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ENSURING PATIENT SAFETY:

OVERSIGHT OF THE U.S. ORGAN PROCUREMENT AND TRANSPLANT SYSTEM

TUESDAY, JULY 22, 2025

House of Representatives,

Subcommittee on Oversight and Investigations,

Committee on Energy and Commerce,

Washington, D.C.

The subcommittee met, pursuant to call, at 10:18 a.m. in Room 2123, Rayburn House Office Building, Hon. John Joyce [chairman of the subcommittee] presiding.

Present: Representatives Joyce, Balderson, Palmer, Weber, Allen, Fulcher, Harshbarger, Guthrie (ex officio); Clarke, DeGette, Tonko, Trahan, Fletcher, Ocasio-Cortez, Mullin, and Pallone (ex officio).

Also present: Representatives Griffith, Bilirakis, Dunn, Miller-Meeks, Cammack, Obernolte, Houchin; Schrier, Landsman, and McClellan.

Staff Present: Ansley Boylan, Director of Operations; Jessica Donlon, General Counsel; Kristin Fritsch (Flukey), Professional Staff Member; Sydney Greene, Director of Finance and Logistics; Jay Gulshen, Chief Counsel; Brittany Havens, Chief Counsel; Annabelle Huffman, Clerk; Megan Jackson, Staff Director; Sophie Khanahmadi, Deputy Staff Director; Giulia Leganski, Chief Counsel; Sarah Meier, Counsel and Parliamentarian; Joel Miller, Chief Counsel; Ben Mullaney, Press Secretary; Seth Ricketts, Special Assistant; Jake Riith, Staff Assistant; Jackson Rudden, Staff Assistant; Chris Sarley, Member Services/Stakeholder Director; Emma Schultheis, Policy Analyst; James Stursberg, Professional Staff Member; Matt VanHyfte, Communications Director; Kim Waskowsky, Professional Staff Member; Katie West, Press Secretary; Lydia Abma, Minority Policy Analyst; Keegan Cardman, Minority Staff Assistant; Aurora Ellis, Minority Law Clerk; Waverly Gordon, Minority Deputy Staff Director and General Counsel; Tiffany Guarascio, Minority Staff Director; La'Zale Johnson, Minority Intern; Elizabeth Kittrie, Minority Health Fellow; Will McAuliffe, Minority Chief Counsel, OI; Christina Parisi, Minority Professional Staff Member; Mary Ann Rickles, Minority Intern; Harry Samuels, Minority Counsel; Samia Shell, Minority Law Clerk; Andrew Souvall, Minority Director of Communications, Outreach, and Member

Services; and Caroline Wood, Minority Research Analyst.

*Mr. Joyce. The Subcommittee on Oversight and Investigations will now come to order.

The chair now recognizes himself for five minutes of an opening statement.

Good morning, and welcome to today's hearing entitled, "Ensuring Public Safety: Oversight of the U.S. Organ Procurement and Transplant System.''

I want to begin this hearing by saying that it is an honor to serve as the chairman of this subcommittee, and I look forward to working on a bipartisan basis to shed light on many areas in need of oversight and reform.

Just last year, 48,000 organ transplants were performed in the United States. Many of us know someone who is an organ donor or an organ recipient. That might be relatives, friends, neighbors, coworkers. These procedures are often lifesaving, and can extend an individual's life by years, if not by decades. While organ transplants are a relief to so many families, there is actually another side to the story that is equally important, and that is the story of the donors and their loved ones.

In September of last year this subcommittee held a hearing to conduct oversight of the organ transplant and procurement system, as well as implementation of the Securing the U.S. Organ Procurement and Transplantation Network Act which was signed into law in September of 2023. During that

hearing certain allegations came to light, raising concerns whether practices and procedures were putting patients' safety at risk.

Following the hearing the Health Resources and Services Administration, known as HRSA, directed the Organ Procurement and Transplantation Network, or OPTN, to investigate the issue to better understand what transpired in one of these alleged incidents. HRSA also conducted its own investigation.

The agency compiled a report that describes practices at the Organ Procurement Organization OPO, formerly known as the Kentucky Organ Donor Affiliates, KODA, but is now known as the Network for Hope. The report also details the failures by the OPO and the OPTN to adequately recognize and respond to poor patient care and quality practices. HRSA then issued a Corrective Action Plan to the OPTN, directing them to take specific actions to address the concerns that were identified in the reviews.

I ask unanimous consent to enter HRSA's report dated March 24, 2025 and HRSA's Corrective Action Plan dated May 28, 2025 into the hearing record.

Without objection, so ordered.

[The information follows:]

**********COMMITTEE INSERT**********

*Mr. Joyce. The report provided a detailed overview of HRSA's investigation, including about what is referred to as the Index Case: OPTN, the OPTN contractor, and KODA, and finally, KODA's organ procurement in recent years. As part of the review of the cases beyond the Index Case, HRSA focused on the overall medical presentation and initial -- and subsequent neurologic status of patients, staff interactions with patients and families, and primary medical teams, and evidence of robust documentation and quality assurance procedures.

Lastly, the report includes an appendix consisting of OPTN's findings following the HRSA-directed review.

For every doctor, one of the most important tenets in the doctor-patient relationship is, above all, do no harm. But what happened in these cases fractured the doctor-patient relationship, and saw patients subjected to pain and suffering that should never have occurred. As a Member of Congress, we all swore an oath to protect the constitutional right to life afforded to each and every American. These incidents cannot be allowed to stand without strict investigation and oversight in the spirit of our constitutional oath.

The Federal Government plays a critical role in ensuring the organizations tasked with administering and overseeing our nation's organ procurement and transplant operate safely,

effectively, and in accordance with the law. Transparency is key to improving the system and repairing the public trust. This committee has and will continue to follow the facts so that we can restore trust and accountability within the system.

I want to thank the witnesses from both panels for joining us today. I look forward to hearing from each of you about the challenges facing the organ procurement and transplant system, the ways that the system can be improved, and how we can ensure the safety of all patients who elect to be organ donors.

[The prepared statement of Mr. Joyce follows:]

**********COMMITTEE INSERT**********

*Mr. Joyce. I now recognize the ranking member of the subcommittee, Ms. Clarke, for her opening statement.

*Ms. Clarke. Thank you very much, Mr. Chairman. I would like to congratulate you on being named the new Oversight and Investigations chair. There is a great deal of important oversight to be done, including today's hearing, and I hope we can work together to shine a light on the 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. The 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 the Network of Hope, was ordered to conduct a self-assessment and concluded that it was, quote, "satisfied and confident in the donation process," end quote. The OPTN initially accepted this conclusion, but 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.

OTPN's [sic] review, quote, "noted as no major patient safety concerns based on their review," end quote. HRSA also concluded its own parallel analysis and concluded that there was, quote, "potentially serious and ongoing patient risk -- excuse me -- and families, as well as failure by the Kentucky OPO and the OTPN [sic] 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. The -- that reporting cites 12 cases across 9 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 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 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, and the CBC Health Brain Trust chairwoman and my fellow E&C member, for her unwavering leadership in transforming the organ procurement system and championing the modernization of the Organ Procurement and Transplantation Network, with President Biden signing into law in September of 2023 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 transport -- 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.

[The prepared statement of Ms. Clarke follows:]

**********COMMITTEE INSERT**********

*Ms. Clarke. Thank you, Mr. Chairman, and I yield back.

*Mr. Joyce. Thank you. The chair now recognizes the chairman of the full committee, Mr. Guthrie, for five minutes for an opening statement.

*The Chair. Thank you, Mr. Chairman. I want to congratulate you on your hearing and your chairmanship of this great subcommittee. And Dr. Dunn, who is here, is going to be -- is the vice chair of the full committee, and I look forward for us all working together.

And I want to kind of set my perspective on the stage today. My mother passed away waiting on a liver. She had end stage liver failure. And so I have been there. I mean, she was called once, so we were sitting in Vanderbilt Hospital, and a surgeon comes in and says, "I am about to jump on a jet and fly to Chattanooga, and so you are sitting there with your family with hope, and you have got the -- thinking of the other family. There is another family in another hospital somewhere else who is having the opposite. Unfortunately, the liver wasn't one that she could use, and so she didn't get called again.

So, we have to get this right. We have to have people -- I am an organ donor, I want to be an organ donor, I am going to continue to be, and hopefully everybody will continue because it really matters. It is life.

But we have to address what is before us and so we can

have confidence in the system. And, you know, not having a hearing where we talk about this in the open, you have the New York Times article, you have all the other things out there, so we have to address this, and we have to have it in a way that we come to a conclusion that we are going to fix this so people can have confidence, and have confidence in the system.

And so we are looking at the HRSA report, and the report obtained by the committee sheds new light on the challenges facing the organ procurement and transplant system and the Organ Procurement Organization, or the OPO, that is subject to HRSA's hearing. It hits close to home. Chairman Joyce talked about it. It is a Kentucky situation, and it is the -- now known as the Network of Hope, following a recent merger.

The report describes what happened to a Kentucky man who was in an organ donor registry, known as the Index Case in this report. After his family consented to organ donation, the HRSA report details the critical failure to reassess that decision following developing circumstances. Specifically, hospital and OPO staff documented improved neurological function at multiple points between the OPO was contacted and when the patient was in the operating room, and an OPO coordinator even escalated statements of concern from hospital staff to the OPO's leadership.

And a lot of the discussions that we have had about this case, a lot of times -- I have heard from several that the OPO was just not involved, that this was completely hospital function. But the report seems to state otherwise, that the person from the procurement was involved. And so I am not going to accept just to dismiss that it was all the hospital's issue. It was both. And it was actually the physician in the operating room who finally just stopped this organ recovery process.

But the report goes further beyond the Index Case. In fact, HRSA determined that of the 351 documented cases reviewed in this investigation, 103, or nearly 30 percent, had concerning features. HRSA found concerning patterns that includes failures to recognize increased neurological function and patients who were previously identified as candidates for organ donation; failure to work collaborative with medical teams; and failure to safeguard decision-making or follow best practices.

The numerous cases within the report show a deeply concerning pattern, and this is why we are having this oversight hearing today. We need to have an open and honest discussion about these failures.

And Dr. Lynch is here. HRSA has a role. And I think when we met, you said we know HRSA has a role. You are a transplant surgeon, and he says we are going to address it,

we are going to fix it, we are going to build confidence in the system.

We just need everybody here today, and both panels to admit that we have issues we have to fix and not just point fingers. I think that has been a concern by some of us on our side, on this side of the dais, I think both sides of the aisle. As you saw the report in -- the HRSA report -- that the OPO on the Index Case just essentially said everything is working, and we know everything is not working, but we need everything to work. And it starts by acknowledging that we have a role in the process of fixing this.

And so we need to admit we have issues. We need to admit there are issues that need to be fixed, and we need to come together and be constructive because I can tell you, as a son of someone that we were praying was going to have an opportunity to have an extended life, just -- I have seen it. And there are families out there today in the same situation we were in that are -- and we want people to donate. I am not going to change my organ donor status. I am going to give it to whoever needs it if the time comes that I am a donor. Hopefully, that is later, rather than sooner, but I want -- I am confident that I want people to have the opportunity to have -- survive and live.

But we don't need to not address this. We absolutely have to address it so the family on the other side of the

phone calls that we got can have confidence that their loved one is giving, and giving in a way that -- I have a friend here from Bullitt County, Kentucky, who has that with her son. Her son was an organ donor, and someone lived -- people live today because of your Keegan, your dear son. And so thanks for being here. And hopefully, people will walk away today knowing we need to address issues, but still confident that they can give life.

[The prepared statement of The Chair follows:]

**********COMMITTEE INSERT**********

*The Chair. So thank you, and I will yield back.

*Mr. Joyce. Thank you. The chair recognizes the ranking member of the full committee, Mr. Pallone, for five minutes of an opening statement.

*Mr. Pallone. Thank you, Chairman Joyce.

Today we are once again examining serious concerns that have been raised about our nation's organ donation system and what needs to be done to fix them. It is critical that the organ donation system continues to improve. Right now there are over 100,000 people waiting for an organ transplant.

The decision of whether to donate lifesaving organs is a deeply personal and meaningful one, and we owe it to everyone involved to make sure the system is working smoothly, and that there is respect for donors and their families throughout the process. And if we don't have that, then we won't have as many donors, obviously. And without donors, the waiting list for organs will only get longer. There will be more suffering and death for those hoping for a transplant. So I am hopeful that today's hearing will help us conduct meaningful oversight and find ways to ensure that our organ procurement and donation system is one that donors and their families can trust.

The Health Resources and Services Administration, HRSA, oversees the Organ Procurement and Transplantation Network, or OPTN, and its members which include transplant hospitals,

Organ Procurement Organizations, labs, and medical and scientific organizations. This hearing focuses on findings and recommendations that were made by HRSA after investigating a specific incident in Kentucky and a series of other cases with similar features handled by the same Organ Procurement Organization, which has since been merged into Networks for Hope.

Sorry, I thought I had turned that off.

HRSA's investigation and report revealed overly aggressive practices by the Kennedy -- the Kentucky OPO that posed risks to patients. These findings should be cause for deep concern and immediate action.

The experience of one patient and his family that was extensively covered in the report is deeply concerning. At numerous points prior to his near donation, signs that he should not have been considered an eligible donor were not acted upon by either the OPO or the hospital. Even more concerning, the HRSA investigation found similar examples of the OPO attempting to push forward with procurement of organs, despite signs of cognitive function in the patients. Now, these procedures were all ultimately not completed, but the OPO's pressure tactics prolonged the process -- processes before they were stopped.

When details of the incident in Kentucky were first reported, there were some key stakeholders who tried to

downplay it before it was fully investigated, and some continue to do so even after seeing the results of HRSA's investigation, and I find this troubling and counterproductive. When there is a problem that affects people's lives, our responsibility is to face it and try to solve it, not sweep it under the rug.

Yesterday HHS announced it would take action against Network for Hope if it does not comply with certain accountability measures.

And there is also new reporting from The New York Times over the weekend, describing numerous other cases from across the country where there were serious errors in the process of determining donation after circulatory death. In some cases, doctors found patients' hearts still beating after they had started the procedure. Other health care providers described donation procedures being initiated prematurely or without a complete assessment of the patient's cognitive condition. These are very disturbing cases, and show why oversight of the donation system is necessary.

Now, last Congress we passed the bipartisan Securing the U.S. Organ Procurement and Transplantation Network Act. This legislation created a foundation for the reforms that HRSA has been able to achieve and that are still in progress. HRSA has used its new authorities and resources to strengthen its oversight over the OPTN, including by creating a new

board of directors and beginning the transition to additional contractors.

But there is a lot more work to do. We need to make sure that there are experienced and qualified staff to continue the work of improving the system and increasing accountability. Secretary Kennedy's massive staff cuts and reorganization plans at HHS will cause great harm to the services it provides to the American people. HHS has not been forthcoming about where the cuts are occurring and what programs may harmed by this so-called reorganization. And committee Democrats will continue to push back against cuts at HRSA and across HHS.

I just want everyone to understand that with someone in charge like Secretary Kennedy, who I really don't think has any idea what he is doing, is hard to be concerned -- to be -- you know, to be convinced that any reorganization could actually be, you know, productive or healthful. But in any case, we will see.

Improvements to the OPTN and increased oversight by HRSA have broad support from this committee, and I hope we can continue to work together to ensure improvements that produce patient safety and create a culture of transparency and accountability. And those changes will increase confidence in the system, hopefully, which in turn could increase organ donations that save the lives of others.

[The prepared statement of Mr. Pallone follows:]

**********COMMITTEE INSERT**********

*Mr. Pallone. So this is a very important hearing. I want to thank you, Mr. Chairman. I yield back.

*Mr. Joyce. That concludes member opening statements. The chair would like to remind members that, pursuant to committee rules, all members' written opening statements will be made part of the record.

We want to thank our witnesses for being here today and taking the time to testify before the subcommittee. You will have the opportunity to give an opening statement followed by a round of questions from members.

Our witness today is Dr. Raymond Lynch, chief organ transplant branch of HRSA, a division of the U.S. Department of Health and Human Services.

We appreciate you being here today, Dr. Lynch, and I look forward to hearing from you.

You are aware that this committee is holding an oversight hearing and, when doing so, has the practice of taking the testimony under oath. Do you have any objection to testifying under oath?

*Dr. Lynch. I do not.

*Mr. Joyce. Seeing no objection, we will proceed. The chair advises that you are entitled to be advised by counsel, pursuant to House rules. Do you desire to be advised by counsel during your testimony today?

*Dr. Lynch. I do not.

*Mr. Joyce. Seeing none, please rise and raise your right hand.

[Witness sworn.]

*Mr. Joyce. Seeing the witness answered in the affirmative, you are now sworn in and under oath, subject to the penalty set forth in title 18, section 1001 of the United States Code.

With that we now recognize Dr. Lynch for five minutes to give your opening statement.

TESTIMONY OF RAYMOND LYNCH, MD, MS, FACS, CHIEF, ORGAN TRANSPLANT BRANCH, HEALTH RESOURCES AND SERVICES ADMINISTRATION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

*Dr. Lynch. Chairman Joyce, Ranking Member Clarke, Chairman Griffith, members of the subcommittee, thank you for the opportunity to testify on behalf of the Health Resources and Services Administration, or HRSA, an agency within the U.S. Department of Health and Human Services.

HRSA's -- closer? Sorry. Do you want me to start over?

Chairman Joyce, Ranking Member Clarke, Chairman Griffith, members of the subcommittee, thank you for the opportunity to testify on behalf of the Health Resources and Services Administration, or HRSA, an agency within the U.S. Department of Health and Human Services.

HRSA's division of organ transplantation oversees the Organ Procurement and Transplantation Network, or OPTN, a public-private partnership established by Congress to provide safe, fair, and consistent access to care across the United States. We thank Congress for the continued leadership on strengthening this mission. It was this committee that last year identified the safety concern we are here today to discuss, and it was through new resources and authorities provided by Congress in 2023 that we've been able to address this issue, as well as others critical to the safety and

welfare of all patients touched by the system.

As you know, the OPTN was established by passage of the National Organ Transplant Act, or NOTA, in 1984. The system includes transplant centers, labs, patient and family representatives, Organ Procurement Organizations -- or OPOs -- who are the federally-designated providers responsible for managing the process of deceased organ donor recovery. The OPTN was designed to create rules for allocating or matching donated organs to transplant candidates.

To create a safe, reliable framework for this, Congress empowered the OPTN, with oversight by HHS, to establish policies for monitoring threats to patient safety or public health. NOTA specified that only a single non-profit contractor with expertise in transplant could support the OPTN, and over the next four decades this role was held by one contractor, the United Network for Organ Sharing, or UNOS.

In the interim, since the passage of NOTA, transplant has grown tremendously. Last year more than 48,000 patients received an organ. Advances in technology and practice have improved organ utilization and patient survival. Congress has continued to enhance transplant access with legal changes to support living donation among individuals with limited financial means and the HOPE Act, which allowed the use of organs from persons living with HIV.

Despite these gains, transplant faces considerable challenges. More than 100,000 individuals are currently on the waitlist, with many more unable to get even that far. Last year more than 11,000 waitlist patients died or became too sick to transplant. HRSA's ability to address these problems was limited by NOTA's stipulation that only a single contractor could service the OPTN.

The potential for structural conflicts of interest where the contractor is responsible for developing policies, assessing compliance, managing the finances, and reporting on the quality and impact of its work was compounded by having the OPTN board of directors also be the board of UNOS. As Congress has noted, this functionally reduced the OPTN board's purview to issues that were amenable to the contractor.

HRSA was further limited by an appropriations cap that left it without adequate staff, technical expertise, and resources. As a whole, these statutory restrictions created a transparent, ineffective, conflict-ridden monopoly that essentially avoided meaningful government oversight.

In 2023 Congress passed the Securing the U.S. OPTN Act, enabling HRSA to fundamentally transform its oversight through clarity on the status of the OPTN, increased appropriations, and the ability to employ multiple contractors. The same year HRSA launched the OPTN

modernization initiative.

A major step in these advances was a spring special election to elect an independent and unconflicted board of directors. These and other improvements to OPTN governance will provide a more transparent, reliable, accountable, and safe system for patients.

The commitment to improving patient safety is central to modernization. Historically, HRSA did not receive complete, consistent, or at times accurate information on safety problems. With the new law, Congress allowed HRSA to strengthen its oversight capacity by obtaining additional technical and subject matter expertise and support. In turn, HRSA has used these resources to create a multi-layered approach to preventing and addressing safety events. The impact of these changes cannot be overstated. In the legacy system concerns of this type are that we are here today to discuss could and did go undetected by the OPTN, or uncorrected by the OPTN, instead of receiving the thorough review and response that we have provided in this case.

As HRSA has stood up its new capabilities, we are grateful to those in the transplant community who have supported modernization. We are also grateful to Congress for recognizing that more than 80 percent of OPTN operations, including patient safety investigations, are supported by patient waitlist registration fees. The temporary authority

granted in this spring's continuing resolution allows HRSA, instead of the contractor, to collect these fees, and is critical to good management and oversight of the OPTN. We're hopeful that Congress will approve this on a permanent basis.

We look forward to working with Congress to meet our shared goal of ensuring fair, safe, and reliable procurement and transplant care across the United States.

[The prepared statement of Dr. Lynch follows:]

**********COMMITTEE INSERT**********

*Mr. Joyce. I thank you for your testimony, and we will now move to questioning. I will begin and recognize myself for five minutes.

Dr. Lynch, to better understand what occurred with the Index Case and how a DCD, or Donation after Cardiac or Circulatory Death, how a case like that works, is it fair to say that it is not a failure in a DCD case if the patient doesn't end up dying in the allotted time, and the process is -- during the procuring of the organs, if it is stopped?

*Dr. Lynch. It's fair to say that the OPO has a duty to look for donors. The prognosis -- meaning planning whether or not an individual will expire within a time period that would allow for the recovery of their organs -- is imprecise. So in good faith cases there will be instances where a patient has a withdrawal of care, is allowed to progress to a natural death, but that occurs over too long of a timeline to make the organs usable.

*Mr. Joyce. And you wouldn't consider that a failure, would you?

*Dr. Lynch. I would not.

*Mr. Joyce. However, it is a failure if at any point in the process leading up to the removal of the patient from life support and declaring that patient is deceased, that the patient shows signs of improvement, neurologic function such as signs of pain or fear. If you see a patient crying, if

you see these kind of neurologic responses, the process should be immediately stopped. Do you agree?

*Dr. Lynch. I agree.

*Mr. Joyce. Or in another case, when a patient was awake and following commands, yet the OPO did not terminate the organ procurement process at the moment the patient exhibited that behavior, is this how a DCD case should work?

*Dr. Lynch. No, it is not.

*Mr. Joyce. Why is that?

