TESTIMONY OF MATTHEW D. WADSWORTH
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SENATE COMMITTEE ON FINANCE
HEALTH CARE SUBCOMMITTEE
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Chairman Cardin, Ranking Member Daines, and Members of the Committee. My name is Matthew Wadsworth, and I serve as the President and CEO of Life Connection of Ohio, the Organ Procurement Organization responsible for facilitating organ donation in northwest and west central Ohio.

My job is to help as many patients as possible receive lifesaving transplants. Most days, I try to do that through continually improving practice at our OPO. But to affect meaningful change at scale, we need federal policy reforms.

The current system is broken. OPOs have geographic monopolies, which has made too many sluggish and complacent, at the expense of patients' lives. There are absolutely no guardrails in place to ensure that OPOs are adequately serving patients, and many of them aren't. And yet the Centers for Medicare and Medicaid Services (CMS) has never once decertified an OPO for performance failures.

In recent years, it appeared as if things may finally be starting to change. CMS finalized new regulations in 2020 to hold OPOs accountable for the first time in 40 years. Three years later CMS has still not taken the steps to provide OPOs with any guidance on how the rule will be enforced, or any indication that it will support meaningful competition to ensure that patients are only served by the best OPOs. Furthermore, CMS has remained silent on waivers filed by hospitals who want to work with higher performing OPOs immediately instead of waiting until 2026.

Additionally, CMS has not yet taken any apparent steps to close a dangerous loophole in the rule which gives OPOs credit for recovery of pancreata that are never transplanted, pancreata labeled for research, and which many OPOs have begun to flagrantly exploit, evidenced by over a 400% increase in the number placed for research since this new rule.

This means that OPOs that are failing at their central task — recovering organs for transplant — can avoid accountability simply by recovering one organ and labeling it research. The fact that executives in our industry lack the moral compass not to exploit this loophole is incredibly perverse; I am deeply appreciative of this Committee for investigating this abuse.

This should be proof positive of a perhaps self-evident notion: OPOs respond to their incentive structure. Unfortunately, those incentives are currently entirely misaligned with what patients need.

This is not only regulatory, but financial; the OPO industry, including OPO boards, are often rife with financial conflicts of interest, which means OPOs all-too-often spend taxpayer resources on special interest projects rather than on investing in organ recovery.

Another issue that deserves urgent attention is the lack of safety guardrails. There isn't even a standardized process for declaring brain death across the country. The reality is that the quality of care that donor patients and donor families receive depends on where in the country someone dies.

The fact that the organ procurement system has been so broken for 40 years speaks directly to the complete abandonment of patients by the organization at the top of the system — UNOS.

Even now, more than three years into this Committee's investigation into UNOS's failures, UNOS has transitioned from an organization that is inept and possibly incompetent to one that takes an active role in preventing patients from being transplanted.

Take, for example, recent reporting in the Washington Post that UNOS is proposing changes to its terms of service which disallow external organizations from conducting data-driven research into the most effective ways to place organs for transplantation, even as organ discard rates skyrocket.

UNOS only appears to be doing this to interfere with the business of a potential competitor for its contract, showing that once again the system has been held hostage by a terrible actor — one which values its own contract far above the lives of the patients we are meant to serve. This is a perfect microcosm of the problem: at every turn UNOS stifles innovation and hides deadly failures, all to keep its monopoly contract.

There are three things the Department of Health and Human Services needs to do immediately to ensure patients receive safe and high-quality organ procurement care:

1) Prepare to enforce the OPO rule, without weakening or delaying it, including closing the pancreas for research loophole, publishing guidance on how the rule will be enforced, and requiring the publication of OPO process data.
2) Break up the OPTN contract and allow for competition so that patients are served by the best in areas such as technology, logistics, data analytics, business development, and process improvement.
3) Eliminate Board and financial conflicts that exist in our industry that prevent OPOs and any OPTN contractors from investing their dollars in areas that grow organ donation and transplantation.

I commend this Committee for introducing legislation to finally break up this monopoly, and I stand ready to work with you in any way possible to ensure that this bill passes. It is the only way this industry will be able to save more patients' lives.

Appendices below

- Appendix A: “Temporal changes in procurement of pancreata for research”, American Journal of Transplantation, May 2023
- Appendix B: Fact-Check of AOPO misinformation sent to House Oversight Committee, Spring 2021, as published by the Project on Government Oversight

Appendix A: “Temporal changes in procurement of pancreata for research”, American Journal of Transplantation, May 2023

Title Page

Manuscript title: Temporal Changes in Procurement of Pancreata for Research

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Abbreviations

Organ procurement organizations (OPOs)

Centers for Medicare and Medicaid Services (CMS)

Organ Procurement and Transplantation Network (OPTN) United Network for Organ Sharing (UNOS)

To the Editor:

Organ procurement organizations (OPOs) are the federal contractors who manage all aspects of deceased organ donation, including procurement of organs from deceased donors for research purposes. In 11/20/2020 the Centers for Medicare and Medicaid Services (CMS) updated the 'Final Rule' for OPO Conditions for Coverage, which included redefining an organ donor for regulatory purposes as an individual with: a) ≥1 organ transplanted; or b) pancreas procured for research or islet cell transplantation (only performed under research protocol).1-3 We sought to evaluate for temporal changes in procurement of pancreata for research purposes, and whether there were changes that coincided with the CMS rule change.

