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ONE HUNDRED SEVENTEENTH CONGRESS

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RANKING MINORITY MEMBER

Congress of the United States
House of Representatives
COMMITTEE ON OVERSIGHT AND REFORM
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September 17, 2021

Dr. Victor J. Dzau, M.D.
President, National Academy of Medicine
The National Academies
500 Fifth Street, N.W.
Washington, D.C. 20001

Dear Dr. Dzau:

The Subcommittee on Economic and Consumer Policy is investigating reports of poor performance, waste, and mismanagement in the organ transplant industry in the United States.[1] We are concerned that entities involved in the organ transplant industry, including organ procurement organizations and industry trade groups, are devoting significant resources to resist increased government oversight and accountability.[2]

In December 2019, Congress authorized $1.5 million in funding for the National Academies of Sciences, Engineering, and Medicine (NASEM) to "examine and recommend improvements to research, policies, and activities related to organ donation and transplantation."[3] In response, NASEM established a committee to study "the economic (costs), ethical, policy, regulatory, and operational issues relevant to organ allocation policy decisions involving deceased donor organs" and make recommendations to "maximize public and professional trust in the organ donation, procurement, allocation, and distribution process."[4] The recommendations are expected to address a number of topics of critical importance to patients

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[1] Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform, *Press Release: Oversight Subcommittee Launches Investigation into Poor Performance, Waste, and Mismanagement in Organ Transplant Industry* (Dec. 23, 2020) (online at https://oversight.house.gov/news/press-releases/oversight-subcommittee-launches-investigation-into-poor-performance-waste-and).

[2] Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform, *Press Release: Oversight Subcommittee Expands Investigation into Fraud, Waste, and Abuse in Organ Transplant Industry* (May 27, 2021) (online at https://oversight.house.gov/news/press-releases/oversight-subcommittee-expands-investigation-into-fraud-waste-and-abuse-in-organ).

[3] Further Consolidated Appropriations Act, 2020, Pub. L. No. 116-94 (2019); Explanatory Statement Submitted by Mrs. Lowey, Chairwoman of the House Committee on Appropriations Regarding H.R. 1865, Further Consolidated Appropriations Act, 2020, H11073 (Dec. 17, 2019).

[4] The National Academies of Sciences, Engineering, and Medicine, *A Fairer and More Equitable, Cost-Effective, and Transparent System of Donor Organ Procurement, Allocation, and Distribution* (online at www.nationalacademies.org/our-work/a-fairer-and-more-equitable-cost-effective-and-transparent-system-of-donor-organ-procurement-allocation-and-distribution#sectionCommittee).

awaiting organ transplant—including increasing organ donation, ensuring fair allocation of organs, and improving organ procurements and allocation policies and procedures. The committee has 17 members and has held 13 meetings to date, of which 10 were conducted as closed sessions.[5] We fully support NASEM's study, which will be critical to ensuring our organ transplant system is efficient and equitable.

However, we are concerned by prior reports of financial conflicts of interest among NASEM committee members conducting important work on other subjects. NASEM is required to identify, review, and respond to significant financial interests and financial conflicts of interests of its members.[6] On August 12, 2021, *Kaiser Health News* reported that NASEM failed to disclose the financial conflicts of committee members who contributed to a February 2021 NASEM report on reducing waste in pharmaceutical supply chains. One member reportedly received consulting income from pharmaceutical companies that earned millions of dollars from billing Medicare for drug waste. The report, which advised against efforts to recoup millions of dollars in discarded drugs and concluded that Medicare should stop tracking drug waste, also did not disclose that NASEM itself has received at least $10 million from major drug makers since 2015, including from companies with financial interests in the outcome of NASEM's work on reducing waste in pharmaceutical supply chains.[7]

The U.S. organ transplant system is in dire need of reform. Our hearing entitled "The Urgent Need to Reform the Organ Transplantation System to Secure More Organs for Waiting, Ailing, and Dying Patients" focused on its many serious problems.[8] Improvements to the system will literally save and vastly improve the lives of patients waiting for organ transplants. It is imperative that recommendations for the organ transplant system be made with that goal in mind, and without interference from those with pecuniary interests in the outcome of NASEM's work.

The Subcommittee seeks to ensure that all relationships between NASEM, its committee members, and the organ procurement industry are properly understood, and any conflicts disclosed. To assist the Subcommittee in its review of this matter, please provide, by October 1, 2021, the following information and documents:

1. A list of all members of NASEM's committee on "A Fairer and More Equitable, Cost-Effective, and Transparent System of Donor Organ Procurement, Allocation,

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[5] The National Academies of Sciences, Engineering, and Medicine, *A Fairer and More Equitable, Cost-Effective, and Transparent System of Donor Organ Procurement, Allocation, and Distribution* (online at www.nationalacademies.org/our-work/a-fairer-and-more-equitable-cost-effective-and-transparent-system-of-donor-organ-procurement-allocation-and-distribution#sectionCommittee) (accessed on Aug. 20. 2021).

