.S. NASEM found that "on average, patients who die waiting for a kidney had offers for 16 kidneys that were ultimately transplanted into other patients, indicating that many transplant centers refuse viable kidney offers on behalf of those on the waiting list (Husain et al., 2019)."*

Fact-check: The NASEM report is currently being investigated by two separate Congressional Committees — House Oversight Committee (see Kaiser Health News) and Senate Finance Committee — for apparent financial conflicts of interest among its members, with the Senate Finance Committee writing upon the publication of the NASEM report: *"We are concerned that the NASEM report seems to align with the lobbying positions of UNOS and the Association of Organ Procurement Organizations (AOPO), and that these recommendations will not address the concerns raised during our investigation."*

AOPO can help shed light on this by sharing any contracts it — or its member OPOs — have signed with any of the consultants who were members of the NASEM study, including Dennis

Wagner of Yes And Leadership. (See Senate Finance letter.) If AOPO is looking for support of the NASEM study as an unbiased, unconflicted resource, there is no reason AOPO shouldn't be willing to share the financial relationships that would inform whether or not such conflicts exist.

Put another way, if there were no conflicts, AOPO would presumably be very eager to clarify that.

AOPO wrote: *Rather than referencing NASEM, however, the New York Times editorial relies on the privately funded Bridgespan study from 2019, which claims that OPOs fail to recover an additional 28,000 organs a year is unrealistic. This estimate would only be possible if all potential organ donors said yes to donation, all their organs were medically suitable for transplant, and transplant centers accepted and successfully transplanted all their organs. The report notes that the figures represent the "full potential" of the system, assuming 100% donation rates and 100% organ utilization, an unfeasible measure in the medical field. OPOs nationwide are unwavering in their commitment to saving patients' lives and reducing the numbers on the waiting list.*

Fact-check: This one is, candidly, quite bizarre, as investigative reporting has already highlighted that the AOPO/OPO talking points about Bridgespan are objectively, factually false. Similarly, a letter to the House Oversight Committee from a then-AOPO board member clarified the same. For the abundance of clarity, I will repeat the fact-check below:
AOPO is simply factually incorrect in its assertion that Bridgespan's study — which was based on peer-reviewed research from leading researchers at the University of Pennsylvania, a former U.S. Surgeon General, and two OPO executives — assumes that "all [of every donor's] organs were medically suitable for transplant."

The study estimates a donor potential of 24,007 annually for the years 2009–2012, and an organ potential of just over 50,000 annually (see figure on page 5). As a matter of simple math, this assumes an average of just over 2 organs transplanted per donor, representing an estimate far more conservative than the 3.45 medically suitable organs recovered per donor which AOPO states is industry average. The methodology for this study is clearly laid out in the peer-review publication. It is unclear why AOPO believes that the study assumes 8 organs per donor, or why they continue to assert it despite numerous fact-checks to the contrary.

Additionally, if AOPO does not like Bridgespan's research, it can also rely on a publicly funded study which HRSA funded and the OPTN performed, which found an even larger donor potential than Bridgespan did. Specifically, the deceased donor potential study, published in 2015, found (see page 8): *"Currently, organs for transplantation are recovered from about 8,000 deceased donors per year, potentially only one-fifth of the true potential. These findings suggest that significant donation potential exists that is not currently being realized."* (Note: the donor potential today is now certainly even much higher, given the above-referenced spikes in donor potential driven by the opioid epidemic and other public health trends.)

Finally, I will also note the incredible irony (or gall?) of AOPO breathlessly asserting that Bridgespan's peer-reviewed 51,000 organ potential conclusion is "unfeasible," while in the very same statement self-celebrating their imagined future success of 50,000 transplants.

AOPO wrote: *Too many patients have put their faith in our system for anyone to waste another minute avoiding responsibility or spreading falsehoods.*

Fact-check: Yes, agreed. Extensive investigative reporting has found that AOPO, many individual OPOs, and UNOS have been responsible for the active spreading of misinformation and outright falsehoods. As far as "avoiding responsibility," not a single sentence in AOPO's comment accepted any responsibility for anything. I wish they had.

Appendix B: October 2022 Fact Check of UNOS Misinformation

Dear Dr. McCauley,

As a 3-time kidney transplant recipient and patient advocate who has previously corrected misinformation from UNOS, I write this letter to:

- Clarify misinformation from your letter dated 28 October 2022, which a UNOS lobbyist is disseminating;
- Alert HRSA Administrator Johnson, the Senate Finance Committee, and the House Oversight Committee as well as Senator Booker and Congressman Jones, to ongoing UNOS efforts to disseminate such misinformation; and
- Most importantly, to express my disappointment at your condescending implication that Ben Jealous, a known civil rights icon and distinguished scholar who has published on organ donation reform issues (see here and here), was unable to understand the pro-patient, pro-equity Congressional letter which he endorsed, in line with his previous advocacy.