We conducted a retrospective cohort study using data from the Organ Procurement and Transplantation Network (OPTN)/United Network for Organ Sharing (UNOS). We evaluated data over a 10-year period from 1/1/2013-12/31/2022. Pancreata donated for research were identified based on OPTN/UNOS codes, and pancreas-only donors were those for whom a pancreas was procured for research, and no other organs were donated. OPTN/UNOS data does not include data on the disposition of the organ, the specifics of the research study, and whether the research was related to all aspects of the pancreas, or solely islet sell isolation.

Based on the new CMS definition of a deceased donor, there was a steady increase in the number of donor with ≥1 organ transplanted, increasing from 11,578 in 2020 to 12,753 in 2022 (Figure 1a), with a more than ten-fold from 2020 (n=25) to 2022 (n=353) in the number of individuals classified as a donor solely because their pancreas was procured for research (Figure 1a). This phenomenon of increased organ procurement for research purposes was limited to pancreata, despite stable numbers of other organs procured for research (data not shown).

The increase in the number of pancreata procured for research varied across OPOs (Figure 1b). Of the 57 OPOs, 8 (14.0%) procured >100 pancreata for research in 2022, accounting for 1,548 (58.2% of the national total) pancreata research procurements. These 8 OPOs were geographically dispersed. The procurement of pancreata research-only donors was also geographically dispersed and concentrated in a small number of OPOs, with nine OPOs procuring ≥20 pancreas research-only donors in 2022, accounting for 242 (68.6% of the national total) pancreas research-only donors (Figure 1c). One OPO (OneLegacy, CAOP) had 74 pancreas research-only donors in 2022, accounting for 21% of the national total.

Over the last two years, there has been a striking increase in the number of pancreata procured for research. As transplant professionals, we are supportive of advancements in the field that may ultimately increase the number and/or longevity of organ transplants. However the temporal relationship to the CMS rule changes mertis further study (e.g., specifics of research studies, disposition of research pancreata) This would include potential re-evaluation of the CMS OPO final rule to determine whether an unintended consequence of the federal rule change is increased procurement of research pancreata to improve an OPOs metric without increasing the number of lifesaving transplants.