*Dr. Lynch. So in DCD the appropriate initial and then the subsequent evaluation is key, identifying those individuals where the injury to the brain is sufficient that they will not recover, and allowing them to progress to a natural death. If over the course of the days between the OPO's initial assessment and when they ultimately go to the operating room, if they are improving, then it is unlikely that they're going to pass in that timeframe, and they're being exposed unnecessarily to harm.

*Mr. Joyce. So continued reevaluation as the process continues has to be part of the process, correct?

*Dr. Lynch. Correct.

*Mr. Joyce. We have seen continued reports of these concerning instances, and an instance at times by both OPOs and the OPTN board and its investigative arm that these cases do not represent a failure in the system.

Based on your opinion as a transplant surgeon, and now in your role of the -- as a chief of organ transplant branch of HRSA, can DCD continue to be done in a way that protects patient safety and honors the sacrifice of what these patients are doing?

*Dr. Lynch. Absolutely. So this is critical to ensuring patients' ability to have their wishes fulfilled. So if you make that brave decision to be an organ donor, and you can pass in a manner that you can be recovered safely as a DCD donor, you should be afforded that right.

We're also relying on these organs to save the lives of other Americans. This is complex care. It's technically demanding, but it's knowable and fixable. This is something that can be done safely.

*Mr. Joyce. As part of the investigation, HRSA analyzed information from over 350 unique cases of ANR patients, or Authorized Not Recovered. This means that the patients were considered for DCD recovery, but no organs were transplanted. The report continues that 103 of these cases, or nearly 30 percent, had concerning features. Could you explain what some of those features are, and what the common themes are in these cases?

*Dr. Lynch. So HRSA's report and, well, what we documented in our Corrective Action Plan essentially identified four problems. There was the inability to perform

a good initial or subsequent neurologic exam and identify those individuals who are likely to progress. There was a poor pattern of collaboration and respect for the input from the primary medical team, the hospital providers. There was poor communication and treatment of families, and then there was poor documentation of what was actually occurring with these patients in the OPO's records.

*Mr. Joyce. Would you say that the issues occurring in these cases are more related to policies on how the situations are handled, or personal errors, or a lack of communication from team? Because there are multiple teams that are involved as this entire process continues.

*Dr. Lynch. So this is -- as I said, this is a technically demanding form of care. It involves good collaboration between the OPO and the hospital. But every area in the country has exactly one OPO. They are the only ones who can provide this care. It is within their scope to make those relationships, do the education for the hospital, and provide that expertise and support to help them.

*Mr. Joyce. I thank you for the clarity of your answers. I think it is important for this discussion.

I now yield five minutes to the ranking member for her five minutes of questioning.

*Ms. Clarke. Thank you, Mr. Chairman.

I want to start by expressing appreciation for the extra

oversight that HRSA has conducted here. Because of that work we have some tangible findings and clear recommendations for process improvements. I would like to talk through HRSA's process in investigating the Kentucky case.

Dr. Lynch, has HRSA ever directed the OT -- excuse me -- the OPTN to initiate an investigation like it did last October regarding the Kentucky Organ Procurement Organization?

*Dr. Lynch. I should clarify, Madam Ranking Member, that this occurred before my time at HRSA, it started in October. But to my knowledge, I am unaware of any such direction.

*Ms. Clarke. Okay, so what has enabled HRSA to direct OPTN to carry out more stringent oversight while also conducting its own parallel analysis?

*Dr. Lynch. To be frank, it's the Securing the U.S. OPTN Act. It's the authority that Congress gave us, the ability to hire in expertise and to stand up a data analysis team to make sure that we can study these problems with the appropriate degree of rigor.

*Ms. Clarke. So why did HRSA determine that this level of oversight was necessary over the Kentucky Oregon -- excuse me, the Kentucky Organ Procurement Organization?

*Dr. Lynch. So the initial decision, again, preceded my individual time at HRSA. But it was a relatively easy

decision to identify this.

On probing, the OPTN contractor had sent a letter to the OPO asking for a detailed list of information. They got back a one-page letter telling them that there was no problem, and that the OPO was satisfied and confident in the process that this patient had undergone. The OPTN and its contractor then elected to close the case. Closing the case without reviewing the documents that you asked for is so inconceivable in a safety investigation that that made HRSA reassess this.

*Ms. Clarke. Very well. The OPTN board of directors is also responsible for enforcing its policies among OPTN members, which include OPOs and transplant hospitals. Dr. Lynch, how does HRSA envision the role of the new OPTN board in conducting oversight?

And what changes should it make from the way things were handled previously?

*Dr. Lynch. So the vision for the OPTN is to provide that system-level oversight. And to be clear, HRSA and other agencies within HHS provide parallel lines of support and oversight for elements of this community. HRSA is the system. By the OPTN, we're able to manage the elements that are within the transplant ecosystem, so to speak. The vision for this is that every patient who is touched by a member of the OPTN system should have their information knowable, and

their experiences, good or bad, should be the basis for subsequent policy-making and policy improvements.

*Ms. Clarke. The findings of the report are deeply concerning, and it is astonishing that no one appears to have thoroughly examined what happened in Kentucky for several years. The incident, including T.J. Hoover, occurred in 2021, but there was no report of the case until 2024. Stronger oversight protocols of the OPTN and more transparency from OPOs would uncover patient safety issues more quickly, enabling more timely improvements.

Dr. Lynch, how does HRSA plan to increase oversight of OPOs specifically, and improve visibility into outcomes for pre-donors, as you mentioned in your testimony?

*Dr. Lynch. So it is a multi-layered approach to this. The first is knowing the data that every patient who is interacted with will have their information known to the government. And that's something called the ventilated patient form in the case of the OPOs that we will know from the time of referral and first contact through either the successful recovery of organs or the end of the OPO's contact with that patient.

And then, in the case where something adverse happens, HRSA has already changed its practice so that, instead of the report going to the OPTN contractor and being triaged there, reports can now come directly to the government for

assessment and direction to the appropriate entities.

*Ms. Clarke. So what triggers that when it comes directly to HRSA? Or is it --

*Dr. Lynch. It's a --

*Ms. Clarke. -- that it goes to both?

*Dr. Lynch. So there are two ways in which a safety event can be reported. One is that it can be reported by the OPTN member itself through their secure portal. A broader way to do it is that anybody involved, anybody with access to an -- the Internet can go to a public-facing website and make a report to HRSA.

*Ms. Clarke. Very well. Are the -- currently -- are there currently other HRSA-led investigations underway that you are able to discuss?

*Dr. Lynch. I would prefer not to discuss them in this setting, but there are investigations undergoing -- are ongoing.

*Ms. Clarke. And how does the Kentucky OPO investigation process inform HRSA -- will approach its oversight and authority going forward?

*Dr. Lynch. So the Corrective Action Plan that HRSA released on May 28 is the first of its kind. This has parallels within other entities within HHS and the rest of the Federal Government. This is meant to immediately mitigate the circumstance at this OPO. But there's also a

broader part to it. Part B addresses the entire system, and we are confident that this pattern of care can be prevented in other OPOs.

*Ms. Clarke. Very well. Mr. Chairman, I yield back.

*Mr. Joyce. The gentlelady yields. The chair recognizes the chairman of the committee, Mr. Guthrie, for his five minutes of questioning.

*The Chair. Thanks, and thanks, Dr. Lynch. Thanks for being here, and thanks for your report. As I said in my opening statement, this is personal to me, and I want people to be organ donors, and I want people to have the ability to have that -- have a full life if they have the access to organs. But we want to make sure everything is right and done correctly.

And one of the things I think you said -- you weren't here at the beginning of this, but you didn't say, hey, I wasn't here so it is not my responsibility at the time. Also, you didn't -- you -- when we had our meeting you didn't say, well, it is somebody else's issue, not mine. You said HRSA has a role in this, and you just got -- started with Ms. Clarke.

So what have you -- what does HRSA need to do different to make more confidence in the system?

*Dr. Lynch. So I'd like to begin by expressing my apologies for the care that was delivered to your

constituents, to the people of Kentucky. It's unacceptable, and it's not something that HRSA is going to let stand. This was the impetus for our Corrective Action Plan to make sure that this did not continue in Kentucky, and that other OPOs could learn by example.

This is HRSA's responsibility. HRSA has this authority delegated by the Secretary, and we intend to make sure that the OPTN and its contractors are able to fulfill this role.

*The Chair. Okay. So thank you. So from your perspective or from HRSA's perspective, what more needs to be done by others, including the hospitals, the OPOs, the OPTNs, all the different groups? What needs to be done differently?

*Dr. Lynch. There's room for improvement by all parties. But the central figure here is the OPO. So nobody proceeds to organ procurement without an OPO's involvement. The OPO is the subject matter expert in this, and they are the ones who drive the process. They conduct the evaluation to identify and manage the donors, and they are responsible for the identification of transplantable organs that will be offered out for matching.

*The Chair. So what do they need to do different to give more confidence to the system?

*Dr. Lynch. So to -- we need better policy within the OPTN to make sure that the -- these lapses in care are preventable. We don't need to --

*The Chair. So what updated policies? What would you suggest?

*Dr. Lynch. So right now there is -- as specified in the regulation, there is attending to public health and patient safety. I think that we can speak definitively to improving DCD policy. This has been something that the OPTN board has discussed and other entities have discussed for years, but no action has been taken.

*The Chair. So those who are listening, it means that the circulatory -- there is two types of -- could you explain the difference in --

*Dr. Lynch. Yes.

*The Chair. -- brain dead and circulatory death?

*Dr. Lynch. So the manner of organ donation and procurement that most people are familiar with is brain death. That is where somebody is legally deceased. Their brain is not functioning, but their body is being maintained on a ventilator and with medical --

*The Chair. And that group, which is a big group -- well, there is a bigger -- unfortunately, because of drug overdose, the bigger group is the second. But that group we are really not questioning today what is been done with them, are we?

*Dr. Lynch. There -- HRSA has ongoing work to make sure that all forms of organ donation and procurement are safe.

*The Chair. But brain dead is not -- this is a different category.

*Dr. Lynch. The case in Kentucky was donation after circulatory death, or DCD. Historically, that was a less common pathway in the United States. Right now it's about 50 percent of the organ donors.

*The Chair. And in our case it is because of, unfortunately, drug overdoses.

So, you kind of answered a lot of my questions. Do you believe the -- so policies and procedures need to be updated, and we need to follow them, obviously. So what -- I mean, what specifically do you think in the Kentucky case would have -- were the -- what was the OPO's responsibility in the Kentucky case, and where do you think it failed?

*Dr. Lynch. So some of this could have been corrected locally. So under CMS regulations which guide an OPO, they're required to have a quality department. Every OPO also has a medical director. Appropriate identification of the donors, appropriate reevaluation of their neurologic status would have prevented many of these errors. Training and good hospital development -- meaning building that collaborative relationship and listening to the medical teams and the families -- would have prevented many of these.

*The Chair. Okay. So, will you commit to ensuring that there will be increased transparency from HRSA if and when it

identifies other issues with organ procurement and -- so those who are responsible for implementation and overseeing organ donation, procurement, and transplants can address these problems?

*Dr. Lynch. Yes.

*The Chair. You commit to working together. Well, you know, I think it is important that, as people are listening to this, there is a distinct difference in the two. I know we need to make sure everything works, but someone who is brain dead versus circulatory death -- and we need to -- and, unfortunately, the cases are rising with circulatory death, so we need to make sure we have the procedures in place to make sure someone is ready to donate before they -- they are -- the process moves forward.

But you have to prepare for it because you know they are going to die. That is the issue, isn't it, is that if they are circulatory death, you remove the -- it is not brain dead. Once you remove the treatment, they are passed. But circulatory death, when you remove the treatment, because they are going to die anyway, then it takes a little while. And that is kind of the space we are worried about, right?

*Dr. Lynch. There is ongoing work. There has been work for many years to try and get better at predicting who will pass and in what timeframe. It remains inexact. But however you're planning on predicting that, you need accurate

information, and that gets down to conducting a good neurologic exam and good history on what is wrong with the patient.

*The Chair. Thank you.

I yield back.

*Mr. Joyce. The gentleman yields. The chair recognizes the ranking member of the entire committee, Mr. Pallone, for his five minutes of questioning.

*Mr. Pallone. Unlike our hearing last September, we have the benefit of HRSA in attendance as a witness, and we have solid, evidence-based examinations conducted by HRSA. It has also directed the OPTN to make a monitoring plan for the Kentucky organization that is the focus of its investigation, and a system-wide policy and protocols to pause the organ procurement process when there are concerns about the patient's status. And these actions, I think, will better protect patients across the country during the pre-donor phase and increase confidence for would-be donors that their safety and interests will be addressed in the process.

But Dr. Lynch, does the Corrective Action Plan which is now public send a message to all OPOs and relevant OPTN members involved in patient care that OPTN oversight is becoming stronger?

And what do you hope the impact of that shift will be on the culture at OPOs and the OPTN?

I have four questions, though, so please be brief.

Oh, your mike is not on. Mine wasn't, either.

*Dr. Lynch. Sorry.

*Mr. Pallone. Go ahead.

*Dr. Lynch. I'd like to emphasize the vast majority of providers are doing this in good faith, and every day they show up trying to do a good job. This shows that HRSA is doing the same, and that we are committed to maintaining a safe environment. And so if they see something that is wrong, that they can plan for a future where we are doing that better.

*Mr. Pallone. All right. And then what was it that you saw in your investigation that made you believe more safeguards were needed specifically for potential donations after circulatory death?

*Dr. Lynch. The primary problem in Kentucky related to them failing to reevaluate their initial neurologic exam and failing to see that, instead of somebody slowly getting worse or staying at a very low level of brain function, that they were in many cases recovering.

*Mr. Pallone. I see. Now HRSA's report concludes that the Kentucky OPO disregarded or dismissed any indication that a patient who was identified as a potential donor would ultimately not be eligible for donation. And from the report, the OPO appears to have been determined to proceed

with the donation protocol until it was forced to stop by a physician's refusal to do the procurement operation, and various hospital staff do not appear to have stepped in to stop the process, either, until the very end. And despite this, some organizations argue that discussing concerning cases like this openly leads to fewer donations and harm to the donation and transplant system.

So, Dr. Lynch, I can't believe I am asking you this because it seems absurd, but what is HRSA's response to criticism that identifying and discussing lapses in patient safety in the OPTN is harmful to the system? I mean, I don't agree with that, but go ahead.

*Dr. Lynch. I'll keep it brief for your other questions. It's twofold. The first is that trust is earned. It's not to be expected. It's earned every day. And the second is that no system ever improved in the dark. We need to have good data. We need to show that we are paying attention.

*Mr. Pallone. And look, the bottom line is transparency is everything. You know, I mean, I have been here a long time, and if you don't have transparency, ultimately, you know, things don't work. So I totally agree with you.

Last question, though you can take time on this. What are specific ways that improved oversight of the system will help restore confidence that the OPTN is safe and effective,

and that people should be organ donors? You have almost two minutes to answer that one.

*Dr. Lynch. So again, the adequate collection of data -- the OPOs already collect these data on the patients with whom they interact -- making sure that that's relayed to the government, and that in turn is able to be used for analysis and for public use. The OPTN already is a leading example of making all data that we have available to researchers and policy advocates. Adding in all the data on either end, the individuals with whom OPOs interact before they are organ donors and the individuals with whom transplant centers interact before they are on the waitlist, will help us to really understand the system and make sure that we're providing consistent, good care.

*Mr. Pallone. All right, thank you.

I mean, if the goal is trust in the system, there has to be consistent standards for all OPOs to avoid disparate treatment for patients based on where they live and receive care. And HRSA's Corrective Action Plan, I think, is a step in that direction. And the OPTN and OPOs should welcome a constructive response from HRSA to prevent egregious incidents that put patients at risk. It is very important.

So with that, Mr. Chairman, thank you. I yield back.

*Mr. Joyce. The gentleman yields. The chair now recognizes the vice chairman of the committee, Mr.

Balderson, for his five minutes of questioning.

*Mr. Balderson. Thank you very much, Mr. Chairman, and congratulations.

Dr. Lynch, thank you for being here today. HRSA's report details many instances where the neurological condition of patients were not thoroughly assessed. Can you provide a few examples of where you found that to be the case?

*Dr. Lynch. The initial one was what we were calling the Index Case. That individual was showing increased signs of consciousness over the day preceding the organ recovery attempt, and then throughout that day of the organ recovery attempt. Despite the OPO noting this in its own electronic medical record, they continued without deviation from the plan, and went to the operating room with the intent of recovering his organs.

*Mr. Balderson. What changes to policy or procedures would you or have you recommended to ensure that patients are thoroughly evaluated prior to moving forward with procurement through the DCD?

*Dr. Lynch. So for DCD to be done in a safe way for any organ -- potential organ donor to be evaluated in a safe way, we need to understand what is wrong with them and to what degree there is chemical manipulation of their neurologic status, by which I mean is this the -- what we're seeing on a

neurologic exam brain function, or is it brain function and being sedated or paralyzed in order to, you know, accomplish other medical tasks?

*Mr. Balderson. Thank you. Dr. Lynch, could you briefly describe what leads to variations in process and procedures related to DCD in hospitals and OPOs?

*Dr. Lynch. So again, the hospital providers have a role in this, but they are dependent on the OPO as their subject matter expert. OPOs have been -- have had -- established areas of care for many years. They have a responsibility to provide procurement care in every hospital in their area, and so they all have hospital development divisions that are supposed to go out and provide education. That education can be in the abstract. A provider may not see somebody who could be an organ donor for many months.

When a potential donors identified by the OPO, they need to provide updated information on what we would term just-in-time training to make sure that there's a good expectation of the respective roles and the ability to reassess if this is a potential organ donor if the neurologic status changes.

*Mr. Balderson. Thank you, and I will follow up with that. And how might this lead to different standards in patient care and occasionally patient outcomes in CDC cases?

*Dr. Lynch. So this is meant to provide consistent care to make sure that the imaginary lines or the invisible lines

over which a patient may move within a state or across states don't affect the quality of neurologic care that they will receive in a hospital, and that they are able to have equal access to being an organ donor if that is the path for them, or to not being subject to that procurement process if it's not appropriate.

*Mr. Balderson. Thank you. Dr. Lynch, has HRSA ever recommended that an OPO be decertified?

*Dr. Lynch. So the decision to decertify an OPO actually rests with CMS, not with HRSA.

*Mr. Balderson. Thank you. Has an OPO ever been decertified?

*Dr. Lynch. No.

*Mr. Balderson. Thank you, Mr. Chairman. I yield back my remaining time.

*Mr. Joyce. The gentleman yields. The chair recognizes the gentlelady from Colorado, Ms. DeGette, for her five minutes of questioning.

*Ms. DeGette. Thank you, Mr. Chairman, and congratulations on ascending to your new role. I know this subcommittee is in capable hands.

And I want to say, as someone who has been on this subcommittee my entire time in Congress, we have spent a lot of time over the years looking at the organ donation rules and practices, and it is really shocking when something like

this happens with all of the effort that Congress has put in and I know agencies like yours, as well.

Last year there were more than 48,000 transplants performed in the United States. But right now there are more than 103,000 people on the national transplant waiting list. And tragically, as you know, Dr. Lynch, about 4,700 patients die every year while waiting for organ donation. And so there is an incentive to find more organs. And it is -- and it is a, you know, it is a lifesaving thing if it is appropriately done, if the person wants to donate their organ, and if in fact they are dead, and in fact -- if it qualifies. That is something we all agree with.

And I am hoping everyone on this subcommittee has checked yes for organ donation, but it is horrifying to everybody to see some of these practices that are being used. And The New York Times has been in the last few weeks doing some very good investigative journalism around this practice of circulatory death certification. And there was just an article dated July 20, updated today in the New York Times about this practice.

Mr. Chairman, I ask unanimous consent to put this article in the record.

*Mr. Joyce. So ordered.

[The information follows:]

**********COMMITTEE INSERT**********

*Ms. DeGette. So what they talk about -- and Dr. Lynch, you talked about it a little bit -- is the increase in the circulatory death process is part of what has led to this problem because, in a rush to get the organs, then many of the providers are saying that this is putting pressure on them to certify death, when in fact the person may be even moving. And I am wondering if you can talk about that just briefly.

*Dr. Lynch. So to be clear, the certification of death is by the donor hospital, not by the OPO. But with regard to what I believe your question is, is that is there increased regulatory oversight in the performance of OPOs that they're required to perform similar to their peers, is that leading to a rise in these events?

*Ms. DeGette. Yes, but the hospitals feel that they are being pressured by the OPOs to certify death. That is what is stated in these articles and by the investigations.

*Dr. Lynch. So my understanding of that article was that the hospitals -- some hospital staff were recorded as saying that the OPOs were more present in their hospital, or they --

*Ms. DeGette. That is correct.

*Dr. Lynch. Yeah. So OPOs are recovering more organs than ever before, and that is a multi-factorial thing. Some of it is related to increased oversight by CMS. Some of it

is related to new technologies.

*Ms. DeGette. Right.

*Dr. Lynch. Some of it is related to the ongoing opioid epidemic. The increased emphasis on performance in any area of medicine is never an excuse for non-compliance.

*Ms. DeGette. That is correct. I want to ask you about the structure because the OPTN board has recently been restructured, but previously the board of directors of UNOS, which was the sole contractor, was also the board of directors. And you said in your written testimony that this governance structure created a potential conflict of interest, and that is -- that goes to what I am talking about. And so I am wondering if you can explain the conflicts of interest as we are trying to do this oversight over these new emerging trends.

*Dr. Lynch. So NOTA, at its time, was a wise piece of legislation. But over time it has shown its flaws. NOTA basically told HHS to build a house for transplant, and it said you can have one contractor, and that contractor is your architect, your builder, and your home inspector. HRSA was in the position of being across the street, and wasn't able to directly oversee those functions. Having a contractor's board also be the board of the government entity, there is no way in which it will not affect the objectivity of that board.

*Ms. DeGette. It is almost a per se conflict of interest, is that right?

*Dr. Lynch. Yes.

*Ms. DeGette. And so does HRSA have a written plan in place to make sure that we have continued safeguards against potential conflicts of interest and make sure this board remains truly independent, going forward?

*Dr. Lynch. Yes. So HRSA this spring created a new board of directors, and that was done through a special nominating committee, what we call the transition nominating committee. They identified individuals who were volunteers coming forward from within the community. They identified a list of criteria to screen them for potential conflicts of interest, including service on the board within the last 10 years, during the period of most concern. And from within a group that passed that conflict check, the community elected a new board.

*Ms. DeGette. Thank you, I yield back.

*Mr. Joyce. The gentlelady yields. The chair recognizes the gentleman from Alabama, Mr. Palmer, for his five minutes of questioning.

*Mr. Palmer. And as the former chairman, I want to congratulate you on chairing the committee, and I know it is going to function extremely well.

