Committee on Energy and Commerce

Opening Statement as Prepared for Delivery of Subcommittee on Oversight and Investigations Ranking Member Yvette Clarke

Hearing on "Ensuring Patient Safety: Oversight of the U.S. Organ Procurement and Transplant System"

July 22, 2025

Thank you, Mr. Chairman.

I want to first congratulate you on being named the new Oversight and Investigations Chair. There is a great deal of important oversight work to be done, including today's hearing, and I hope we can work together to shine a light on problems across the broad jurisdiction of the Committee and ensure that our government is working to improve the lives of Americans.

Today's hearing is an important step toward improving confidence in America's organ donation system by confronting some of its problems head-on.

The Health Resources and Services Administration, or HRSA, and the entity that it oversees, the Organ Procurement and Transplantation Network, or OPTN, reacted to a troubling story that came to light during a hearing in this subcommittee last year.

In that case, a patient in a Kentucky hospital had been identified as a likely donor and, with the consent of his family, began the various tests and procedures necessary to evaluate the viability of his organs for donation prior to his removal from life support.

At numerous points throughout the process, both hospital staff and the staff from the organ procurement organization noted potential signs of consciousness and discomfort from the patient.

Nevertheless, the process proceeded all the way to the point that the patient was in the operating room.

At that point, however, the surgeon ultimately refused to operate, stating they felt the operation would be inhumane and unethical.

That patient ultimately recovered and was later discharged from the hospital and is still alive today.

As a result of this particular incident being raised at last year's hearing, a series of investigations took place.

First, the Kentucky organ procurement organization—KODA, which is now a part of Network for Hope—was ordered to conduct a self-assessment and concluded that it was, quote,

"satisfied and confident in the donation process." The OPTN initially accepted this conclusion despite KODA not providing any documents to substantiate it.

HRSA then fortunately stepped in and required OPTN to press KODA for more information and conduct a broader analysis of KODA's practices in certain cases.

OPTN's review, quote, "noted no major patient safety concerns based on their review," end quote.

HRSA also conducted its own parallel analysis and concluded that there was, quote, "potentially serious and ongoing risk to patients and families, as well as failures by [the Kentucky OPO] and the OPTN to adequately recognize and respond to poor patient care and quality practices," end quote.

HRSA's investigation identified 103 out of 351 examined cases that had, quote "concerning features." This is a stark warning.

And what is concerning is not only the gravity of this warning but the lack of urgency from the OPO and the OPTN, both of which were content with the way things were being handled.

In fact, instead of doing a serious assessment of the case, the Kentucky OPO retaliated against the whistleblower that brought the initial Kentucky case to light by pressuring the whistleblower's employer to fire them.

This is reflective of a cover-up culture, not a culture of concern for patient safety.

New reporting from the New York Times over the weekend indicates that a case like that in Kentucky is not an isolated event.

That reporting cites twelve cases across nine states that all raise concerns about how OPOs and donor hospitals are handling potential donors that are near death and might die from what is called circulatory death rather than brain death.

As a follow up to its investigation, HRSA has already directed the OPTN Board to take corrective action to make a series of policy and process improvements that may prevent future similar cases from occurring.

This new reporting further demonstrates that additional guidance and oversight is needed across the entire system.

HRSA's recent actions are a positive step in the right direction, and I thank the witnesses for their testimony today so that we can better understand what is going wrong and how to fix it.

I am also deeply grateful to my sister – Congresswoman Robin Kelly, CBC Health Braintrust Chairwoman and my fellow E&C Member, for her unwavering leadership in

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transforming the organ procurement system and championing the modernization of the Organ Procurement and Transplantation Network with President Biden signing into law the bipartisan, *Securing the U.S. Organ Procurement and Transplantation Network Act* (H.R. 2544).

Her tireless advocacy has paved the way for a more equitable, efficient, and lifesaving transplant system for all Americans.

Organ donations save lives, but we won't have enough organ donors if patients and their families do not have confidence in the safety and sanctity of the process.

Thank you, Mr. Chairman. I yield back.