WRITTEN TESTIMONY OF Raymond J. Lynch, MD, MS, FACS Professor of Surgery and Public Health Director, Transplantation Quality and Outcomes The Pennsylvania State College of Medicine at Hershey BEFORE THE SENATE FINANCE COMMITTEE JULY 20, 2023

Chairman Wyden, Ranking Member Crapo, and Members of the Committee, my name is Raymond Lynch. I am a liver and kidney transplant surgeon and professor of surgery and public health at Penn State College of Medicine in Hershey, Pennsylvania. Thank you for the opportunity to speak today.

In my time as a surgeon, I have had the privilege of recovering organs from more than 200 generous, compassionate organ donor patients. I have performed hundreds of liver and kidney transplants. I have published more than 50 peer-reviewed papers in academic medical journals, and I am the principal investigator of an NIH-funded grant to study and improve organ procurement clinical care in Veterans Administration medical centers.¹

I am here because Congress has the ability to take action to save the lives of my transplant waitlist patients. I am here to advocate not only for their chance at a life-saving transplant, but also to ask for your help in improving a system that thousands of patients depend on. I ask the Committee to take concrete steps to make organ procurement and transplant safer, more reliable, and more effective for all patients, by:

 Supporting legislation that permits authentic competition for the OPTN contract, allowing specialized, highly skilled organizations the opportunity to move our transplant system into the 21st century.

¹ Doby, B. L., Brockmeier, D., Lee, K. J., Jasien, C., Gallini, J., Cui, X., Zhang, R. H., Karp, S. J., Marklin, G., & Lynch, R. J. (2021). Opportunity to increase deceased donation for United States veterans. *American Journal of Transplantation : official journal of the American Society of Transplantation and the American Society of Transplant Surgeons*, *21*(11), 3758–3764. <u>https://doi.org/10.1111/ajt.16773</u>

- Ensuring that CMS and HRSA collect and report on how OPO workers provide clinical care, in the same way that CMS provides data on clinical care and healthcare organizations in all other parts of our healthcare system.
- Ensuring that CMS enforces the current OPO performance threshold without delay or dilution.

I want to take a moment to differentiate between *organ donation*, the altruistic decision that the donor patients and their families make to help others, and *organ procurement*, the clinical care provided by staff at organ procurement organizations, that turns those gifts into usable organs for transplant.

Organ procurement is a clinical specialty – the last medical care that many patients will ever receive. It is fully reimbursed by the federal government, and it is administered by providers – the OPOs – who are the <u>only</u> provider option in their respective territories.

Fundamentally, when we talk about organ procurement, we are talking about healthcare and healthcare providers, such as hospitals or nephrologists. Just like any other providers, OPO workers evaluate patients, gather information from patient health records, make clinical judgements, and intervene medically to get the best possible outcome.

Right now, patient care delivered by OPOs is some of the least visible in American healthcare.²

I can't tell you how many patients were evaluated by OPO workers in 2022. I can't tell you how many patients were examined, or how many families were given appropriate information and care regarding the option for donation, or even how many times an OPO worker showed up to a hospital for this critical duty.²

I don't know of any other contractors or providers in American healthcare, especially ones that are reimbursed by CMS, that have so little information reported about what patient care is actually occurring.

² Doby, B. L., Boyarsky, B. J., Gentry, S., & Segev, D. L. (2019). Improving OPO performance through national data availability. *American Journal of Transplantation : official journal of the American Society of Transplantation and the American Society of Transplant Surgeons*, *19*(10), 2675–2677. https://doi.org/10.1111/ajt.15508

This lack of information about what OPO providers actually do for patients is a root cause of the variability of rates of organ procurement around the country.³ My own research has shown that what we euphemistically call "OPO performance" is a measurable restriction on the supply of organs that results in the unnecessary deaths of patients with organ failure.^{3,4} For example, if the lowest performing or Tier 3 OPOs had simply reached the median level of performance between 2013 and 2019, there would have been 4,957 more organ donors, yielding an estimated 5641 kidneys, 2678 livers, 1047 hearts, 1895 lungs, and 446 pancreases for transplant.⁴