[6] 40 C.F.R. § 50.601–50.607 (2011).

[7] *National Academies' Report Took Pharma-Friendly Stance After Millions in Gifts from Drugmakers*, Kaiser Health News (Aug. 12, 2021) (online at https://khn.org/news/article/national-academies-big-pharma-support-drug-waste-report/).

[8] Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform, *Hearing on the Urgent Need to Reform the Organ Transplantation System to Secure More Organs for Waiting, Ailing, and Dying Patients* (May 4, 2021) (online at https://oversight.house.gov/legislation/hearings/the-urgent-need-to-reform-the-organ-transplantation-system-to-secure-more).

and Distribution" with current or past financial interests in or relationships with entities involved in organ or tissue procurement or transplantation, including but not limited to organ procurement organizations, tissue donation businesses, or related trade associations;

2. Conflict of Interest and Disclosure Forms for Committees Used in the Development of Findings, Conclusions, and Recommendations for all NASEM committee members on "A Fairer and More Equitable, Cost-Effective, and Transparent System of Donor Organ Procurement, Allocation, and Distribution";

3. Documents sufficient to show 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;

4. An explanation of whether NASEM plans to disclose any financial interests and relationships identified in response to Request 1 in its report on "A Fairer and More Equitable, Cost-Effective, and Transparent System of Donor Organ Procurement, Allocation, and Distribution" and detailed explanations for any financial interest or relationship that NASEM does not plan to disclose; and

5. All conflict of interest policies in effect from December 2019 through the present.

The Committee on Oversight and Reform is the principal oversight committee of the House of Representatives and has broad authority to investigate "any matter" at "any time" under House Rule X. If you have any questions regarding this request, please contact Subcommittee staff at (202) 225-5051.

Sincerely,

Raja Krishnamoorthi
Chairman
Subcommittee on Economic and Consumer Policy

Katie Porter
Member
Subcommittee on Economic and Consumer Policy

Enclosure

cc: The Honorable Michael Cloud, Ranking Member
Subcommittee on Economic and Consumer Policy

Responding to Oversight Committee Document Requests

1. In complying with this request, produce all responsive documents that are in your possession, custody, or control, whether held by you or your past or present agents, employees, and representatives acting on your behalf. Produce all documents that you have a legal right to obtain, that you have a right to copy, or to which you have access, as well as documents that you have placed in the temporary possession, custody, or control of any third party.

2. Requested documents, and all documents reasonably related to the requested documents, should not be destroyed, altered, removed, transferred, or otherwise made inaccessible to the Committee.

3. In the event that any entity, organization, or individual denoted in this request is or has been known by any name other than that herein denoted, the request shall be read also to include that alternative identification.

4. The Committee's preference is to receive documents in electronic form (i.e., CD, memory stick, thumb drive, or secure file transfer) in lieu of paper productions.

5. Documents produced in electronic format should be organized, identified, and indexed electronically.

6. Electronic document productions should be prepared according to the following standards:

    a. The production should consist of single page Tagged Image File ("TIF"), files accompanied by a Concordance-format load file, an Opticon reference file, and a file defining the fields and character lengths of the load file.

    b. Document numbers in the load file should match document Bates numbers and TIF file names.

    c. If the production is completed through a series of multiple partial productions, field names and file order in all load files should match.

    d. All electronic documents produced to the Committee should include the following fields of metadata specific to each document, and no modifications should be made to the original metadata:

        BEGDOC, ENDDOC, TEXT, BEGATTACH, ENDATTACH, PAGECOUNT, CUSTODIAN, RECORDTYPE, DATE, TIME, SENTDATE, SENTTIME, BEGINDATE, BEGINTIME, ENDDATE, ENDTIME, AUTHOR, FROM, CC, TO, BCC, SUBJECT, TITLE, FILENAME, FILEEXT, FILESIZE, DATECREATED, TIMECREATED, DATELASTMOD, TIMELASTMOD,

INTMSGID, INTMSGHEADER, NATIVELINK, INTFILPATH, EXCEPTION, BEGATTACH.

7. Documents produced to the Committee should include an index describing the contents of the production. To the extent more than one CD, hard drive, memory stick, thumb drive, zip file, box, or folder is produced, each should contain an index describing its contents.

8. Documents produced in response to this request shall be produced together with copies of file labels, dividers, or identifying markers with which they were associated when the request was served.

9. When you produce documents, you should identify the paragraph(s) or request(s) in the Committee's letter to which the documents respond.

10. The fact that any other person or entity also possesses non-identical or identical copies of the same documents shall not be a basis to withhold any information.

11. The pendency of or potential for litigation shall not be a basis to withhold any information.

12. In accordance with 5 U.S.C.§ 552(d), the Freedom of Information Act (FOIA) and any statutory exemptions to FOIA shall not be a basis for withholding any information.