Acknowledgments
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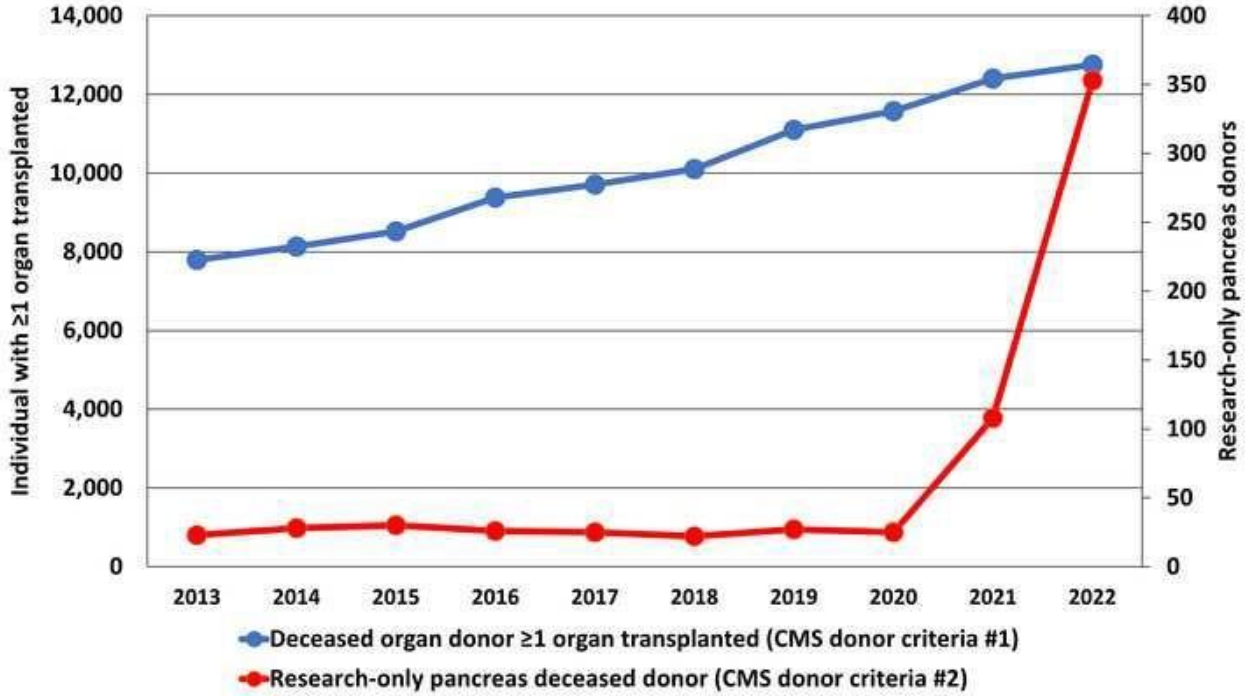
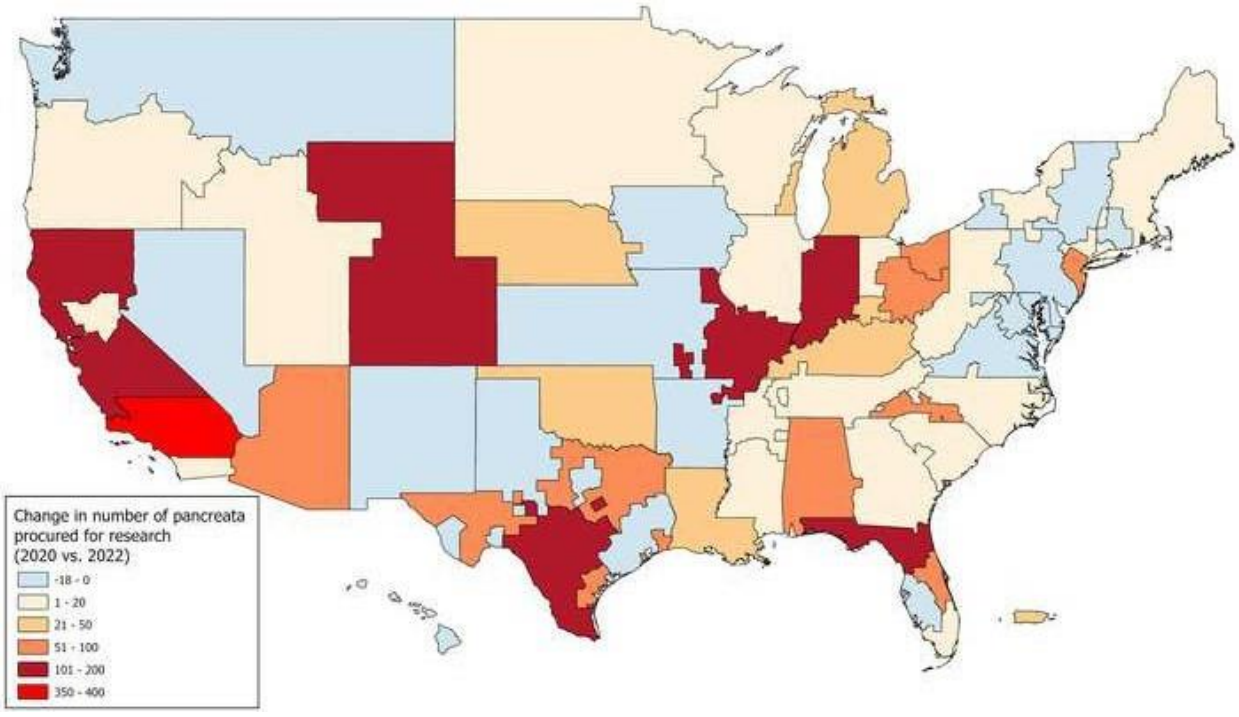
Figures and Figure Legends

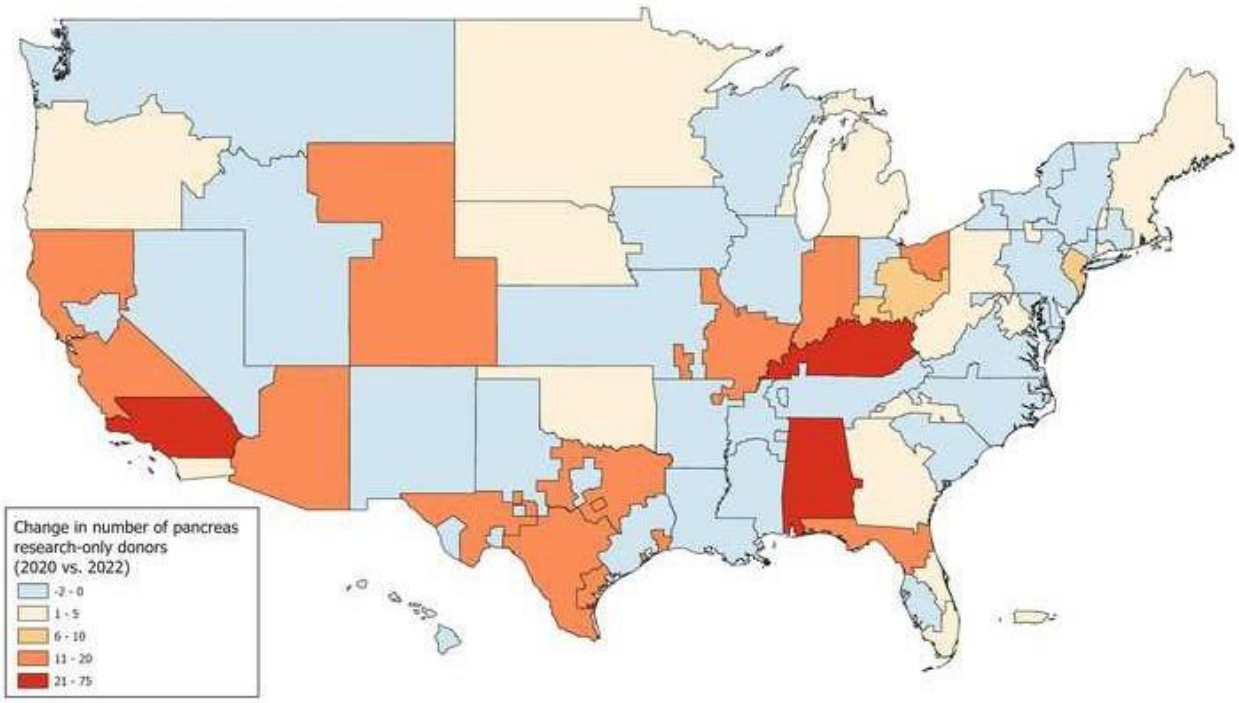
1. Figure 1 (three panels):
    a. Figure 1a: Annual number of deceased donors based on CMS criteria of ≥1 organ transplant or a pancreas procured for research or islet cells from 2013-2022
    b. Figure 1b: OPO-level changes change in total pancreata procured for research in 2022 vs 2020
    c. Figure 1c: OPO-level changes in the number of individuals classified as an organ donor solely due to having their pancreas procured for research in 2022 vs 2020

