August 27, 2025

**VIA EMAIL AND MAIL c/o Annabelle Huffman, Legislative Clerk**

The Honorable John Joyce
Chairman of the Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Yvette Clarke
Ranking Member of the Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
U.S. House of Representatives
Washington, D.C. 20515

**RE: Responses to Questions for the Record Following the "Ensuring Patient Safety: Oversight of the U.S. Organ Procurement and Transplant System" Hearing Before the Subcommittee on Oversight and Investigations**

Dear Chairman Joyce and Ranking Member Clarke:

Thank you for the opportunity to testify before the Subcommittee on Oversight and Investigations on July 22, 2025.

My responses to the questions submitted by Subcommittee members are attached. Please do not hesitate to contact me if you require any additional information.

Very truly yours,

Richard N. Formica Jr., MD

Richard N. Formica, Jr., MD
Former President
Organ Procurement & Transplantation Network

Responses to Additional Questions for the Record

*The Honorable John Joyce, M.D. (R-PA)*

1. **How has the OPTN historically handled the complaints that it received, particularly complaints about patient safety issues?**
    a. **Was this true of all safety complaints that it received?**

**Response:** Patient safety was at the forefront of the OPTN's efforts throughout my tenure as OPTN President and in my prior work volunteering for the OPTN in various capacities. The OPTN addressed any complaints it received regarding potential patient safety concerns with utmost professionalism, with the objective of improving the performance of OPTN members to minimize the potential for future issues.

In my experience, the process by which the OPTN responded to patient safety concerns changed with the adoption of the OPTN's whistleblower policy in 2024. Prior to the adoption of this policy, patient safety concerns would either be reported first through the Patient Safety Portal or via email to one of the contractor's policy analysts. Patient safety concerns were then referred to the OPTN Membership and Professional Standards Committee (the "MPSC"). The contractor would obtain initial information. With this initial information, the MPSC leadership would decide whether or not the review can occur with the submitted information or whether an on-site visit by a team of peers would be required. From there, the evaluation would proceed based on what was necessary, given the facts of each case. I personally participated in many of these reviews during my five years on the MPSC, including on-site visits. All of these efforts were very exhaustive.

After the adoption of the whistleblower policy in 2024, in addition to the Patient Safety Portal, patient safety concerns could also be submitted through the Whistleblower Pathway. A policy analyst from the contractor would review the complaint with the OPTN president to assist in the triaging decision. During my tenure as the OPTN President, this was in effect for approximately 6 months. During that time, I do not recall a patient safety complaint coming in through this pathway. The complaints that came in were related to human resources and did not concern alleged patient safety events.

The OPTN is also very concerned about issues of culture at the institution, which can create an unsafe environment for transplantation. Therefore, if the complaint implied the work environment posed a potential threat to patient safety, even if the Scientific Registry of Transplant Recipients ("SRTR") outcomes data did not demonstrate an issue, the MPSC would investigate the complaint. I personally participated in one such review. This review resulted in the program voluntarily inactivating itself, restarting itself with new leadership, and demonstrating improved quality and an improved environment over a subsequent 12-month period before being released from review. In total, that process took approximately 18 to 24

months. In the end, it resulted in a transplant program being reopened in an area that needed its services.

Finally, the OPTN monitors patient safety through the six-month program-specific reports generated by the SRTR. Any programs underperforming on Patient Waitlist Survival, Organ Offer Acceptance Rates, and three-month and one-year graft survival rates are reviewed by the Membership and Professional Standards Committee. As mentioned above, the specific steps taken in the review would depend on the information of a given case.

During my tenure on the MPSC, in any six-month period, there were between 70 and 100 transplant programs under some form of MPSC review. During that time, approximately 20 programs entered a new review, and a similar number exited review.

2. **Are you aware of any instances in which any individuals affiliated with the OPTN, or UNOS, retaliated against individuals who tried to report concerns to the nation's organ procurement and transplantation system, particularly patient safety concerns?**

**Response:** I am not aware of any instances of retaliation against individuals or entities that reported concerns to the OPTN. Furthermore, to protect against the possibility of retaliation, the OPTN developed a safe and anonymous mechanism for reporting patient safety concerns – the Patient Safety Portal. During my tenure on the MPSC, I worked on numerous cases that came in through this mechanism, and in all instances, the complaints were investigated, and the reporters' identities were kept confidential to prevent retaliation at their home institutions.