Mr. Lynch, in your written testimony -- I want to read

something, and I quote -- "As HRSA was directing the OPTN to conduct the review of practices, an industry trade group, the Association of Organ Procurement Organizations, publicized an open letter characterizing the ongoing effort to improve patient safety through enhanced oversight as a misinformation conspiracy campaign, and concluded it is time for it to stop,'' and it was signed by more than 20 of the UNOS staff. Would that letter constitute an attempt to obstruct HRSA's investigation?

*Dr. Lynch. The legal definition of obstruct, I don't believe I would be the --

*Mr. Palmer. I am not -- I don't -- I am not talking about a legal definition.

*Dr. Lynch. It was concerning to HRSA that numerous high-ranking members of the contractor and members of the OPTN board did sign that, and in the review committee that we directed the OPTN to undertake, we asked that nobody who was a signer to that be a part.

*Mr. Palmer. But basically they were saying there is nothing to be seen here.

*Dr. Lynch. That's correct.

*Mr. Palmer. Okay, but that is not the first time you have had issues. Your written testimony also notes that, historically, HRSA did not receive complete, consistent, and at times accurate information regarding patient safety and

complaints and concerns raised by the OPTN members and other stakeholders. So if there is any consistency here, it is a consistency in trying to shield what they were actually doing.

*Dr. Lynch. So one of the problems with having a single contractor environment is that if it's responsible for devising the policies, anything that's happening that's out of compliance with the policies could be seen as a failure of that first process. So it is --

*Mr. Palmer. Now, what I am -- I am not trying to necessarily throw people under the bus because I am an organ donor, it is on my driver's license, and I realize the consequence of this. We had a lot of discussion about this before we ever had the hearing. But at the same time, we have got a responsibility to make sure that people know that this process will be conducted humanely, that it will be conducted legally, and that the people who are doing it have, at the very minimal, the best interest of the individual donor and the families that are involved.

And from your own written testimony and from the report from HRSA, I mean, there is multiple instances here where it appears that they were -- I use the word "obstruct,'' but clearly impeding an effort to expose some major problems, particularly in Kentucky.

*Dr. Lynch. We are -- we have a plan which is already

in place to prevent that in the future, which includes making sure that --

*Mr. Palmer. I understand. But what I am trying to say is that we are trying to conduct an oversight hearing to reach -- to come up with some solutions, which I think your efforts are excellent from what I have read, and that is exactly what you are trying to do. But I think there has got to be some accountability. There were clearly some things that happened that I think could constitute euthanasia. I mean, if the patient is dying but they take the patient's organs before they die, that is euthanasia.

*Dr. Lynch. When we identify conduct that we find is at odds with the OPTN contractor's duty, we have notified them of the expectation to perform better.

*Mr. Palmer. Well, again, as I -- we had this discussion before we had this hearing. We want to make sure that the American public knows that if they are willing to become an organ donor, they are going to be treated humanely and legally, and that the family's wishes will be respected, and that you are not going to have these horrible situations like we have seen here in Kentucky and some other places, frankly.

And my main concern is that you are able to do your oversight function without interference from anyone. I really am disappointed that 20 people signed this letter,

which to me constitutes obstruction of a legitimate investigation, which the investigation uncovered some serious, serious problems. And I just want to know if there is any consequences that anyone will be held responsible for what -- for how they conducted this.

And going on reading through your testimony, there were other examples where you weren't given accurate information. I don't -- I won't say that it was fraudulent, but it was clearly intended to not reach the conclusion that you needed to reach.

*Dr. Lynch. So when we identify a deficiency, we do communicate that in the contracting manner.

*Mr. Palmer. But what are the consequences?

*Dr. Lynch. As a non-contracting expert, there is a stepwise progression in noting a government contractor's ability to perform its functions effectively. The consequence that is within my direct scope is that we do not take these things on faith. We are trying to make sure that this is something that the government has the accountability. We have now the resources to get this done, so we double-check the work.

*Mr. Palmer. My time is expired, Mr. Chairman. I yield back.

*Mr. Joyce. The gentleman yields. The chair recognizes the gentleman from New York, Mr. Tonko, for his five minutes

of questioning.

*Mr. Tonko. Thank you, Mr. Chair and congratulations on your appointment. I look forward to working with you. And I thank you and Congresswoman Clarke for hosting this hearing.

Families of patients have to make agonizing decisions about the care of their loved ones under great stress. This is especially true when their loved one is on life support and may be nearing death. It is essential that the communication with families by hospital staff and OPOs about the patient's condition is indeed accurate and delivered appropriately so families can make well-informed decisions that respect the wishes of their loved one.

HRSA's investigation identified a troubling record of the Kentucky OPO's communication with patient families. In one case the OPO employees seeking consent to begin preparation for organ donation spoke with the patient's brother, who had a cognitive impairment. This individual was described as, and I quote, “childlike” in case records. In a separate case, the OPOs spoke with two family members who were , quote, “clearly inebriated.”

So Dr. Lynch, in your review did you determine why the OPO would approach family members like those in these examples who are not in a position to make serious decisions like consent for organ donation?

*Dr. Lynch. The records that we reviewed don't describe

the motives of the individuals that did this, but the inability to reconsider the options and to consider the humanity and the autonomy of these patients and their families is troubling.

*Mr. Tonko. And were OPO employees responsible for seeking consent from families for organ donation trained to interact with families this way?

*Dr. Lynch. That would be one of the core functions expected of the OPO.

*Mr. Tonko. And what do you think needs to change so this doesn't keep happening?

*Dr. Lynch. So we have a Corrective Action Plan in place that includes the requirement that the OPO perform up-to-date education and setting expectations with the family, with the health care team, and then making sure that if at any point either the health care team or the family has a concern, that there is a pause in the process to allow for adjudication of that.

*Mr. Tonko. Thank you. And this seems like a manipulative and overly aggressive strategy. The sister of the Kentucky patient has said that she was never told that her brother had started to wake up after she had given consent for donation. She says she only found out years later.

So Doctor, the Corrective Action Plan from HRSA directs

the OPTN to develop system-wide policies for improving communication with families and empowering them, along with medical teams and other involved stakeholders, to request a pause in response to a patient's changing condition. What are the gaps in patient family communication that you found in your investigation?

*Dr. Lynch. So this is, as you pointed out, one of the most horrible and challenging times in a family's life. The events that lead to somebody becoming a potential organ donor are usually sudden and tragic. Interacting with a grieving family, helping them to make educated decisions, providing compassionate and fair information and a complete sense of what the procurement process will look like, those are skills. They are skills that some OPOs clearly perform better than others, but they are skills for which the OPO is responsible.

*Mr. Tonko. Thank you. And why did HRSA conclude that the creation of a system-wide policy that includes a clear role for patient families was necessary?

And what do you hope will change after that policy is in place?

*Dr. Lynch. One of the things that we have done with the new and unconflicted board that came in was to help them understand that -- the greater system of patients than we normally hear from. And the new board on its first meeting

heard from a family member who is a nurse of 25 years experience. Her sister was a kidney transplant recipient, but her nephew, unfortunately, had suffered poor care from a different OPO -- not from the OPO that we're here today discussing.

Making sure that we make clear to the OPTN, to its members that this is something that matters, that the -- you know, to paraphrase a 100-year-old sentiment, the key to the care of the patient is caring for the patient. Those are the key elements here.

*Mr. Tonko. Thank you. And how will HRSA evaluate the effectiveness of the OPTN board's policy proposals and oversee compliance of the policies when they are established?

*Dr. Lynch. As we move forward with this, we have several ongoing innovative areas of improving patient safety. We are making sure that there is appropriate patient and family representation on these deliberative groups, on these committees within the OPTN, so that those perspectives can be honored. That's one of the key parts.

*Mr. Tonko. Well, again, thank you. And the committee looks forward to receiving updates as the OPTN board and HRSA collaborate on clarifying this policy that will affirm the communication throughout the process leading up to planned organ donation that patient families are entitled to. So it is obviously needed, and your efforts are a step in the right

direction. And for that I thank you.

And Mr. Chair, I yield back.

*Mr. Joyce. The gentleman yields. The chair recognizes the gentleman from Idaho, Mr. Fulcher, for his five minutes of questioning.

*Mr. Fulcher. Thank you, Mr. Chairman.

Mr. Lynch, thank you for being here today. Some of us have not been through this process personally, and I think that might be a blessing. But at the same time that may also indicate that we are less familiar with some of the particulars that you are addressing here today. And I know that some of us have come back to you with the same general topic a time or two, and I am probably no different, but I want to frame this in a way that may open you up to make some comments that you haven't to some of the other questions. And it has to do, of course, with the public safety responsibility that we have on the congressional side and just the public trust that we want to try to foster.

So it is essential for those of us here on the congressional panel to investigate and address situations that could result in harm to public safety, including improper practices in organ donation. We are also sensitive, as has been pointed out, that this can have an impact on the public perception of the process.

So in light of all of that, can you just take a moment

and perhaps touch on some specific steps that HRSA can take to make sure that public trust is where it needs to be?

Microphone.

*Dr. Lynch. Public trust is earned, and it is something that should not be expected in this process. We have an opt-in system. There are 170 million Americans who have made the brave choice that they would wish to be an organ donor. We want to be able to reassure them that the care that they will get is safe, that the documentation of their status, their wishes, and their progress through the system is safe and complete. That is being addressed through the policy directive that we have.

In cases where an individual identifies something that was adverse, we want to make sure that all those concerns are relayed to us and are able to be directed to the appropriate entities. That doesn't mean that every report we get is going to be substantiated, but they should all have their review.

*Mr. Fulcher. Thank you for that. In your written testimony there was a quote that I picked out there that I want to just refresh your memory on. And here is your quote, and I have got a question related to it. You said that HRSA aims to foster an environment where providers, patients, and families feel safe to report their concerns. And if an individual who has -- like me, with very little or no

experience with an organ donation system and got a concern and want to report that, does HRSA have an easy-to-access navigate mechanism to report or to make a report?

*Dr. Lynch. Yes. This spring we unveiled a new website. OPTN complaints, OPTN whistleblower, any entry of words like that will bring you to a government website to make such a complaint. And then, in the evaluation of those, it's critical to have a denominator, so to speak. So getting those other data to know how often -- if a negative event happened, how often is that occurring, essentially creating a rate for it. And so that's why getting a better data environment with the ventilated patient form is so deeply important.

*Mr. Fulcher. With that, Mr. Chairman, I will just make the closing comment that, you know, some of the things that we get involved with on this committee may not be in our real sphere of expertise, but it is also a reminder of just how important some of these components are. And in this one it is truly impactful on life and death.

So thank you for what you do, and let's all just commit ourselves to trying to make the process better.

With that, Mr. Chairman, I yield back.

*Mr. Joyce. The gentleman yields. The chair recognizes the gentlelady from Massachusetts, Mrs. Trahan, for her five minutes of questioning.

*Mrs. Trahan. Thank you, Mr. Chairman, and thank you, Dr. Lynch, for testifying today.

Everyone involved in organ donation and transplantation, from government organizations to clinicians to families, is trying to do the right thing. I believe that. But what we are looking at today is a system in chaos. Too many adverse events are being reported, too many patients are being skipped on waiting lists, and too many donor cases raise deeply troubling questions. We are hearing about people showing signs of consciousness during donation prep, patients being approached for consent while coming off of sedation, families feeling rushed, doctors feeling pressured. That is not how trust is built or maintained.

And one way we can maintain trust is by ensuring the integrity and security of the decades of patient data that power the system, especially as we move away from a single vendor model. Dr. Lynch, has HRSA developed a plan to open up UNOS's technology systems to new contractors in a way that protects patient privacy and ensures continuity of care?

*Dr. Lynch. So the plan for that is evolving as we continue to get new information and as our capacity to conduct oversight and safety reviews grows.

*Mrs. Trahan. I am happy to hear that because it isn't just new vendors that will need UNOS's cooperation to modernize the OPTN. The Federal Government will also need

unfettered access over the systems it paid for, starting with HRSA.

It may surprise some to know that for years HRSA has reportedly not had the power to fully review or access the computer systems that run the organ transplant network, including the code that makes matches and stores patient data. That means the government hasn't had a clear view into how the system works or where the risks are, which is especially concerning now, as the system is being overhauled.

So Dr. Lynch, how is HRSA making sure it now has full access to the data and systems it needs to successfully carry out this transition?

*Dr. Lynch. That also is a -- it is an excellent question. It's an ongoing area of work. So these are government data. These belong to the taxpayers who paid for it. And the individual patient data and the information that's used to maintain the system should be available to the contractors.

As we've moved into the multi-vendor environment, we've had what we call discovery contractors who have aided us with critical assessments of various elements of the system. Getting complete compliance from the legacy contractor is an ongoing area of work.

*Mrs. Trahan. Yes, we know that this transition is complex, but it's also necessary. For too long one

contractor has controlled the entire OPTN system, including its data and its IT infrastructure. And now, as new vendors are brought in to modernize the network, these are growing concerns that control -- there are growing concerns that control -- system code and data is being held hostage, potentially slowing down progress.

I am especially troubled by the reports that UNOS may have even put a price tag on its systems, effectively a ransom that government must pay to access taxpayer-funded technology. Dr. Lynch, to your knowledge, has UNOS ever obstructed or delayed government access to its technology or demanded compensation in order to turn over code and data?

*Dr. Lynch. Yes.

*Mrs. Trahan. Thank you for that brevity and honesty. I mean, at the end of the day, secure, uninterrupted access to OPTN's technology, especially code and data, isn't just a technical issue. It is a matter of trust, accountability, and patient safety. And that has to be non-negotiable. So I thank you for your testimony, for your helping us with our second panel.

And I yield back.

*Mr. Joyce. The gentlelady yields. The chair now recognizes the gentlelady from Tennessee, Dr. Harshbarger, for her five minutes of questioning.

*Mrs. Harshbarger. Thank you, Mr. Chairman, and thank

you for being here, sir.

During a potential donor evaluation an OPO must verify that death has been pronounced according to applicable local, state, and federal laws. Are there any examples in the report where a time of death was not declared?

*Dr. Lynch. The OPTN report did note one in which a five-minute interval between the initial and subsequent time of death was not adequately observed.

*Mrs. Harshbarger. Just one, then?

*Dr. Lynch. I believe so in the OPTN report --

*Mrs. Harshbarger. Okay.

*Dr. Lynch. -- yeah.

*Mrs. Harshbarger. HRSA mentions in the report that KODA has retaliated against a congressional whistleblower. Could you explain what occurred in that particular instance, and are you aware of other instances in which a hospital, an OPTN, UNOS, or anyone else that is part of the organ procurement and transplant ecosystem retaliating against someone who reported instances of misconduct?

*Dr. Lynch. So our awareness of that reported retaliation is based on media descriptions of it. That is not something that HRSA has direct knowledge of, but it was described that a third party was pressured by the OPO to withdraw their contract with that individual.

*Mrs. Harshbarger. Okay, so a third party. All right.

*Dr. Lynch. Sorry, I realize I forgot to answer the second part of your question.

The chilling effect that instances like the open letter to which others have made reference today -- it really can't be underestimated. The sense that to criticize the system is to break the system or is to break faith with the leadership of the system has had a decided toll on an individual's willingness to work on reform and to come forward when they have individual knowledge of an event.

*Mrs. Harshbarger. Absolutely. It will deter that from happening.

HRSA's report clearly states that a central tenet of DCD procurement is that, until the patients pass, they remain under the care of the hospital's medical team. Can you provide any examples of cases where these lines may have been blurred?

*Dr. Lynch. I'm sorry, could you repeat the very last part?

*Mrs. Harshbarger. Could you provide any example of cases where these lines may have been blurred?

*Dr. Lynch. Sure. So I think it's important to level set here. I apologize, I'll use a little bit of time. The OPO does not have the authority to make patient care orders, but they do change what happens to these patients. And that is a standard part of DCD.

If you imagine two twins who've had the same neurologic injury, one is pursued for organ procurement and the other isn't. They both get the same care at the end of their life in regard to what's supposed to happen to them, that is the ideal, but the one who is being followed as a potential donor has additional blood work done. They may have more invasive tests like a bronchoscopy, where they have their lungs examined, or a cardiac catheterization as the index patient in our review had happen. Those are not done for the care of that individual, they're done to evaluate the quality of those organs.

And OPOs commonly have what they call DCD order sets. We had numerous instances in our review where, despite that being a good practice in terms of making sure that these organs can save the lives of others, the DCD order sets may have been forcing or giving hospital staff the sense that they were being forced to do things that they believed were unethical, unnecessary, or unwise.

*Mrs. Harshbarger. Okay, well, I guess my question is why is that problematic? And is it considered a breach in protocol?

*Dr. Lynch. So DCD suffers from a lack of good descriptive policies nationwide. We need to have consistency in this. We need to restore the public's trust in this because it is a safe way to recover organs and to provide

care for people who are at the end of their lives if it is done well.

*Mrs. Harshbarger. Yes. Well, that is a risk to patient safety. In your opinion, what aspects of DCD procurement make this process controversial?

*Dr. Lynch. So the -- death is a touchy subject for almost everybody. And as opposed to the finality of somebody being legally brain dead --

*Mrs. Harshbarger. Yes.

*Dr. Lynch. -- predicting that they will pass away in a time that is consistent with having their organs recovered, it is inexact.

*Mrs. Harshbarger. Yes.

*Dr. Lynch. And a good faith assessment can be wrong. But making a good faith assessment requires good data. So this can be fixed and the trust restored by making sure that people are performing adequate exams.

*Mrs. Harshbarger. Okay. Thank you, sir.

And Mr. Chairman, I yield back.

*Mr. Joyce. The gentlelady yields. The chair recognizes the gentlewoman from New York, Ms. Alexandra Ocasio-Cortez.

*Ms. Ocasio-Cortez. Thank you so much, Mr. Chairman.

The ability to transplant an organ from one person to another is one of the great successes of modern medicine, and

the United States's organ transplant system is responsible for saving so many lives, and also for the loved ones of those who have lost family members and friends to actually see their gifts live on in others. And because organ transplants do save lives, the system we have in the United States needs to work well. There are so many people responsible for ensuring that it does.

Dr. Lynch, can you briefly describe the circumstances in which most organ donations occur?

*Dr. Lynch. So I agree with your sentiments completely. This is a public good. This is something that restores hope to individuals who have suffered loss in the case of the donor families, and it literally restores life to people on the waitlist.

The way that this process works is that the OPO is the central figure in it. The OPO staff are supposed to show up to a hospital, identify individuals who are neurologically injured, either if they're already brain dead or if they're progressing in that fashion, or if they're not brain dead or not believed to be progressing that way, if they have a poor prognosis and the family is considering moving towards end-of-life care.

The OPO then facilitates getting adequate information about the donor, which means blood work, a history and physical, and in some cases invasive tests. And then they

facilitate the operation where other parties, usually staff from transplant centers, come to that donor hospital and recover the organs.

*Ms. Ocasio-Cortez. Thank you. And it is often a patient's loved ones and their family or friends that often have to make this difficult decision. And as you mentioned, the individuals who often help them make those decisions are from OPOs, or Organ Procurement Organizations.

Dr. Lynch, can you explain a little bit further about what an Organ Procurement Organization is for people who are learning what this -- how the system works?

*Dr. Lynch. Sure. OPOs are almost a unique element of the American healthcare landscape. They serve two different populations. They serve those patients who are the potential donors, and they serve the potential recipients with the organs that they recover. They also have a unique situation in that they are made whole on their costs completely by the Federal Government. They also have a situation where the patients with whom they interact are at their most vulnerable. They're neurologically injured or deceased, so they're not going to speak up about the care that they receive.

*Ms. Ocasio-Cortez. Thank you. And in the way that the system is set up, there is currently only one Organ Procurement Organization in any given reason, and -- in any

given region, and which sometimes means that individuals may have little choice between OPOs.

Dr. Lynch, I have a report issued by your agency, HRSA, in March of this year. And the report found cases where organ -- where the organ procurement system has at times not worked properly and patient safety was jeopardized. Now, I think it is very important that, in order to protect individuals and not to raise too much of an alarm, by and large our organ procurement system works well, but we also want to protect the integrity of that system and ensure that we investigate any situations where a question may be raised.

The report found cases where the organ procurement system has not worked properly, and some of these do not appear to be isolated incidents. We do have a case of a woman in her thirties which was reported just two days ago in the New York Times. In 2022, Daniela Gallegos was hospitalized and went into a coma. Doctors thought that she would not survive, and her family agreed to donate her organs. However, it seemed that Daniela started to improve, responding to touch and trying to move. Yet the Organ Procurement Organization serving her area pushed towards surgery for organ removal and donation anyway. However -- and the system did work -- thankfully, hospital staff refused to move forward with the procedure, and Ms. Gallegos has actually made a full recovery.

I would like to submit her statement to the record.

*Mr. Joyce. Without objection, so ordered.

[The information follows:]

**********COMMITTEE INSERT**********

*Ms. Ocasio-Cortez. According to your -- to HRSA's report, there have been about 100 unique cases that had , quote-unquote, "concerning features." Now, that does not mean that they were all like Daniela Gallegos's case. But Dr. Lynch, HRSA has investigated additional cases and -- sorry -- has and the OPO was found to have pressured the medical team to move forward with this. Is that -- is that accurate?

And if so, how many organ -- what would be the standards for an Organ Procurement Organization to be on a path to decertification, and what would the line be for that?

*Dr. Lynch. So I'll start with the decertification decision would not rest with HRSA. That would be within CMS. I won't speak to Ms. Gallegos's case. There are numerous cases that have been reported to HRSA. We have ongoing reviews and we have made referrals to partner agencies.

The Corrective Action Plan that we have for Kentucky, as we are hearing about these other cases in other areas, also includes a plan to make the OPTN make this safe nationwide. And we believe that that will address the type of error that you're describing.

*Ms. Ocasio-Cortez. Great. Thank you very much.

*Mr. Joyce. The gentlelady yields. The chair recognizes the gentleman from Texas, Mr. Weber, for his five minutes of questioning.

*Mr. Weber. Thank you, Chairman.

Dr. Lynch, I guess I have to confess that I don't know a lot about you -- background, college, qualifications. Can you help us with that?

*Dr. Lynch. Yes. I joined HRSA in October of last year. Prior to that I was an abdominal transplant surgeon. I'm board certified in surgery, and I have been a doctor for 20 years.

*Mr. Weber. Board certified in abdominal surgery. And I guess without going into too many of the "details,'' but there is other organs. So does that cover pretty much all --

*Dr. Lynch. Sure, so my board certification is in general surgery through the American Board of Surgery. And then I did complete a further certification through the American Society of Transplant Surgeons.

*Mr. Weber. Okay, I guess what colleges did you go to? I am just curious.

*Dr. Lynch. I got my undergrad degree from Boston College. I got my medical degree and a master's in immunobiology from Yale University. And then I did my post-graduate residency, my surgical training, at the University of Michigan and my abdominal transplant fellowship at Emory University.