References

1. Center for Medicare and Medicaid Services. Organ Procurement Organization (OPO) Conditions for Coverage Final Rule: Revisions to Outcome Measures for OPOs CMS-3380-F. Accessed January 19, 2023, https://www.cms.gov/newsroom/fact-sheets/organ-procurement-organization-opo-conditions-coverage-final-rule-revisions-outcome-measures-opos
2. Heinze G, Wallisch C, Dunkler D. Variable selection - A review and recommendations for the practicing statistician. Biom J. May 2018;60(3):431-449. doi:10.1002/bimj.201700067
3. US Department of Health and Human Services. Advancing American Kidney Health. Accessed January 19, 2023, https://aspe.hhs.gov/sites/default/files/private/pdf/262046/AdvancingAmericanKidneyHealth.pdf


14,000
12,000
10,000
8,000
6,000
4,000
2,000
0
Individual with ≥1 organ transplanted
400
350
300
250
200
150
100
50
0
Research-only pancreas donors
2013
2014
2015
2016
2017
2018
2019
2020
2021
2022
Deceased organ donor ≥1 organ transplanted (CMS donor criteria #1)
Research-only pancreas deceased donor (CMS donor criteria #2)


Change in number of pancreata procured for research (2020 vs. 2022)
-18 - 0
1 - 20
21 - 50
51 - 100
101 - 200
350 - 400



Appendix B: Fact-Check of AOPO misinformation sent to House Oversight Committee

Dear Chairman Krishnamoorthi and Representative Porter,

I write today to thank you for your much-needed oversight of the U.S. organ procurement system in effort to ensure it is working effectively and transparently on behalf of patients. Given COVID-19 leaves patients with organ failure particularly at risk, and the disease itself is also damaging patients' organs, and given your point that OPO is an urgent healthcare equity issue, your investigation is particularly important to some of our country's most vulnerable patients.

I am an organ procurement organization (OPO) CEOs and currently a member of the Association of Organ Procurement Organizations (AOPO), which also makes me an AOPO Board Member. As such, I understand that AOPO recently responded to the Committee's oversight letter, and I wanted to clarify that I had not seen AOPO's response before it was sent; I do not feel it represents my views, nor do I feel it is grounded in science.

Given this, I felt a duty to clarify misstatements and misrepresentations contained within AOPO's letter. The irony is not lost on me that, in response to the Committee's inquiry about bad-faith lobbying, AOPO's 8-page letter necessitated a 10-page fact-check.

I hope to serve as a resource in your ongoing inquiry. Patients deserve transparency and accountability.

Signed,
Matt Wadsworth

AOPO wrote: *In 2020, OPOs increased organ donation by 6%, which makes ten consecutive years of growth over which time organ donation has increased by 58%. As a result of these improvements since 2010, there are now, on average, 110 lifesaving, deceased donor organ transplants per million population, and 128 living and deceased transplants per million.*

Fact check/relevant context: As has been well-documented, and has certainly been pointed out to AOPO repeatedly (see fact-check letter from the former Chief Technology Officer of the U.S. Department of Health and Human Services (HHS)), the increase in donation in absolute terms over the last ten years does not owe to OPO improvements, but rather an expanding donor pool. In fact, peer-reviewed research finds: *"it is indisputable that nationally the increased number of donors is almost wholly attributable to the drug epidemic, and reflects the byproduct of a national tragedy, rather than an improved system to be celebrated."*

Peer-reviewed research in the Journal of the American Medical Association from authors including DJ Patil, the former Chief Data Scientist of the United States under President Obama, finds that advancements in transplant science have also contributed to an expanding donor pool. In fact, after controlling for increases owing to the opioid epidemic, as well as transplant center advancements which have increased the absolute size of the donor pool, over the last nine years it turns out the OPO industry has not even kept pace with simple population growth.

This should not be surprising given the lack of structural incentives for OPO improvement and innovation. As the Washington Post editorial board noted: *"in a system in which [OPOs] have an effective monopoly on organ recovery within their zones, there are few incentives for them to improve unless decertification is a serious possibility."*

While the OPO industry, on net, actually seems to have backslid over the last ten years relative to donor potential, there have certainly been individual OPOs that exhibited improvement. As research finds, this has largely resulted from replacing underperforming OPO leadership, as well as, tellingly, a response to the very oversight pressure that AOPO is fighting.