3. **In Appendix 1 of HRSA's report, which is a copy of the OPTN's findings of the HRSA directed investigation, there is a summary chart of the type and number of records received and reviewed. There is a column labeled "not reviewed," and in that column there are 47 donor and patient records: 16 process and protocol documents; and 16 huddle records. Why did so many documents and records go unreviewed by OPTN?**
    a. **How was the OPTN able to conclude that "overall there were no major patient safety concerns" if it did not review all the documents and records?**

**Response:** As I stated in my written and oral testimony, the investigation of KYDA was unique compared to other OPTN investigations. It required setting up a new committee of volunteer reviewers to assess these documents. Additionally, HRSA imposed restrictions on the OPTN regarding who could be selected to participate in the review committee, making it difficult to populate it with the necessary number of individuals who possessed the required expertise. As a result, the OPTN only had a small number of volunteers who

were responsible for a significant volume of work under a short deadline. The eight volunteer reviewers had only 21 days to review over 360 cases, as well as 95 additional documents, which exceeded 35,000 pages, and write a report. These volunteers had to continue to perform their regular duties at their home institutions during the course of this review.

Given that the deadline for the formal report was approaching and that these unreviewed charts represented only approximately 10% of all of the records, I concluded we had reviewed a representative sample of sufficient size to complete the report.

I am including with this answer a string of emails that begins on February 6th, 2025, when the review started. It demonstrates that the OPTN was actively monitoring the pace and findings of the review. It also reflects the decision-making process once the OPTN and HRSA became aware that the volunteers were unable to complete the review within the requested time. It also includes a communication I had with HRSA Associate Administrator Dr. Suma Nair, stating that the OPTN Board of Directors would assist in completing the review of the remaining records if deemed necessary by HRSA.

Attachment: "Feb communication with reviewers.pdf"

4. **In your written testimony, you note that the OPTN had, before the 2021 index case became known, been focused on improving policy surrounding DCD donation. What specific DCD policy had the OPTN been focused on?**

**Response:** As the rate of DCD donation has increased, the OPTN has been aware of the need to obtain better information on this type of donation and to update policies to better reflect the current state of practice.

**Modifications to the Deceased Donor Registration (DDR)**
This modification improved overall data quality in the OPTN Computer System Deceased Donor Registration (DDR) form. Changes included updates to donation after circulatory death (DCD) terminology and removal of outdated fields. Approved by the OPTN Board of Directors in 2021, it was implemented in 2023. More details are available at https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/modify-the-deceased-donor-registration-ddr-form/.

**Enhancements to OPTN Donor Data and Matching System Clinical Data Collection**
This policy proposal will streamline communication of DCD donor information between OPOs and transplant hospitals, improving offer evaluation and allocation efficiency. Ten data elements related to DCD, including normothermic regional perfusion (NRP), will be added to the OPTN Computer System. Approved by the OPTN Board of Directors in 2022, it is pending final Office of Management and Budget (OMB) approval with a release date scheduled for fall 2025. More details are available

at https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/enhancements-to-optn-donor-data-and-matching-system-clinical-data-collection/.

**Review of DCD Policies**
This project reviewed all OPTN DCD policies due to the significant increase in DCD donations since their last update in 2014. The OPTN OPO Committee developed proposed policy changes for public comment to allow more flexibility on the timing of the family discussions for potential donation while maintaining safeguards, along with a new policy to address when brain dead donors are recovered under DCD protocols. The OPTN OPO Committee paused this project temporarily to focus on a new June 2025 HRSA directive on DCD policy development.

**HRSA Directive for OPTN DCD Policy Development**
Following the June 2025 HRSA directive, the OPTN is developing policies to improve safeguards for potential DCD patients and increase the information shared with patient families. One policy under current development will include a "pause" in procurement efforts if there is concern for unrecognized neurological improvement or potential pain. The proposal is due for HRSA review in November 2025. More information is available at https://optn.transplant.hrsa.gov/media/st5azvje/opo-corrective-action-plan-and-optn-directive_5282025_redacted_508.pdf.

*Note: The following projects focus specifically on Normothermic Regional Perfusion (NRP) but are included to address the request for "the project that was to begin this spring." NRP is an organ recovery technique with is used in DCD donation.*

**Ethical Analysis of Normothermic Regional Perfusion** This white paper provides a comprehensive overview of the ethical implications and guidelines for the use of Normothermic Regional Perfusion ("NRP"). It was approved by the OPTN Board of Directors in 2023. More information is available at https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/ethical-analysis-of-normothermic-regional-perfusion/.

**Standardize Practice in the use of Normothermic Regional Perfusion**
This project aims to establish standardized practices for NRP in organ procurement. Proposed guidance would cover key personnel, pre-procedure huddles, surgical approach, technical standards, and quality control. The project was initiated at the request of the OPTN Executive Committee in 2024 following a critical comment received on NRP. Public comment on this proposal, originally planned for spring 2025, was put on hold following a HRSA request to pause the project, pending additional direction. Information on the critical comment and subsequent HRSA directive is available at https://optn.transplant.hrsa.gov/policies-bylaws/optn-critical-comments-and-directives/.

