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United States Senate

COMMITTEE ON FINANCE

WASHINGTON, DC 20510-6200

November 17, 2022

Dr. Victor J. Dzau
President
National Academies of Sciences, Engineering and Medicine

Dear President Dzau:

We write to express our concern about potential conflicts of interest among National Academy of Sciences, Engineering, and Medicine (NASEM) committee members. Specifically, we are concerned that conflicts may have tainted NASEM's recent report titled "Realizing the Promise of Equity in the Organ Transplantation System" (herein referred to as the "NASEM report").¹ Therefore, we seek clarity on NASEM's process for evaluating potential and actual conflicts of interest as well as information on what knowledge, if any, NASEM had regarding conflicts of interest among committee members involved in the NASEM report.

On August 3, 2022, the Senate Finance Committee held a hearing to discuss Chairman Wyden and Senator Grassley's investigation into the United States' Organ Procurement and Transplantation Network (OPTN) and the government contractor responsible for OPTN oversight, the United Network for Organ Sharing (UNOS).² Since the hearing, it has come to our attention that some in the transplant industry are lobbying the U.S. Department of Health and Human Services (HHS) to implement the NASEM report recommendations. While we welcome a constructive dialog in addressing the shortcomings of the transplantation system, we are concerned about the appearance of conflicts of interest among NASEM committee members, particularly those who appear to have a financial stake in the implementation of NASEM's recommendations.

In fact, this is not the first time NASEM committee members have been accused of conflicts of interest. On September 17, 2021, the Washington Post identified potential conflicts of interest

¹ Kenneth W. Kizer et al., *A Fairer More Equitable, Cost-Effective, and Transparent System of Donor Organ Procurement, Allocation, and Distribution*, NATIONAL ACADEMIES SCIENCES ENGINEERING MEDICINE (2022), <https://www.nationalacademies.org/our-work/a-fairer-and-more-equitable-cost-effective-and-transparent-system-of-donor-organ-procurement-allocation-and-distribution>.

² See Press Release, Ron Wyden, Chairman, S. Comm. on Finance, Statement at Finance Committee Hearing on the Urgent Need to Address Failures in the Organ Transplant System (Aug. 3, 2022), <https://www.finance.senate.gov/chairmans-news/wyden-statement-at-finance-committee-hearing-on-the-urgent-need-to-address-failures-in-the-organ-transplant-system>.

between Yolanda T. Becker, an Organ Transplant Committee member, and her work with the consulting firm Transplant Solutions.³ Similarly, on September 17, 2021, Representative Raja Krishnamoorthi and Representative Katie Porter wrote NASEM requesting detailed information about potential conflicts of interest.⁴ The results of this inquiry are not publicly available.

Despite these concerns, when NASEM issued their report, “Realizing the Promise of Equity in the Organ Transplantation System”⁵ in February 2022, at least two members of the committee had employment ties that raised conflict of interest concerns.⁶ Several NASEM committee members are also engaged in consulting agreements with organ procurement organizations (OPOs) that could stand to gain financially if policymakers act on the NASEM recommendations.⁷ We have also heard reports of financial ties among these consultants and others under contract with HHS to evaluate possible reforms to OPTN policy. During the course of our investigation, the Committee received credible allegations that a member of the study panel was investigated by their employer and ultimately removed from employment due to concerns about inappropriate influence on the NASEM study and other activities in the field of organ transplantation.

We are concerned that the NASEM report seems to align with the lobbying positions of UNOS and the Association of Organ Procurement Organizations (AOPO), and that these recommendations will not address the concerns raised during our investigation.⁸ For example, we highlighted numerous adverse patient safety events resulting from a lack of quality control at OPOs.⁹ However, the NASEM report does not include recommendations that address patient safety events. Furthermore, the NASEM report recommends that HHS provide Donor Care Units

³ See Lenny Bernstein, *Former surgeon resigns from National Academies panel on transplant reform*, WASHINGTON POST (Sept. 17, 2021 at 7:36 PM), https://www.washingtonpost.com/health/academies-organ-transplant/2021/09/17/4f872b78-17d5-11ec-a5e5-ceecb895922f_story.html.