According to research supported by Schmidt Futures and Arnold Ventures, "S*ince the [2019] executive order announcing the proposed new metrics and increased oversight, data show that OPO performance has already begun to improve, perhaps early evidence of the 'Hawthorne effect' (i.e., increased scrutiny and observation by itself drives behavior change that leads to improved outcomes). That such gains were possible, and yet unmade prior to the executive order, underscores the importance for HHS to institutionalize such regulatory pressure for OPOs to improve performance.*"

I applaud the Committee's active interest in oversight and reforms on behalf of patients, and would be happy to serve as a resource to support any current or future lines of inquiry.

Lastly, AOPO also includes living donor transplants per million population "as a result of [OPO] improvements." This is curious, as OPOs are in no way involved with living donation. In fact,

there is anecdotal evidence to suggest that increases in living donation occur, at least in part, as a reaction to OPO failures.

AOPO wrote: *Your December 23 letter references a figure of 28,000 available organs from deceased donors that could be procured for transplantation, but ultimately are not transplanted. However, the non-peer reviewed consultant's report on which this number is based shows that it presumes many conditions which are unrealistic.*

Fact check/relevant context: As has been pointed out to AOPO before in previous fact-checks to misleading AOPO claims, the 28,000 available organs number does, in fact, come from peer-reviewed research co-authored by researchers from the University of Pennsylvania, a former Surgeon General of the United States, and two OPO executives, validated against administrative data voluntarily provided by two OPOs. Notably, in AOPO's public comment to HHS regarding the then-proposed OPO rule, AOPO cited this very peer-reviewed research as the most accurate published estimate of donor potential (see page 497):

"An important starting point is to define the donor pool. Published estimates range from 10,500 to 24,000 to 37,000 to a staggering 272,000; however, literature and published studies based on review of hospital records suggest a figure closer to 20,000 to 24,000."

As noted in AOPO's citation, the latter figure, which AOPO notes is based on review of hospital records, refers to the research from which the 28,000 figure was derived.

Additionally, as has also been previously pointed out to AOPO, the write-up of this study also specifically states that the donor potential research is meant to inform the scale of what is possible: *"It is important to note that the above figures represent the 'full potential' of the system, assuming 100-percent donation rates and 100-percent organ utilization. Achieving even 20-percent of this potential improvement would result in approximately 6,000 lives saved per year and $2.6 billion in taxpayer savings over five years."*

These projections are in line with HHS's projections for expected increase in donations resulting from the increased accountability brought by the new metrics. If the 58% increase in donations over the last ten years were truly the result of OPO improvements (rather than an ever-growing donor pool), it is unclear why AOPO seemingly believes a relatively modest prospective increase would be unattainable.

AOPO wrote: *To achieve this [28,000] number of organs, all of the following conditions would be necessary:*

- *100% of donor hospitals would have to notify their local OPO in a timely manner of 100% of all potential organ donors.*
- *100% of the potential donors would need to be registered as an organ donor or alternatively 100% of families of potential donors must approve the donation. Currently, CMS requires a conversion rate of 75%.*
- *100% of all eight organs must meet medical suitability for transplant.*

- *100% of organs must be accepted by the transplant centers to which they are offered. Currently, on average 3.45 organs recovered from a donor are considered medically suitable and accepted for transplantation.*

  While we recognize there is room for improvement in the number of available organs, basing a regulation on the assumption of 100% success rates in each of these categories is simply unrealistic for OPOs, donor hospitals, and transplant centers to achieve.

Fact check/relevant context: As noted above, neither the study AOPO references, nor HHS's Final Rule - which was based on HHS's independent analysis - presume that OPOs can or should recover 100% of potential. As such, it is not necessary to respond to every point above.

It is important to note, however, that AOPO is simply factually incorrect in its assertion that the donor potential study in question assumes that "100% of all eight organs must meet medical suitability for transplant." The study estimates a donor potential of 24,007 annually for the years 2009-2012 (see Figure 1) (note: this number has since increased for reasons explained above), and an organ potential of just over 50,000 annually (see Figure 2).

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.

In response to AOPO's assertion that "100% of donor hospitals would have to notify their local OPO in a timely manner of 100% of all potential organ donors", I note a quote from Tom Mone, CEO of the OPO based in Los Angeles, in the New York Times: "*If I can't engage the hospitals and inspire them and motivate them to actively participate in donation, and we are not performing at the expected levels, the buck has to stop with our leadership*." I agree with Mr. Mone on this point.

Regarding the AOPO position that many organs that OPOs recover are not ultimately utilized by transplant centers, please see a report from alumni of the United States Digital Service regarding the myriad reasons organs, even once recovered, are not transplanted. While some percentage of these discards do owe to transplant center behavior, much also owes to differential ability and effort from OPOs in placing organs, a dynamic which CMS noted in the Final Rule, and which AOPO continually minimizes or outright ignores.