*Mr. Weber. Okay. Would you say that you have performed a number of transplants? Is it 20, 120, or what

would you --

*Dr. Lynch. Hundreds.

*Mr. Weber. Hundreds? Two or three hundred?

*Dr. Lynch. More than that. I don't recall the exact number, but more than that.

*Mr. Weber. Right. And so most all of them, your -- with your background and with your expertise, were for transplants?

*Dr. Lynch. After I finished my fellowship I focused on transplant surgery, yes.

*Mr. Weber. And how many years ago was that?

*Dr. Lynch. I finished my fellowship in 2014.

*Mr. Weber. In 2014? You are going to be like me, an old-timer.

*Dr. Lynch. I don't believe I should comment on that.

[Laughter.]

*Mr. Weber. Well, you don't have as much gray hair as I do, so I will give you that.

Well, let me get you, if you don't mind, to describe the events that led to the development of HRSA's report dated March 24 of 2025. And how did HRSA first become aware of these patient safety concerns?

*Dr. Lynch. So this specific concern was brought to HRSA's attention during a meeting -- or a hearing of this committee on September 11 of last year. The next day the

OPTN contractor directed the OPO, Kentucky Organ Donor Associates -- or Agency -- to respond with records. They responded on the 20th of September with a single-page letter that disputed the substance of the report that was given to this committee, but did not provide any of the records that were asked for by the OPTN contractor.

I believe four days later the OPTN and the contractor closed the case. Now, this was before my time at HRSA, but HRSA staff who were in attendance at that virtual call were not satisfied that a thorough review had been done, and directed the OPTN and its contractor to reopen the case and actually review the records that had been requested.

*Mr. Weber. So when did you get on board with HRSA?

*Dr. Lynch. October 21.

*Mr. Weber. Oh, so very recently. Okay. So you said the call was made September the 11 of last year. Who made that call?

*Dr. Lynch. There was an individual who provided a letter that was discussed in a hearing of this committee.

*Mr. Weber. Well, I guess without, you know, violating somebody's privacy or something, was that a patient or was it somebody who worked in the industry?

*Dr. Lynch. It's been reported in the media it was an individual who was a former employee of that OPO who still worked in the transplant space.

*Mr. Weber. And who is still working and still there today?

*Dr. Lynch. No, they lost their employment.

*Mr. Weber. Okay. If you went -- if you were notified of that -- I think you gave the dates, but how long -- exactly what was the timeline? September the 11th? And when was it terminated again?

*Dr. Lynch. So they received the single-page letter on the 20th, and they terminated it on the 24th.

*Mr. Weber. Thank you. How many individuals were involved in actually developing that report?

*Dr. Lynch. The report that -- the letter that the OPO sent back?

*Mr. Weber. And the response.

*Dr. Lynch. And their response? I don't know.

*Mr. Weber. You don't know?

*Dr. Lynch. The OPO --

*Mr. Weber. Who has oversight of that?

*Dr. Lynch. So HRSA has oversight over the OPO and the -- or through the OPTN, and that is why HRSA reopened that investigation.

*Mr. Weber. And who in HRSA has that oversight?

*Dr. Lynch. It is authority delegated through the Secretary to the associate administrator.

*Mr. Weber. And we would hope that that is a licensed

physician that has as much experience.

*Dr. Lynch. So the associate administrator, through the authorities that have been granted by the Securing Act, has hired in a lot of expertise, subject matter expertise, data analytics expertise to assist with that.

*Mr. Weber. Okay, Mr. Chairman, I yield back.

*Mr. Joyce. The gentleman yields. The chair now recognizes the gentleman, Mr. Mullin, for his five minutes of questioning.

*Mr. Mullin. Thank you, Mr. Chair. Dr. Lynch, thank you for being here today. And Mr. Chair, thank you for calling this hearing to discuss such an important issue.

Right now there are over 100,000 Americans on the transplant waiting list hoping to receive the phone call saying that they will finally be getting their transplant. While we must address flaws in this system, it is important to also recognize that it saves lives. Just last year there were over 48,000 transplants in the U.S., the most ever, and that was made possible by over 24,000 unique donors. And yet we still don't have enough donors. Thirteen people die every day waiting for an organ in the U.S.

To reduce needless deaths, I believe that Congress must work to strengthen the public's trust in the transplant system. Donors need to trust that their selfless gift will be used wisely not only by the dedicated medical teams

performing lifesaving transplants, but also by a Federal Government that prioritizes safety and conducts strong oversight.

While I am confident that many OPOs are highly committed to ensuring rigorous safety protocols, HRSA's investigation highlights some inconsistencies regarding how much authority is given to OPO staff during the organ donation process. In a medical setting, confusion can have heavy consequences.

OPTN policy states that when evaluating whether the patient would be eligible for donation after cardiac death, called DCD, quote, "The primary health care team and the OPO must evaluate potential DCD donors to determine if the patient meets the OPO's criteria for DCD donation," end quote.

Dr. Lynch, in your assessment, how is that collaboration -- that collaborative evaluation supposed to happen?

And is there a lack of clarity about this policy that needs to be addressed by the -- by OPTN or HRSA?

And if so, what steps are being taken to provide that clarity?

*Dr. Lynch. This is a public good. Transplant is a good thing. It is a focus for the Federal Government. Three successive administrations have worked to build our ability to deal with this, and we've enjoyed support from Congress in that role.

The work that is done here, the collaboration between the OPO and the primary hospital, is one where the OPO is the driver. They are the one with whom the decision to proceed down that procurement pathway begins and ends. The hospital cannot force them to do that. The family cannot force them to do that. The OPO is the subject matter expert, and it is their call on what constitutes a potential organ donor.

*Mr. Mullin. So I want to ensure that we aren't only reactively conducting oversight after a horrifying case and examples of those cases. Oversight over the transplant system needs to be forward-thinking and proactive. So Dr. Lynch, are there any other strategies that HRSA is considering to improve the interaction between OPO staff and hospital staff and their respective roles on these DCD cases?

*Dr. Lynch. So there's two elements to that. The first is that, as you say, proactive is best here. Developing a true denominator for all these interactions is important. We know that over 1.1 million cases last year, an individual was referred to an OPO. Many of those individuals recovered, they were -- a referral was made and the OPO not -- opted not to proceed with evaluation.

But HRSA's ability right now to know what happened at subsequent steps until somebody was an organ donor with what's called a UNOS ID is poor. We're improving that. And I think the best way to understand the utility of that is if

you ask somebody is air travel safe because there was an air disaster yesterday, you would want to know how many flights happened yesterday or last year to know if it's a single event or a common event. That is what we are doing here.

In terms of providing the education and making sure that roles are understood and that the goals of care are collaborative, that is something that is an OPO's obligation to perform. They can do that in the abstract, so to speak, making sure that hospital staff are made aware. And then, when a potential donor patient is identified, they should have just-in-time training to go through what the steps that will follow are, and to give everybody a clear understanding that if the patient status changes and they would not be considered a candidate, that the process should be halted or can at least be temporarily halted while that's investigated.

*Mr. Mullin. I appreciate that. Thank you for your report and your continued work.

Clear delineation of the roles of OPOs and hospitals is essential to avoid preventable harm to potential organ donors. Far too many people die each day waiting for an organ. It is critical that patients and their families have confidence in the decision to being an organ donor, a noble decision that could one day save a life.

And with that I yield back.

*Mr. Joyce. The gentleman yields. The chair recognizes

the gentleman from Florida, Dr. Dunn, for his five minutes of questioning.

*Mr. Dunn. Thank you very much, Mr. Chairman, and I want to thank you for holding this important hearing.

While I was practicing as a physician, I performed organ donation surgeries and transplants. And drawing on my experience I was shocked when reviewing the reports for this hearing. They are deeply disturbing. Transplant services depend on the generous donors that they -- and they must have 100 percent trust in us in all things on these donations. I was horrified by the findings, and commit to working to ensure that these stories do not repeat.

Dr. Lynch, I do want to first commend you for your work with HRSA while compiling this investigation. And based on your testimony, I must say it seems that there was an effort by others to downplay the facts. HRSA didn't let that happen, and I thank you for that. Has HRSA been made aware of additional patient failures like those outlined in these reports?

*Dr. Lynch. Thank you. I'd like to acknowledge the division of transplant, and the HRSA, and the Secretary as a whole. This is a team sport, and this has been one in which I believe everybody shares the goals and has shared the work in generating reports like this.

We are aware of other instances. And in fact, as we

conducted our review of the OPO in question here in Kentucky, they -- even after the September event that was made aware -- they were made aware of in this hearing, and after their merger with another OPO, subsequent reporting came to us from individuals within the community identifying cases of concern. We did substantiate cases of concern in that time period, even during that era.

*Mr. Dunn. I trust HRSA will investigate those, as well, and I appreciate your attention to these important investigations that reestablish the public trust in all of us.

I remain concerned that the OPO responsible for the particular blatant failures we read about here today continues to operate, even if under a new name. And I believe that HHS should consider all options to protect patients, including considering decertifying OPOs with a record of failure in this regard.

Finally, perhaps HRSA or the OPOs, whoever is in charge of -- who makes these rules should consider demanding the use of standard protocols for brain death -- we always used brain death, not circulatory death when I was in practice -- in all cases of drug overdose. That seems to be the most common type of patient who gets confused in these situations with circulatory death. Yes or no -- and they are much more difficult people to -- or patients to understand. Is that a

fair consideration?

*Dr. Lynch. To determine a brain death -- determination of brain death really does require a rigorous evaluation. And a layman's way of describing it is that nothing is wrong with the brain, except that it is not working. The brain should be warm. The person can't be hypothermic. They can't be without oxygen. They can't have too low a blood pressure that would make your or my brain not work well, and they can't be medicated or paralyzed so that we're not getting an accurate assessment of that. Those things are well described in, you know, consensus guidelines that are used as the basis for many state laws, and they are knowable.

*Mr. Dunn. Well, that was always the standard that we applied, and I have to say this: a circulatory death standard is -- it seems to be the thing confusing the issue. So I urge you to revisit that.

And with that, Mr. Chairman, I yield back. Thank you.

*Mr. Joyce. The gentleman yields. The chair recognizes the gentlelady from Washington, Dr. Schrier, for her five minutes of questioning.

*Ms. Schrier. Thank you, Mr. Chairman. Thank you, Ranking Member Clarke. Thank you, Dr. Lynch, for being here today. And let me just say it is such a pleasure to see my friend, John Joyce, with gavel in hand.

And I want to say congratulations and thank you to you.

I would like to start today just by pointing out how incredible and what a blessing organ donation is. I don't want to lose sight of that in all of this discussion. A single donor can save, by my count, up to eight lives, can bring sight to the blind, can help burn victims, and so much more. And the families and individuals who make this noble decision to donate their organs to save others should be thanked and honored, and that is why it is so important to address the recent widely-publicized donor safety concerns.

And I just want to be really clear that what has been documented by the HRSA report and the New York Times investigation is egregious, and no patient or their family should ever have to worry about carelessness or recklessness or harm after making this very noble, selfless decision to help others. And that is why it is so important that we get these questions right today.

The process of organ procurement and donation involves multiple parties. It is a pretty complex and integrated system. Healthcare providers, hospitals, organ procurement and transplantation networks, and HRSA, the Health Resources and Services Administration, all working together with this common goal of saving lives.

And as we see the fast growth in organ donation in this country and the relatively new -- relatively new focus on donation after circulatory death, I am concerned that medical

training and education may not be keeping pace with the often medically complex decisions and requirements for declaring circulatory death.

And so, Dr. Lynch, I just first wanted to touch on -- and, really, following up on Representative Mullin's question, what gaps are there in the training for providers involved in procurement procedures and those responsible for declaring death?

Particularly, if you could, point out what could be done better to avoid errors.

*Dr. Lynch. So an individual provider's familiarity with organ donation and procurement in general may vary, and with DCD it may vary considerably. The failsafe here is that the OPO is the expert, the coordinators who go on site and the individuals to whom they report are the experts. They do this every day all year long, and they have an established area in which they do it. So they should know the hospitals where they need to work to provide extra support.

One of the concerning aspects that HRSA found in its review was that these events appeared to be more frequent, relative to the number of attempted donor recoveries in small hospitals, and that speaks to the quality of the education and support that was being provided. Support can be a good thing, but it should never be mistaken for bullying or for telling somebody that this is just how it is. And the

instances that we documented are concerning that those things may have been confused.

*Ms. Schrier. I think it is a very interesting point to point out that it is in smaller community hospitals, not the trauma centers where you would get massive volume and have a lot of experience with this. I just wanted to point that in other areas of medicine -- when I was practicing, you know -- a woman comes in, a pregnant woman, for delivery. There is a standard order sheet. You check boxes and make sure you haven't forgotten anything. When you do hospital orders we had a mnemonic that helped us remember not to forget fluids or not to forget checking blood pressures, those kinds of things.

And so I am wondering if anybody is considering a -- just a procedural standard. Even the procedural pause that we take before operation happens because of some tragedies there, and is used to prevent that. Is anybody working on a standard checklist? You know, check this many minutes later, check that many minutes later. Make sure they are not on opioids, whatever it is to --

*Dr. Lynch. So --

*Ms. Schrier. -- make it foolproof.

*Dr. Lynch. So I would agree with you. Many of my friends are in areas of medicine other than transplant, and this is perplexing to them because we appear to have skipped a

generation relative to when I was in medical school. The Institute of Medicine -- now what's called the National Academy of Science, Engineering, and Medicine -- issued "To Err is Human,'` showing that, you know, that preventable medical errors were causing unnecessary death. That led to a revolution in acknowledging error, in preventing it through increased data reporting, increased general and up-to-the-minute education and things like the timeout. These things are knowable and fixable. This is care. This is safe if it is practiced well. It is being practiced well in many areas of the country. HRSA's Corrective Action Plan and directive to the OPTN are to make sure that it is consistently safe across the country.

*Ms. Schrier. Thank you very much, and thank you for your contribution to hundreds of patients who are now alive because of your transplantations.

*Mr. Joyce. The gentlelady yields. The gentleman from Georgia, Mr. Allen, is recognized for his five minutes of questioning.

*Mr. Allen. I thank the chairman.

Dr. Lynch, HRSA details several examples concerning interactions with patients' families in obtaining consent from next of kin. In one of these interactions the report describes how OPO staff proceeded with obtaining authorization from two family members, despite witnessing the

next of kin take psychoactive medication immediately prior to the discussion.

Are there or should there be protocols in place that do not allow for consent if a family member or next of kin or under the influence?

*Dr. Lynch. As a non-lawyer, I will speak in a generality, but I believe local, state, and Federal laws address consent, and making sure that an individual has the capacity to do so involves their mental state, yes.

*Mr. Allen. Okay. There have been concerns about the risk of conflicts of interest in the organ procurement and transplant system, particularly as it relates to UNOS and OPTN. And your testimony notes that UNOS was the only entity to hold the contract to support OPTN for the past 40 years. As a result of that, the board of directors responsible for OPTN governance was the same as the corporate board of UNOS, which created a potential conflict of interest.

What insights do you have into these potential conflicts of interest, and what is being done to address those issues?

*Dr. Lynch. So that was a source of strong concern that was noted by multiple congressional investigations, the lack of objectivity, the lack of independence for a board that feels that it has to answer to the OPTN, the government entity, and also to the corporate entity, to the contractor.

So making sure that they were independent boards from

each other, and then making sure that the individuals who occupied that board had the best information and had a clear understanding of their obligations to the OPTN was a key part of the modernization initiative.

With the authorities granted by the Securing Act in 2023 we were able to achieve that aim, and we had a special election this spring. The new board has been sworn in on July 1, and this election actually had an unprecedented high level of turnout from within the community. So we believe there is excitement and enthusiasm for this.

*Mr. Allen. Good. While the report analyzes cases across KODA's regional jurisdiction, HRSA's analysis found that there were disproportionate gains in procurement in certain sectors. What kinds of trends did you see with organ procurement in smaller, more rural hospitals?

*Dr. Lynch. So we found two trends in the smaller hospitals relative to larger ones. The first was that there were more cases that did not proceed to the recovery of organs relative -- you know, essentially, the number of times they tried was lower. And then in those cases where they did not proceed to organ recovery, there was a higher instance -- a higher rate of concerning findings in those smaller hospitals.

*Mr. Allen. For additional context, the report illustrates that there were proportionately more ANR cases

per successful donor procurement at smaller hospitals than those with higher proportions of rural patients, and that a higher fraction of the ANR cases at smaller hospitals and those with more rural population showed features of concern. Could you elaborate on those findings, and what this means in the broader context of OPOs?

*Dr. Lynch. So again, the right to be an organ donor is recognized. This is something that, if you've made that decision for care or your family makes that decision for care, it should be honored and it should be honored in a safe, consistent way. The small hospitals, we believe, did not receive adequate support from the OPO, and that is based on a number of the features that we saw, specifically the interactions with staff.

*Mr. Allen. Good. Well, thank you so much.

And with that, Mr. Chairman, I yield back.

*Mr. Joyce. The gentleman yields. The chair recognizes the gentlelady from Indiana, Mrs. Houchin, for her five minutes of questioning.

*Mrs. Houchin. Thank you, Mr. Chairman, and congratulations on your chairmanship of this subcommittee. I am grateful for the opportunity to weigh in on this extremely important topic.

Every year, tens of thousands of lives are saved because individuals make the courageous and selfless decision to

donate their organs. The reality is organ donation is rare. Only about one percent of people who register as a donor are eligible to donate their organs at the time of death. That is why we must treat every case with the utmost care, integrity, and accountability. When we fail to maintain rigorous oversight and ensure ethical practices, we risk eroding public confidence in the foundation of that system.

Today's hearing not only touches on the safety of individual patients, but the sustainability of the organ donation system. HRSA's report lays out deeply troubling findings, particularly with respect to the actions of the Kentucky Organ Donor Affiliates, or KYDA, now called the Network for Hope. These findings hit particularly close to home for me, as the organization under investigation serves my hometown community of southern Indiana.

The actions of KYDA to repeatedly continue to pursue organ recovery despite multiple signs of neurological function is not just alarming, it is morally and clinically indefensible. We are talking here about vulnerable patients, rural patients struggling with drug addiction, grieving families facing impossible decisions.

When the public places trust in our Organ Procurement Organizations, that trust must be earned and honored every single time. The failure to act upon clear signs of life, ignoring the pleading pressure by -- placed by hospital

staff, and the absence of non-partial accountability mechanisms raise serious questions about oversight and safeguards in the system.

Dr. Lynch, your report makes it clear that existing protocols were not followed. Why did the oversight framework in place fail before the incidents were reported, and is it a broader systemic issue or is it limited to KYDA?

*Dr. Lynch. Unfortunately, it is not limited to KYDA. During the course of this investigation we received concerns that were in areas served by other OPOs.

*Mrs. Houchin. I am --

*Dr. Lynch. The failure here is at multiple levels. So the OPO has a responsibility to conduct quality reviews and to conduct good oversight, to conduct good training for its staff to make sure that they know what to look for, and to make sure that they feel empowered to stop the process. These are all important things at a local level.

HRSA's oversight here is through the OPTN on the system. And the OPTN and its contractors's review of this was poor.

*Mrs. Houchin. Thank you.

*Dr. Lynch. All right.

*Mrs. Houchin. I am very concerned that we wouldn't know about this, had it not been necessarily for the whistleblower who notified that -- wrote a letter to the committee alleging that a patient had been inaccurately

pronounced brain dead and was pursued as an organ donor by KYDA. And per the report, the patient who was the victim of a drug overdose showed clear signs of life at multiple points, but KYDA senior staff directed that the organ recovery proceed.

We would not necessarily know about the depths that this has gone at KYDA, were it not for that whistleblower who was subsequently fired by a procurement agency. Is that your understanding?

*Dr. Lynch. Yes.

*Mrs. Houchin. So I am concerned about what appears to be -- and I think some of your testimony today reflects this, that there is an apparent conflict of interest in the oversight that HRSA is now working to correct. And I want to thank you for that on behalf of the constituents that I represent.

But I wanted to get your thoughts on -- you know, we talk about the ANRs that we know about with respect to DCD procurements. How many DCD procurements were completed by KYDA during the HRSA review process, do you know that?

*Dr. Lynch. I can't speak to -- I can't recall, to be perfectly honest, the exact number. But it was -- I believe the ratio overall was about 1 to 1, so on the order of 300 maybe.

*Mrs. Houchin. So you can understand that I might be

concerned that the ANRs are just the ones that we know about, and that some that were completed, they were followed through with, despite the warning signs that may have been present with the ANRs.

*Dr. Lynch. That's a valid concern.

*Mrs. Houchin. Well, I just want, in the remaining time I have, I know that HRSA has asked OPTN to report on within 30 days some of their findings. Have you received anything from OPTN at this point that met your metric to develop and implement a 12-month monitoring plan for KYDA? Have they done that?

*Dr. Lynch. Yes, we have started on that process and had meetings with them.

*Mrs. Houchin. Okay. They are supposed to issue that report on how they are going to monitor it. Have they done that?

*Dr. Lynch. That is due at the end of this month.

*Mrs. Houchin. Okay. Well, I want to thank you for being here today. I look forward to us working together to improve accountability and transparency in our donation system.

I remain concerned. It is clear there is a lot of work to be done to restore trust in the organ procurement network, particularly with respect to the troubling findings of KYDA.

My last question with the time I have is, do you have

concerns that KYDA is continuing under the current framework, given the concerns that have been shared to the committee?

*Dr. Lynch. We believe that the Corrective Action Plan that we're putting into place will enable them to perform in a safe fashion.

*Mrs. Houchin. Thank you. I yield back.

*Mr. Joyce. The gentlelady yields. The chair recognizes the gentlewoman from Iowa, Dr. Miller-Meeks, for her five minutes of questioning.

*Mrs. Miller-Meeks. Thank you very much, Mr. Chairman, and I want to thank the witnesses of both panels for testifying before the subcommittee today.

I probably have a unique perspective coming into this hearing. So first and foremost, I was a newly-made lieutenant at Walter Reed, where, having been an emergency room nurse, I was then a neurosurgical nurse working on a floor that had comatose patients, brain dead patients. And talking with family members, doing studies to ensure they were brain dead, and then talking to those family members about organ donation. Then I did that as an emergency room doctor, serving on trauma, doing a general surgery, general surgery internship in a very busy hospital, Bear County Hospital in San Antonio. And then finally through my residency in ophthalmology.

So both as a nurse and as a physician, I have been in

those very delicate conversations with family members, determining first and foremost that their family member is in fact brain dead, and may not continue to have a viable life. And then, as a physician and ophthalmologist doing vision-saving corneal transplant surgery on children, on adults with chemical injury or heritable diseases. And so when I say that donation is only possible due to the public trust and the generosity of donor families, I know that firsthand.

