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A YEAR REMOVED: OVERSIGHT OF SECURING THE U.S. ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK ACT IMPLEMENTATION

WEDNESDAY, SEPTEMBER 11, 2024

House of Representatives,

Subcommittee on Oversight and Investigations,

Committee on Energy and Commerce,

Washington, D.C.

The Subcommittee met, pursuant to call, at 10:32 a.m. in Room 2322, Rayburn House Office Building, Hon. Morgan Griffith [Chairman of the Subcommittee] presiding.

Present: Representatives Griffith, Burgess, Guthrie, Palmer, Lesko, Armstrong, Cammack, Rodgers (ex officio); Castor, Schakowsky, Tonko, Ruiz, and Pallone (ex officio).

Also present: Representatives Bucshon; and Dingell.

Staff Present: Sean Brebbia, Chief Counsel; Deep Buddharaju, Senior Counsel; Sydney Greene, Director of

Operations; Lauren Kennedy, Clerk; Emily King, Member Services Director; Chris Krepich, Press Secretary; Kristen Pinnock, GAO Detailee; Gavin Proffitt, Professional Staff Member; Lydia Abma, Minority Policy Analyst; Austin Flack, Minority Professional Staff Member; Tiffany Guarascio, Minority Staff Director; Mary Koenen, Minority GAO Detailee; Will McAuliffe, Minority Chief Counsel, Oversight and Investigations; Constance O'Connor, Minority Senior Counsel; Christina Parisi, Minority Professional Staff Member; Harry Samuels, Minority Oversight Counsel; Andrew Souvall, Minority Director of Communications, Outreach, and Member Services; and Caroline Wood, Minority Research Analyst.

*Mr. Griffith. I ask all our guests to please take their seats, and I will now call the Subcommittee on Oversight and Investigations to order.

Before I recognize myself for my opening statement, both myself and Ms. Castor are going to take a point of personal privilege.

I think everybody who is probably over the age of about 28 or 30 remembers where they were on 9/11 in 2001. I was in my small law office in Salem, Virginia. My bookkeeper was in to do some work on the books. She was watching television and called me in and said, "Oh my gosh, a plane just flew into the World Trade Center.'' Obviously, there was a lot of concern and a lot of questions when the second plane hit. We knew the United States of America was under attack. By the time the day was over, thousands of innocent citizens and first responders would be dead.

We had heroism, whether it be on the plane that didn't hit the United States Capitol, whether it be at the Pentagon, or whether it be in the World Trade Centers, heroism that this country should never forget. And so I wanted to start this meeting just making sure that we recall that we should never forget the sacrifices made by those on that day and the subsequent years trying to bring justice to the perpetrators who orchestrated and planned that attack.

With that I yield now to Ms. Castor for comments on

9/11.

*Ms. Castor. Well, thank you, Mr. Chairman. We will never forget the heroism of the first responders that day who flooded into the towers to save our fellow Americans. We will not -- we will never forget the terror inflicted upon this country and how we responded by coming together to stand up for freedom and respect for all who were the ultimate sacrifice here at home and abroad.

I also remember very well, after dropping my daughters off at preschool and I had taken a little break from the law firm, what that meant in the Tampa Bay area that was home to United States Central Command. And I want to give a -- really, tell all of our service members how much gratitude we have for their service and sacrifice, as well.

Thank you, and I yield back.

*Mr. Griffith. Thank you very much. Very, very nice comments. And now I recognize myself for an opening statement.

Today's hearing is an opportunity to examine the National Organ Procurement System and provide oversight into the implementation of the Securing the U.S. Organ Procurement and Transplantation Network Act.

The current state of organ transplantation in our country is inadequate and must be addressed. There are over 100,000 individuals waiting for an organ transplant, and

about 17 people die each day waiting for the organ transplant. Notwithstanding the need for viable organs, according to one study there are more than 28,000 viable organs that are not recovered each year, and we must do better.

In 1984 the National Organ Transplant Act was signed into law that created a national framework for organ transplants. The bill established the Organ Procurement and Transplantation Network, or OPTN, which created a public-private partnership that implements and oversees the Organ Donation and Transplant System. Currently, the sole contractor responsible for operating the OPTN is the United States Network for Organ Sharing, or UNOS. They have been the sole contractor since 1986.