Additionally, much of the problem also results from the deeply outdated UNOS technology system on which organ offers are made, and I note the House Appropriations Committee's 2020 Report calling for increased competition for the Organ Procurement and Transplantation Network (OPTN): "*The Committee supports HHS's Request for Information for the technology system over which these organ offers are facilitated and encourages HHS to promote competition for this contract.*"

Finally, AOPO's assertion that the regulation is "bas[ed] on…the assumption of 100% success rates in each of these categories is simply unrealistic for OPOs, donor hospitals, and transplant centers to achieve" is nonsensical. As AOPO presumably - although perhaps not necessarily - understands, the new regulation simply evaluates OPOs compared against each other. This is in effort to address the unexplainable performance variability of 470% across OPOs.

In no way is the regulation based on the assumption that any OPO will achieve 100% success rates. In actuality, it is this very recognition that informs the rationale for comparing OPOs relative to each other rather than on an absolute basis.

AOPO wrote: *The prevalence of organs being lost or delayed on commercial flights or other transportation is extremely rare.*

Fact check/relevant context: Investigative reporting from Kaiser Health News reviewed 8,800 organ and tissue shipments handled by the UNOS Organ Center and found, *"between 2014 and 2019 nearly 170 organs could not be transplanted and almost 370 endured "near misses," with delays of two hours or more, after transportation problems."*

These data indicate that multiple organs are lost or damaged in transit every month, and have been for years. In total, about 7% of all organs shipped by the UNOS Organ Center experience transportation problems, which means, as noted by the American Society of Nephrology: *"UNOS is approximately 15 times as likely to lose, damage or mishandle an organ as the airline industry is your luggage."*

Organs handled by the UNOS Organ Center represent only a small subset of all organs shipped, with the balance of cases handled by the OPO, either directly or via a courier engaged by the OPO. Research indicates that this process is highly variable and often inefficient.

AOPO wrote: *In addition, through the adoption and deployment of perfusion technologies, OPOs are using innovative techniques to help drive substantial increases in donation and transplantation of organs. We now have normothermic perfusion devices for hearts, lungs and livers. These technologies, which preserve organs for longer periods of time, are especially important during Donation After Circulatory Death ("DCD") – which refers to recovery of organs for the purpose of transplantation from patients whose death was confirmed using cardio-respiratory criteria. In 2020, DCD donations increased by 18.6% over 2019 and this trend will continue with advancements in perfusion technologies.*

Fact check/relevant context: This seems to validate that the increases in donations AOPO cites are, at least in part, driven by scientific advancements driven by transplant centers, rather than by OPO performance improvements. In most cases, the perfusion machines AOPO references are owned and operated by transplant centers, rather than OPOs.

AOPO wrote: *OPOs Are Highly Regulated Organizations Held to Accountable Standards*

Fact check/relevant context: As has been highlighted in previous fact-checks of misleading AOPO claims, while OPOs are titularly regulated by various bodies, none of that oversight is

functionally effective. As the New York Times editorial board wrote, "*an astounding lack of accountability and oversight in the nation's creaking, monopolistic organ transplant system is allowing hundreds of thousands of potential organ donations to fall through the cracks*."

For example, and as your oversight letter to AOPO correctly noted, while OPOs report performance data to CMS, AOPO itself has argued that such data should not be legally enforced because it is "unaudited and self-reported [and] there is no provision for even random audits," and the former Chief Data Scientist of the United States has gone as far as to characterize OPO data reporting as "functionally useless."

It is unclear what AOPO means by "Held to Accountable Standards", but no OPO has ever lost a contract for underperformance, despite what even AOPO implicitly concedes has been massive historical underperformance.

Consider AOPO's position that OPOs have improved performance by 58% in ten years, which AOPO implies is not related to an expanding donor pool. If this were true - and, again, peer-reviewed data clearly finds it is not - then AOPO's position would simultaneously suggest that the OPO industry was underperforming by at least 58% ten years ago; and that, despite no OPO losing its contract for that underperformance, OPOs are held to "Accountable Standards."

For further analysis of the systemic failures of OPO oversight, see a new report from alumni of the United States Digital Service, which finds "Failures within the U.S. organ donation and transplantation system – which disproportionately harm patients of color – are left unaddressed by oversight bodies."

AOPO wrote: *Indeed, this model is replicated world-wide; none of the countries with high performing deceased donation utilize or permit entities to compete in a free-market system for the recovery of deceased organ donation. The reality is that having OPOs, or other potentially for-profit entities, competing for organs would be antithetical to the very purpose of donation as a precious resource requiring public trust and not a commercial enterprise.*

Fact check/relevant context: It is unclear why AOPO makes this assertion - which mirrors similar, uninformed statements from some OPOs and/or their surrogates - as no one is proposing a free-market for organs. By statute, OPOs must be non-profit entities, and in no way does HHS's regulation introduce a free market (though, to the extent that AOPO is concerned that for-profit, commercial activities would undermine public trust in organ donation, I would encourage them to support the Committee's oversight requests seeking to understand the extent to which OPOs are already engaged in such activities).

The actual issue at hand is simply how to increase transparency and accountability for OPOs using objective data, specifically because OPOs operate as non-profit, geographic monopolies in the public trust. As a past president of AOPO wrote: "*All OPOs operate as geographic monopolies, which means we have neither regulatory nor competitive pressure to provide high service to patients. And while there may be legitimate reasons for at least some monopolism*

(e.g., potential donor families should not have two OPOs competing for their attention), the trade-off must be increased transparency and oversight."