And following the September 24, 2024 hearing and the subsequent story regarding Kentucky's case in October, the Iowa Donor Network experienced a 78 percent increase in registry removal requests, with 193 requests compared to the same time in the previous year in which we received 75 requests. And the sharp increase in registry removal requests following recent events clearly demonstrates how fragile this trust can be, and how vital it is that we protect and restore it.

And I know, Dr. Lynch, that that is also what you would like to do, and I know that's what OPTN and UNOS wants to do, as well.

So I have a little bit different history than other people, and I haven't removed from my driver's license -- nor has my husband -- that we are donors and that we want to donate and provide that lifesaving or sight-saving organ if we are healthy enough to do so to someone else, child or

adult.

And this is not a system that has been in place for a long time. I mean, the system that I worked at as a nurse and a physician, we didn't have the 2023 Securing U.S. Organ Procurement and Transportation network, the OPTN network. So it is newly established. And I think it is unfortunate that we are going through a process now where there will be, as we learn from one another, recommendations and processes that need to -- have to be changed.

Dr. Lynch, can you detail how much of the funding has been allocated to date, and where that funding has gone that has been provided to HRSA to improve the systems?

*Dr. Lynch. Sure, thank you for your perspective. We share that in HRSA. This is something that -- we want the public to feel that it is -- you know, we are worthy of trust in the system. And for those family members of individuals who have gone through the process, we want them to be able to feel consolation and pride that their loved ones made that choice.

So in terms of funding, before the Securing the U.S. OPTN Act, HRSA was limited by statute at $7 million. I believe in the last year it was 23 million that we spent since the Securing Act.

We have undertaken several tasks. From an operations perspective, the most important is that we now have not just

one operations contractor, the legacy one, we have a new contractor, AIR, which is providing support to the board, and that helps them to have independence from the rest of the system.

We also conduct a lot of what we call discovery tasks or discovery contracts, which are really to get external expert opinion. And then, from within that, pull from the community to understand all elements -- logistics allocation, policy-making, communications technology.

*Mrs. Miller-Meeks. I have a bill, the Organ Donation Referral Improvement Act, which directs HHS to study and promote the widespread adoption of automated electronic referrals for organ donation. However, HRSA could initiate this transition on its own. Are you familiar with automated referral?

And if so, have you worked with health systems and OPOs to further understand how it could be implemented on a wide scale?

*Dr. Lynch. I'm familiar with the concept of automated donor referrals. I'm unfamiliar with your piece of legislation. I'd be happy to look at it.

*Mrs. Miller-Meeks. Thank you. I think further collaboration, working together, standards and processes in place, will help restore the trust of the American people in organ donation, which is an extraordinarily valuable service

that we do.

*Mr. Joyce. The gentlelady yields. Dr. Lynch, thank you for your attention, and thank you for your candor this morning.

I do have just two brief follow-up questions. The report details instances in which patients are being evaluated after they have received sedatives and paralytics. In one instance the report notes -- and I am quoting -- "a lack of understanding of concern regarding the effects of medications on the patient's neurologic status extended right up to the point of going into the operating room in preparation for procurement of the organs for transplantation.'' Can you explain to us why it is so alarming that patients are being evaluated while they are under the influence of sedatives and paralytics, right up to the point where a neurologic evaluation might be adversely affected?

*Dr. Lynch. So it's an excellent question. The basis for this is making sure that we're actually understanding the neurologic injury or the remaining neurologic status of the patient. And so if you have somebody who is just sedated and paralyzed, you're going to make an assessment of them that they may have no reflexes or that they may have a very depressed level.

*Mr. Joyce. Would that be an adequate assessment?

*Dr. Lynch. No, no.

*Mr. Joyce. Are there protocols that need to be developed as far as -- as the progression of the evaluation right up to the time of procurement, is there an ability to assess what drugs can be effectively administered and what drugs should not be administered?

*Dr. Lynch. Those are critical elements of HRSA's Corrective Action Plan and system directive is to make sure that we understand what the neurologic status is, and that everybody involved has got a clear picture of the patient's real situation and prognosis.

*Mr. Joyce. Is there any uniformity with the current system where different sedatives or different medications prior to the procedures for the procurement are not utilized or shouldn't be utilized, or recommendations that they be avoided?

*Dr. Lynch. There are no set protocols or policies that apply across all OPTN members, no.

*Mr. Joyce. I thank you for the follow-up question. I thank you again for being present here today.

Seeing that there are no further members wishing to ask questions, I would ask our witnesses -- I would thank our witness again, Dr. Lynch, for being present here today.

We will take a quick recess to allow the witness table to be set for the second panel. We are in recess.

[Recess.]

*Mr. Joyce. The subcommittee will come back to order.

We want to thank our witnesses for being here today and for taking time to testify before the subcommittee.

You will have the opportunity to give an opening statement, followed by a round of questions from members.

Our witnesses today are Barry Massa, chief executive officer for the Network for Hope; Maureen McBride, chief executive officer for United Network for Organ Sharing; Dr. Richard Formica, former president of Organ Procurement and Transportation Network board of directors; and John Magee, MD, president of Organ Procurement and Transplantation Network board of directors.

We appreciate all of you being here, and I look forward to hearing from you individually.

You are aware that the committee is holding an oversight hearing and, when doing so, has had the practice of taking the testimony under oath. Do you have an objection to testifying under oath?

Seeing no objections, we will proceed. The chair advises that you are entitled to be advised by counsel, pursuant to House rules. Do you desire to be advised by counsel during your testimony today?

Seeing none, please rise, raise your right hand.

[Witnesses sworn.]

*Mr. Joyce. Seeing the witnesses answered in the affirmative, you are now sworn in and under oath, subject to the penalties set forth in title 18, section 1001 in the United States Code.

With that we will now recognize Mr. Massa for five minutes to give an opening statement.

TESTIMONY OF BARRY MASSA, CHIEF EXECUTIVE OFFICER, NETWORK FOR HOPE; MAUREEN MCBRIDE, PHD, CHIEF EXECUTIVE OFFICER, UNITED NETWORK FOR ORGAN SHARING; RICHARD FORMICA, MD, FORMER PRESIDENT, ORGAN PROCUREMENT AND TRANSPLANTATION, NETWORK BOARD OF DIRECTORS; AND JOHN C. MAGEE, MD, PRESIDENT, ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK BOARD OF DIRECTORS

TESTIMONY OF BARRY MASSA

*Mr. Massa. Chairman Joyce, Chairman Guthrie, Ranking Member Clarke, and Ranking Member Pallone, and members of the subcommittee, thank you for inviting Network for Hope to testify at this hearing. My name is Barry Massa. I'm the CEO for Network for Hope, the federally-designated Organ Procurement Organization responsible for facilitating organ donation in Kentucky, parts of Ohio, West Virginia, and Indiana.

Network for Hope was formed in October of 2024, with the merger of Kentucky Organ Donor Affiliates and Life Center Organ Donor Network. I have had the privilege of dedicating the majority of my professional life to honoring the selfless and courageous individuals, along with their families, who give the gift of life to the more than 100,000 people currently waiting to receive a lifesaving transplant.

OPOs play a vital and unique role. These community-

based not-for-profits are exclusively designated to facilitate the deceased donation process. At Network for Hope we recognize that organ donation and transplant system cannot succeed without public trust, and that public trust must be earned.

Every stakeholder in this complex ecosystem can and should always strive to be better, and Network for Hope is no exception. The work that we as OPOs do can mean the difference in whether a family will be able to share another birthday with a loved one or have the opportunity to make more treasured memories with friends. None of this is lost on us. It is what drives us.

There are a few points I want to make abundantly clear. OPOs do not provide health care. OPOs do not participate in the decision to withdraw life-sustaining care. OPOs are not involved nor have any say in the declaration of a patient's death. OPOs do not recover organs from living patients. And OPOs only facilitate the organ recovery process from deceased patients.

Since first receiving the March 2025 HRSA report just a few days ago, thanks to the actions taken by this committee, it is clear that the report's allegations and contents are serious and alarming. We are in the process of expeditiously reviewing the issues cited in the report and addressing the concerns raised therein.

Let me be very clear about my next statement. Patient safety is at the forefront of everything that we do. I want to assure the subcommittee that Network for Hope will take any appropriate action necessary to continue to implement policies and procedures to continuously improve and be better and, most importantly, ensure and promote patient safety. You and the citizens we serve should expect nothing less.

We also welcome oversight and share your goal of ensuring the highest standards in organ donation and transplantation.

I'd like to introduce and recognize two individuals joining us today who have been personally impacted by organ donation. Sitting just behind me is Ms. Adria Johnson, a mother, organ donation advocate, and the CEO of Metro United Way in Louisville, Kentucky. Her son, KJ, became a DCD donor in 2010 at the age of 29. His selfless choice directly saved three lives. His heart went to a man in his thirties, and two mothers each received one of KJ's kidneys.

Also with us today is Ms. Shannon Atkins, also of Louisville, Kentucky. Three years after her eldest son, U.S. Marine Sergeant Michael Atkins was killed in action, Shannon's six-year-old son, Keegan, passed away. Shannon and her husband made the courageous decision to donate Keegan's organs. As an organ donor, Keegan saved the lives of four children and one adult.

Adria and Shannon have both turned unimaginable loss into miracles for others and their families, and continue to advocate for organ donation, and we are deeply grateful for their support.

For myself, like many in our field, my passion for donation is very personal. Many years ago, even before joining Life Center, a close friend's daughter, Aubrey, received a double lung transplant at just the age of 18 months old. Aubrey lived for another 18 months before unexpectedly passing away and, upon her passing, became an eye donor, a cornea donor. The stories like Aubrey's, KJ's, and Keegan's are what has driven me to advocate for all who are on the transplant list and to ensure OPOs like Network for Hope can meet the growing need effectively and safely.

Again, thank you for the opportunity to be here today. I look forward to continuing to work together collaboratively to improve the donation process.

And as Congressman Guthrie stated, we have to get this right. Thank you.

[The prepared statement of Mr. Massa follows:]

**********COMMITTEE INSERT**********

*Mr. Joyce. Thank you, Mr. Massa.

Dr. McBride, you are recognized for your five-minute statement.

TESTIMONY OF MAUREEN MCBRIDE

*Dr. McBride. Good afternoon, Chairman Joyce, Ranking Member Clarke, and members of the committee. My name is Dr. Maureen McBride, and I am the CEO of UNOS. I am a PhD biostatistician, and I have spent my career working to ensure more Americans are able to receive the gift of life. Thank you for inviting me to be here today.

Organ donation and transplant is also my life's work. It's personal to me and my colleagues at UNOS, many of whom have been touched by organ donation or transplant. We go to work every day to support a system that is safe, fair, and effective for both donors and patients. We do that in a very specific way by supporting the nation's Organ Procurement and Transplant Network, or OPTN, under contract with HRSA.

Our work to support the OPTN includes managing the national transplant waitlist and organ matching system, providing support to the OPTN volunteers during policy development and compliance oversight processes, and collecting and maintaining OPTN data on behalf of HRSA.

I'm incredibly proud that every day, more than 100 lifesaving transplants occur through the national network that UNOS supports, and that our organization has played a role in giving more than one million Americans a second chance at life. To lead UNOS is to be reminded every day of

the connection between life and death. Every transplant is a second chance, and some are born from tragedy, A life cut short, a loved one gone. I've heard countless stories that broke my heart And stories that remind me of the true power of giving.

Consider the experience of one of my colleagues at UNOS whose father passed away in 2023 at the age of 54. Walking alongside him to the operating room during his honor walk was the most difficult moment of her life. And yet she willingly shares his story to inspire others to become organ donors. Generous people like her father enabled more than 48,000 transplants last year.

I also get to celebrate the milestones of other colleagues who are transplant recipients. They work at UNOS because they feel compelled by their personal journey and our mission. They are living full lives thanks to the immeasurable gift of more time.

It's important to understand that UNOS is only one stakeholder in a very complex system, and when it comes to our support of the OPTN we work at the direction of HRSA. As we have seen, the system is not perfect, and improvements do need to be made. The case in Kentucky shows that more work must be done to strengthen safeguards, promote patient safety reporting, and adopt more reforms.

However, it's important to understand that UNOS had no

direct role in the care ever provided to patients. We do not direct day-to-day operations at local hospitals. We do not work with families to secure organ donation or with hospitals to make donor referrals. We have no influence on patient care protocols, and we do not make determinations of death or direct medical decisions.

But let me be clear. UNOS is here to work with all of you to make this system better. UNOS alone cannot make all the necessary changes to improve the system, but we are ready to collaborate. That's why today I call on Congress to require CMS and HRSA to work together to establish a no-wrong-door comprehensive patient safety reporting system. Any patient, family member, or health professional who has witnessed or experienced poor care should have a clear path for reporting their concerns. Since more than 95 percent of hospitals are not members of the OPTN, CMS and HRSA must work together to close the reporting gap.

UNOS remains deeply committed to working with Congress, HRSA, CMS, and the community to ensure that the system is safe, fair, and effective. In addition to the no-wrong-door reporting system, I recommend three more reforms: implementing automated deceased donor referrals; mandating a national tracking system for donor organs; and migrating the OPTN computer system to the cloud. I've outlined these and other reforms in my written testimony.

I did not become CEO to maintain the status quo. The organ and transplant system is founded on trust. To continue to earn and keep that trust we must work collaboratively to improve the system that serves as a beacon of hope for patients and families across America. Thank you.

[The prepared statement of Dr. McBride follows:]

**********COMMITTEE INSERT**********

*Mr. Joyce. Thank you, Dr. McBride.

Dr. Formica, you are recognized for your five minutes.

TESTIMONY OF RICHARD FORMICA

*Dr. Formica. Chairman Joyce, Ranking Member Clarke, I appreciate the opportunity to provide testimony on this very important topic. My name is Rich Formica. I'm a kidney doctor who practices transplant medicine. I'm a professor and the director of transplant medicine at Yale University School of Medicine. However, today I'm testifying on my own behalf, not on behalf of Yale University, and the views expressed are my own and not those of the university. I've also volunteered for the OPTN since 2008.

The OPTN is composed of more than 450 volunteers who represent the entire transplant ecosystem, including physicians, surgeons, representatives of OPOs, and, most importantly, organ recipients, living donors, and deceased donor families. We all volunteer because we believe in the mission of transplantation, caring for patients with end organ failure, and particularly honoring the selfless gifts of deceased donors and their families. For the past 40 years members of the transplant community have volunteered their time and expertise to the OPTN.

For the year from July 1, 2023 to June 30, 2024, the OPTN consisted of 459 individual volunteers filling 599 positions. A conservative estimate of the 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, and excellent patient outcomes. Over the past decade these volunteer hours have positively contributed to the improvement in the nation's transplant system. Major policy achievements include the kidney allocation system of 2014, the simultaneous liver kidney allocation policy of 2017, the Transplant Center's performance monitoring policy, the removal of donor service areas from the allocation of all organs, and the removal of race from the calculation of EGFR. These efforts have significantly improved both equity and fairness in the transplant system while allowing us to serve an ever-increasing number of patients.

I would now like to take a few moments to address the issues we're discussing today.

First I think it's important to clarify the role of the OPTN's authority to address incidents like the one we are discussing. 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 waitlist and recipients of solid organs.

In addition, in collaboration with CMS, the OPTN oversees performance and adherence to policy of OPOs, as well as the safety aspects of transporting and transplanting

deceased donor organs into transplant recipients. The OPTN option does not have oversight of donor hospitals, and this limitation creates challenges when attempting to merge the OPTN's role in overseeing the donation process with CMS's role in the oversight of hospitals caring for patients who are being considered as potential donors after circulatory death.

You know, while as a physician I have some strong opinions about medical care that is rendered to patients, when I'm acting in my role as an OPTN representative I don't have that oversight authority. Until the time of their death they remain 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 are those policies that govern OPOs' data collection and record-keeping responsibilities, restrictions on how the OPO staff can interact with families who are being considered -- or families whose family members are being considered as donors after circulatory death, timeout procedures, 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 we were responding to the secretarial directive to review the charts of patients considered as potential DCD donors who did not pass away and therefore did

not progress to donation at KYDA, the OPTN reviewed these cases based upon KYDA's adherence to OPTN policy 2.15. And based upon the directions of HRSA, we did not review the Index Case.

I think it's important to note that this was a unique review for the OPTN, and we didn't have a precedent for it. It required setting up a new committee of volunteer reviewers to assess these documents, conducting a review of 35,000 pages of documents under a very compressed timeline. And we had some restrictions on the experts who we could ask to participate in the review.

However, I'm quite proud of the work that the committee did because, despite the limitations, the recommendations that the board of directors made to the Secretary are, in essence, the same concerns that were expressed by HRSA. I'd be happy to detail those in more detail later.

Finally, for many years the OPTN has been focused on improving policy surrounding DCD donation, and a mere search of the OPTN website can show you all the initiatives we've taken. And I personally feel, as technology has advanced, this is a topic that we have to address even more acutely.

So thank you for the opportunity to testify, and I look forward to answering any and all of your questions. Thank you.

[The prepared statement of Dr. Formica follows:]

**********COMMITTEE INSERT**********

*Mr. Joyce. Thank you, Dr. Formica.

Dr. Magee, you are now available to present for five minutes.

TESTIMONY OF JOHN C. MAGEE

*Dr. Magee. Thank you, Chairman Guthrie, Chairman Joyce, Ranking Member Clarke, and members of the committee. I also want to thank you for letting Dr. Formica exceed his time limit and give input. Thank you, I appreciate that, I know the regulations.

Members, thank you for the opportunity to speak today on behalf of the Organ Procurement and Transplantation Network Board. A little over three months -- three weeks ago I was elected to serve as the volunteer president of the OPTN board of directors. While I may be new to the OPTN board, I've been a transplant surgeon for over 25 years. I entered this field because it embodies the endless potential of humanity and the best of health care in the United States. The guiding principles for our organs -- our nation's donation and transplant system are respect for the life and dignity of the potential organ donors and transplant candidates.

Respect for the autonomy of our donor heroes and their families to make decisions is first and foremost. Over my career I've had the privilege of witnessing these principles in action. As a surgeon who has participated in many deceased donor procedures, I'm always impacted by both the tragedy of sudden loss and the amazing altruism of donors and their loved ones.

I'm also impressed by the teams present. The operating room can be intense and crowded. In my lived experience, staff from the donor hospital, OPO, and transplant teams strive to work collaboratively with a deep reverence for our shared mission: honor the donor's wishes to help save lives.

As a surgeon who sees children and adults who can benefit from transplantation, I also understand the intense feelings of fear, hope, and uncertainty for the future. I welcome the members of this committee to observe these processes firsthand, and I will be happy to facilitate this opportunity. I would also be happy to facilitate any interactions with the donor families and transplant recipients.

I do want to take a moment to recognize any individuals or families who have experienced interactions with the donation process where there was any lack of respect for the dignity of donors and families. Trust is the foundation of our organ donation system.

Each of -- each member of the donation and transplant community is a steward of our foundational principles. We both must acknowledge areas of improvement and necessary change. This is our path to ensuring that our system maintains trust while continuing growth and innovation. For our donors, our patients, and all those who may need us in the future, it is our obligation to commit to embracing

complete transparency, accountability, and oversight.

Over the last 40 years, donation and transplant professionals have evolved and innovated to serve our donors and our patients. Our systems and policies need to keep pace. I know we can do this. It is in this context that I decided to step forward for consideration to serve as the president of the OPTN board.

The newly elected OPTN board fully supports modernization efforts and commends Congress for its leadership in improving the system through the passage of the Securing the U.S. OPTN Act, as well as other legislation to help donors and families. Working through the private-public partnership that was established by NOTA in 1984 -- at a time I was in my first month of medical school -- and working with HRSA, the OPTN modernization effort has already completed considerable work to guide ongoing reform.

As we move forward to improve our system, our donors and our patients need us to do so responsibly. Disruption and recklessness can lead to unintended consequences. But above all, we must maintain trust in the system. Our goal is to constantly improve the system without losing the principles upon which it was built. We will do this by embracing transparency, accountability, and oversight.

On behalf of the newly elected OPTN board, I look forward to working with you as partners in finding solutions

necessary to honor the wishes and -- of donors and saving more lives. Thank you.

[The prepared statement of Dr. Magee follows:]

**********COMMITTEE INSERT**********

*Mr. Joyce. I want to thank all the witnesses for your testimony. We will now move to questioning. I will begin and recognize myself for five minutes.

Mr. Massa, when looking at how your OPO handled the Index Case from the HRSA report -- very simply, yes or no -- do you still maintain the ascertation from your testimony that all of the relevant OPTN policy, regulation, statute, and rule were followed by KODA in the handling of the DCD case?

*Mr. Massa. Thank you, Chairman Joyce, for your question.

That case was very complex and during a very complex time. If you recall, in 2021 we were in the midst of COVID. And I think that impacted the communication that we had within our -- between our hospital and our team. And while I'm not using that as an excuse, I do think it added to the complexity of it.

With that said, we know that a successful donation experience happens when there is frequent communication. And I think in that case -- in this case that we're talking about -- the communication could have been vastly improved.

*Mr. Joyce. And if that communication wasn't where it should have been, can you say, yes or no, was policy, regulation, statute, and rule, was that followed?

*Mr. Massa. The DCD process was followed. Yes, sir.

But again, I think --

*Mr. Joyce. In light of the horrific pain and suffering that the Index patient endured, do you agree, then, if it was followed, and what we have read about this case, do you think that stricter standards need to be in place so that patient safety -- so that we never hear again about a patient suffering this horrific pain?

*Mr. Massa. We never want another experience like this, as well, and --

*Mr. Joyce. So do you think that --

*Mr. Massa. -- we are going to administer --

*Mr. Joyce. Yes or no, do you think that stricter standards should be in place?

*Mr. Massa. We are going to follow the recommendations of HRSA, and we are glad to have more oversight to make sure that we restore the public trust.

*Mr. Joyce. Mr. Massa, moving on -- and we have heard this from Dr. Lynch's testimony today -- do you or anyone in your organization play a role in retaliation against the incident reporter in the Index Case who, according to the HRSA report, was fired from another job in the organ transplant space following outreach from KODA just two days after this committee's hearing last year when the Index Case was first discussed?

*Mr. Massa. No, sir. If you look at the facts -- I

welcome every member of the subcommittee to look at the actual facts of that case, or of that situation. There was no retaliation. If there was retaliation, that would not be tolerated within Network for Hope.

*Mr. Joyce. Is the individual who is now in charge of the OPO -- have you looked into any possible retaliation against this -- retroactively looked at any retaliation against this or any other whistleblowers?

*Mr. Massa. I have.

*Mr. Joyce. And what have you found?

