"A Year Removed: Oversight of Securing the U.S. Organ Procurement and Transplantation Network Act Implementation"

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Chairman Griffith, Ranking Member Castor, Full Committee Chairwoman McMorris Rodgers and Ranking Member Pallone, Members of the O&I Subcommittee, I am grateful for the opportunity to testify today.

My name is Seth Karp, and I am a liver transplant surgeon, Surgeon-in-Chief, and former director of organ transplantation at Vanderbilt University Medical Center in Nashville, Tennessee. At Vanderbilt, we maintain one of the largest transplant

centers by transplant volume and serve as one of the largest donor hospitals in the United States.

My professional career has been rooted in the transplant community, as a surgeon, program director, researcher, advocate and former Organ Procurement and Transplantation Network (OPTN) and United Network for Organ Sharing (UNOS) board and committee member. I have witnessed firsthand how organ transplantation profoundly affects the lives of patients and their loved ones, as well as the galling shortcomings of the current transplant system.

My comments today will focus on recent and continuing governance problems at the OPTN and conclude with a list of recommendations.

Congress achieved important reform in passage of the Securing the U.S. Organ Procurement and Transplantation Network Act in 2023. Of course, several Members of this Committee were instrumental in that reform legislation. Thank you for continued oversight by this body to ensure implementation of this Act moves forward as statutorily directed and in the best interest of patients.

In addition to my clinical duties, I am part of a research group that has published in peer reviewed journals on improving organ donation in the U.S. In 2021, I testified at a similar hearing before the U.S. House Committee on Oversight. Unfortunately, I have to repeat today where I ended more than 3 years ago. **If we get the policy right, there are enough organs in the U.S. for everyone who needs a liver, heart, or lung, and enough kidneys to dramatically decrease the waiting times for those who need one.** It is in our power to save more lives.

During that previous hearing I testified with Tonya Ingram, a courageous young woman waiting for a kidney transplant. Unfortunately, her worst fears came true, and like the nearly 12,000 patients who die or are removed from the list every year because they are too sick, Tonya tragically died without having received a transplant.[1]

For more than 20 years, research has repeatedly shown the number of potential donors in the United States is about 300% of the actual number of donors.[2,3,4] In contrast, just a 20-30% increase in organs would be enough to save every person that died or was delisted for a heart, lung or liver.

We can and must do better. Work by a colleague, Dr. Ray Lynch, demonstrated significant increases in donation at an organ procurement organization – an OPO – where he helped institute best practices.[5] Work by one OPO CEO, Matt Wadsworth, doubled donation at two separate sites over four years.[6] If we could reproduce this work, thousands of lives would be saved.

How did we got here and how do we fix the system?

The National Organ Transplant Act sets out the responsibilities of the OPTN.[7] The instructions are mostly administrative, but the statute also makes clear the OPTN shall work actively to increase the supply of donated organs. In HRSA's final rule establishing the OPTN, it is also clear that OPO performance evaluation is a key function and that the OPTN has the power to recommend termination of reimbursement under Medicare and Medicaid for poor performance, effectively putting an OPO out of business.[8]

But the OPTN has failed to adequately oversee the transplant community. The problem is that for 40 years, the Boards of OPTN, the oversight body created by statute, and the contractor, UNOS, have effectively acted as one-and-the-same. I

have personally witnessed this as a member of both Boards. This egregious conflict of interest has allowed industry insiders to fill positions of power, prevent enforcement of the statutes, and permit special interests to capture the system. All of this is occurring with a lack of adequate oversight from government regulators. And as I testify today, the OPTN board is filled with people who were UNOS board members as recently as a few months ago.

I would like to state clearly: patients are continuing to die in the U.S. waiting for an organ due to self-interest, incompetence, corruption, and mismanagement at OPTN.

As a researcher, surgeon, and board member, I have witnessed OPTN contractor cover-ups in broad daylight and in back rooms.

In broad daylight, the Board:

- ignored research showing a 400% difference between the best and worst performing OPOs, and that there could be a 300% increase in donors;[9]
- claimed that they had no ability to oversee OPO performance;

- lobbied against the bipartisan data-driven measures eventually finalized by CMS;
- passed policies that were not data driven;
- actively suppressed data suggesting new policies would increase organ discards and lead to more patient deaths;
- continues to ignore the increased discards, logistical complexity, travel times, and costs generated by recent allocation policies.[10,11]
- defined equity in transplantation only after a patient made it to the list, an insensitive definition that ignores the difficulty that patients from disadvantaged communities have simply getting on the list; and
- failed to sufficiently focus on improving donation.

In back rooms, OPTN leaders:

- created processes to assure no OPO would ever be held accountable for its poor performance;
- worked to prevent competition in the contract bidding process, including through disseminating misinformation about the Securing the U.S. Organ Procurement and Transplantation Network Act;

- threatened to sabotage any new contractor by refusing to share data and information systems;
- spent taxpayer money on a corporate consultant to convince the Board that having the policymaking body and the contractor have the same board was good governance;
- intimidated those in the community with whom they disagreed;
- tried to minimize a major patient data breach, and a basic error that saw patients of O blood type disadvantaged for lung offers;
- denigrated suffering patients in rural and poorer areas of the U.S.;
- did not sufficiently prioritize the needs of children, who should receive more priority in the allocation of organs.

I am grateful for the Committee's leadership on this issue. You empowered HRSA to break up the transplant monopoly. You can help ensure the law is implemented, and corrupt influences cannot retain what Congresswoman Eshoo from this Committee called a "stranglehold" on the system.

In closing, my recommendations are as follows:

1) Renew a focus on improving donation, and instruct HRSA and the OPTN to take actionable steps to increase the number of organs available for transplant.
2) Ensure that HHS replaces the OPTN Board by appointing members who will serve patient interests. HHS should not permit industry to select the new board. Reconstituting a newly named board with the same group of individuals from previous governances is not reform.
3) Ensure enforcement of the OPO Final Rule, which will hold OPOs accountable for their performance and drive improvements for patients.
4) Continue your oversight of the OPTN contracting process to ensure each contract and program component is written with full accountability and open data access for the entire community.
5) And, please, on behalf of the generous organ donor families across the country and 100,000 Americans on the organ waiting list, task HHS with ensuring that the OPTN is held accountable for its performance.

Thank you for the opportunity to speak with you today. I welcome any questions you may have.

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