Regarding AOPO's invoking of the need for public trust, I highlight CMS's comment in the Final Rule that *"The current OPO outcome measures are not sufficiently objective and transparent to ensure public trust."* Thank you for your support of HHS's Final Rule.

AOPO wrote: *Additionally, every OPO is also required to submit an annual cost report for audit to ensure compliance with CMS allowable expenses.*

Fact check/relevant context: As the Committee's oversight itself indicated, previous audits from the Office of the Inspector General (OIG) have detailed fraud, waste and abuse at certain OPOs, though, inexplicably, and as your colleagues on the Senate Finance Committee have noted, the OIG has not conducted further audits since these findings.

Additionally, as a recent report from the Bridgespan Group highlights, there is much reason to question whether CMS's current definition of "allowable expenses" for OPOs does, in fact, serve patients: "*OPOs are reimbursed based on self-reported costs — passing these costs along to the Centers for Medicare & Medicaid Services (CMS) and transplant centers — regardless of performance. The current OPO payment model does not give OPOs an incentive to reallocate resources in order to increase the number of organs available for transplant, and it reimburses OPOs for costs that may not, in fact, help produce the desired outcomes.*"

AOPO wrote: *Equally important, the Health Resources and Services Administration ("HRSA") oversees the OPTN contract.*

Fact check/relevant context: I refer you to research from alumni of the United States Digital regarding deficiencies in HRSA's management of the OPTN contract, including a roadmap for how HHS can more effectively manage this contract going forward.

As a factual matter, as of January 15, 2021, HHS has moved the Division of Transplantation from HRSA to the Office of the Assistant Secretary for Health (OASH), in line with calls from patient advocates to bring more active oversight of the OPTN going forward.

AOPO wrote: *The OPTN performs ongoing reviews of OPO performance and compliance with OPTN policy. The OPTN also surveys all OPOs every 3 years to ensure they are in compliance with operating and productivity requirements. Finally, the Food and Drug Administration regulates all tissue recovery within an OPO.*

Fact check/relevant context: As covered comprehensively in the aforementioned report by alumni of the United States Digital Service, UNOS, which currently operates as the OPTN, is deeply conflicted. As the LA Times has noted in investigative reporting, UNOS is a "reluctant enforcer" with "collegiality built into [its] very structure." Senators Grassley and Young have characterized UNOS's oversight over its members as "the fox guarding the hen house."

The FDA's regulation of tissue recovery is confined only to clinical regulation; there is no oversight over OPO business practices related to tissue donation.

AOPO wrote: *If any OPO fails to meet the regulatory standards put forth by these federal organizations, they must commit to a performance improvement plan to continue organ recovery operations in their DSA.*

Fact check/relevant context: As detailed in a new report from the Bridgespan Group: "*Further strengthening the case for [OPO] decertifications: there is no evidence to suggest that HHS's alternatives have ever been successful. Specifically, in 2012, HHS placed an underperforming OPO on a "performance improvement plan" in lieu of decertification, in hopes that such a governmental plan would lead the OPO to turn around. As noted in the Washington Post, since 2012, CMS has required the OPO to submit at least three "corrective action plans." Despite such plans, for at least the past eight years, the OPO "has consistently registered one of the poorest performances in the nation," and "ranked as the country's second-worst OPO [in 2017]."*

Representatives Porter and Bass have highlighted the ineffectiveness of OPO performance improvement plans in a previous oversight letter. And as the past president of AOPO has written, if *"an OPO is not able to rise to the challenge of a high standard, the focus of our attention and energy must be on better serving patients on the national waitlist [by replacing them with a higher performing OPO, as HHS's Final Rule will enable], not on protecting specific OPOs."*

AOPO wrote: *OPOs have not, as you assert in your letters, misrepresented their efficiency at identifying donors and recovering transplantable organs. In support of this allegation, you cite an opinion piece and a non-peer reviewed report that is based on faulty data and funded by committed critics of OPOs. OPOs report data on identifying donors and recovering transplantable organs consistent with government requirements.*

Fact check/relevant context: The data cited by the New York Times - in which a whistleblower said "I used to work at an OPO and we reported false numbers to make it appear we were doing better than we were" - is based on peer-reviewed research which AOPO cited in its HHS public comment as the single most accurate estimate of donor potential. Criticism of OPOs from disinterested third-parties, informed by objective, peer-reviewed data, is a logical response, and only further validates the need for HHS's OPO reforms.

More importantly, OPOs have written to the White House Office of Management and Budget (OMB) that, currently, *"the data that OPOs submit to CMS in connection with the outcome measures is self-reported and unaudited...errors have been found in the data on which CMS has relied as the basis for judging OPO performance.. [and that] clearly, this type of 'evidence; fails to meet any reasonable definition of empirical."*

To the extent that OPO reporting has, in fact, been "consistent with government requirements" and yet OPO-reported data still is not legally enforceable, this only underscores the importance

of HHS's Final Rule, which AOPO has vigorously opposed and continues to oppose. Thank you for your support of HHS's pro-patient, pro-accountability reforms.

