## United States Senate

WASHINGTON, DC 20510

July 2, 2025

## VIA ELECTRONIC TRANSMISSION

The Honorable Robert F. Kennedy Jr. Secretary Department of Health and Human Services

Dear Secretary Kennedy:

On August 3, 2022, the Senate Finance Committee held a hearing titled, "A System in Need of Repair: Addressing Organizational Failures of the U.S.'s Organ Procurement and Transplantation Network."<sup>1</sup> The hearing highlighted the Committee's bipartisan investigation into the organ transplant system, which found that, among other serious concerns, the Organ Procurement and Transplantation Network (OPTN) failed to provide adequate oversight of the nation's organ procurement organizations (OPOs). These findings led to the passage of the bipartisan Securing the U.S. OPTN Act (the Act), which was intended to remove barriers to efficient and effective operation of the OPTN, as well as provide a pathway to competition to operate the OPTN.<sup>2</sup>

Last year, we became aware of a Kentucky case in which 36-year-old Anthony Thomas "TJ" Hoover reportedly awoke on an operating table just before his organs were to be recovered after he had been declared dead.<sup>3</sup> According to reports and information provided to us, as Hoover began responding to stimuli the presiding surgeon tasked with recovering his organs refused to continue, at which point the case coordinator from the Kentucky Organ Donor Affiliates (KODA), the OPO handling the recovery, allegedly called her supervisor for advice.<sup>4</sup> A witness reported that on this phone call, the KODA coordinator was told to "find another doctor to do it."<sup>5</sup> While the surgical recovery of Hoover's organs was cancelled, several KODA employees allegedly resigned their positions as a direct result of the troubling allegations that the OPO pressured both its own staff and hospital staff to remove organs from a man who was not deceased.<sup>6</sup>

Mr. Hoover's case was the center of a recent article addressing patient safety at the Kentucky OPO.<sup>7</sup> That article highlighted the alleged patient safety failures at KODA and found

<sup>&</sup>lt;sup>1</sup> United States Committee on Finance, Full Committee Hearing, *A System in Need of Repair: Addressing Organizational Failures of the U.S.'s Organ Procurement and Transplantation Network*, August 3, 2022, at <a href="https://www.finance.senate.gov/hearings/a-system-in-need-of-repair-addressing-organizational-failures-of-the-uss-organ-procurement-and-transplantation-network">https://www.finance.senate.gov/hearings/a-system-in-need-of-repair-addressing-organizational-failures-of-the-uss-organ-procurement-and-transplantation-network</a>.

<sup>&</sup>lt;sup>2</sup> Securing the U.S. Organ Procurement and Transplantation Network Act, 42 U.S.C. 201, https://www.congress.gov/118/plaws/publ14/PLAW-118publ14.pdf.

<sup>&</sup>lt;sup>3</sup> Rob Stein, '*Horrifying' Mistake to Take Organs from a Living Person was Averted, Witnesses Say*, NPR, Oct. 17, 2024, <u>https://www.npr.org/sections/shots-health-news/2024/10/16/nx-s1-5113976/organ-transplantion-mistake-brain-dead-surgery-still-alive</u>.

<sup>&</sup>lt;sup>4</sup> Id.

<sup>&</sup>lt;sup>5</sup> Id.

<sup>&</sup>lt;sup>6</sup> Information provided to the Committee.

<sup>&</sup>lt;sup>7</sup> Brian M. Rosenthal, *Doctors Were Preparing to Remove Their Organs. Then They Woke Up*, The New York Times, June 6, 2025, <u>https://www.nytimes.com/2025/06/06/us/kentucky-organ-donations.html?searchResultPosition=2</u>.

that Mr. Hoover's case was not an isolated incident. In fact, it was one of 73 cases over the past four years where KODA officials "should have considered stopping sooner" as the patient began showing signs of recovery.<sup>8</sup> According to the article, an investigation by Health Resources and Services Administration (HRSA) flagged 103 such cases as having "concerning features" and found that KODA employees pressured families into allowing donation while repeatedly pushing hospital staff to initiate organ recovery despite signs that patients were recovering.<sup>9</sup> It was also reported that employees were unaware that sedatives or other drugs could be affecting patients' neurological condition, a glaring lapse in training and oversight if accurate.<sup>10</sup> This startling accumulation of concerning cases in only four years at a single OPO lays bare the urgent need for oversight from HHS, its components, and the OPTN to keep patients safe and confidence in this vital system strong.