These missing organs are equivalent to 9.4% of the total number of kidney candidates who died or were delisted over the study period, as well as 14.0% of the liver candidates, 22.5% of heart candidates, 75.6% of lung candidates, and 23.0% of pancreas candidates.⁴

Because I am a researcher, I just read you a list of calculated values. But because I am a physician, I want you all to think of each of the patients behind those numbers, with names like LaQuayia Goldring, Donna Cryer, and Molly McCarthy.

Because many OPOs operate in a low-quality data environment and without appropriate oversight, 4,957 patients did not get adequate organ procurement care. Without procurement care, organs weren't made available for transplant. Patients like Ms. Goldring, Ms. Cryer, and Ms. McCarthy then carry the burden for the failures of our system.

OPO clinical work is not visible, not benchmark-able, and not able to be evaluated, analyzed, or compared.² This can and must be remediated if we want to improve the organ supply. Much of the hidden data about how OPOs provide care to patients is known to one entity in the system: UNOS.⁴

The frontline OPO providers who administer procurement care are some of the most dedicated and hardest working individuals in medicine. UNOS could report on how well and how equitably care is delivered by OPO workers at every step. Yet, UNOS has actively refused to help OPOs get better at

³ Johnson, W., Kraft, K., Chotai, P., Lynch, R., Dittus, R. S., Goldberg, D., Ye, F., Doby, B., Schaubel, D. E., Shah, M. B., & Karp, S. J. (2023). Variability in Organ Procurement Organization Performance by Individual Hospital in the United States. *JAMA Surgery*, *158*(4), 404–409. <u>https://doi.org/10.1001/jamasurg.2022.7853</u>

⁴ Lynch, R. J., Doby, B. L., Goldberg, D. S., Lee, K. J., Cimeno, A., & Karp, S. J. (2022). Procurement characteristics of high- and low-performing OPOs as seen in OPTN/SRTR data. *American Journal of Transplantation : official journal of the American Society of Transplantation and the American Society of Transplant Surgeons*, 22(2), 455–463. <u>https://doi.org/10.1111/ajt.16832</u>

providing care. Instead of offering assistance, UNOS has advocated for a deadly status quo, where fearmongering and finger pointing take the place of concrete, achievable action to address quality of patient care. Even worse, UNOS frequently claims recent increases in organ donors as measures of their own success. I have published peer-reviewed research that reveals a primary driver of a large portion of those increases: the American opioid epidemic.⁵ Between 2009 and 2018, of the 2,700 additional organ donors procured, 94.6% died from a "drug-related" cause. Increasing, tragic deaths driven by this epidemic in our communities should not function as a commendation for UNOS.

The current OPTN contractor, UNOS, is <u>simply not capable</u> of managing a safe, effective, and innovative transplant system. I know many of us have served to the best of our ability on UNOS committees, and I want to emphasize that I entirely direct my critical comments to UNOS leadership and their network of cronies. In spite of our best efforts, UNOS's incompetent policymaking and ineffectual oversight prevents patients from becoming organ donors or receiving transplants. Instead of UNOS, which is a legacy contractor with a proven history of obstructive and self-serving behavior, we need a new network of highly skilled specialist organizations, each attending to areas of expertise in the management of the OPTN contract.

I ask you to listen to patients, researchers and frontline healthcare workers at OPOs, transplant centers, and hospitals. I ask you to remove the burden from patients and put a new OPTN contractor to work my patients' lives depend on it.

⁵ Goldberg, D., & Lynch, R. (2020). Response to: Deceased donors: Defining drug-related deaths. *Clinical Transplantation*, *34*(5), e13828. https://doi.org/10.1111/ctr.13828