**Data Collection on Normothermic Regional Perfusion (NRP) and Machine Perfusion**

This proposal would add multiple data fields to the OPTN Computer System regarding machine perfusion device use, including NRP. Data would capture details such as organs attempted for recovery/recovered using NRP, NRP type, performer of NRP or machine perfusion, and start/stop times for NRP or machine perfusion. Data would help inform future policy changes. The OPTN Policy Oversight Committee recommended the proposal go out for public comment in August 2025. HRSA has indicated that data collection should move forward once it is aligned with the HRSA direction from the critical comment. More information on the HRSA directive is available at https://optn.transplant.hrsa.gov/policies-bylaws/optn-critical-comments-and-directives/.

5. **In your written testimony, you state that "technology has advanced faster than our ethical understanding of the circumstances and our policies that govern them." Do you have any ethical concerns as it relates to DCD organ procurement? If so, please explain?**

**Response:** I have no ethical concerns about the practice of donation after circulatory death (DCD). Prior to discussing my concerns, I would like to explain the DCD process.

A patient (the word *patient* is used intentionally because, before death, anyone being considered for potential DCD donation is alive and therefore still a patient) who has suffered a non-survivable neurological injury may be assessed for DCD donation if the family, together with the hospital care team, has decided to withdraw life-sustaining ventilator support. The decision to pursue donation is made either because the patient previously registered as an organ donor or their family members authorized organ donation after their death. In such circumstances where the family has decided to withdraw life-sustaining ventilator support and authorize organ donation, the patient is assessed to determine if they are medically suitable as a potential DCD donor. This includes serology testing for infectious diseases and organ function assessments. If medically suitable as a potential DCD donor, the patient is then moved either to the intensive care unit or the operating room for withdrawal of life support and the provision of comfort care. The physicians and nurses caring for the patient are present (and not the organ recovery team) during the withdrawal of life support to provide palliative care to the patient. If the patient's circulation ceases (no pulse) within a specified period of time, usually 90-120 minutes, and after an observation period (usually 5 minutes), to ensure the heart does not restart, the patient is declared dead by a hospital doctor who is not part of the organ transplant team. Once deceased, the term "donor" may be appropriately used. At this point in time, the organ surgical recovery team will then be allowed into the operating room and will recover the organs. This process of DCD donation is, in my opinion, both appropriate and ethically justified as it honors the directive of donation, which is to help others through lifesaving organ donation and transplantation. It also adheres to a guiding principle of organ donation and transplantation called "the dead

donor rule." This ethical principle states that organs can only be recovered after death, and the recovery process cannot cause the donor's death.

While I have no concerns about the practice of DCD donation in general, there are areas within this field where advancements in technology are outpacing our ethical understanding. For example, I have some concerns with the technique of organ perfusion utilized in the donor's body after the death of the patient during the DCD process, called thoracic normothermic regional perfusion (TA-NRP). After the patient is declared dead and the organ surgical recovery team is permitted to enter the operating room, TA-NRP may be used to perfuse the thoracic organs in order to minimize damage and maintain a better state during the surgical recovery process, which provides improved outcomes for transplantation of DCD organs. My concern is that the use of TA-NRP for organ recovery, which uses the re-establishment of circulation in the heart to preserve the organ quality, may conflict with the current legal definition of death, which states that death occurs when there is an irreversible (permanent) loss of circulation. Although it occurs through mechanical means and follows both a natural loss of circulation and a period of time without blood flow, TA-NRP results in the reestablishment of blood flow through the donor's heart and back out through the body (although not to the brain). Thus, this innovation of TA-NRP has outpaced our understanding of the definition of "circulation" in a way that challenges the ethical underpinning of how we define and declare death, which is at the core of DCD donation. I have no concerns that harm is being done to the deceased donor in such cases where TA-NRP is employed. The use of TA-NRP does not harm the deceased donor - the perfusion of blood in the deceased donor does not resuscitate the decedent. However, public perception of the organ donation and transplantation process is very important, and explaining the nuances of this discussion about the definition of death and irreversible cessation of circulation is very difficult. This could lead to either intentional or unintentional misinterpretation that may decrease life-saving organ donation. This will jeopardize the lives of patients with organ failure who are awaiting transplantation because a life-saving organ may not be available.

*The Honorable Russ Fulcher, (R-ID)*

1. **In your testimony you said that "[until] the time of death... [organ donors] remain under the care of the donor hospital." Yet, the HRSA report describes a concerning breakdown in this essential chain of separation in the donation process. During your tenure, how did OPTN create concrete policies that ensure that the separation of care was properly followed?**

   **Response:** During my tenure as OPTN president, DCD donation was governed by OPTN policy *2.15 DCD Donation.* I have provided a copy of this policy in my previously submitted documents for the record. However, as stated above in my answer to

Congressman John Joyce, MD, the OPTN has recognized that the DCD donation policy needs to be updated and was beginning to work on it during my tenure. Specifically, the timing of the approach to a potential donor's family needs to be flexible to account for the clinical situation that may be unfolding. Additionally, there needs to be additional clarification regarding how a brain-dead donor can be recovered under DCD protocols. This policy work was still pending at the end of my one-year term as president.