We are also aware of a similar case of alleged patient endangerment involving a Mississippi based OPO. According to reports and disclosures to us, Ms. Paula Denison arrived at a Jackson, Mississippi area hospital on March 17, 2022, suffering from a headache and altered mental state.<sup>11</sup> Ms. Denison was declared brain dead a few hours later, at which point representatives of the Mississippi Organ Recovery Agency (MORA) were called to begin the process of procuring Ms. Denison's organs and tissues for donation.<sup>12</sup> Reportedly, on the following day, while MORA coordinators were preparing Ms. Denison for organ recovery, she began responding to stimuli and otherwise exhibiting signs of life.<sup>13</sup> Despite these indications that Ms. Denison was not deceased, she was not transported back to the receiving hospital until the next morning, which is also when MORA staff decided to tell her family that she was not deca.<sup>14</sup> Ms. Denison passed away at that hospital days later.<sup>15</sup>

Additionally, we have concerns regarding the practice of normothermic regional perfusion (NRP), which was the subject of a critical comment submitted to the OPTN on September 27, 2024.<sup>16</sup> According to the OPTN Ethics Committee:

NRP is a procedure used to recover organs from certain donors who have been declared dead by circulatory criteria. It involves using a machine to pass blood through organs in a person's body after the heart has stopped beating and a waiting period has been observed. Vessels are clamped during this procedure to prevent blood flow to the brain.<sup>17</sup>

<sup>&</sup>lt;sup>8</sup> Id.

<sup>&</sup>lt;sup>9</sup> Id.

<sup>&</sup>lt;sup>10</sup> Id.

<sup>&</sup>lt;sup>11</sup> Wyatt Emmerich, *Mississippi Organ Donor Lawsuit is Chilling Tale of Aggressive Harvesting*, The Panolian, Nov. 2, 2023, https://panolian.com/2023/11/02/mississippi-organ-donor-lawsuit-is-chilling-tale-of-aggressive-harvesting/.

<sup>&</sup>lt;sup>12</sup> Id.

<sup>&</sup>lt;sup>13</sup> Id.

<sup>&</sup>lt;sup>14</sup> Id.

<sup>&</sup>lt;sup>15</sup> Id.

<sup>&</sup>lt;sup>16</sup> Health Resources & Services Administration (HRSA), Letter from HRSA Associate Administrator Suma Nair to Organ Procurement and Transplantation Network (OPTN) President Richard N. Formica Jr., Sept. 27, 2024, https://hrsa.unos.org/media/ak1hwvdo/09272024-nrp-critical-comment-letter-508-v2.pdf.

<sup>&</sup>lt;sup>17</sup> OPTN, White Paper Analyzes Ethical Issues in Normothermic Regional Perfusion, March 8, 2024, at

https://optn.transplant.hrsa.gov/news/white-paper-analyzes-ethical-issues-in-normothermic-regional-perfusion/.

The critical comment alleged that as OPOs across the country have seen a large growth in the number of organ donations from circulatory death donors (DCD), the OPTN "has failed to establish policy requirements for the practice of [NRP]" despite the OPTN's statutory obligation to create these requirements.<sup>18</sup>

It is the responsibility of Congress and the Administration to ensure that the U.S. organ procurement and transplantation system operates as an efficient, modern structure that provides lifesaving care to tens of thousands of Americans every year. To fulfill this goal, the system must be free of doubt that patient and donor safety is the paramount goal of the entities that have been given charge over organ recovery and transplantation.

So that Congress may conduct objective and independent oversight of the allegations raised by public reporting and the critical comment letter, please provide answers to the following no later than July 11, 2025:

- 1) The New York Times article from June 6, referenced above, includes findings from a HRSA investigation into Donation after Circulatory Death (DCD) at KODA. It found that DCD use has nearly doubled in the last four years and was used for more than half of recoveries at KODA over that time. This may represent a troubling trend in organ donation that Congress needs robust information on. We request that HHS provide a) a full copy, along with all supporting records,<sup>19</sup> of the HRSA investigatory report referenced in the article; and b) any other investigations, reports, analyses, or communications regarding the use of and rise in DCD operations in the national transplant system.
- All documentation of any other similar organ donor safety complaints, whether the case resulted in organ donation or not, received directly by HHS, to include the Centers for Medicare and Medicaid Services (CMS) and HRSA, over the past two years involving an OPTN member organization.

Thank you for your prompt review and response. If you have any questions, please contact Shade Streeter with Ranking Member Wyden's staff at (202) 573-0569 or Tucker Akin with Chairman Grassley's staff at (202) 224-5225.

Sincerely,

<sup>&</sup>lt;sup>18</sup> *Id.* at 2; *see also* 42 U.S.C. 274.

<sup>&</sup>lt;sup>19</sup> "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 or not they resulted in final documents).

Secretary Kennedy July 2, 2025 Page 4 of 4

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Ron Wyden United States Senator Ranking Member, Committee on Finance

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Charles E. Grassley United States Senator Chairman, Committee on the Judiciary