AOPO wrote: *Far from lobbying against such reforms, as your letter alleges…AOPO has advocated on behalf of its member OPOs as part of a committed effort to work collaboratively with policymakers.*

Fact check/relevant context: Whether AOPO has "worked collaboratively with policymakers" is a matter of judgment, and, in this case, I will defer to yours, though will note that the emails and other communications you have requested from AOPO would certainly inform such a judgment, and also note from investigative reporting from the Project on Government Oversight: *"UNOS did not deny that industry players are lobbying to undermine the president's reform initiative."*

AOPO wrote: *It is worth noting that AOPO's 501(c)(3) entity will continue to exist, and that the 501(c)(6) organization will act as a complimentary [sic] organization.*

Fact check/relevant context: It is my understanding as an AOPO board member that, counter to AOPO's representation to the Committee, the 501(c)(6) will serve as the primary program.

I call your attention to the following email sent from Steve Miller to all OPO CEOs and Executive Directors, dated June 2, 2020 at 8:19 PM EST, and subsequently covered in investigative reporting from the Project on Government Oversight:

"*As noted above, we are recommending spending down the funds in the 501(c)(3) to the level determined by the Executive Committee while transitioning operations to the new 501(c)(6). To accomplish this, all new dues and revenue streams will be directed into the 501(c)(6), while all spending not related to advocacy will be paid out of the 501(c)(3). Any spending related to advocacy will be paid out of the 501(c)(6). This will allow reserves to be built up in the 501(c)(6) while spending down the funds in the 501(c)(3) to the level determined by the Executive Committee. The full transition in operations will take approximately 12 to 24 months to finalize.*"

AOPO wrote: *AOPO's recent advocacy efforts are aimed at ensuring those reforms are thoughtful and driven by science. The OPO community supports independently verifiable metrics based on sound data. AOPO believed the proposed metrics included in the 2020 OPO Rule failed to meet this standard on several fronts.*

Fact check/relevant context: As highlighted above, AOPO's claims that its policy positions are "driven by science" is spurious. HHS's Final Rule has been supported by the former Chief Data Scientist of the United States as well as the Day One Project at the Federation of American Scientists, among other expert researchers.

AOPO wrote: *AOPO's recent efforts to add a 501(c)(6) entity to the overall organization is part of an effort to engage more effectively in First Amendment-protected advocacy.*

Fact check/relevant context: No one is questioning AOPO's protections under the First Amendment. The problem is that AOPO is using these protections to promote spurious claims in order to push anti-accountability, anti-patient policies.

AOPO wrote: *The Chief of Mortality Statistics Branch at the CDC's National Center for Health Certificates recently stated, "1 in 3 death certificates were already wrong before COVID-19." While he later revised this estimate down to 25%, still an unacceptable high error rate when determining donor potential for OPOs.*

Fact check/relevant context: As has been pointed out in previous fact-checks of misleading AOPO claims, *"Almost all errors in death certificate data pertain to the chain of events leading to death, not the final cause, so do not impact the ultimate determination as to whether the donor was viable for transplant. In fact, 92% of all causes of donor death are asphyxiation, blunt injury, drug intoxication, gunshot wounds, drowning, stroke, or cardiovascular causes, which is obvious to diagnose. AOPO's invoking of "death certificate errors" is a red herring."*

More simply, organ donation-eligible deaths represent a subset of all deaths which are uniquely insulated from the issues AOPO cites. For further information, I also refer to the Committee to peer-reviewed research in the Journal of the American Medical Association.

AOPO wrote: *The concern that death certificates are a poor data source for accurately calculating the denominator for donation rate was echoed in the public comments to the 2020 OPO Rule's performance measure regulation made by a wide range of expert stakeholders in the field including medical examiners.*

Fact check/relevant context: I refer the Committee to extensive reporting in the LA Times detailing how OPOs have been able to co-opt medical examiners for lobbying purposes through gifts, sponsorships, and other forms of payment.

AOPO wrote: *AOPO also had strong reservations regarding the 2020 OPO Rule's proposed threshold to pass CMS certification of OPOs at the top 25%.*

Fact check/relevant context: Much of OPO and AOPO messaging has centered on a misleading message that the new rule would necessarily result in 75% of OPOs being decertified, even despite various fact-check responses. Presumably, the emails and other communications that the Committee is seeking would inform whether such statements reflect AOPO's complete misunderstanding of the mechanics of the rule versus a more willful misrepresentation.

AOPO wrote: *Despite all the challenges brought about by the pandemic, OPOs recovered almost 1,000 more organs that were transplanted in 2020 than during 2019, a 6% increase, which led to a 3% increase in transplants from deceased donors.*

Fact check/relevant context: Recent reporting in the New York Times finds that, as a second order-effect of the pandemic, drug overdose deaths represented a record high in 2020. While AOPO represents that the increase in donation in 2020 was "despite" the pandemic, the data suggest that the increase actually resulted *from* the pandemic.

On a personal level, I find AOPO's use of the pandemic to deflect criticism to be exploitative, and also call the Committee's attention to a comment from an OPO executive at a UNOS conference that: "OPOs are fortunate for COVID", which afforded AOPO more time to "organize and lobby harder against proposed rules to implement reform."