Richard Formica, MD
Former President of the Organ Procurement and Transplantation Network
Testimony to the Congressional Energy and Commerce Committee, Subcommittee on Health, regarding the event at the Organ Procurement Organization, KDYA

Thank you for the opportunity to provide testimony on this very important topic. My name is Richard Formica. I am a full-time kidney doctor who practices transplant medicine. I am a teacher and the Director of Transplant Medicine at Yale School of Medicine. I am testifying on my own behalf today, not on behalf of Yale University, and the views expressed are my own and not those of the university. In addition to these professional commitments, I have proudly volunteered countless hours for the Organ Procurement and Transplantation Network (OPTN) since 2008. During that time, I chaired the following committees: the Kidney Transplantation Committee during the development and implementation of the 2014 Kidney Allocation System, the Simultaneous Liver and Kidney Transplantation Committee that developed the Simultaneous Liver and Kidney allocation policy, and the Membership and Professional Standards subcommittee that developed Enhanced Outcomes Metrics to assess transplant program performance. I also served on the Geography Committee that was created to rapidly address the Secretarial directive to remove donor service areas from the organ allocation policies. I have also served on the MPSC for five years, and most recently, I have had the honor of serving the transplant community as Vice President and, until June 30 of this year, President of the OPTN.

The OPTN is composed of more than 450 volunteers who represent the entire spectrum of the transplant ecosystem, including physicians, surgeons, representatives of organ procurement organizations, and, most importantly, organ recipients, living donors, and deceased donor families. We all volunteer because we believe in the mission of transplantation and caring for patients with end-organ failure, and in honoring and respecting the gifts of the true heroes of

organ transplantation – the donors and their families. When the National Organ Transplantation Act of 1984 was enacted, legislators recognized the complexity of solid organ transplantation and the necessity of entrusting experts in the field with developing policy and conducting peer review. For the past 40 years, members of the transplant community have volunteered their time and expertise to the OPTN. For the academic year from July 1, 2023, to June 30, 2024, the OPTN consisted of 459 individual volunteers filling 599 positions. A conservative estimate of the number of hours these volunteers contributed to the OPTN that year is 41,762. Over the years, these efforts have resulted in the United States having the highest organ donation and transplant rates in the world, along with outstanding patient outcomes.

Over the past decade, in particular, these volunteer hours have made a significant positive contribution to the improvement of the nation's transplant system. Major policy achievements include the Kidney Allocation System of 2014, the Simultaneous Liver Kidney Allocation policy of 2017, the Liver Share 35 policy, the Transplant Centers Performance Monitoring policy, the removal of DSA from the allocation of all organs policy, the Lung Continuous Distribution policy, and the removal of race from the eGFR calculation policy. All of these efforts have significantly improved both equity and fairness in the transplant system, while allowing it to serve an ever-increasing number of patients. Additionally, over the past 36 months, OPTN volunteers have fully embraced the modernization effort. Their efforts have helped HRSA turn the conceptual idea of modernizing the OPTN into reality. These efforts include the board leadership helping HRSA to construct a new framework for running the OPTN in compliance with the 2023 changes to NOTA, the finance committee’s method of prioritizing projects to improve fiscal responsibility, the policy oversight committee’s efforts to categorize better and weight these projects so the board has a balanced assessment of them and working with HRSA

on administration of this complex and interconnected system with multiple vendors. I am personally very appreciative of the efforts the OPTN volunteers have made over the years to improve this system, and I am proud to call them colleagues and friends.

I would now like to address some of the issues that may be addressed during this hearing. First, I would also like to clarify the scope of the OPTN's authority to address incidents like the one that occurred here. In addition to its policy development and organ allocation responsibilities, the OPTN is responsible for overseeing transplant programs regarding their compliance with policy, transplant outcomes, and the safety of candidates on the transplant waitlist and the recipients of solid organs. Additionally, in collaboration with CMS, the OPTN oversees the performance and adherence to policy of organ procurement organizations, as well as the safety aspects of transporting and transplanting deceased donor organs into transplant recipients. The OPTN does not have oversight of donor hospitals. This limitation creates challenges when attempting to merge the OPTN's role in overseeing the donation process with CMS's oversight of hospitals caring for patients who are being considered as potential donors after circulatory death. While I, as a physician, may have an opinion about the medical care rendered to a patient, as an OPTN representative, I do not have oversight authority. Until the time of their death, they remain under the care of the donor hospital and the physicians who treat them. Prior to death, the only policies that fall under the oversight of the OPTN as it is currently configured are those that govern OPOs' data collection and record-keeping responsibilities, restrictions on how OPO staff may interact with the families of patients who may be considered for DCD organ donation, time out protocols, and explicitly stating that anyone participating in the organ recovery or transplant process may not be present during the time that withdrawal of care is initiated and death is declared. Therefore, when responding to the Secretarial directive to review the charts of potential

DCD donors who did not progress to donation, did not pass away, at KDYA, the OPTN reviewed these cases based on the OPTN expectations of KDYA regarding adherence to OPTN policy 2.15, "Requirements for Controlled Donation after Circulatory Death (DCD) Protocols." Finally, the OPTN was given explicit instructions not to review the index case or have it influence the conclusions reached.

The OPTN recognizes the authority of the Secretary to direct the OPTN to conduct reviews. However, it is essential to note that the nature of this review was unique to the OPTN and had no precedent. 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. Additionally, while the total process spanned approximately four months, delays resulted in the eight reviewers having only 21 days to review over 360 cases, as well as 95 additional documents, which exceeded 35,000 pages, and write a report. In the end, the findings that the OPTN delivered to HRSA:

*"The OPTN Board Recommends the Secretary (1) require KDYA to perform a root cause analysis of KDYA's failure to adhere to its own policies, including, but not limited to, failure to comply with the Five Minute Observation Rule, (2) require KDYA to develop and adhere to a KDYA policy that clarifies who is a suitable candidate as a DCD donor, and (3) require KDYA to develop a policy that allows any individual to stop progression of a donation if they identify a patient safety issue."*

These recommendations are, in essence, the same as the concerns expressed by HRSA in their report, having benefited from reviewing the OPTN's report and having more time to conduct their review with staff entirely dedicated to the process. This is tangible evidence of the wisdom of the original framers of NOTA, who believed that the expertise and lived experience of experts in the transplant community are critical for the operations and oversight of the OPTN. They also recognized that a collaborative relationship with federal oversight authorities leads to balanced and reasonable results.

Finally, the OPTN had, before this event in 2021 became known, been focused on improving policy surrounding DCD donation. Evidence of this can be found on the OPTN website. It has been, and remains, my opinion that this is an essential project for the entire field of transplantation. As is often the case, technology has advanced faster than our ethical understanding of the circumstances and our policies that govern them.

Thank you for the opportunity to testify and I look forward to your questions.

**Attachments:**

1. OPTN policy
2. OPTN policy 2.15
3. 1 Email chain October - Feb KYDA
4. Manuscript - “the_economic_value_of_volunteers_directing_and.30”
5. Letter – “Donation-Transplant-Community-Open-Letter-on-Misinformation-1”