*Mr. Massa. I found that, in this case specifically that we're talking about, there was no retaliation. And I go back to the letters that we sent to this committee on December 17 and January 3 in response to that --

*Mr. Joyce. Will you commit to us that if there is any incident that would occur in the future, and it would be brought to the attention -- that there will be no retaliation, that you will work to make sure that those who bring these cases forward where someone is undergoing additions -- and moving forward in the transplant process and is not felt to be an appropriate candidate, that there will be no efforts of retaliation against that individual?

*Mr. Massa. That is correct. And I could tell you that we have a policy in place that not only the expectation is to bring that forward, but it says in the policy it is an

obligation for anyone --

*Mr. Joyce. Thank you for that commitment, and thank you for that obligation.

Dr. Formica, it has been alleged that the OPTN has a history of dismissing and downplaying serious allegations of risk to patient safety like in oversight of the Index Case, where you dismissed nearly proceedings with organ harvesting on a patient who ultimately was discharged from the hospital alive. And I'm quoting. You said, "A nice story for the patient.'' Yes or no? Did the OPTN, under your leadership, adequately investigate and respond to all reported concerns?

*Dr. Formica. Chairman, I think this case highlights some of the challenges we face in the OPTN. I learned of this case after the MPSC had decided not to pursue that, when HRSA instructed us to begin the larger investigation.

In retrospect, had I heard about that sooner -- because I'm aware of the larger context of what's going on right now -- I would have asked for a deeper investigation.

*Mr. Joyce. So why did HRSA need to direct the OPTN to reopen their investigation of KODA, and eventually issue a Corrective Action Plan dictating how further action must be handled?

*Dr. Formica. I think that demonstrates the collaborative nature between the OPTN and HRSA, frankly, and I think that's why it works well.

*Mr. Joyce. But if --

*Dr. Formica. But the OPTN --

*Mr. Joyce. -- these safeguards were in place, would that have needed to occur?

*Dr. Formica. The OPTN is composed of volunteers who are also conducting their normal day jobs, and were facilitated by contractors that help provide the infrastructure around which we provide our work. As we've moved through the transition period, some of that fluid communication back and forth has taken some time to work out new pathways.

*Mr. Joyce. But you have all talked about trust. And now that trust has been violated. I think it's been fractured. Do you feel that that lack of communication that existed continues to exist today?

*Dr. Formica. I actually think it's getting better every day. When you've moved from an environment where you have one contractor facilitating all the activities of the OPTN to multiple contractors now facilitating that, it takes some time to work out the pathways for --

*Mr. Joyce. I think it is clear to all of us on this committee, both sides of the aisle, that that communication needs to improve, that collaboration needs to improve, and that there needs to be the safety of the patients that ultimately guides whether or not they are viable candidates

for the transplants that are so necessary for the health of so many Americans.

I thank the panel for being here today. I now yield five minutes to the ranking member for her line of questioning.

*Ms. Clarke. Thank you very much, Mr. Chairman.

This committee's bipartisan investigation has highlighted concerning reports -- highlighted that concerning reports have emerged that the organ donation system has become unsafe, inequitable, self-dealing, and retaliatory.

In addition to serving as the ranking member of the Oversight and Investigations Subcommittee for Energy and Commerce, I am also the chair of the Congressional Black Caucus. I am committed to ensuring that Black Americans have equal access to life-and-death organ donation and transplant services. However, by all accounts, the U.S. organ donation system is dangerously inequitable for Black patients.

UNOS is facing multiple lawsuits related to practices that discriminated against Black patients, moving them further down the waiting list. And earlier this year The New York Times ran a front page story titled, "Organ Transplant System in Chaos as Waiting Lists are Ignored," which has detailed how organ contractors are systemically ignoring the organ transplant waiting list in order to preference hospitals serving whiter and wealthier patient populations.

The reporting was clear: disregarding the list has worsened disparities.

I want to be clear. Disregarding the list, a process that has become rampant under the OPTN and UNOS, is a violation of basic trust, and is killing vulnerable patients.

This committee is investigating systemic inequity in the organ donation system that has happened under UNOS's watch. So Dr. McBride, I am looking for a yes-or-no answer. Is UNOS currently being sued for racist practices which disadvantaged Black patients on the kidney waiting list based on junk science, which assumes that they have more muscle mass?

*Dr. McBride. Thank you, Congresswoman.

It is true that there are current lawsuits against UNOS in its role as the OPTN contractor for decisions that the OPTN board made regarding organ allocation policy.

*Ms. Clarke. Did at a past US -- excuse me, at a past UNOS board meeting write -- excuse me, did a past UNOS board member write that Black and rural Americans are less deserving of lifesaving organ transplants because they are quote, “dumb” for where they live?

*Dr. McBride. I am unable to comment on that, Congresswoman.

*Ms. Clarke. Well, that has been what has been reported.

And Dr. McBride, The New York Times has written on chaos

in the waiting list due to rampant skipping of the list, a practice which has exploded while UNOS has been the operations contractor for the OPTN. Does the OPTN's data indicate that this practice of wait list skipping in general harmed Black patients?

*Dr. McBride. Thank you, Congresswoman.

I would like to first clarify that UNOS's role is to support the OPTN and its policy-making and oversight decision-making process. UNOS does not make policies for the transplant community. We support the committees that are made up of volunteers from the community to implement those policy decisions.

I 100 percent agree with you that skipping the list is not an acceptable practice, and the OPTN has been working very hard to address those problems. They have a number of efforts that are underway to address that situation. Unfortunately, many of them have been paused, but we are -- I would encourage HRSA and the OPTN to resume that work so that this issue can be addressed in a fulsome manner.

*Ms. Clarke. This is disturbing, extremely disturbing. You know, we are talking life and death, and I am assuming that, as a civil society, we are seeing donors across the board from every community, and we expect that recipients would be similarly reflected. And so I think there is a lot of work to do here within this ecosystem that has been

created.

And Mr. Chairman, my hope is that when you report back to us, all of this has been dealt with effectively, efficiently, so that, again, the integrity of this lifesaving enterprise meets the standards that all Americans expect from the work that you do on our behalf. With that, Mr. Chairman, I yield back.

*Mr. Joyce. The gentlelady yields. The chair recognizes the chairman of the committee, Mr. Guthrie, for his five minutes of questioning.

*The Chair. Thank you. Thank you all for being here. As I said earlier, this is very important to me. And we got to get this right. We absolutely have to get it right.

So, Mr. Massa, obviously, the Kentucky case is important to me as well. It should be important to all of us. You know, the response that KYDA -- I know that you came after that, but the response in the report quote is "The potential donor was treated'' -- on the Kentucky Index case -- "was treated following standard protocols for DCD. The proper guardrails were in place, and worked to the expectations, policies, and procedures for all regulatory agencies. KYDA is satisfied and confident in the donation process.''

Do you think that was an adequate response to the issue of that case? That seemed to be the gist of the response back.

*Mr. Massa. Thank you, Congressman Guthrie, for your question. As I mentioned before, we know that with any successful donation, it occurs with frequent communication. And I think in this case, especially given that it was very unique, both the circumstances and the time, that even further communication needed to be done on this case. And I don't think that occurred on that case.

*The Chair. But when the --

*Mr. Massa. I think the process --

*The Chair. When the OPTN asked for KYDA to give them a response, that is the response of -- when they did an assessment of what happened, that is their actual response. It is not this happened during the case or didn't -- the response was everything essentially was fine.

*Mr. Massa. Well, again, I think on this particular case, the process was followed --

*The Chair. You think everything was --

*Mr. Massa. The process was followed, but there was a lot of unique things that could have been done better.

*The Chair. Okay, so thanks. And so also it said the records provided to HRSA show potentially -- okay. So how does Network of Hope plan to address the issues identified in the report, particularly the report says records provided to HRSA show potentially serious and ongoing risks to patients, families, as well as failures by KYDA and the OPTN to

adequately recognize and respond to poor patient care and quality practices?

*Mr. Massa. I am sorry --

*The Chair. So that was in the report to you. I know that some have said that is the hospital's situation, but as it applies to OPTN or your network, how do you respond -- plan to respond to that, I guess?

*Mr. Massa. As far as the things that we have put in place?

*The Chair. It says, failed to recognize poor patient care and quality practices. So how are you responding to that? Are you changing your procedures for that, or from the HRSA --

*Mr. Massa. We have changed --

*The Chair. I know you just got it a week ago, but what -- I know you have had to have digested it, but what is your first take on it? I know you haven't had a chance to implement --

*Mr. Massa. We took these -- everything that was reported in that report very seriously. And we have -- we are doing our own internal investigation into these cases.

As you have mentioned, we just got this report a few days ago, thanks to this committee. But one thing in the report that's making it difficult is that the donor numbers being used in the report do not match the donor numbers that

we provided. So we're trying to do a crosswalk, and we've asked for a crosswalk of that -- those donor numbers so we could get into the specifics that we have not yet received.

*The Chair. Okay --

*Mr. Massa. But given that --

*The Chair. We will work with Dr. Lynch to make sure you get that.

But given -- I mean, the overall confidence in the system, what is your assessment of what is going on today, the confidence in the system that we can have?

*Mr. Massa. Well, I think the changes that we have put in place with Network for Hope bring about more trust into the system. We have devised a checklist for every nurse that is on a DCD case, and we provide that to them in real time. We did the same thing with every attending physician, a checklist so that they know what their role is on the DCD donor, as well as what the role of the hospital is, as well as the role of the OPO.

We also developed a 10-minute video that they can access through a QR code that literally goes from the very beginning of a DCD donor to the very end, and everything that's expected in between. We've implemented hard stops so that during any part of the process we have huddles with everyone involved in the care and the treatment of that DCD donor so that if any concerns are raised, they could raise those

concerns at that time or at other times in the process.

So I think we've put together quite a bit of changes since that case, and I think going forward we would never have a case like that again.

*The Chair. And so there just seemed to be some tone of -- in the report -- of several cases -- I think about 30 percent of the cases they looked at -- that had some issues.

So not just the Kentucky Index Case, but overall, how are you planning to address -- so like I said, I want everybody to sign up to be an organ donor.

*Mr. Massa. And we want the same thing. And as I mentioned, we are putting in multiple changes in our processes so that these kind of things do not reoccur, and we're still doing our investigation into those cases. But as I mentioned, we take this seriously and we're going to work with HRSA to implement the changes that they want.

*The Chair. Thank you.

My time is expired, and I yield back.

*Mr. Joyce. The gentleman yields. The chair recognizes Ms. DeGette for her five minutes of questioning.

*Ms. DeGette. Thank you very much, Mr. Chairman.

Well, I just want to reiterate all of us feel strongly that we should support organ donation, and that we should support a strong system. But I want to say it is -- sitting here today, it has been chilling to me to hear how you

describe what has been happening in these very generic, pablum terms, saying things like it is time to accelerate improvements in our systems and policies, et cetera, et cetera.

After we have shifted more towards circulatory death for donation standards, we have seen an increase in these terrible stories of patients that have been repeated in the New York Times and other places of what people are going through. And this Times -- well, the incident that forms the basis of this, the person was putting his knees to his chest, he was moaning. People are moaning. And Kentucky is the only one that the Times is investigating here, but HRSA investigated seven -- 350 cases in Kentucky; 73 instances should have stopped sooner, and 103 had concerning features. And that, to me, shows that HRSA was not convinced that those people were actually at a position where their organs should have been harvested.

So I guess I will say anything we can do to improve and to make sure this never happens again not just in Kentucky, but anywhere in this country, you have got our bipartisan agreement to do that, because we keep thinking we fixed this. So I have some questions about this.

Last September, UNOS sent the Kentucky OPO KODA -- and now Network for Hope -- a request for information on what happened. In response, all they got was a single-page letter

in which KODA provided zero requested information, disavowed any responsibility, and said quote, "The proper guidelines were in place and worked," unquote. After the letter was received, OPTN then deemed KODA's response sufficient and closed their investigation. HRSA ordered them to reopen the investigation October 1.

So Dr. Formica, I want to ask you. You were the president of OPTN when it sent the first request to KODA in September. Knowing what you know now, do you believe the initial response was sufficient, yes or no?

*Dr. Formica. No.

*Ms. DeGette. Okay. After KODA's incomplete response, did the OPTN press KODA for the requested information before HRSA got involved?

*Dr. Formica. We did not.

*Ms. DeGette. And how did you determine that the allegations against KODA were unfounded when they gave you so little information to work with?

*Dr. Formica. Congresswoman, I was not involved in that decision directly.

*Ms. DeGette. So you don't know.

*Dr. Formica. I only know what I've heard through -- second hand, and I don't want to -- I don't feel I should discuss second-hand information.

*Ms. DeGette. Is the person you heard it from still

around?

*Dr. Formica. No.

*Ms. DeGette. Okay.

*Dr. Formica. But I share your --

*Ms. DeGette. Well, I am going to --

*Dr. Formica. I agree with you.

*Ms. DeGette. -- be following up with some questions about that.

[The information follows:]

**********COMMITTEE INSERT**********

*Ms. DeGette. Now, once KODA -- as I said, once KODA finally provided the OPTN with the initially-requested information, the OPTN's ensuing four-month investigation identified no major concerns. But when HRSA did their own parallel investigation, it found deeply damning information about this case.

Hospital staff made clear they were uncomfortable with the amount of reflexes T.J. Hoover was expressing, and that quote, "This was euthanasia," unquote. So Dr. Formica, knowing now what you know, do you stand by the OPTN's initial decision to close the case?

*Dr. Formica. I do not.

*Ms. DeGette. Okay. And knowing what we know now, do you stand by the OPTN's full report finding, quote, "no major patient safety concerns," unquote?

*Dr. Formica. Congressman, I do stand by that report because we conducted the report that we were requested to do based on OPTN policy 2.15.

Now, I agree that HRSA's report -- and HRSA looked into this more detailed, which is -- they should do that. But from OPTN policy perspectives, we conducted the investigation --

*Ms. DeGette. So do you believe OPTN should have more robust policy perspectives so that it is not making these conclusions on an -- on a -- obvious, obvious, serious

error?

*Dr. Formica. As the past president of the OPTN, my opinion is this is a topic that needs much more thoughtful discussion about making policy.

*Ms. DeGette. Dr. Magee, you nodded your head when I said that. What --

*Dr. Magee. I believe in a system which -- you have used that word. It's a system. It's -- exists in the healthcare system. There's organ transplantation system, there's OPTN, and we're a sliver of that. So we need a system, we need a robust process --

*Ms. DeGette. Much more robust than we have got now.

*Dr. Magee. Yes. And the system may be robust enough, but the responsibilities aren't delineated enough.

*Ms. DeGette. That is correct.

*Dr. Magee. And I think that we need to work on that collaboration, because this is not okay.

*Ms. DeGette. Okay, yes. We can't keep making this mistake. People are dying.

And I yield back.

*Mr. Joyce. The gentlelady yields. The chair recognizes the vice chairman of the committee, Mr. Balderson, for five minutes of questioning.

*Mr. Balderson. Thank you, Mr. Chairman.

Mr. Massa, let me start off with you. Your testimony

notes that KODA and Network for Hope strongly deny these accusations. What accusation specifically does Network for Hope deny?

*Mr. Massa. I'm not sure I -- which report is that? I'm sorry.

*Mr. Balderson. So the accusations that have been out there, the Network for Hope has specifically said they deny these accusations.

I mean, are you referring to the same accusations? You've denied the accusations. What accusations are you denying?

*Mr. Massa. No, sir. I think that relates to the initial accusations with the Index Case that we talked about before, and that patient was initially said to be brain dead, which that patient was never pronounced brain death. And also it said that there was organs recovered from that Index Case, and that was not the case, as well.

*Mr. Balderson. Okay, thank you. A follow-up, you mentioned to Chairman Guthrie in viewing the report you were having difficulty matching cases with your records. Is it accurate to say Network for Hope has all the underlying documents that were provided to HRSA by your OPO for HRSA's review?

*Mr. Massa. We do. We do. And we have -- we are doing our own extensive review, but it would be helpful if we had

their numbering system so we don't have to go back and guess which one it is, and go through all 350 charts that we provided.

*Mr. Balderson. Okay. Thank you. I'll move on to Dr. McBride.

Thank you. Your written testimony notes that the system is not without flaws. What flaws are you referring to?

*Dr. McBride. Well, I think every conversation we've had this morning indicates where there are opportunities for improvement. And as I suggested in my testimony, I think that one of the most concerning aspects of that Index Case was that it was not brought to this committee until 2024, when in fact it happened in 2021.

And so, if we create a more robust reporting system for patients to be able to take these instances when they feel like they have not been treated well to a central reporting system that can send the information to the appropriate oversight body, it can be acted on more quickly. It shouldn't take three years before a family can take that to something.

You know, when a family is going through this kind of devastating loss, they are not aware necessarily of UNOS and the OPTN and HRSA and CMS. So that's why we need a system that is easy to understand for patients and for healthcare workers alike. You know, there were people in that hospital

who had concerns. They didn't know where to take their concerns. So let's fix that so these issues can be addressed more quickly.

*Mr. Balderson. And you feel like we are in a better place with what we are going through, moving forward?

*Dr. McBride. I think that would create a better place, for sure.

*Mr. Balderson. Did -- you reported it to the OPO?

*Dr. McBride. I am sorry.

*Mr. Balderson. You reported it to the OPO?

*Dr. McBride. We at UNOS learned of the case during the hearing in September, and we reported the case to the MPSC and to HRSA the next day, as we were required to do.

*Mr. Balderson. Okay, I apologize. The past, they stated that they reported to the OPO at the time the occurrences happened.

*Dr. McBride. Yeah, and I'm not familiar with what they might have reported to the OPO.

*Mr. Balderson. Okay. I appreciate that. Thank you.

Mr. Massa, I want to move back to you with my last question. I am coming back to you. Is Network for Hope engaged in any training and education for its staff to ensure that the types of concerning family interactions detailed in HRSA report do not happen again?

*Mr. Massa. Yes, sir. We are doing that as we speak.

Our training has been ongoing, and we have, as I mentioned before, implemented several changes, especially as it relates to DCD donation and providing not only to our staff, but to the hospitals, as well, to make sure that everybody understands their role in this process. Because again, as I mentioned, communication is the key to making a successful DCD donor, and we have to get this right.

*Mr. Balderson. Okay.

*Mr. Joyce. Would the gentleman yield his remaining time to me?

*Mr. Balderson. Mr. Chairman, I yield.

*Mr. Joyce. Mr. Massa, an additional question. You talked about the Index Case being unique. I think you have used that term two or three times. I am perplexed by that because I view each donor case as being unique. And where is our disconnect here?

Donors go through -- and their families -- and I don't think that anyone wants to think it is a cookie cutter donor case. So what is so unique about the donor case in the report that you have used that term two or three times here?

*Mr. Massa. Thank you, Chairman Joyce.

When I'm using the word "unique,'' I just think it's an unusual circumstance. Typically, we do not see --

*Mr. Joyce. I think I wanted to use the word "horrifying,'' but is that what you are equating unique with?

This was a horrifying experience.

*Mr. Massa. I am --

*Mr. Joyce. It is not unique. Each case that comes forward, family members making this decision, it is a unique situation.

*Mr. Massa. Correct.

*Mr. Joyce. The index case is a horrifying case. Do you agree?

*Mr. Massa. It was definitely a case that we do not see every day, that is for sure.

*Mr. Joyce. I am sorry. It is -- I hope you don't see this every day. Do you agree that this is a horrifying case?

*Mr. Massa. Seeing somebody like that myself personally, yes, I think I would be --

*Mr. Joyce. Thank you.

*Mr. Massa. -- disturbed.

*Mr. Joyce. I will yield back. The gentleman yields back, and we recognize Dr. Harshbarger for her five minutes of questioning.

*Mrs. Harshbarger. Thank you, Mr. Chairman, and thank you to the witnesses here today.

Dr. McBride, your written testimony notes that the OPTN makes policy decisions through its board of directors and committees, and that UNOS is not the OPTN. Later in your written testimony, however, you note that UNOS's board had to

serve -- also serve as the OPTN's board, and that was the case until March 30, 2024. Is that correct?

*Dr. McBride. Yes, that's correct.

*Mrs. Harshbarger. Okay. And while HRSA established an independent OPTN board in July of 2024 and awarded the contract to support them to the American Institutes for Research in August of 2024, is it fair to say that UNOS is still helping to support the board, and still supports the OPTN in other ways?

*Dr. McBride. Yes, that is true. HRSA has not yet modified our existing contract to remove the board support --

*Mrs. Harshbarger. Okay.

*Dr. McBride. -- work for us.

*Mrs. Harshbarger. Okay. Thank you, ma'am.

Dr. Formica, how does the OPTN justify closing this case only two business days after receiving Network for Hope's response, despite not receiving the patient-level materials or administrative documents requested?

*Dr. Formica. Congresswoman, as I stated before, I don't think the case should have been closed after two days.

*Mrs. Harshbarger. Yeah.

*Dr. Formica. I'm not going to defend that happening.

*Mrs. Harshbarger. Very good. Thank you, sir. I'll continue on with you. In the Corrective Action Plan dated May 28, 2025 HRSA directed OPTN to develop and implement a

12-month OPTN MPSC monitoring plan for KYDA within 30 days. If so, what are the details of this plan? And have they had any impact so far? And if not, why?

*Dr. Formica. Congresswoman, that happened during the transition from myself to Dr. Magee, so I started the process by setting up the committees to begin working on that. But I wouldn't comment on what has happened since I am no longer the president.

*Mrs. Harshbarger. Okay. Dr. Magee --

*Dr. Magee. Thank --

*Mrs. Harshbarger. -- what actions has Network -- well, go ahead and answer that question, and then I will go to my next one.

*Dr. Magee. Thank you. That work is ongoing. We're picking up where they left off.

Some of this -- you know, this happened three years ago. Discussion -- or events that happened in the past, getting people focused on it can change things a lot independent of a change in a regulation. So we want to make sure the regulations, policies, anything match the right thing. But a lot of stuff I think has happened.

I think people feel more comfortable speaking out. I'm not sure changing the website to -- changing the website of the reporting for the bedside nurse, whether it's HRSA.gov or OPTN, I'm not quite sure that has achieved its effect it. So

we need to think about how to make sure they can do that well. Sorry.

*Mrs. Harshbarger. Let me ask you the next question. What actions has Network for Hope taken to address the issues identified in HRSA report, whether that be actions directly related to the Corrective Action Plan, or actions that are separate and apart from the Corrective Action Plan. Dr. Magee, did you hear that?

*Dr. Magee. I was -- I thought you were talking --

*Mrs. Harshbarger. You thought I was talking to Dr. Formica, didn't --

*Dr. Magee. No, I thought you were talking to Mr. Massa. The Corrective Action Plan for the Kentucky OPO, that is due -- that's been implemented. There's another report that's due on the 28th of this month.

*Mrs. Harshbarger. Okay. And this is all the witnesses, okay?