During the past 38 years there have been a myriad of issues plaguing this Organ Transplant System. While UNOS has provided beneficial services to organ transplant patients, there have been many examples of them operating inefficiently. I believe this is largely due to them having a monopoly currently.

Also there are questions around potential conflicts of interest. For example, partially due to certain agency regulations, some members of the UNOS board also sit on the board of the OPTN. And let me remind you, this is the oversight organization that is supposed to be overseeing

UNOS.

According to a Senate Finance Committee report, between 2010 and 2020 more than 1,100 complaints were filed by patients, families, transplant centers, and others regarding the Organ Transplant System. These inefficiencies are due to the lack of oversight and management of organ procurement organizations, or OPOs. OPOs are responsible for the procurement of organs for transplantation and are overseen by UNOS.

There have been many reported cases of transportation failures which has led to organs being unavailable or having to cancel transplant procedures. In 2018 there was a human heart left behind on a commercial airplane. Another mind boggling story was in 2020, when a kidney was accidentally thrown in the trash by an OPO staff, causing it to be unusable.

There are currently 56 OPOs operating in the U.S. The current system we have in place is a patchwork of OPOs that must rely on commercial couriers and airlines to transfer the organ. If we can track our Amazon order for socks every step of the way, we should be able to track something as valuable as human organs due to be transplanted to save a life. The lack of accountability must be addressed in creating more stable and reliable system.

There are other failures that show there needs to be an

overhaul of how the Organ Transplant System operates. That is what spurred H.R. 2544, the Securing the U.S. Organ Procurement and Transplantation Network Act, led by Energy and Commerce members Dr. Bucshon and Ms. Kelly. It was signed into law in 2023, and was unanimously passed by this committee and both the House and the Senate.

This bill allows for multiple entities to bid for certain contracts for functions such as logistics and health IT within the organ transplant network. This allows for companies with expertise in certain areas to competitively bid for contracts and end UNOS's monopoly over the organ transplant process.

The bill also ensures accountability by having separate boards within the transplant system. Within Health and Human Services we have the Health Resources and Services Administration, or HRSA, which houses the entire Organ Transplant System. They will now have the authority to modernize the Organ Transplant System. It is Congress's job to ensure that HRSA successfully implements this law so that the previous failures do not happen. Proper implementation is vital to saving lives.

On top of modernizing the Organ Transplant System, HHS and Congress must be open to approving new and innovative solutions to help address the organ shortage we are facing. For example, in my district alone we have a company that

develops genetically modified organs from pigs that can be transplanted into humans, and Virginia Tech has partnered with a doctor in my district to develop an innovative technology that can resuscitate and keep organs viable for longer periods of time from trauma patients.

I am hopeful we are moving in the right direction to help mitigate the failures of our current organ transplantation system, but more must be done. Congress will be watching to ensure the new law is implemented effectively, and that we do not face the same mistakes in the future.

[The prepared statement of Mr. Griffith follows:]

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

*Mr. Griffith. With that I yield back, and now recognize Ms. Castor for her five minutes for an opening statement.

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

The Organ Procurement and Transplantation Network, OPTN, is the nationwide system coordinating the logistics of all organ donations and transplants in the United States. Forty-six thousand transplants were performed in twenty-twenty-three, while more than one hundred thousand patients are currently on the waiting list. And to save as many lives as possible, the system must be both efficient and equitable.

A single contractor, UNOS, has managed the entire OPTN system since its inception. We have seen evidence of the often dangerous consequences of this 40-year monopoly uncovered by Federal audits, congressional investigations, and public reporting. Tragically, a lack of competition and accountability appears to have eliminated any incentive for UNOS to improve and update its woefully inadequate operations, and that must change.

Last year Democrats and Republicans from this committee championed a bill which President Biden signed into law to reform that system. That new law requires a competitive contracting process for the separate components of OPTN, which will lead to competent contractors with appropriate expertise at every level.

At the same time, the Health Resources and Services Administration, HRSA, is re-establishing its oversight authority through its own modernization initiative which is backed by additional authorities and increased funding in last year's bipartisan reform legislation. According to HRSA, there are about 400 members of the OPTN, including transplant centers, organ procurement organizations that currently handle the logistics of matching and transporting donated organs for transplants and labs.

