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United States Senate

COMMITTEE ON FINANCE

WASHINGTON, DC 20510-6200

September 5, 2023

VIA ELECTRONIC TRANSMISSION

Ms. Colleen McCarthy
President, Association of Organ Procurement Organizations (AOPO)
Vice President of Organ and Tissue Donation
Versiti Wisconsin
638 N 18th Street
Milwaukee, WI 53233

Dear Ms. McCarthy:

As part of our ongoing investigation into the U.S. organ donation system, we write with concerns about potential serious and compromising conflicts of interest among organ procurement organizations (OPOs) and their leadership's financial and business relationships.¹

Investigative reporting has uncovered that some OPO executives may have financial interests in for-profit companies conducting business with OPTN members.² OPOs and their executives

¹ *A System in Need of Repair: Addressing Organizational Failures of the U.S.'s Organ Procurement and Transplantation Network*, Before Sen. Comm. on Finance, 117th Cong. (Aug. 3, 2022), available at [https://www.finance.senate.gov/imo/media/doc/UNOS%20Hearing%20Confidential%20Memo%20\(FOR%20RELEASE\)%20on%20website.pdf](https://www.finance.senate.gov/imo/media/doc/UNOS%20Hearing%20Confidential%20Memo%20(FOR%20RELEASE)%20on%20website.pdf).

² Melody Petersen and David Willman, *How organ and tissue donation companies worked their way into the county morgue* (The Los Angeles Times, 2019), available at <https://www.latimes.com/business/la-fi-how-body-brokers-took-over-county-morgue-20190408-story.html>; Jim Doyle, *Mid-America Transplant Services and Its Officials Move into For-profit Ventures* (2012), available at https://www.stltoday.com/business/local/mid-america-transplant-services-and-its-officials-move-into-for-profit-ventures/article_f37bb65b-f000-5bf7-bc00-097b2f6341f5.html; BLOOM WORKS: THE COSTLY EFFECTS OF AN OUTDATED ORGAN DONATION SYSTEM, available at <https://bloomworks.digital/organdonationreform/Tissue-Donation>; Alex Ferrer, "Whistleblower threatened with being cremated alive after exposing mortuary kickback scheme," CBS NEWS (June 14, 2019) (reporting that after blowing the whistle to expose how taxpayers were being "ripped off," the whistleblower was "blackballed" from the entire industry, his boss threatened to "kill his family, and told him that he would be "cremated alive."), available at

have engaged in a complex web of financial relationships with tissue processors, researchers, testing laboratories, and logistics providers, which have the potential for creating conflicts of interest.³ Some OPOs have also engaged in criminal activity. For example, in 2012, federal investigators uncovered an illegal kickback scheme between an OPO and a local funeral home, resulting in OPO executives being sentenced to federal prison.⁴ The Committee has also heard testimony⁵ and received credible allegations that senior members of the current OPTN contractor, the United Network for Organ Sharing's (UNOS) patient protection and policy-making committees may harbor undisclosed for-profit interests and may be leveraging their UNOS leadership positions to self-enrich at the expense of patient care.

Currently, the Organ Procurement and Transplantation Network (OPTN), the government contractor charged with oversight of the transplant system, does not collect OPO's financial information such as financial relationships, board member compensation or affiliated businesses.⁶ Additionally, even when formal complaints regarding concerning financial relationships are raised to the OPTN, the current OPTN contractor, the United Network for Organ Sharing (UNOS), has ignored them. As evidenced in the Senate Committee on Finance's 2022 bipartisan report, initial complaints brought to UNOS about the 2012 FBI case discussed above were not acted on.⁷ These financial relationships require additional scrutiny.

These alleged conflicting financial and business relationships pose serious risks to those in need of a lifesaving organ transplant. As noted in our October 2020 letter to Health and Human Services (HHS), "OPOs have greater financial incentives to focus more on tissue recovery compared to their incentives to recover lifesaving organs."⁸ Additionally, investigative reporting has highlighted that, "80% of [OPOs] were harvesting tissues and sending them in exchange for fees to tissue processors and distributors, many of which are for-profit companies...Today the

<https://www.cbsnews.com/news/whistleblowerthreatened-with-being-cremated-alive-after-exposing-mortuary-kickback-scheme/>.

³ *Id.*

⁴ Press Release, Federal Bureau of Investigation, Former Alabama Organ Center Executive Sentenced for Fraud (May 16, 2012), available at <https://archives.fbi.gov/archives/birmingham/press-releases/2012/former-alabama-organ-center-executive-sentenced-for-fraud>.

⁵ *The Cost of Inaction and the Urgent Need to Reform the U.S. Transplant System*, Before Sen. Comm. on Finance, Subcomm. on Health Care, 118th Cong. (July 20, 2023), available at https://www.finance.senate.gov/imo/media/doc/0720_wadsworth_testimony.pdf.

⁶ UNOS response to February 10, 2020 Senate Finance Committee inquiry, available at <https://www.finance.senate.gov/imo/media/doc/Response%20to%202.10.20%20Letter%20from%20Sens%20Grassley%20Wyden%20Young%20and%20Cardin.pdf>.

⁷ *A System in Need of Repair: Addressing Organizational Failures of the U.S.'s Organ Procurement and Transplantation Network*, Before Sen. Comm. on Finance, 117th Cong. (Aug. 3, 2022), available at [https://www.finance.senate.gov/imo/media/doc/UNOS%20Hearing%20Confidential%20Memo%20\(FOR%20RELEASE\)%20on%20website.pdf](https://www.finance.senate.gov/imo/media/doc/UNOS%20Hearing%20Confidential%20Memo%20(FOR%20RELEASE)%20on%20website.pdf).