On the last point, I note the irony that it was your letter to Mr. Jealous which demonstrated a shocking grasp of basic facts and context, which I will address below. People are dying while UNOS is spending its time protecting its reputation and contract, and I fear that should the day come that I need another kidney, I, too, will die if the status quo is allowed to continue.
Urgently submitted,

Molly McCarthy
3x Kidney Transplant Recipient
Vice Chair, OPTN Patient Affairs Committee
Redmond, WA

You stated: "The number of deceased donor transplants has increased every year for the last nine consecutive years to a record high of 41,356 transplants in 2021. The number of deceased donors has increased every year for the past eleven consecutive years, for a record high of 13,863 in 2021. Deceased organ donor recoveries have increased 58% since 2007."

Fact-check: These statistics are wildly devoid of context, as has been pointed out repeatedly in response to misleading UNOS lobbying. As former United States Chief 1 Data Scientist DJ Patil has published, "To deflect criticism, OPOs and UNOS have lobbied aggressively to confuse the recent increases in organ donors from opioid and other external causes (i.e., non-medical deaths like trauma, substance use, and suicide) with improved performance overall. If donation numbers are increasing, their argument goes, then the system must be performing well, and so the push for reform must be misguided. This is a cynical attempt to politically profit from the opioid scourge and other second-order effects of the deadly pandemic, mischaracterizing the data to evade accountability."

In fact, peer-reviewed data published in JAMA has found that, after controlling for increases in donation outside of OPO control (e.g., public health trends), donation rates in recent years have not even kept pace with simple population growth (see data visualization - here).

The fact that UNOS does not seem to understand the drivers of donation, or even how to describe procurement practice in the U.S., calls into question its ability to identify and rectify system failures, and further underscores the need for additional data transparency and competition for the OPTN contract, the two very suggestions proposed by Senator Booker and Congressman Jones.

You stated: "A single study from 2003 as cited in the "Dear Colleague" letter cannot responsibly be applied to the state of the organ donation and transplant system of 2022, much less serve as the basis for a system overhaul. A great deal has changed in nearly 20 years, and the study from 2003 does not reflect those reforms, new polices [sic], improvements and new data."

Fact-check: By no means is a single study from 2003 the "basis" for a system overhaul; it is rather one data point in a litany of evidence, and in the estimation of countless experts who have noted deadly system deficiencies. For example, the Senate Finance Committee, now more than two years into a bipartisan investigation into UNOS, recently published a report concluding that "From the top down, the U.S. transplant network is not working, putting Americans' lives at risk."

Similarly, the United States Digital Service (USDS) published a scathing report about the state of UNOS's technology entitled "Lives Are At Stake", and determined that "it has become apparent that the organ transplantation system in this country is not set up to enable the best outcomes for patients waiting for life-saving transplants. In order to properly and equitably support the critical needs of these patients, the ecosystem needs to be vastly restructured."

The reforms called for in the Congressional sign-on letter are broadly supported by pro-patient groups including the National Kidney Foundation, American Society of Nephrology, Global Liver Institute and Organize; equity leaders including the ACLU, Just Equity for Health, Health Justice, Empower Her Health, and the Institute for Antiracism in Medicine; and editorial boards including the New York Times; as well as the House Appropriations Committee and leaders from the House Oversight Committee and Congressional Black Caucus.

In fact, perhaps most interestingly, the reason that there have not been more peer-reviewed studies on inequitable care provision for patients of color since 2003 is that the United States is unique among mature international transplant systems in its failure to make transparent the data necessary to evaluate such OPO performance. Additionally, based on other proxy points, there is every reason to believe this inequitable care persists. For example, based on the most recent data available from CMS, there is a 10x variability in OPO recovery rates among Black donors. If UNOS is objecting to opening OPO data, as called for in the Congressional letter you object to, that seems designed to prevent this very analysis, thereby continuing to mask such inequities. Any position against opening OPO data is antithetical to patient needs.

You stated: "The results of new organ allocation policies have shown large gains in access to transplant for waitlisted patients of color. One report shows significant increases in the number of kidney transplants for key populations, including a 23% gain for Black patients, 31% for Hispanic patients, and 21% for Asian patients."

Fact-check: Per above, this is reflects a complete misunderstanding of the role public health trends - including increases in opioid deaths, gun deaths, fatal car accidents, and suicides as second-order effects of the Covid pandemic - which have increased the absolute number of organ donation eligible deaths.

Additionally, some of the increase also appears to have resulted from increased public scrutiny of the organ donation system, as well as CMS's recent regulatory interventions to hold OPOs accountable, both of which UNOS has vehemently opposed, including through untoward tactics such as the dissemination of misinformation.

You stated: "The assertion that an additional 28,000 transplants are possible reflects a poor understanding of how donation works and reveals a faulty assumption that every person who has died in a hospital is a "potential donor," even if they were not medically cleared to be an organ donor. Less than 1% of all deaths in the U.S. occur in ways clinically compatible with organ donation; people who die of cancer, sepsis, certain infectious diseases, or organ failure cannot be cleared for donation by the OPO based on medical criteria established by transplant physicians for the safety of their patients."

