

Additional Questions for the Record

Dr. Seth Karp, M.D., Surgeon-in-Chief, Vanderbilt University Medical Center

The Honorable Cathy McMorris Rodgers

1. Dr. Karp, with your experience on committees like the Membership and Professional Standards Committee (MPSC), how does the Organ Procurement and Transplantation Network (OPTN) accountability system function? Can you provide examples of its successes or failures, and how would you improve the MPSC?
2. Dr. Karp, the federal authorities are actively investigating OPOs in at least five states. One piece of the investigation appears to be whether any of the nonprofit OPOs have violated the federal False Claims Act by knowingly billing Medicare for unallowable costs.¹ How does this fraud affect patients and what does the OPTN do to prevent fraudulent claims? Please elaborate on how these allegations or cases are investigated.
3. Dr. Karp, with the recent contract awarded to The American Institutes for Research (AIR) to manage the independent OPTN Board, there has been debate within the community about how the board should be formed. During a staff briefing, HRSA mentioned that some surgeon groups are advocating for elections rather than appointments. Given your experience as a surgeon and former member of OPTN executive committees, what is your perspective on this debate?
4. Dr. Karp, what key factors do you believe will ensure that the independent board holds the maximum amount of credibility?
5. Dr. Karp, we have received credible allegations of misconduct, mistreatment of patients and falsified records by Organ Procurement Organizations. Why do you think whistleblowers brought these concerns to the Committee rather than reporting them to the appropriate oversight body?
6. Dr. Karp, could you please share known instances of whistleblower retaliation? Please provide as much detail as possible.
7. Dr. Karp, you served on the OPTN board. How many times have you seen the OPTN recommend to the Centers for Medicare and Medicaid Services that they remove a contract from a dangerous OPO?
8. Dr. Karp, what measures would you recommend to improve the transparency and accountability of OPOs across the U.S.?

¹ <https://www.washingtonpost.com/health/2024/02/26/organ-transplant-investigation/>

9. Dr. Karp, I understand that the majority of individuals who work with and for the OPTN are serving with their best intentions for a very difficult and emotional mission. However, I remain concerned over the current state of OPOs across the United States is safe for Americans. What can be done to improve patient-safety concern?
10. Dr. Karp, the Securing the U.S. Organ Procurement and Transplantation Act aims to foster competition by allowing HRSA to select the best contractors for OPTN functions. However, I am concerned HRSA may not have a real chance to pilot technologies that could replace the UNOS system. Are there alternative ways HRSA could test commercial solutions that would enhance competition? What specific benefits would this provide, and how could it improve the system's functionality or transparency?
11. Dr. Karp, reports indicate that UNOS's technology platform is outdated, fragile, and unreliable for a system critical to saving lives.² Despite this, it seems HRSA may extend the technology contract to UNOS, and UNOS claims no other organization can manage the platform. However, I'm aware of commercial solutions that could be quickly implemented. Should we be evaluating these options now to ensure we have the best system in place?
12. Dr. Karp, what do you see as the most significant challenges facing the OPTN in terms of accountability and oversight, and how can these be addressed in the current system?
13. Dr. Karp, what role do you think third-party audits or reviews should play in improving transparency within OPOs and the OPTN?

The Honorable Raul Ruiz, M.D.

1. Because patients receiving organ transplants must be on immunosuppressing drugs to prevent organ rejection, serious infections are very common among patients with transplants. Growing antimicrobial resistance is making it extremely difficult and, in some cases, impossible to treat these infections, as our arsenal of effective antimicrobial drugs is running out. The development of novel antimicrobials is essential to successful organ transplants, and that is why I am a proud cosponsor of the bipartisan PASTEUR Act to strengthen antimicrobial R&D, and I urge Congress to pass this bill this year. Patients cannot wait any longer. Can you please share how you see antibiotic resistant infections threatening transplant patients and why you believe that we must develop novel antimicrobial therapies?

² United States Digital Service. "Lives Are at Stake: The Government's Role in Modernizing the OPTN." January 5th, 2021. Dep't of Health and Human Serv. Off. of Inspector General, The Health Resources and Services Administration
Should Improve Its Oversight of the Cybersecurity of the Organ Procurement and Transplantation Network, A-18-21-11400 (Aug. 2022), <https://oig.hhs.gov/oas/reports/region18/182111400.pdf>.