HRSA's report notes that in a 2023 case OPO staff proceeded with obtaining authorization from two family members, despite witnessing the next of kin take psychoactive medication immediately prior to the consent discussion. OPO staff documented impairment on the part of both family members during the consent discussion, as well as concerns from multiple hospital staff that the family were clearly inebriated and -- or high off of something.

Are there adequate policies now and procedures in place to prevent these type of interactions from happening?

*Mr. Massa. Congresswoman, I can take that.

*Mrs. Harshbarger. Yes.

*Mr. Massa. And thank you for your question. Absolutely. And that is -- we take that very, very seriously. We have made changes in our training, as well as in our policies to make sure that never happens again. And if it does, there will be some changes and disciplinary procedures taken.

*Mrs. Harshbarger. Yes. Anybody else have any comments?

Yes, sir.

*Dr. Magee. The principles of informed consent are very straightforward and fear -- and clear. One principle would be you cannot get consent from somebody that's under the influence. It is -- in that case, though, that shows a nuance that if I gave what's called first person authorization or, like, my last will and testament, that state -- that stands, despite what somebody else would do. So in that case I would ask, what was that?

But you cannot get consent. You can't grant first person authorization or get consent if you're under the influence.

*Mrs. Harshbarger. Makes sense to me.

I guess this is to Dr. Formica. I have 30 seconds left. As doctors with experience in transplant medicine -- this could go to Dr. Magee, too -- what is your reaction to the idea of a patient being on sedatives, and in some cases multiple sedatives, while they are being assessed?

*Dr. Formica. I'm going to speak from the perspective of a doctor that doesn't care for those patients. So there may be nuances, but to me that sounds kind of frightening, I'll be honest with you.

I think, though, to get -- you also made an important comment, though, about consent. And you're 100 percent correct. And that shows you some of the challenges of policy. OPTN policy says you must obtain consent. I will be honest with you. I would presume that people would then behave like they were trained, and obtain proper consent. And I would never think, at least on a first pass, that I would have to write a policy explicitly saying, oh, and by the way, they shouldn't be on -- I mean, that's hard for me to process, based on my training.

*Mrs. Harshbarger. Well, it is --

*Dr. Formica. So I think I share your --

*Mrs. Harshbarger. It is like --

*Dr. Formica. I share your concern over that.

*Mrs. Harshbarger. In a handbook, if you don't put you cannot steal, then they are going to challenge you. It is

crazy.

Yes, sir.

*Dr. Magee. That's a great question. And again, it's nuanced because patients that are suffering who the family and doctors are going to withdraw support of, goal one, hurt nobody. Don't prolong suffering.

*Mrs. Harshbarger. Yes.

*Dr. Magee. So we -- it's reasonable and appropriate to give pain medicines to people that are in pain. There's a concept of double effect, which is you can do things that are for the good, even if they have some unintended consequences. And even sitting here today, it's easy to think paralytics, there are things that stop you from paralyzing. That would be bad. But people that are -- have had really bad lung injuries and have had a massive brain injury might be paralyzed so their breathing works -- the breathing machine works better for them.

*Mrs. Harshbarger. Yes.

*Dr. Magee. So that would be -- again, we just need to develop the rules.

*Mrs. Harshbarger. Yes.

*Dr. Magee. And it depends on the diagnosis. Thank you so much.

*Mrs. Harshbarger. Well, I thank you. And Mr. Chairman, I yield back.

*Mr. Joyce. The gentlelady yields. The chair recognizes the gentleman from New York, Mr. Tonko, for five minutes of questioning.

*Mr. Tonko. Thank you, Mr. Chair.

Dr. Formica, in your testimony you state that the nature of the OPTN review of KODA had no precedent. How did the OPTN or MPSC approach patient safety reviews in the past, and what was different about this review?

*Dr. Formica. So that's a very important question. So in the context of the MPSC, there will be either an outcome results that are bad -- so a program will be performing poorly, there could -- we've had many cases. I've been involved in two where there's been direct complaints about culture. We've actually closed a program around that concept, but it's more focused on a specific event and a specific, you know, program or something that's a little more tangible.

This review was taken out of the MPSC, so we had to stand up a committee that didn't exist already. So we had to solicit volunteers to do that, try to populate them with the expertise. And then, frankly, the volume was huge. It was 360 cases, it was 95 sets of protocols, documents, et cetera. It was over 35,000 pages of material.

And although the process began in September, I was only able to release that information to my volunteers on February

the 6th to meet a February 28 deadline for a written report.

*Mr. Tonko. Thank you. An enhanced approach to oversight of the OPTN is a positive development, and HRSA's review reached several troubling conclusions that I believe need to be addressed. HRSA's investigation observed a variation in level of care, depending on the hospital in which they were being treated within KODA's service area, implying that KODA's management changes depending on the surroundings.

It should go without saying that OPOs need to act responsibly with the patient's best interests in mind, no matter where that patient is being treated. So Mr. Massa, can you tell me whether your OPO employees are supposed to apply different practices to potential donation after circulatory death processes depending on the hospital?

*Mr. Massa. No, sir. We have developed a checklist for every nurse that's involved on a DCD process, as well as the attending physician that clearly states what the role of the OPO is at that time, as well as that of the hospital so they can know what to expect, what their role is during that DCD donor. Because as you mentioned, with an urban hospital maybe they have more experience with DCD donation, but in a rural hospital they may not.

So in real time on that case, as we approach that case or have -- we come on site for that case, we are providing

them with these documents that they could then see in real time so that they know what to expect and what duties that they have.

And we also developed a 10-minute video that they can access through their QR code that, again, walks them through the process from beginning to end, and in that 10 minutes goes over that DCD process. So we have developed that just for this case.

*Mr. Tonko. Well, let me read from HRSA's report which presents data from your records that shows that KODA's Authorized Not Recovered cases, where donation processes were started but organs were not procured are more prevalent at small and rural hospitals. HRSA indicates, and I quote, "These trends suggest that patients may experience variable care from KODA, depending on the hospital in which they are seen," end quote.

So Dr. Formica, did the OPTN board run a similar analysis about cases like this comparing different hospital settings?

*Dr. Formica. No, we did not.

*Mr. Tonko. So Mr. Massa, your website states your OPO serves 7 million people and includes 188 hospitals. Is that correct?

*Mr. Massa. Yes, sir.

*Mr. Tonko. The HRSA reports includes some complaints

from hospital staff about their interactions with your OPO. So Mr. Massa, how does Network for Hope address any complaints it receives from hospital staff?

*Mr. Massa. So we take any complaint from a hospital very seriously. I myself get involved, as well. We also have the ability for anybody in the hospital to provide a complaint or a concern through a QR code that would remain anonymous because we want to make sure that we are getting that information because together, and working together, we can have process improvement. So we encourage people to do that, and we welcome that.

*Mr. Tonko. I had one other question -- I am running out of time -- for Dr. Magee, which we will get to the committee.

[The information follows:]

**********COMMITTEE INSERT**********

*Mr. Tonko. But I hope the new OPTN board will give special attention to these situations. Rural communities have some of the nation's most vulnerable patients, who often already face obstacles to health care. If OPOs are acting in a way that can put those patients at greater risk of mistreatment, that is simply unacceptable and certainly deserves far more scrutiny.

And with that, Mr. Chair, I yield back.

*Mr. Joyce. The gentleman yields. The chair recognizes the gentleman from Alabama, Mr. Palmer, for his five minutes of questioning.

*Mr. Palmer. Thank you, Mr. Chairman. Thank the witnesses for being here.

Mr. Massa, why were all the materials requested by the Network of Hope for the OPTN Membership and Professional Standards Committee in the letter of September 12, 2024 not originally provided?

*Mr. Massa. Thank you for that question, sir. Initially, that request --

*Mr. Palmer. Why were they not provided? We are not going to filibuster the time. Why were they not provided?

*Mr. Massa. That request was in regards to Mr. Hoover being a brain dead donor, as well as organs being recovered. So we've provided the information that that was -- those were inaccurate.

In addition, they asked for a summary, which we provided.

*Mr. Palmer. Mr. Formica, in your written testimony you said the few recommendations that OPTN made are, in essence, the same as the concerns expressed by HRSA in their report. In your honest assessment, do you really believe that OPTN and HRSA's findings were the same?

*Dr. Formica. I do, in that the concept of developing better protocols to identify who is a suitable donor --

*Mr. Palmer. Well, how do you justify closing the case only two business days after receiving Network for Hope's response, despite not receiving patient-level materials or administrative documents requested?

*Dr. Formica. Well, I'm -- Congressman, I'm not justifying that. That was through the MPSC. That should not have happened. I was referring to the larger investigation that we did afterwards.

*Mr. Palmer. But in your written testimony you also note that the UNOS staff, as the HRSA contractor supporting the OPTN, assisted OPTN's MPSC volunteers in their review. How did UNOS assist the MPSC in its review?

*Dr. Formica. I'm not familiar with that in my written testimony.

*Mr. Palmer. The reason I am asking these questions is in Mr. Lynch's testimony he points out that the Association

of Organ Procurement Organizations publicized an open letter characterizing the ongoing effort to improve patient safety through enhanced oversight as a misinformation conspiracy campaign, and concluded it is time to stop. Among the signatories to this letter were more than 20 UNOS staff signing with their corporate affiliation.

Dr. McBride, did you sign that letter?

*Dr. McBride. Yes, I did.

*Mr. Palmer. Why?

*Dr. McBride. Congressman, let me start off by saying that I disagree with the way that letter has been characterized.

*Mr. Palmer. Well, it has been characterized by HRSA this way, and it creates some serious concerns on our behalf.

*Dr. McBride. I'm happy to share --

*Mr. Palmer. Dr. Formica, did you sign that letter?

*Dr. Formica. I did not.

*Mr. Palmer. You did not? And you are president of the UNOS board?

*Dr. Formica. No, I was president --

*Mr. Palmer. No, you were --

*Dr. Formica. -- of the OPTN.

*Mr. Palmer. -- president of OPTN. And you didn't sign it.

How about you, Dr. Magee?

*Dr. Magee. I did not see it -- sign it or see it.

*Mr. Palmer. Okay. Dr. McBride, continuing in your response, why did you and 20 other UNOS staff sign that letter? It appears to me to be obstruction of an inquiry.

*Dr. McBride. Congressman, I respectfully disagree with that assessment. I'm happy to provide the letter to this committee.

What I believe it asked for was an open dialog between Members of Congress, experts within the OPTN, and HRSA to get to the bottom --

*Mr. Palmer. But the letter --

*Dr. McBride. -- of the situation.

*Mr. Palmer. -- calls it a misinformation conspiracy campaign.

*Dr. McBride. The letter referred to allegations that were hearsay.

*Mr. Palmer. And you called it --

*Dr. McBride. It did not --

*Mr. Palmer. You called for it to stop.

*Dr. McBride. I called for hearsay to stop, and I called for -- the letter called for an open dialog between Congress --

*Mr. Palmer. So you are saying that the allegations that have been made in regard to an attempt to procure organs from living donors is hearsay?

*Dr. McBride. The letter referred to the testimony at the hearing last September.

*Mr. Palmer. I am asking you -- are you saying that the attempt to procure organs from a living donor is hearsay, that that didn't happen?

*Dr. McBride. No, I'm not saying that it didn't happen. I'm saying that the letter called for a stop to unfounded allegations. And UNOS has always supported full, open, and fully transparent investigations, and that has always been our position.

*Mr. Palmer. You have created a situation here that I am very concerned about, and we discussed this at length before this hearing, about how this is going to impact the general public's decisions on whether or not to donate their organs. And I am not satisfied with what I have heard in the hearing thus far today. This -- I think this is extremely serious. I think there is -- there needs to be some serious reform.

I thank the chairman for holding the hearing, but I just want to be very sensitive about the signals that this sends, and the fact -- and I disagree with you, I think you intended to influence the outcome of HRSA's research.

I yield back.

*Mr. Joyce. The gentleman yields. The chair recognizes the gentlelady from Massachusetts, Mrs. Trahan, for five

minutes of questions.

*Mrs. Trahan. Thank you, Mr. Chairman.

There is no question that UNOS technology powers the OPTN. DropNet, for -- DonorNet, excuse me, for example, allows OPOs to manage deceased donor data, launch match runs, and make organ offers to transplant hospitals.

Dr. McBride, is it fair to say that the OPTN would not be possible without the technology systems that UNOS builds and maintains?

*Dr. McBride. Yes, that's correct.

*Mrs. Trahan. Thank you. So given the centrality of technology in the OPTN, it is vital that its systems are secure, reliable, and easy to use. Indeed, in recent years many Federal technologists with backgrounds in the private sector were dispatched to HRSA. Their mission was to inspect the code of the OPTN to look for bugs, inefficiencies, and opportunities, and implement fixes. I imagine they expected to spend their time solving the gnarly problems plaguing the OPTN's technology systems.

As it turned out, these mission-driven software engineers and data scientists struggled to even gain access to code and data, stymied by a resistant UNOS. This is unacceptable. If taxpayers fund a piece of technology, the Federal Government should own it, full stop. Dr. McBride, do you believe the Federal Government is the rightful owner of

the source code underlying the OPTN, and therefore should be able to freely inspect, develop, and share that code?

*Dr. McBride. Thank you, Congresswoman.

Under our current contract with the OPTN, the contract clearly states that the contract -- that the computer system is owned by UNOS. This is a contract between HRSA and --

*Mrs. Trahan. So you don't believe that the government should have the right to freely inspect that data that taxpayers fund?

*Dr. McBride. I 100 percent agree that they should, and they have. They came to our office this most recent December, and were able to freely and openly look at our computer system.

*Mrs. Trahan. Well, according to an internal memo, government experts had never been able to inspect UNOS's systems in the 30-plus years of the transplantation network's lifetime. Dr. McBride, your predecessor criticized that memo, contending that government officials could review the OPTN source code, provided that they physically visit the UNOS office under strict supervision.

Now, I will be frank, that doesn't look like an open collaboration to me. It looks like chaperoning. To your knowledge, has UNOS ever obstructed or otherwise delayed government access to its technology, including by requiring HRSA engineers to physically visit UNOS facilities to view

system code?

*Dr. McBride. I can't speak to what happened during my predecessor's term as CEO. I can tell you that HRSA has been welcomed into our office to look at our computer system. We have --

*Mrs. Trahan. So under your --

*Dr. McBride. -- conversations with them twice a week about what was happening in the OPTN system. It is a very open, collaborative process.

*Mrs. Trahan. Well, maybe under your tenure there have been changes made. It is not what we have -- what we understand to be true. I was outraged at public reporting from 2022 that indicated HRSA's technology officials were told it would cost the government nearly $55 million to purchase UNOS's technology systems. So begs the question, has UNOS ever set a price tag on government access to the technology or data -- or data technology that I must point out once again taxpayers paid for? And if so, what is that number?

*Dr. McBride. So the data in the OPTN computer system are completely available to HRSA and to anyone else who is --

*Mrs. Trahan. Without obstruction, without delays?

*Dr. McBride. That's correct.

*Mrs. Trahan. You know, Mr. Chairman, the public record, as well as Dr. Lynch's answers to me, appear to

contradict the answer.

I ask unanimous consent to enter into the record a Washington Post article detailing how UNOS told the government it would have to pay $55 million to acquire its technology, should the OPTN contract ever be opened.

*Mr. Joyce. So ordered.

[The information follows:]

**********COMMITTEE INSERT**********

*Mrs. Trahan. Thank you.

Here is the bottom line: I am concerned UNOS is holding the organ transplantation system and its technology, in particular, hostage. UNOS has consistently shown resistance to Federal efforts to modernize the technology and operationalize its data.

We all have a role to play in changing the organ transplantation network for the better. No one, Congress included, should escape accountability and scrutiny.

I thank the chairman, and I will yield back.

*Mr. Joyce. The gentlelady yields. The chair recognizes Mr. Allen for five minutes of questioning.

*Mr. Allen. Thank you, Mr. Chairman.

Dr. Formica, HRSA's report notes that, in most cases, once authorization had been obtained and the coordinator's attention turned to operative logistics, there was scant subsequent recording of patient's clinic condition. What are OPTN's policies as it relates to data and record-keeping?

*Dr. Formica. The OPTN stipulates that OPOs have to collect and retain data points. I would be not accurate if I tried to tell you what all those data points are.

I think the challenge from where I sit as a clinician is having OPO staffers in a hospital of varying degrees of medical training -- because they're not physicians, some are nurses and most are not -- doing physical exams, neurological

exams, making assessments of patients. That makes me feel uneasy.

*Mr. Allen. Do you believe there should be more thorough records when assessing a patient's neurologic condition prior to recovery efforts?

*Dr. Formica. Answering from the perspective of a physician in the hospital, absolutely. That needs to be documented by the physicians that are caring for the patient because they're making life-and-death decisions.

To the degree to which an OPO would be documenting that finding, taking it from the medical record, I think they should be doing that, as well. I don't feel comfortable having an OPO making an assessment of that, though. I think that must stay in the hands of the patient's physicians.

*Mr. Allen. Okay, thank you.

Mr. Massa, do you believe that Network for Hope has a culture that encourages the reporting of complaints or concerns, historically and currently?

*Mr. Massa. Yes, sir. Matter of fact, our policy states that not only do we encourage that, but you are obligated to do so. And if a complaint is -- they do not feel comfortable raising a complaint to a corporate compliance officer or their supervisor or a member of the executive team, they could do so anonymously through a QR code, and they remain -- it's completely confidential of who

that person is.

And so again, we encourage people to do this.

*Mr. Allen. The OPOs are required to provide organ donation data to transplant hospitals they have agreements with. What is included in this data, Ms. Massa?

*Mr. Massa. With the transplant? Everything related to the donor, including any lab test, their blood type, serologies, testing, all the background related to the person's uniform risk assessment, as far as their background. So there's quite an extensive list of information provided to the transplant center before they accept a organ.

*Mr. Allen. What about complaints, for instance, related to a potential donor? Would they be included in this data?

*Mr. Massa. Oh, we actually provide a way for hospitals to make a complaint. And again, we offer that ability to do it confidentially, as well.

*Mr. Allen. Okay, all right, great. Well, thank you.

And Mr. Chairman, I yield back.

*Mr. Joyce. The gentleman yields. The chair recognizes the gentlewoman from Washington, Dr. Schrier, for five minutes of questioning.

*Ms. Schrier. Thank you, Mr. Chairman, and thank you to our panel here today.

During the first panel with Dr. Lynch we talked about --

well, first I just open by -- I want to say thank you to everybody involved in the organ transplantation space, because it is such a blessing and such a lifesaver for so many people out there. And what I want is for this process to be safe, and for the public to have full confidence that when they get that pink heart on their driver's license that I have, that my son has, and that when they make that decision, that altruistic decision to save somebody else's life, that it is going to be done responsibly and safely. And that is the whole point of this hearing.

And so one of the things that I ask about, especially as a doc, just thinking about how we function, how we prevent errors, knowing that that is a human risk, I asked Dr. Lynch, is there a checklist? We have a checklist. And when we admit somebody to the hospital -- so we don't forget something like to provide fluids. We have a hospital for -- a list for labor and delivery to make sure that we don't overlook anything with labor and delivery. We have the procedural pause before any operation to make sure everybody in the room is clear on what the -- what the standards are. We have sepsis pathways.

And so I thought, well, is there a pathway for declaring circulatory death? Because that seems to be where these issues have come up. And his answer was that the OPOs, the Organ Procurement Organizations, are really the experts in

this. And so I just want to pose this question to all four of you: Do you have the list? What can you do to really guarantee no errors?

*Mr. Massa. If you don't mind, I'll go first. Thank you. Thank you, Congresswoman, for your question, I appreciate it.

For us, as I mentioned, as the OPO, we have developed these checklists specifically designed for nurses on a case, as well as the attending physician, to do exactly like you said in terms of going down the list, making sure nothing is forgotten, and making sure that they understand their role as well as the role of the OPO during those cases.

We -- OPOs, like I said in my initial testimony, do not declare death. So that is reliant upon a independent surgeon not involved in donation or transplantation to come in and pronounce death. And as Dr. Formica said in his testimony, we are not even in the room at that time.

So while OPOs are the ones determining if a patient is suitable for donation, as far as determining death, that is actually done by the physician. And currently there really isn't any good tool to determine if a patient is going to die in that 90-minute timeframe.

*Ms. Schrier. I mean, it feels like that is the gap, that your checklist is -- is this suitable? Does this person have hepatitis B that could be transmitted through

transplantation? Is there CMV? It could be have we talked with the family? Have we gotten sign-off? But the list that is really at the crux of this matter that we are discussing today is how do you not mess up when you are saying, okay, it is all right to go to the operating room? Do you have a list that says must not have had an opioid in X number of hours, must not have had a -- you know, any kind of -- any kind of sedative or paralytic for a certain amount of time? Where is -- where is that list?

*Dr. Formica. Barry, can I take that?

So, Congresswoman, I think your question is -- that is the question that needs to be resolved. And I was told when I was preparing for this that I should bring ideas. So from 20 years of working on the OPTN, I'll tell you how I would like that fixed.

It crosses over two domains of responsibility. The OPTN has responsibility, and the donor hospital has responsibility, and they're governed by different organizations. If there could be an ability to say that once a patient is identified as a potential donor, protocols from the hospital side -- i.e. under CMS -- could be harmonized with protocols from the OPTN side, meaning HRSA and OPTN, and those individual patients then would fall under a standard set of protocols that would be agreed upon by people who are more knowledgeable than me on that topic. But then the OPTN

could get the donor hospital to do the things that needed to be happening, and vice versa. And then there could be accountability.

And I think that would be -- if you were to say one thing that could move us towards making people feel more confident in the system is we'd have one set of oversight, we'd have one set of protocols, we could work on those protocols, and then we could act on those protocols and refine them as they go forward, instead of refining one and then having to wait for the other one, and back and forth.

*Ms. Schrier. I think that would restore a lot of public confidence. And I think it's just the smart -- and really, should be a standard thing to do to have everybody on board. Thank you, I appreciate your candor.

And I yield back.

*Mr. Joyce. The gentlelady yields. The chair recognizes the gentleman from Florida, Dr. Dunn, for five minutes of questions.

*Mr. Dunn. Thank you very much, Mr. Chair.

As a doctor, it pains me to read about the patient in Kentucky. While being prepped for donation, obviously, he woke up and thrashing around, felt terrified. Fortunately, one of the doctors performing a pre-donation procedure expressed his discomfort. But the OPO who was present actually disagreed with him, shot him down, said -- the OPO

staffer notes indicate he was accusing him of euthanasia.

Embarrassingly, on the honor walk for this patient, the patient was regaining consciousness. And when he brought -- was brought to the operating room, he was actually curled up in a ball, his knees on his chest. Thank goodness for the doctor in the operating room. This is a story that seems to be more fitting for a horror movie than a congressional hearing, frankly.

Mr. Massa, you are the CEO of Network for Hope. Less than a year ago you merged with KODA. In what capacity does the former CEO of KODA serve in your organization now?