My Tampa Bay district is home to Tampa General Hospital, which is the fourth largest transplant center by volume in the nation. They serve some of our sickest neighbors, and have successfully performed some of the most complex liver and kidney transplants in Florida, and they have done this for 50 years. They work hand in glove with Lifelink of Florida, an organ procurement organization serving west and southwest Florida that has increased organ donors and transplants over the last five years. They are very interested in these reforms, and are committed to the highest quality of care.

Together, the OPTN members are responsible for coordinating the many intricate steps to procure donated organs and safely deliver them to a transplant center and awaiting patient. This complex process is vital to get right, and we need accountability at each stage.

Earlier this year we took another bipartisan step towards reforms by launching an ongoing committee investigation to examine several issues that have plagued the OPTN under UNOS's management including outdated technology and cybersecurity systems, conflicts of interest, interfering with policy, and dismissal or unwillingness to address patient safety concerns and improve equity of access to the system.

We also have engaged with HRSA for updates on the status of reform implementation and how the agency was preparing to issue new OPTN contracts to correct past issues. I hope today's hearing is another constructive step forward as we hear from providers and patient advocates who can direct our focus on the specific areas of the OPTN where there are clear opportunities for positive change. Fundamentally, changing a nationwide program is no easy feat. HRSA's progress so far has been encouraging, but there is more to do, and it is important for Congress to remain vigilant as we monitor the ongoing changes.

There are few issues that garner unanimous agreement in Congress these days, but reforming the OPTN has been one of them. Organ donors, recipients, and their families deserve a system that works in their best interest. So we must continue our bipartisan dedication toward that goal by supporting the agency with sufficient funding and exercising

constructive oversight through the modernization. I am glad we are continuing the bipartisan work with today's hearing.

[The prepared statement of Ms. Castor follows:]

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

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

*Mr. Griffith. The gentlelady yields back. I now recognize the gentlelady who is the chair of the full committee, Mrs. Rodgers, for her five-minute opening statement.

*The Chair. Thank you, Chair Griffith. I appreciate you holding this important hearing.

We are here today because lives are on the line. Every day 17 people die waiting for an organ transplant. Many more suffer through years of fear and uncertainty, not knowing if they will get the lifesaving care they need in time. And surviving family members of those willing to donate their organs and tissue deserve to know that their loved one's act of selflessness is put to good use.

Nearly a year ago the Securing the U.S. Organ Procurement and Transplantation Network Act passed Congress unanimously and was signed into law by President Biden. I am grateful to my colleagues, Dr. Bucshon and Representative Kelly, for their bipartisan work in getting this Act signed into law. The bill sent a clear message that the Organ Procurement and Transplant Network, or OPTN, was in desperate need of reform.

As many of my colleagues and certainly our witnesses know, patients are waiting far too long for lifesaving organ transplants. Tragically, some lose their lives waiting,

victims of a system that is still struggling through a transition away from an old, broken model. And that is why it is so important that this committee remains informed about the effort to modernize the OPTN.

I am grateful to hear from our witnesses today about their experience with the law's implementation, and to understand the remaining problems that need to be addressed.

While the leaders of key organizations involved in this process -- Health Resources and Services Administration Administrator Carol Johnson and OPTN Board President Dr. Richard Formica -- were unable to testify today, the committee looks forward to receiving transparent and comprehensive updates from both of them moving forward also.

The OPTN plays a critical role in saving lives. However, systematic inefficiencies, outdated practices, and a lack of accountability have hindered its ability to fulfill that mission. The committee has a duty to ensure that the changes we put in place are happening. We need to know that conflicts of interest are being eliminated throughout the OPTN, and we need to know that the OPTN is managed in a way that puts patient safety and well-being first. We cannot allow the status quo to continue any longer.

Changing the name of the governing bodies of the OPTN but keeping the same individuals in place who failed to provide true oversight in the past is unacceptable. There

are inefficiencies, and the lack of accountability have cost people their lives. The American people deserve better, and we are here today seeking that on their behalf. I am proud of the bipartisan work of this committee in passing the Securing the U.S. Organ Procurement and Transplantation Network Act, but it does not mean that our work is over. While the law is an important first step, challenges remain.