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October 7, 2024

VIA EMAIL

Caroline Hales, M.S.W.
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Re: Response to email communication of 9.17.24

Dear Ms. Hales:

I am writing in response to your request for information related to recent testimony before the U.S. House of Representatives Energy and Commerce Committee Oversight and Investigations Subcommittee (“the Committee”). Given the focus of your inquiry centers upon questions from Members of Congress and witness responses to the same during the Committee’s hearing September 11, 2024, entitled “A Year Removed: Oversight of Securing the U.S. Organ Procurement and Transplantation Network Act Implementation”, I have copied Committee leadership for awareness. Thank you for your attention to concerns voiced by me and others related to the safety, efficiency and fairness of the transplant system for patients.

Firstly, I would like to state that in review of my given testimony to the Committee and recorded transcripts of the hearing, I am not aware of gross factual errors or misstatements made by me in need of correction. I offer this assertion because in multiple public communiques UNOS has accused me of false statements.^{1 2} I am hopeful that your inquiry on the substantive concerns voiced by witnesses at the hearing is a refutation of what initially appeared in UNOS media statements to be a strategy to discredit or defame and even threaten individuals bringing concerns before congressional oversight bodies.

Your inquiry asks about A) testimony given on incidents of organ recovery where the donor’s declaration of death might be in question and B) testimony given regarding incidents of delay in courier transportation of donated organs. I will address each topic in turn.

¹ “UNOS sets the record straight”, Sep 12, 2024. [UNOS sets the record straight - UNOS](#)

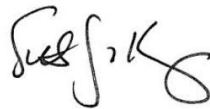
² “UNOS fires back at defamatory statements that it has acted unlawfully”, September 13, 2024. [UNOS fires back at defamatory statements that it has acted unlawfully | News Direct](#)

As you can review from my prepared written testimony and opening statement to the Committee, I did not broach the topic of situations where a donor's declaration of death might be in question.³ That topic was initially raised in the hearing by Members of the Committee and other witnesses. In fact, in response to direct questions from Members of the Committee I stressed such situations are "very rare". In response to questions, I attempted to explain that there are cases "when we [the transplant team] feel that a patient is dead and something happens that makes us wonder about that." In my years of clinical practice as a transplant surgeon it is my experience that any situation that arises to question a death declaration immediately stops all aspects of organ recovery. Furthermore, all members of the care and transplant teams are empowered to stop proceedings if there is any question a donor may still be alive. I do not have firsthand knowledge of cases where OPO officials or anyone else for that matter urged organ recovery begin or recommence when a donor's declaration of death was in question. I find allegations that this has occurred extremely troubling, and I strongly support fulsome investigation by all appropriate parties.

The second topic your email raised was about delays in donor organ transportation. Unfortunately, I have experienced with some degree of routine courier delays and tracking errors for organs in transit. In my opinion, the absence of a professionalized logistics vendor to ensure each donated organ is actively tracked throughout its transit is a major failing of the current OPTN structure. I share the sentiments expressed by Congressman Griffith at the hearing that "if we can track a pair of socks sent by Amazon, we ought to be able to track the organs." To provide the Committee an elucidating example, I described a recent case where "I had accepted a liver from Chicago and was told the organ was going to get there at a certain time...and I'm waiting and waiting and waiting...and I call up and they say, well, the courier never showed up." Delays of this nature are common enough under the current system that transplant teams do not report them if delay does not result in an organ discard or adverse impact on a transplant recipient, as there is little confidence reporting courier issues will lead to system improvement until the OPTN deploys and requires technology capable of tracking organs in transit in real time. That was the policy point I was attempting to make in my comments to the Committee.

It would not be appropriate for me to provide patient identifying information in this written response; however, please let me know if I can be of further assistance.

Sincerely,



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cc: Rep. Morgan Griffith, O&I Subcommittee Chair
Rep. Kathy Castor, O&I Subcommittee Ranking Member

³ Prepared Testimony of Seth J. Karp to the House Energy and Commerce Oversight and Investigations Subcommittee."
https://d1dth6e84htgma.cloudfront.net/Written_Testimony_Karp_2d96c30e16.pdf