⁴ See Press Release, Raja Krishnamoorthi, Chairman, H. Subcomm. on Economic and Consumer Policy and Katie Porter, Member, H. Subcomm. on Economic and Consumer Policy, Chair Krishnamoorthi and Rep. Porter Request Documents Regarding Potential Conflicts of Interest in Organ Transplant Industry Study (Sept. 17, 2021), <https://oversight.house.gov/news/press-releases/chair-krishnamoorthi-and-rep-porter-request-documents-regarding-potential>.

⁵ See Press Release, Nat’l. Acad. of Sciences, Engineering, and Medicine, *New Report Recommends Changes to U.S. Organ Transplant System to Improve Fairness and Equity, Reduce Nonuse of Donated Organs, and Improve the System’s Overall Performance* (Feb. 25, 2022), <https://www.nationalacademies.org/news/2022/02/new-report-recommends-changes-to-u-s-organ-transplant-system-to-improve-fairness-and-equity-reduce-nonuse-of-donated-organs-and-improve-the-systems-overall-performance>.

⁶ See “Us” is a Big Group, YES AND LEADERSHIP LLC (last visited Sept. 13, 2022), <https://yesandleadership.com/%22us%22-is-a-big-group>; *About Us*, TRANSPLANT SOLUTIONS LLC (last visited Sept. 13, 2022), <https://transplantsolutionsllc.com/about-us/>.

⁷ See *Services*, YES AND LEADERSHIP LLC (last visited Sept. 13, 2022), <https://yesandleadership.com/services>; <https://yesandleadership.com/about-us>; YES AND LEADERSHIP LLC, *supra* note 5.

⁸ Letter from Jan Finn, President, Association of Organ Procurement Organization to Chiquita Brooks-LaSure, Administrator, Centers for Medicare and Medicaid Services, U.S. Department of Health and Human Services (Feb. 1, 2022), <https://6e4.64e.myftpupload.com/wp-content/uploads/2022/02/FINAL-AOPO-CMS-RFI-Response-2.pdf>.

⁹ See *A System in Need of Repair: Addressing Organizational Failures of the U.S.’s Organ Procurement and Transplantation Network: Hearing Before the S. Comm. on Finance*, 116th Cong. (Aug. 3, 2020) (Memorandum to SFC Majority/Minority Health LA’s), [https://www.finance.senate.gov/imo/media/doc/UNOS%20Hearing%20Confidential%20Memo%20\(FOR%20RELEASE\).pdf](https://www.finance.senate.gov/imo/media/doc/UNOS%20Hearing%20Confidential%20Memo%20(FOR%20RELEASE).pdf).

(DCUs) to all OPOs, a recommendation promoted by AOPO.¹⁰ (The Committee’s investigation identified numerous lapses in patient safety resulting from ineffective OPO oversight.) Without additional oversight and quality control measures, the expanded use of DCUs could lead to increased incidences of donor mismanagement by OPO staff or increased patient safety events.

Given these concerns, please produce the following documents by December 16, 2022, so that we may evaluate potential and actual conflicts among NASEM committee members:

1. Copies of all NASEM policies in place during the development of “A Fairer and More Equitable, Cost-Effective, and Transparent System of Donor Organ Procurement, Allocation, and Distribution.”
2. A list of NASEM committee members involved in and/or responsible for the development of findings, conclusions, and recommendations for “A Fairer and More Equitable, Cost-Effective, and Transparent System of Donor Organ Procurement, Allocation, and Distribution.” For these members, please also provide their financial interests in entities involved in organ or tissue procurement or transplantation, including but not limited to, OPOs, tissue donation businesses, or related trade associations.
3. Copies of conflict of interest and disclosure forms used by NASEM committee members involved in and/or responsible for the development of findings, conclusions, and recommendations for “A Fairer and More Equitable, Cost-Effective, and Transparent System of Donor Organ Procurement, Allocation, and Distribution.”
4. Documents relating to any funds received by NASEM from entities involved in organ or tissue procurement or transplantation from 2015 to present, including but not limited to, organ procurement organizations, tissue donation businesses, or related trade associations.

If you have any questions, please contact Melissa Dickerson of Chairman Wyden’s staff or Caitlin Soto of Senator Grassley’s staff.

¹⁰ See *A System in Need of Repair: Addressing Organizational Failures of the U.S.’s Organ Procurement and Transplantation Network*, *supra* note 9.

Sincerely,



Ron Wyden
Chairman
Committee on Finance



Chuck E. Grassley
Member
Committee on Finance



Benjamin L. Cardin
Member
Committee on Finance



Todd Young
Member
Committee on Finance