Some of our witnesses today are not only advocates, but are also performing organ transplantation surgeries. They are on the front lines, and it is critical that their voices be heard.

We must ensure that the promises of our bipartisan reforms do not go unfulfilled, but lead to real improvements and better outcomes. This hearing is an opportunity to learn more about what is happening, to ask tough questions, to demand accountability, and ensure that we save as many lives as possible.

Past congressional hearings focused on the United Network for Organ Sharing as the sole contractor and manager of the OPTN, but that is not today's hearing. Today is about people. It is about patients waiting for an organ transplant, families who have lost loved ones, and the lives we can save if both Congress and HRSA get this implementation right.

I am committed to continuing to work in a bipartisan

manner to modernize the OPTN, ensure transparency, hold people accountable, and ensure that every lifesaving organ is used to its fullest potential.

Again, thank you to all our witnesses for being here today. We look forward to your testimony.

[The prepared statement of The Chair follows:]

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

*The Chair. And I yield back.

*Mr. Griffith. The gentlelady yields back. I now recognize the gentleman who is the ranking member, Mr. Pallone, for his five minutes for an opening statement.

*Mr. Pallone. Thank you, Mr. Chairman. Sorry, thank you, Mr. Chairman.

I am pleased that today's hearing gives us the opportunity to start assessing the progress that the Health Resources and Services Administration, or HRSA, is making implementing the bipartisan Securing the U.S. Organ Procurement and Transplantation Network Act since it became law last year.

Now, that bill, led by our colleagues, Representative Bucshon and Kelly, was passed unanimously in both the House and Senate. This overwhelming support demonstrates the broad bipartisan agreement that the OPTN needed to be reformed to work more effectively for the patients across the country who need and receive organ transplants every year.

More than 100,000 Americans are on the National Transplant Waiting List and, tragically, 6,000 Americans die each year waiting for a transplant. And this problem disproportionately affects people of color and people living in rural communities. For nearly 40 years the OPTN has been wholly operated by a single contractor, the United Network for Organ Sharing, or UNOS, and this monopoly has made it

very difficult to improve the system. It has pushed out potential competition and prevented innovation from other contractors who may be better suited to operate specific components of the OPTN.

HRSA had begun some reforms to the system through its OPTN modernization initiative, but it did not have all the authorities and resources required to give the system the complete overhaul that is needed. And that is why Congress and the Biden-Harris Administration have taken important steps with last year's bipartisan legislation to break up OPTN's monopoly by empowering HRSA to issue contracts to multiple vendors for various components of the network.

The need for reform was obvious. Significant evidence of mismanagement of the OPTN by UNOS has come to light. This was particularly troubling, given the wide array of OPTN members that UNOS has been responsible for overseeing and coordinating, and this included 56 organ procurement organizations, hundreds of transplant hospitals and laboratories, and numerous medical scientific organizations.

So we must now ensure that reforms are properly implemented so we can restore trust in the system and make sure it is best serving patients. And while much more work remains to be done, HRSA has taken significant steps in the right direction. HRSA has begun to untangle the OPTN board of directors from the current and future contractors managing

the system. The OPTN board has historically been identical to the board of directors at UNOS, creating clear conflicts of interest and poor safeguards for patient safety. The OPTN board is now incorporated as a separate entity, and planning is underway for new board elections with assistance from a new contractor.

The changes that HRSA is undertaking should transform the way that OPTN has operated, and provide enormous benefits for those who engage with this lifesaving system. Building strong accountability mechanisms and clearer transparency into the system is critical, and constructive oversight from Congress, as well as adequate funding for HRSA, is essential to implementing necessary reforms and saving lives.

As part of our oversight efforts earlier this year our committee began a bipartisan investigation demanding accountability from UNOS for reported incidents of mismanagement, and looking forward by requesting details from HRSA on how the agency is approaching the OPTN reform. And this investigation is ongoing, and I hope that more information about what has gone wrong in the past provides lessons for building a stronger OPTN for the future.

So I want to thank our witnesses for being here to provide perspectives on how to improve the OPTN and to push forward HRSA's modernization efforts.

