

July 18, 2025

The Honorable John Joyce, MD Chair Oversight & Investigations House Energy & Commerce 2125 Rayburn House Office Bldg Washington, D.C. 20515 The Honorable Yvette D. Clarke Ranking Member Oversight & Investigations House Energy & Commerce 2322A Rayburn House Office Bldg Washington, D.C. 20515

Delivered Electronically

Subject: July 22, 2025 hearing, "Ensuring Patient Safety: Oversight of the U.S. Organ Procurement and Transplant System."

Dear Congressman Joyce and Congresswoman Clarke:

The American Society of Transplant Surgeons (ASTS) is a medical specialty society representing approximately 2,400 professionals dedicated to excellence in transplantation surgery. ASTS thanks the committee and subcommittee for its efforts to ensure patient safety and appropriate federal oversight of the Nation's organ transplantation system.

The authorizing statute guiding transplantation is the National Organ Transplant Act (NOTA) which established a public-private partnership known as Organ Procurement and Transplantation Network (OPTN) that oversees the national distribution of organs. The public-private partnership has two key elements – government oversight and coordination of organ donation and transplantation guided by the expertise and experience of transplant community stakeholders. This careful balanced approach to transplantation was intentional and clearly outlined in the NOTA to protect the public interest and to assure Americans that they can be confident in the equitable access, value and safety of the transplant system.

We appreciate and respect that the subcommittee and full committee play an invaluable role in ensuring patient safety. In anticipation of the upcoming hearing noticed for July 22, 2025, we ask that the American public be informed about organ donation and transplantation in the context of a national system that over the last 70 years has saved and improved the quality of life for over a million individuals and their families. Unlike any other form of medicine, transplantation relies almost entirely on altruistic donors and their families who give the Gift of Life. This gift catalyzes the coordinated effort of a large team of highly trained transplant professionals who are urgently mobilized for each transplant surgery. The system is complex, and there are codified policies and procedures to govern critical steps. We ask that the conduct of the hearing minimize the chance for misinformation or sensationalism by the media or misunderstanding by the public by providing foundational information at the outset of the hearing as indicated below.

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We strongly urge subcommittee members to be highly skeptical of media distortions, to ask probing questions of panel experts, to seek to fully understand the processes, laws, and policies already in place to prevent patient harm, and to strive to fully include the transplant community in working with the government to ensure patient safety. Detailed below are critically important requests that we hope will assist you in your work.

Prior to this hearing, ASTS appreciated the opportunity to brief committee staff on our views on patient safety and government oversight of organ donation and transplantation and believe it is important to note several critical facts for all committee members and staff.

Potential Harm of Sensationalist Media

- We are concerned that sensationalist misinformation disseminated by the news media is driving an emerging crisis in confidence in transplantation. In the last year, the New York Times published a series of stories with headlines including the following: "Doctors Were Preparing to Remove Their Organs. Then They Woke Up," "Organ Transplant System 'in Chaos' as Waiting Lists Are Ignored," and another NYT posting entitled, "The Organ Transplant List is Being Ignored". The headlines and a great deal of the information in the stories propagate misinformation or misleading information.
- After the Times story ran such a story in September 2024, an average of 170 people a day removed themselves from the national donor registry in the week following this media coverage 10 times more than the same week in 2023. This actual impact might include far more delisting as this figure does not include emailed removal requests or removals from state registries. There was also a significant ripple effect internationally. Less than a year later, HRSA prepared a report that was provided to the *New York Times* without first having been provided to the transplant community and this action resulted in the publication of the June 6th article entitled "Doctors Were Preparing to Remove Their Organs. Then They Woke Up." Contrary to the implication of the article, it is NOT the case that patients who are declared dead come to life on the operating tables in preparation for organ procurement. If the Committee's investigation arrives at the same conclusion, we strongly urge the Committee to make this clear during the hearing to avoid misunderstanding by the public about the nature of improper or deficient practices.

Consider Clinical Facts on Donation after Death

"Controlled donation after circulatory death (DCD)" is a well-defined and heavily regulated clinical process addressed in considerable detail in professional standards and policy. Several societies have developed guidelines for DCD donation, and all call for an observation period after death, separation between the decision to withdraw life-sustaining treatment (WLST) and donation, and separation between the patient care and procurement teams. (see attached "DBD vs. DCD" document that briefly outlines steps in organ donation after brain death (DBD) or DCD and the team member responsibilities in each pathway)



- In DCD cases, the patient's care team, in consultation with the patient's family, make the heartrending decision to withdraw life-sustaining treatment to a critically ill patient, based on the conclusion that there is no overall benefit in continuing life-sustaining support. If and only if the patient or the patient's family makes the decision to withdraw life support, an Organ Procurement Organization (OPO) is authorized to approach the patient's family to discuss organ donation. If legal consent is obtained (dependent on state law), the OPO works with the patient's care team to obtain the clinical and other information necessary to determine whether the patient's organs are suitable for transplantation and to facilitate matching with candidates on the transplant waiting list.
- Notably, the clinical care of the patient remains in the hands of the patient's care team until
 death is declared by a member of that team. Neither the surgeon on site to procure a
 deceased donor's organ(s), nor the recipient's transplant surgeon (if different), nor OPO
 personnel has any role in the declaration of death.
- Significantly, organs are not procured from all potential DCD donors whose life sustaining support is withdrawn. For example, not uncommonly, a potential DCD donor does not proceed to cardiac death within a time frame compatible with organ viability, and in these cases, his or her organs may not be suitable for transplantation. In circumstances where the case is cancelled, the patient is transported back to the hospital or to hospice care.

We share the subcommittee's goals to protect not only the public's trust in the transplantation system but also to uphold this subcommittee's longstanding tradition of thorough, detailed, and transparent investigations that can lead to concrete policy solutions if systemic failures are identified. We are eager to share our expertise in such investigations and in working in close collaboration with the federal government and its agencies to further improve transplantation for the American public and ask that you partner with us to do so.

Thank you for your consideration.

Ginny L. Bumgardner, MD, PhD, FACS

Please see ASTS Surgical Standards and Guidelines

¹ "People opt out of organ donation programs after reports of a man mistakenly declared dead." AP News. https://apnews.com/article/organ-donor-transplant-kentucky-8f42ad402445a91e981327abb009906c