13. Pursuant to 5 U.S.C. § 552a(b)(9), the Privacy Act shall not be a basis for withholding information.

14. If compliance with the request cannot be made in full by the specified return date, compliance shall be made to the extent possible by that date. An explanation of why full compliance is not possible shall be provided along with any partial production.

15. In the event that a document is withheld on the basis of privilege, provide a privilege log containing the following information concerning any such document: (a) every privilege asserted; (b) the type of document; (c) the general subject matter; (d) the date, author, addressee, and any other recipient(s); (e) the relationship of the author and addressee to each other; and (f) the basis for the privilege(s) asserted.

16. If any document responsive to this request was, but no longer is, in your possession, custody, or control, identify the document (by date, author, subject, and recipients), and explain the circumstances under which the document ceased to be in your possession, custody, or control.

17. If a date or other descriptive detail set forth in this request referring to a document is inaccurate, but the actual date or other descriptive detail is known to you or is otherwise apparent from the context of the request, produce all documents that would be responsive as if the date or other descriptive detail were correct.

18. This request is continuing in nature and applies to any newly-discovered information. Any record, document, compilation of data, or information not produced because it has not been located or discovered by the return date shall be produced immediately upon subsequent location or discovery.

19. All documents shall be Bates-stamped sequentially and produced sequentially.

20. Two sets of each production shall be delivered, one set to the Majority Staff and one set to the Minority Staff. When documents are produced to the Committee, production sets shall be delivered to the Majority Staff in Room 2157 of the Rayburn House Office Building and the Minority Staff in Room 2105 of the Rayburn House Office Building.

21. Upon completion of the production, submit a written certification, signed by you or your counsel, stating that: (1) a diligent search has been completed of all documents in your possession, custody, or control that reasonably could contain responsive documents; and (2) all documents located during the search that are responsive have been produced to the Committee.

Definitions

1. The term "document" means any written, recorded, or graphic matter of any nature whatsoever, regardless of how recorded, and whether original or copy, including, but not limited to, the following: memoranda, reports, expense reports, books, manuals, instructions, financial reports, data, working papers, records, notes, letters, notices, confirmations, telegrams, receipts, appraisals, pamphlets, magazines, newspapers, prospectuses, communications, electronic mail (email), contracts, cables, notations of any type of conversation, telephone call, meeting or other inter-office or intra-office communication, bulletins, printed matter, computer printouts, teletypes, invoices, transcripts, diaries, analyses, returns, summaries, minutes, bills, accounts, estimates, projections, comparisons, messages, correspondence, press releases, circulars, financial statements, reviews, opinions, offers, studies and investigations, questionnaires and surveys, and work sheets (and all drafts, preliminary versions, alterations, modifications, revisions, changes, and amendments of any of the foregoing, as well as any attachments or appendices thereto), and graphic or oral records or representations of any kind (including without limitation, photographs, charts, graphs, microfiche, microfilm, videotape, recordings and motion pictures), and electronic, mechanical, and electric records or representations of any kind (including, without limitation, tapes, cassettes, disks, and recordings) and other written, printed, typed, or other graphic or recorded matter of any kind or nature, however produced or reproduced, and whether preserved in writing, film, tape, disk, videotape, or otherwise. A document bearing any notation not a part of the original text is to be considered a separate document. A draft or non-identical copy is a separate document within the meaning of this term.

2. The term "communication" means each manner or means of disclosure or exchange of information, regardless of means utilized, whether oral, electronic, by document or otherwise, and whether in a meeting, by telephone, facsimile, mail, releases, electronic

message including email (desktop or mobile device), text message, instant message, MMS or SMS message, message application, or otherwise.

3. The terms “and” and “or” shall be construed broadly and either conjunctively or disjunctively to bring within the scope of this request any information that might otherwise be construed to be outside its scope. The singular includes plural number, and vice versa. The masculine includes the feminine and neutral genders.

4. The term “including” shall be construed broadly to mean “including, but not limited to.”

5. The term “Company” means the named legal entity as well as any units, firms, partnerships, associations, corporations, limited liability companies, trusts, subsidiaries, affiliates, divisions, departments, branches, joint ventures, proprietorships, syndicates, or other legal, business or government entities over which the named legal entity exercises control or in which the named entity has any ownership whatsoever.

6. The term “identify,” when used in a question about individuals, means to provide the following information: (a) the individual’s complete name and title; (b) the individual’s business or personal address and phone number; and (c) any and all known aliases.

7. The term “related to” or “referring or relating to,” with respect to any given subject, means anything that constitutes, contains, embodies, reflects, identifies, states, refers to, deals with, or is pertinent to that subject in any manner whatsoever.

8. The term “employee” means any past or present agent, borrowed employee, casual employee, consultant, contractor, de facto employee, detailee, fellow, independent contractor, intern, joint adventurer, loaned employee, officer, part-time employee, permanent employee, provisional employee, special government employee, subcontractor, or any other type of service provider.

9. The term “individual” means all natural persons and all persons or entities acting on their behalf.