[The prepared statement of Mr. Pallone follows:]

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

*Mr. Pallone. And with that, Mr. Chairman, thank you, and I yield back.

*Mr. Griffith. Thank you. The gentleman yields back. That concludes members' opening statements.

The chair reminds members that, pursuant to the committee rules, all members' written opening statements will be made a part of the record, but make sure you provide those opening statements to the clerk promptly.

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

Today's witnesses are Greg Segal, founder and CEO of Organize; Dr. Robert Cannon, associate professor of surgery and surgical director for liver transplant, University of Alabama at Birmingham; Dr. Seth Karp, surgeon in chief, Vanderbilt University Medical Center; Dr. Jesse Roach, senior vice president of government relations, National Kidney Foundation.

We appreciate you all being here today and look forward to hearing from you all.

You all are aware that this subcommittee is holding an oversight hearing. And when doing so, it is the practice of this subcommittee to take testimony under oath. Do you have an objection to testifying under oath?

Seeing that the witnesses have responded with no objection, we will proceed.

The chair advises you further that you are entitled to be advised by counsel, pursuant to House rules. Do any of you desire to be advised by counsel today during your testimony?

Again, seeing none, if you would, please rise if you can and raise your right hand.

[Witnesses sworn.]

*Mr. Griffith. And you all may be seated.

Seeing that the witnesses all answered in the affirmative, you are now sworn in and under oath, subject to the penalties set forth in Title 18, Section 1001 of the United States Code.

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

Mr. Segal?

TESTIMONY OF GREG SEGAL, FOUNDER AND CEO, ORGANIZE; DR. ROBERT CANNON, M.D., ASSOCIATE PROFESSOR OF SURGERY, UNIVERSITY OF ALABAMA AT BIRMINGHAM, SURGICAL DIRECTOR FOR LIVER TRANSPLANT; DR. SETH KARP, M.D., SURGEON-IN-CHIEF, VANDERBILT UNIVERSITY MEDICAL CENTER; AND DR. JESSE ROACH, SENIOR VICE PRESIDENT OF GOVERNMENT RELATIONS, NATIONAL KIDNEY FOUNDATION

TESTIMONY OF GREG SEGAL

*Mr. Segal. Chairman Griffith, Ranking Member Castor, and members of the committee, thank you for your oversight on this life and death issue.

Organ donation is deeply personal for me. My father waited five years for a heart transplant, needing three open heart surgeries just to survive. He was literally in the car to see an end-of-life counselor when a heart finally became available for him. Nine months later my aunt received a heart transplant, as well, which is when we learned that we have a very rare genetic condition in our family that causes heart failure. A few years later another of my aunts died in need of a heart, and I now have two younger siblings and three cousins who will very likely need heart transplants, as well.

To help families like mine I founded Organize, a patient

advocacy non-profit which advocates for reforms to increase accountability in the Organ Donation System, and from 2015 to 2016 we served in a policy development role in the Department of Health and Human Services.

It was then, during our time at HHS, that I became overwhelmed with whistleblower allegations of widespread abuse within the OPTN, including credible allegations of rampant Medicare fraud, including OPO executives joyriding on taxpayer-funded private jets intended for the transport of organs; of unsafe patient care, including the hastening of death with fentanyl and the falsification of medical records; the harvesting of organs from patients who whistleblowers believe would otherwise have survived; the preferencing of White, wealthy, and famous people on the organ transplant waiting list; of kickback schemes between OPO executives and tissue processors, aviation companies, and medical device companies; of OPO executives directing staff to deprioritize care for Black patients, often using derogatory language that I will not repeat here or elsewhere; and OPTN leaders attempting to solicit bribes from other OPTN members in exchange for inappropriately clearing them of any wrongdoing in patient safety investigations.

To be clear, while I have found these allegations credible, and in some cases have received extensive supporting documentation, I am not an oversight body and I do

not have the capacity to fully investigate these claims myself, though I sincerely hope that this committee will do so for these whistleblowers all told me the same thing, that they were reaching out to me rather than to the OPTN because they had absolutely no faith in the OPTN process, that their complaints would just get buried, and that they would suffer career-ending retaliation simply for raising these issues in the first place.