⁸ PAUL ROSENBERG ET AL., *Transforming Organ Donation In America* (2020), available at <https://www.bridgespan.org/getmedia/4905f7a5-41d7-4240-bd31-0017ec500029/Bridgespan-OPO-Report-FINAL-Appendix-A.pdf>.

selling of human tissue is a multibillion-dollar global business.”⁹ As the only organizations federally certified to procure organs for transplant, these financial incentives are concerning as they potentially incentivize OPOs to prioritize profit over procuring organs for lifesaving transplant.¹⁰

We are also troubled by the lack of transparency in the current system, which allows OPO executives to potentially maintain personal financial interests in entities doing business with OPOs or other members of the OPTN, especially those financial interests which may affect patient care. We are also concerned about financial relationships and conflicts of interest from OPOs with outside entities, as well as volume-based incentives that may distort OPO priorities regarding the delivery of organ procurement.¹¹

The Senate Committee on Finance has broad subject matter jurisdiction over our nation’s tax and health laws and policies.¹² Your organizations maintain non-profit tax status and receive federal Medicare and Medicaid taxpayer dollars, which avails you of the Senate Committee on Finance’s oversight and jurisdiction. To evaluate and better understand your OPO’s financial and business relationships, please provide the following information no later than September 19, 2023:

- 1) Describe all personal financial interests or business relationships you and/or other board members or executives of your OPO or any related entities (e.g., related foundations or institutes) had from 2015 to the present, or continue to maintain, with any for-profit or non-profit organization that conducts business with your or another OPO or other OPTN member.¹³
- 2) For each interest and relationship described in question 1, provide all records.¹⁴

⁹ Melody Petersen and David Willman, *How organ and tissue donation companies worked their way into the county morgue* (The Los Angeles Times, 2019), available at <https://www.latimes.com/business/la-fi-how-body-brokers-took-over-county-morgue-20190408-story.html>.

¹⁰ Center for Medicare and Medicaid Fact Sheet (Nov 2020), “OPOs are the entities legally permitted to recover organs from deceased donors and also provide support to donor families, clinical management of organ donors, and professional and public education about organ donation.” <https://www.cms.gov/newsroom/fact-sheets/organ-procurement-organization-opo-conditions-coverage-final-rule-revisions-outcome-measures-opos>.

¹¹ PAUL ROSENBERG ET AL. Transforming Organ Donation In America (2020), available at <https://www.bridgespan.org/getmedia/4905f7a5-41d7-4240-bd31-0017ec500029/Bridgespan-OPO-Report-FINAL-Appendix-A.pdf>.

¹² <https://www.finance.senate.gov/about/jurisdiction>.

¹³ Including, but not limited to, any financial interest or paid relationships (including speaker fees and consulting fees) with medical device companies, including perfusion technologies, normothermic machine perfusion (NMP), and normothermic regional perfusion (NRP); tissue processing entities; aviation and logistics companies; pharmaceutical companies; telecommunications or communication center outsourcing companies (e.g., Statline); travel OPO coordinator/import/other allied transplant or perfusion staffing companies; other OPOs, or other transplant-related companies/organizations, and other international entities.

¹⁴ “Records” include any written, recorded, or graphic material of any kind, including letters, memoranda, reports, notes, electronic data (e-mails, email attachments, and any other electronically-created or stored information), calendar entries, inter-office communications, meeting minutes, phone/voice mail or recordings/records of verbal communications, and drafts (whether they resulted in final documents).

- 3) For each interest and relationship described in question 1, describe the process by which all conflicts were publicly disclosed. Provide all records.
- 4) For each interest and relationship described in question 1, provide all communications in which you have promoted these organizations to other OPOs or OPTN members and a description of the basis for which you promoted the organizations.
- 5) From 2015 to the date of this letter, provide copies of all agreements between you and the OPO, including any incentive-based bonuses related to volume, revenue, and other metrics.
- 6) From 2010 to the date of this letter, provide the standard acquisition costs (SAC) your OPO charged for each organ type.
- 7) From 2015 to the date of this letter, provide the bylaws and policies submitted to CMS as part of any CMS surveys of your OPO (both recertification and complaint investigations).
- 8) From 2015 to the date of this letter, for each of your board(s), provide the bylaws and policies that address potential conflicts of interest (financial and personal), length of terms, and criteria for selecting and removing members.
- 9) From 2015 to the date of this letter, provide all memoranda of understanding (MOU) your organization had with tissue banks, including those that address any conflicts between organ recovery and tissue recovery and those that were submitted to CMS as part of any CMS survey of your OPO (both recertification and complaint investigations).

Thank you in advance for your response.

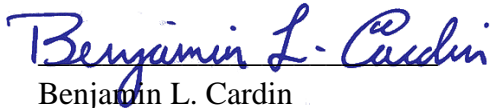
Sincerely,

A handwritten signature in blue ink that reads "Ron Wyden".

Ron Wyden
Chairman
Committee on Finance

A handwritten signature in blue ink that reads "Chuck Grassley".

Charles E. Grassley
Member
Committee on Finance

A handwritten signature in blue ink that reads "Benjamin L. Cardin".

Benjamin L. Cardin
Member
Committee on Finance

A handwritten signature in blue ink that reads "Todd Young".

Todd Young
Member
Committee on Finance