*Mr. Massa. The former CEO of Kentucky Organ Donor Affiliates currently serves as our COO. We made several changes in the executive --

*Mr. Dunn. Okay, COO. So -- and you have other KODA organ operations staff, perhaps surgeons, who are still with you?

*Mr. Massa. They are, but not in their same role. Everybody in -- within the executive team took a much more --

*Mr. Dunn. I am just going to say --

*Mr. Massa. -- focused responsibility.

*Mr. Dunn. -- I find it concerning that anyone involved in this misconduct is continuing to work with you in the field, frankly.

As a medical doctor, I find the recent increase in

donations after circulatory death as opposed to brain death particularly concerning. We always used brain death as a criteria when I was in the business, and brain death confirmed by multiple physicians. I am concerned that the current safeguards in the DCD process are simply not enough to secure patient safety.

Dr. McBride, I am under the impression that UNOS plays a role in encouraging patient -- organ procurement, rather, through the DCD type recovery -- that is the circulatory death.

And I want -- Mr. Chairman, I am going to offer into record two articles. The first says Twenty-six OPOs join new UNOS-led collaborative to increase DCD donor recoveries. And that one is dated April of 2021. And the second one is UNOS using collaborative improvement model to increase DCD lung transplantation.

I ask unanimous consent to have these placed into the record.

*Mr. Joyce. So ordered.

[The information follows:]

**********COMMITTEE INSERT**********

*Mr. Dunn. Thank you.

I obtained these, by the way, through the Wayback Machine, because they are no longer on your website. They have been taken down. It is suggested that there was a reason you took them down. Was there, Dr. McBride?

*Dr. McBride. Thank you for the question, Congressman. Those reports refer to a collaborative work project that was done in -- under the direction of HRSA and in partnership with the OPTN.

*Mr. Dunn. Okay, so --

*Dr. McBride. To support the transplant --

*Mr. Dunn. I am going to just reclaim my time because we are running out.

You know, last year's hearing on this subcommittee, after that the association of your organ procurement -- penned a letter openly criticizing this congressional committee for advancing false, misleading, and unsupported allegations. After reviewing and hearing all the data here today, do you still agree with that?

*Dr. McBride. Congressman, I disagree with the way that letter has been characterized.

*Mr. Dunn. All right.

*Dr. McBride. I believe the letter actually called for an open conversation with Congress, with experts in the organ donation --

*Mr. Dunn. Let me just say I think it is disturbing to me that anyone would consider that congressional oversight, which is one of our jobs, is somehow damaging to public trust. Congressional oversight doesn't harm public trust. What happens to -- the public trust gets harmed when our trusted partners in organ procurement disregard process and put patients in danger.

Several of you lectured us today on the importance of transplant surgery and transplant donors. I promise you, we understand the importance of transplantation doctors and lay people in Congress alike. But it is not right, it is not moral, it is not ethical to kill a patient who can potentially live and take their organs.

And if America fears that your OPOs are doing that, you are going to lose your pool of donors, simply. Americans should be confident that you are performing your own oversight and we are, too. I commit that we will continue to provide oversight, and we will do everything in our power to make sure the bad actors in this field do not continue to behave this way. Thank you.

I yield back.

*Mr. Joyce. The gentleman yields. The gentlelady from Virginia, Ms. McClellan, is recognized for five minutes of questions.

*Ms. McClellan. Thank you, Chairman Joyce and to

Ranking Member Clarke, for convening this very important hearing.

Our nation's organ procurement and transplantation system requires strong coordination between Federal agencies, the Organ Procurement and Transplant Network, organ procurement organizations, and hospitals.

Now, the current OPTN contractor, UNOS, is based in my district. And over the years when I was a state legislator I had a chance to visit their office several times and hear updates about the modernization process. These conversations have taught me that the -- there is a very complex but critically important organ transplantation system in place that depends on having the public's trust, and we agree that there is always room for improvement to better protect patients while saving lives.

Now, while we are in this oversight hearing I do want to highlight my bipartisan bill with Congressman Rob Wittman, H.R. 330, the Organ Donation Referral Improvement Act, that requires the Department of Human Services to study how automatic electronic donor referral systems can help eliminate barriers to successful organ transplantation. And this would be one step towards minimizing error and enhancing patient safety, and I appreciate today's discussion about other reforms and challenges that are needed.

So I want to ask Dr. McBride. In your testimony you

emphasize UNOS's role as a contractor supporting the OPTN with four decades of experience. From your perspective, what are the most important reforms that we need to make to improve the organ procurement and transplantation system to better protect patients while saving as many lives as possible?

*Dr. McBride. Thank you, Congresswoman, and thank you for the support of the automated donor referral bill. We really appreciate it.

There are many reforms that we have discussed, and we have discussed some of them today. I think based on the topic of this hearing, the most important one is to create a reporting system where patients, members of the healthcare community can provide information about potential wrongdoing for their loved one or their family member.

The fact that it took three years for the Index case, as it's been referred to, to come to light is unacceptable, and I hope that this Congress will push HRSA and CMS to create a system that can be available to all patients and families to make it easy for them to make these kinds of conversations public so that it can be forwarded to the right oversight body to be addressed.

*Ms. McClellan. Thank you, and I like Dr. Formica's words of wisdom to come with solutions, so I am trying to give you all an opportunity to do that.

But for Dr. McBride, how can the OPTN improve oversight of OPOs to prevent the tragic situations that were discussed today?

*Dr. McBride. I think piggybacking off of Dr. Formica's comments, you know, there is a split in the oversight of the organ donation and transplant system. So CMS has oversight over hospitals, and the OPTN has oversight under HRSA of the transplant hospitals, the OPOs, and the histocompatibility labs. That split in oversight does leave room for communication gaps and opportunities for further improvement.

So I do think consolidation of the entire transplant ecosystem under a single government regulatory body could provide benefits to the transplant community.

*Ms. McClellan. And are there any other resources or authorities that we would need to provide to accomplish that?

*Dr. McBride. I believe Congress has the authority to do that.

*Ms. McClellan. Okay. And Dr. Formica, I don't know if there is anything you would like to add on to that.

*Dr. Formica. Yeah, I'll just echo that. As a program director, I prepare for an OPTN audit every three years and a CMS audit every five years, and they don't cover the same topics. So --

*Ms. McClellan. Okay. And in the 55 seconds I have left, Dr. Massa or Dr. Magee, if there is anything else you

would like to add on what you think Congress could do either in your answer now or that you would like to provide on the record, I do want to give you all an opportunity. And it is probably going to have to be in writing on the record later.

I want to give each of you the opportunity from your perspective to say what changes need to be made, and that recognizes the complexity of this process and how we have three different, you know, systems working together, whether it is the hospital, whether it is the procurement organization or UNOS, and they all have different governing structures and different things and places, and things fall through the cracks. So if you could provide us, from your perspective, everything you think Congress needs to do to prevent these tragedies from happening, I would appreciate it. Thank you.

I yield back.

*Mr. Joyce. The gentlelady yields. I would like to note that, as discussed in panel one, that HRSA already has a system for individuals to report.

With that the chair recognizes the gentlelady from Iowa, Dr. Miller-Meeks, for five minutes of questioning.

*Mrs. Miller-Meeks. Thank you, Mr. Chairman. And again, I want to thank our witnesses. If you were here in the first panel, you heard about my unique perspective in this matter, but I am going to repeat it.

So I started my career as a nurse. So after having done med surge nursing and emergency room nursing as a newly minted lieutenant stationed at Walter Reed, I was placed on a neurosurgery floor. And we had a variety of patients, patients who were comatose from traumatic brain injury, patients who had ruptured aneurisms, strokes, or hemorrhagic strokes. And it was left to the nurse to have these very difficult conversations with family members whether or not to remove their family member from life support and how to navigate and support that family, and then the secondary conversation of whether they would be an organ donor. That held me very well as I went on to medicine and medical school and did emergency room trauma surgery.

I did a general surgery internship, even though I was going into ophthalmology. I was on the transplant service. So again, as the intern, having these conversations with family members in a system that did not exist then as it does today, and -- very challenging to talk to family members about removing an individual from life support, that they are given all the medical knowledge that we had and a belief in God that they were not going to recover, and then to secondarily have conversations about donating organs.

We certainly have progressed since then. You have advance directives. You have conversations with family -- not enough. On our license, driver's license, you can elect

to donate. And then, as an ophthalmologist, performing transplants for vision. And I can tell you how grateful individuals are, how parents are for their child who has an inherited disease and can't see to then see. Adults who have traumatic injuries from chemicals, alkali burns before we had stem cells, which we can now also transplant. And then those with keratoconus or other inheritable eye diseases. And to be part of that network of given vision and, in fact, giving life, and that requires trust. And it requires trust of those who donate, the family members who have to make that decision in the absence of consciousness for their loved one, and then in those that receive organs, knowing that they came from a place of appreciation, gratitude, and love.

So there is a trust within this system that I think is extraordinarily important for all of us. Not a new concept, but this merging and arrangement of the -- in September 2023, Securing the U.S. Organ Procurement and Transplantation Network Act, when it was signed into to law, is to help with this disparity of education, communication, involving people so that there are more organs available to save life and to save vision.

And so I would just say, having been in medicine and in this, the first thing you want to do is admit you have a problem. You want to acknowledge that problem and you want to offer solutions. So Dr. McBride and Dr. Formica, I

appreciate you offering solutions. I think what is imperative is that UNOS, OPTN, HRSA, and CMS all come together and develop those standards. We know that if somebody is and an addict and overdoses, that brain function can be altered by the medications that they may have been on, or sedatives. And this delicate dance that we do -- and I call it a dance, and it is the wrong word, but this conversation we have with families so that we can help to continue that trust.

I strongly support what you are doing, but I would like the commitment from all of you that you will work to have these conversations where there does not even need to be congressional action, that you will work with HRSA, CMS to bring this system together to have the appropriate standards and guidelines in place so that families, patients, and those who are transplanting and nurses working in that area have the assurance that that will occur.

Dr. Massa?

*Mr. Massa. Absolutely, and thank you for everything that you did in support of donation and making sure those people received their second chance.

*Mrs. Miller-Meeks. Dr. McBride?

*Dr. McBride. Absolutely. Thank you, Congresswoman, for everything.

*Mrs. Miller-Meeks. Dr. Formica?

*Dr. Formica. I agree with you completely, so --

*Mrs. Miller-Meeks. Thank you.

*Dr. Magee. Absolutely, and if we need more help we are coming to you.

*Mrs. Miller-Meeks. Thank you, and thank you for the suggestions that you gave us and recommendations that we can act upon. Thank you.

I yield back.

*Mr. Joyce. The gentlelady yields. The chair recognizes the gentlewoman from Florida, Mrs. Cammack, for her five minutes of questioning.

*Mrs. Cammack. Thank you, Mr. Chairman. Thank you to our second panel of witnesses for appearing here today.

Now, as everyone knows, this committee has been investigating corruption from organ contractors for more than a year. In fact, I was in the last hearing that we had on this, and it was quite a contentious hearing.

One issue that is pretty close to my heart is ensuring equal access for lifesaving transplants for patients with disabilities. Just last month the House passed a bipartisan bill that I was proud to lead alongside my friend and colleague, Debbie Dingell, to end organ transplant discrimination against individuals with disabilities.

So it is with total horror that I read a recent investigative report highlighting one of the most horrific

cases of patient abuses. The New York Times detailed what happened to Misty Hawkins last year. She was a vibrant woman in Alabama who loved movies and dancing, but she also had a lifelong cognitive disability. After a tragic incident, Misty's mother agreed to organ donation. And I am quoting from the report here about what happened next. "A surgeon made an incision in her chest and sawed through her breastbone. Doctors discovered that her heart was still beating. She appeared to be breathing. They were slicing into Ms. Hawkins while she was still alive.''

Now, this is not the first time that something like this has happened. In 2021 a doctor filed a case report about a woman with Down syndrome who was in an operating room being treated as an organ donor. During the harvesting of her organs, staff realized that her aortic and renal arteries were pumping and pulsing. In other words, she was not dead. The patient was given powerful drugs, fentanyl and lorazepam. And then, according to the doctor filing the case report, 18 minutes after she was first pronounced dead she was pronounced dead a second time.

This is something that you would see in the movies. But unfortunately, we are seeing real-world examples of this today.

So I am going to start with you, Mr. Formica. As a physician, I am sure you are as horrified as I am. Were you

invited to participate in the hearing on organ transplants last year?

*Dr. Formica. I was invited, yes.

*Mrs. Cammack. Why did you not appear?

*Dr. Formica. I was given about four days' notice and couldn't get away from my clinical responsibilities.

*Mrs. Cammack. I understand. Now, we discussed this back then, but I want to bring it to you now. HRSA's report included two particularly damaging conclusions about the Federal organ contractor assigned to Kentucky, including "its failure to recognize neurologic function inconsistent or unfavorable for organ donation, and its failure to work collaboratively with patients' primary medical teams.'‘

If there are reasons to believe that some organ contractors are failing to recognize neurologic function issues inconsistent with organ donation -- in other words, the patients could never recover or they were not suitable for organ donation -- then I am even more concerned about what that means for care given to patients with disabilities. Are you tracking with me?

*Dr. Formica. Yeah, absolutely.

*Mrs. Cammack. Okay, so --

*Dr. Formica. I share your concern about the patients with disabilities.

*Mrs. Cammack. So -- and you are under oath, so I want

you to very clearly detail if you have heard of other reports similar to this, with the very basic failures that have been outlined in what I have said.

*Dr. Formica. The reports I've heard -- I've read that New York Times article. I shared your -- I don't even know the verbs to put in there, so I won't do that. I've heard from HRSA secondhand that there's other cases. I have never been given the primary data for those.

*Mrs. Cammack. Really?

*Dr. Formica. Yeah. No, really. We have not been given access to the primary cases. We were told that they were happening. I haven't seen them. I haven't seen the -- the only thing I know about the Index Case which we're discussing here is the HRSA report. I was -- the OPTN was not given the data for that one. We were told not to review that case.

*Mrs. Cammack. And just so we have this on the record, you recently -- you have since left, but you were the president.

*Dr. Formica. I was the president up until June 30, yes.

*Mrs. Cammack. Okay. Now, you are aware of the bipartisan report from our friends in the Senate that found that the Miami OPO, for example, recovered organs from a donor before the donor's heart stopped and against the

family's wishes.

*Dr. Formica. I've heard that case, yes. I --

*Mrs. Cammack. But you just said that you really hadn't.

*Dr. Formica. I haven't seen primary data on that, Congresswoman. So I've heard these cases. I can tell you that the Miami OPO has been under review with the OPTN, and I -- the last -- my last act as a president with my board was to send a letter to the Secretary asking for assistance in managing that case.

*Mrs. Cammack. But, I mean, the report is public. So, I mean your --

*Dr. Formica. Congressman, I've heard these -- I know what you're saying. I've heard these cases, but I don't have any primary data. I've been a spectator to those --

*Mrs. Cammack. I am sure --

*Dr. Formica. -- cases, as well.

*Mrs. Cammack. -- that brings the families of these individuals great comfort that you haven't seen primary data, despite the fact that many of these reports are public record.

I mean, this is outrageous that this is happening in the United States. This is the stuff that you hear in third-world countries. I mean, it is clear that a 40-year experiment of letting organ contractors police themselves has

left our most vulnerable neighbors to endure unimaginable abuse and torture. So I think it is clear that a lot more work has to be done here.

While I appreciate your time here, I think many of the answers have left us with a lot more questions than answers.

So with that, my time has expired, Mr. Chairman, I yield.

*Mr. Joyce. The gentlelady yields.

In follow-up, Dr. Formica, didn't you serve on the MPSC? Wouldn't you have access to this information and this data?

*Dr. Formica. So MPSC members are assigned to different cases. So if a case comes in from, say, a transplant program, there may be three reviewers assigned to that case, and they would not be assigned to look at other programs.

I mean, there's just so much work to be done that it's divvied up. And if you haven't seen -- if you're not assigned to the primary case, you just hear about it in discussion.

*Mr. Joyce. Define for us -- as a physician, I have been in discussions, but how would those discussions occur when you said you would hear them in discussion? Would they be case presentations that were presented at large? It is -- you are not the primary assignee for the case, but how were those discussions occurring, to Representative Cammack's point?

*Dr. Formica. Yeah, so if you were -- and I don't recall the Florida case that you're discussing there, because I was not -- I was on and off the MPSC for various times, so I don't recall that one.

The -- a case would be presented with maybe three primary reviewers. It would be discussed from the data perspective, and then the MPSC is actually composed of either 42 or 46 members. I'm not entirely sure of the exact number. And then there would be an open discussion about -- we'd ask -- you know, I'd ask a question. What did you find? They would answer that back. But we wouldn't necessarily see the primary data if you weren't the reviewers.

*Mr. Joyce. Thank you for the explanation. The gentlelady yields. The chair recognizes the gentlewoman from Indiana, Mrs. Houchin, for five minutes of questioning.

*Mrs. Houchin. Thank you, Mr. Chairman. Thank you for the witnesses for being here.

Mr. Massa, we have heard a lot during this hearing about some of the deeply concerning and, frankly, unacceptable incidents that have taken place over the last few years, particularly involving Network for Hope. I hope your presence on the panel today is an indication of Network for Hope's acknowledgment of previous shortcomings and your willingness to work together to improve our organ donation systems for both patients and OPOs.

In addition to addressing the pattern of high-risk DCD procurement practices, HRSA's Corrective Action Plan notes that the OPTN within 180 days is to propose a requirement for the OPTN to be informed of any requested or triggered pause in procurement efforts if there is a concern for unrecognized neurological improvement or potential for a patient to experience pain in the act of procuring organs. It notes that these pauses will be reviewed during monthly meetings.

Mr. Massa, has Network for Hope implemented its own protocols to pause procurement in these cases currently?

*Mr. Massa. First of all, thank you for your questions and your comments.

We have. We do have established huddles and hard stops during the donation process, especially with DCD donors, to make sure that everyone -- we get everybody on the health care team together, everybody involved in that DCD donor. If there is any concerns, they could address them at that time. There are multiple huddles during that process.

*Mrs. Houchin. Were those protocols in place before the HRSA report came out and their recommendations? Were those protocols in place?

*Mr. Massa. They were.

*Mrs. Houchin. And why were they not followed?

*Mr. Massa. The huddles were followed. Yes, they were.

*Mrs. Houchin. It is clear that in many cases they were

not followed, especially because I know you mentioned that the whistleblower who was allegedly not retaliated against spoke of at least one instance where the doctor suggested that the procedure stop.

Has Networks for --

*Mr. Massa. Those were put in -- just to correct --

*Mrs. Houchin. Let me --

*Mr. Massa. Those were put in place in -- after the merger.

*Mrs. Houchin. Thank you. Why did Network for Hope not document drug overdose as the mechanism of death in nearly 75 percent of the cases reviewed by HRSA, with evidence of patient drug intoxication?

*Mr. Massa. We saw that same report, and we are looking at all those, and we have boosted our documentation process. We have additional training on documentation.

*Mrs. Houchin. The question, Ms. Massa, is why were those not documented?

*Mr. Massa. Those happened prior to the merger. I can't really speak to that. But since the merger I can tell you our policy is more robust as it comes to documentation.

*Mrs. Houchin. HRSA points out in their Corrective Action Plan that this suggests that there is a systemic concern regarding the treatment of potential DCD donors by KYDA staff. How do you explain that?

*Mr. Massa. Again, I can only address the things that occurred post-merger, and I can tell you that --

*Mrs. Houchin. When was -- what date was the merger, Mr. Massa?

*Mr. Massa. Pardon me.

*Mrs. Houchin. When was the merger?

*Mr. Massa. October 1 of 2024. And --

*Mrs. Houchin. Was the merger a result of this whistleblower's -- and the findings from this committee, was it a result of that?

*Mr. Massa. Not at all.

*Mrs. Houchin. It just followed that.

*Mr. Massa. I think that situation --

*Mrs. Houchin. September 11, 2024 was the --

*Mr. Massa. Yeah, it did follow that, that's correct.

*Mrs. Houchin. -- the hearing, it followed that. But it wasn't a result of that.

*Mr. Massa. No, ma'am.

*Mrs. Houchin. Okay. Given that at least 98 -- or 30 percent, nearly -- of the cases investigated in the HRSA report involved patients who were intoxicated with opioids, amphetamines, or cocaine, are there or should there be any special protocols in place for when a patient is intoxicated?

*Mr. Massa. Absolutely, and we have those policies in place now, and we are going to abide by everything that the -

- HRSA recommended in their letter.

*Mrs. Houchin. Can you understand, Mr. Massa, the concern that we have for the public, given the fact that the organizations seem to be -- and maybe this is not the case, but they seem to be taking advantage of vulnerable families during their most difficult time. The HRSA report indicated a troubling lack of care and concern for patients who are potentially intoxicated by overdose, as if their lives are less than.

*Mr. Massa. That is never the case. And yes, we do find those alarming. And we -- as I mentioned, I can't do anything about what happened prior to the merger. I can post-merger, and I can tell you those things are going to be rectified.

*Mrs. Houchin. Thank you very much. I hope today's hearing will bring clarity on how the failures have happened, what steps need to be taking place with HRSA, OPTN, the contractors so that we can ensure that these incidents never happen again. I thank you for your testimony today.

*Mr. Massa. Thank you.

*Mrs. Houchin. I yield back.

*Mr. Joyce. The gentlelady yields.

Before we conclude this hearing I want to take a brief moment to emphasize the importance of the work that this subcommittee is undertaking today.

It is critical that the 170 million Americans who have made the selfless choice to register as organ donors and to give the ultimate gift to another person upon their death, that they feel safe, that they feel protected in that decision. To honor that commitment and that sacrifice, that pledge that these individuals have made, that their loved ones -- that they must understand that we will fully investigate all claims that could cause fear or mistrust in the decision that they have made, and ensure that events that we have heard today would hopefully never occur today.

A significant concern is from the HRSA report that there were 103 of the 351 examined cases with concerning features. These were not unique. These are horrific reports. That is a 30 percent occurrence rate, and it affirms the need for this subcommittee -- it affirms the need for this investigation to occur.

Seeing that there are no further members wishing to ask questions, I want to thank the witnesses for being here today.

I ask unanimous consent to insert in the record the documents included on the staff document hearing list.

And without objection, so ordered.

[The information follows:]

**********COMMITTEE INSERT**********

*Mr. Joyce. Pursuant to committee rules, I remind members that they have 10 business days to submit additional requests for the record, and I ask the witnesses to submit their responses -- again, within 10 business days upon receipt of their questions. Members should request -- should submit their questions by the close of business on Tuesday, August 5.

Without objection, the subcommittee is adjourned.

[Whereupon, at 2:29 p.m., the subcommittee was adjourned.]