So I instead began referring whistleblowers to congressional oversight bodies and, as appropriate, to law enforcement. And that's when industry interests came after me. An OPO lobbyist launched an offensive and antisemitic astroturf campaign, falsely implying that I'm lying, that my aunt died in need of a heart transplant, and that I harbor undisclosed financial motivations. These allegations are categorically false, but that still did not stop Dr. Rich Formica, now the OPTN president, from sharing this astroturf campaign in a national op ed, which is when things became even worse. Friends at OPOs began to tell me that their colleagues would openly brag about their intentions to purposefully mismanage my care, to "dismember me,'' and to "make me unrecognizable to my own mother.'' I've even been told that if I don't stop my advocacy that my brother and sister will never get transplants.

This has been the cost of advocating for higher

standards of patient care, the cost of publishing research critical of the OPTN, and the cost of being an older brother who is just trying to save his little brother and sister's lives.

OPOs are a multi-billion-dollar, taxpayer-funded industry of unaccountable body brokers, and the whistleblower retaliation is a feature and not a bug. The current OPTN structure not only protects industry interests, but actively incentivizes and even rewards these abhorrent behaviors.

The question now is far beyond whether the OPTN has failed patients, but whether such failures rise to the level of gross or even criminal negligence. The solutions are clear: holding HRSA accountable by ensuring the intent of the Securing the U.S. Organ Procurement and Transplantation Network Act, the law that this committee worked tirelessly to pass in a unanimous, bipartisan effort, is realized; by breaking up monopoly control through competitive, accountable contracts; by appointing an OPTN board that is truly independent of industry control and financial conflicts; and by seeing through oversight every credible allegation of fraud and patient abuse so that perpetrators are brought to justice, and so that patients have the safe and effective organ donation system that they deserve and that we've been promised.

I'd like to close by thanking the committee for its

oversight and all they can do to see these reforms through.

[The prepared statement of Mr. Segal follows:]

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

*Mr. Griffith. I thank you, Mr. Segal.

I am asked by the audio people to remind everybody to please pull your microphone up. It makes the sound clearer for the folks who are watching it, either live at home or later on reruns on C-SPAN. So yes, for storage purposes, they always tilt them down and then we have to ask folks to tilt them up.

Dr. Cannon, you are now recognized for five minutes for your opening statement.

TESTIMONY OF DR. ROBERT CANNON

*Dr. Cannon. Chairs Griffith and Rodgers, Ranking Members Castor and Pallone, and members of the committee, thank you for the opportunity to speak with you today.

On my desk there's a handwritten note from a patient's family thanking me for saving their daughter's life with a liver transplant. I keep it there to remind me of the awesome privilege and responsibility I have as a transplant surgeon to serve patients in their time of greatest need.

The true heroes in the story of transplantation are not physicians, however, but rather are the donors and families who give selflessly in what may be the darkest moment of their lives, patients suffering from organ failure, waiting for a phone call that may never come, and the thousands of organ donation and transplant professionals who bridge the gap between them.

I'd like to speak with you today about --

[Audio malfunction.]

*Dr. Cannon. -- let these heroes down. The OPTN contract has been held by UNOS for nearly 40 years. The men and women of UNOS during this time have done some lifesaving work to facilitate the smooth operation of our transplant system.

Another key role in the transplant system is occupied by

Organ Procurement Organizations, or OPOs, which are federally-designated non-profit organizations tasked with overseeing all aspects of organ donation within their territory. Dedicated OPO professionals meet families in their darkest moments and work to bring hope from tragedy. They are the bedrock upon which our system rests, and I offer them my sincerest thanks and gratitude.

The transplant system is built upon trust. But sadly, this trust has been broken by a broken and corrupted OPTN. Until recently, OPOs were allowed to self-determine which deaths within their territory represented potential donors, leaving the door open for manipulation of the performance metrics by which they were evaluated. Although CMS reformed this metric in 2022, the SRTR contractor refuses to recognize this reform measure, and OPO lobbyists continue to oppose it through fear.

The OPTN has similarly been allowed to control the collection and dissemination of data, essentially blinding HRSA to their true performance. The whole system lacks sufficient oversight and accountability, resulting in actions that are abusive and harmful to patients. I've had an OPO administrator recommend I proceed with organ procurement despite legitimate concerns that the donor was still alive. I've had a 21-year-old patient dying from liver failure have a perfect organ taken away from her by an OPO that was

unwilling to provide an extra hour to find a plane to transport the organ. Our complaint in this instance went unanswered.