Fact-check: This is objectively false. The 28,000 number in no way assumes that every person who dies in a hospital is a "potential donor." The research itself, which was peer-review published by leading researchers, a former United States Surgeon General, and two OPO executives, explains that "These estimates were compared to patient-level data from chart review from two large OPOs" and found that "Among 2,907,658 inpatient deaths from 2009-2012, 96,028 (3.3%) were a "possible deceased-organ donor." The 3 methodology, which your letter entirely misrepresents, is clearly laid out in Figure 1 of the peer-review analysis.

The 28,000 number is significantly more conservative than UNOS's own analysis, funded by HHS, which found in 2015 (see page 8) that: "Currently, organs for transplantation are recovered from about 8,000 deceased donors per year, potentially only one-fifth of the true potential. These findings suggest that significant donation potential exists that is not currently being realized."

The mischaracterization of this research seems to parrot lobbying points from an OPO special interest misinformation campaign, including which the Project on Government Oversight characterized as "replete with personal attacks, and political maneuvering" - as well as a particularly odious astroturf campaign run by a lobbyist for the New Jersey OPO - and which is currently animating a House Oversight Committee investigation into OPO anti-patient lobbying.

Lastly, the research identifying 28,000 additional potential transplants - which you seem to, albeit based on a complete misunderstanding of the underlying, reject as impossible - calculated those numbers based on a total organ of just over 50,000 annually (see Figure 2). I note the irony that UNOS has never once publicly rebuked AOPO's 50,000 organs campaign.

As a matter of basic math and logic, I do not understand how you can simultaneously believe that 50,000 organs can be wholly impossible as a denominator in peer-reviewed research, and yet laudable when promoted in industry lobbying materials as a numerator.
I also highlight previous fact-checks of these same industry talking points which have been sent to other Congressional offices.

You stated: “Our national, forty-two member board of directors is comprised of [sic] a broad, diverse cross-section of the community, and includes [sic] one quarter patient and donor affairs representatives, one quarter donation and transplant professionals, and half physicians and surgeons. Together with HRSA, the OPTN board serves as the voice of the community.”

Fact-check: I note emails from UNOS’s previous CEO Brian Shepard, which were unsealed by a federal judge, revealing his belief that UNOS “do[es]n’t have a real board.” I also note that, far from being the “voice of the community”, that UNOS has lobbied against accountability reforms championed by “every major patient group” engaged in transplant advocacy - including leadership and members of the OPTN’s own Patient Affairs Committee - and that Senate Finance Committee testimony from UNOS board members has detailed a culture of retaliation and retribution.

You stated: “In February 2022, the OPTN welcomed a report from the National Academies of Science, Engineering and Medicine (NASEM), a congressionally-mandated two-year study including a diversity of stakeholders, donation and transplant experts, and patient and donor perspectives.”

Fact-check: The NASEM organ donation study is under investigation from the House Oversight Committee for conflicts of interest among its committee members, which included two past UNOS presidents. This appears to be just another example in a long history of UNOS attempts at regulatory capture, dating back to at least 1999, when Forbes characterized UNOS as a “cartel” and “the federal monopoly that's chilling the supply of transplantable organs and letting Americans who need them die needlessly.”

You stated: “In contrast to this approach, the development of the U.S. Digital Service’s unreleased report referenced in this letter was conducted without our engagement, and was developed without review of the OPTN, UNOS or any of its technology infrastructure.”

Fact-check: The reason that the USDS report was conducted “without [UNOS’s] engagement” is because, as the Washington Post reported, “UNOS has not allowed anyone in government to analyze its code base, instead providing only the English-language description of it, known as pseudocode, officials said. That surprised Digital Service analysts; it was the only time that its engineers’ request to inspect code used by government agencies and contractors has been refused on nearly 100 occasions, according to the former White House adviser who was involved but not authorized to speak.”

This seems to be part of a larger pattern of UNOS obstructionism, including, as the Senate Finance Committee report detailed, “Resistance to Requests for Information and a Valid Subpoena.”

You stated: “The challenges that face the system are complex and multifaceted, and no one entity can address them all.”

Fact-check: This is actually correct, and presumably is precisely why, in part, the Congressional letter from Senator Booker and Congressman Jones urges HHS to demonopolize the OPTN contract, in line with so many leaders in Congress as well as external stakeholders.

Dr. McCauley, in closing and as discussed at our virtual meeting on 13 Oct 2022, I continue to be extremely concerned at what appears to me to be an utter lack of accountability on the part of UNOS to face its failings. It's hard for me not to read your letter and see it as anything more than a purposeful effort to mislead investigators, patients and the general public. As a recipient and on behalf of patients across this country, I implore you and the UNOS leadership to stop investing your time in these evasive letters, tactics and misleading PR, and instead to invest the time in addressing the issues for which UNOS is being investigated

Appendix C: OPTN Patient Affairs Committee Statement For the Record for Senate Finance Committee August 2022 Hearing

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,

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

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