Unfortunately, stories such as these are not isolated instances. At present, approximately 20 percent of kidneys are allocated out of sequence, meaning that patients with higher priority on the list were never given an opportunity to receive these organs. While this practice may reflect the best effort of an OPO to avoid organ wastage, the epidemic of out-of-sequence allocation represents a workaround for failed policies that were pushed through a system rife with corruption.

I've read hundreds of pages of emails in which high-ranking UNOS and OPTN officials, along with a small group of OPO and transplant physician leaders, schemed to undo years of policy development to push through their own agenda instead. In the course of this process, individual OPTN executive committee members instructed their supposed regulators at HRSA on how to respond to threatened lawsuits in a manner that favored their interests. Those who opposed this group were subject to retaliation and intimidation. People in large swaths of the country were derided by expletives by those in power, by the OPTN and UNOS, and patients suffering from organ failure who had not made it to the waitlist were dismissed as unimportant.

Rather than being censured or removed from office for this behavior, the then-CEO of UNOS was instead issued an official commendation from the OPTN for his work.

The OPTN Modernization Act was intended to right this ship. However, the process continues to be undermined, and the same actors remain in power. For example, the current president of the now-independent OPTN board has a history of seeking to intimidate and retaliate against those who do not tow the OPTN party line, including those testifying to Congress as I am today and those who are unable to testify out of fear of further retaliation. The HRSA officials who so willingly did the bidding of the OPTN remain in office, hindering effective change. With such resistance to reform, our transplant system can never reach its true potential and it's patients who are paying the price.

The OPTN has lost its way. Congress has taken a step in the right direction, but has not yet gone far enough. And we need you to go further.

Now, let me be clear. I'm not asking that Congress make specific medical policy, but what I am asking for is a modernized National Organ Transplant Act, which gives HRSA the tools to ensure that regulation and oversight are impartial, data driven, and transparent. Only then can we realize -- fully realize -- our mandate to serve all Americans suffering from organ failure. Thank you.

[The prepared statement of Dr. Cannon follows:]

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

*Mr. Griffith. Thank you. I now recognize Dr. Karp for his five minutes of an opening statement.

Dr. Karp?

*Dr. Karp. Can you hear me? Is this on? Are we clear?

*Mr. Griffith. All right. I think you are on.

*Dr. Karp. Great.

TESTIMONY OF DR. SETH KARP

*Dr. Karp. Good morning, Chairman Griffith, Ranking Member Castor, full committee Chairwoman McMorris Rodgers, and Ranking Member Pallone, members of the O&I Subcommittee. I'm grateful for the opportunity to testify today.

I'm a liver transplant surgeon, a surgeon in chief, and former director of transplantation at Vanderbilt University Medical Center. We are one of the largest transplant centers and donor hospitals in the U.S. I previously served on the board of UNOS and the OPTN, and so I know what happens on the inside.

In 2021 I testified before the U.S. House Committee on Oversight and Reform. During that hearing Tonya Ingram, who was waiting for a kidney transplant, also testified. Unfortunately, her worst fears came true, and she tragically died without a transplant. I'm here to tell you that that tragedy likely could have been avoided. Twenty years of research consistently shows that the number of possible donors in the U.S. is about 300 percent of the actual number of donors. In contrast, just a 20 to 30 percent increase in organs would be enough to save the life of every person that died waiting for a heart, a lung, or a liver, and would dramatically reduce the waiting times for kidney transplant. We must do better, and we must save more patients' lives.

So how did we get here, and what do we do? The National Organ Transplant Act and the OPTN final rule, as you have mentioned, gives the OPTN the responsibility to increase the organ supply and hold Organ Procurement Organizations, OPOs, accountable for poor performance. The problem is that, for 40 years, the boards of the OPTN, the oversight body, and the contractor, UNOS, have been the same, and they have sought to protect OPTN members instead of patients. This egregious conflict of interest has permitted industry insiders to capture this system. As I testify today, the OPTN board is still filled with people who are UNOS board members as recently as a few months ago.

I would like to state clearly patients are continuing to die in the United States waiting for an organ due to self interest, incompetence, and mismanagement at the OPTN. As a researcher, surgeon and board member I have witnessed OPTN cover-ups both in broad daylight and in back rooms.

In broad daylight the OPTN ignores research that shows the huge numbers of missed donors and lobbies against bipartisan, data-driven measures to hold OPOs accountable. In broad daylight the OPTN suppresses data, suggesting that new policies would increase organ discards and lead to more patient deaths, and continues to ignore the increased discards, complexity, and cost generated by their new policies.

In broad daylight the OPTN takes credit for increased donation, even though these numbers are driven by technological advances and deaths from the opioid epidemic.

In the back room OPTN leaders assure no OPO leader will ever be held accountable for poor performance, seeks to prevent competition in the OPTN contract bidding process, threatens to sabotage any new contractor by refusing to release data and share information systems, intimidated and retaliated against those in the community with whom they disagreed, tried to minimize a major patient data breach and an error that disadvantaged patients of O blood type from receiving lungs. They denigrate suffering patients in the poorest areas of the country, and they do not sufficiently prioritize the needs of children.

I'm so grateful for the committee's leadership and the work you've done on this important issue. You've empowered HRSA to break up the national organ monopoly, but I'm not seeing much from the OPTN that goes along with the reforms that you are trying to put in place. I'm grateful for the excellent investigative staff of this committee for their tireless work. But understand, without your continued oversight OPTN leaders will continue to gut meaningful reforms. They're doing that now.

For the generous donor families across the country and the 100,000 Americans on the organ transplant waiting list, I

urge you to enforce the law that mandates the OPTN work to increase the organ supply; ensure that HHS appoints a brand new board for the OPTN that does not include even a single person who has contributed to this gross mismanagement; ensure enforcement of the OPO final rule, which will finally hold opioids accountable and save lives; ensure that every OPTN contract is written with accountability and open access to all data to break what Congresswoman Eshoo from this committee called a stranglehold on the system; and please continue your oversight.

Thank you for the honor of speaking with you today. I look forward to your questions.

[The prepared statement of Dr. Karp follows:]

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

*Mr. Griffith. Thank you very much. I now recognize Dr. Roach for his five-minute opening statement.

TESTIMONY OF DR. JESSE ROACH

*Dr. Roach. Thank you. Chair McMorris Rodgers, Chair Griffith, Ranking Member Pallone, Ranking Member Castor, and distinguished members of the committee, thank you for the opportunity to testify today on behalf of the National Kidney Foundation and patients with kidney disease.

I'm Dr. Jesse Roach, and in addition to leading the government relations department at the National Kidney Foundation I'm a nephrologist who has worked with many adult and pediatric patients in kidney failure and throughout their transplant process. I am grateful to be here today to speak on behalf of the over 800,000 people living with kidney failure and the nearly 90,000 people in the kidney transplant waitlist. These patients, who wake up every day hoping for a lifesaving transplant, are the reason we are all here today.

The passage of this Act brought hope to these patients and their families. It promised a more equitable, transparent, and patient-centric organ donation and transplant system. Today we are beginning to see that promise materialize, but there is still much work to be done to truly meet the needs of those waiting for another chance at life.

HRSA's OPTN Modernization Initiative is a comprehensive effort to address longstanding challenges in our organ

donation and transplant system. For patients, this initiative represents potential for shorter wait times, better matched organs, and, ultimately, more lives saved. We commend Congress and HRSA for taking on this ambitious project and for the progress made thus far.

But while progress has been made, we remain concerned about the lack of transparency, patient focus, and equity in the Organ Transplant System, and are deeply troubled by the increasing number of kidneys that are thrown away each year. One in four recovered kidneys are not transplanted, and in 2023 there were 8,574 kidneys recovered with the intent to transplant but that were later discarded. That comes out to about 23 kidneys wasted per day. At the same time, an average of 12 people die each day waiting for a kidney transplant. This is a system failure, and it's completely unacceptable.

To further strengthen the implementation of the Act and directly benefit patients, we recommend that HRSA's request for proposals and the final OPTN contract include provisions that, one, explicitly state how vendors and HRSA itself will be held accountable for maximizing every organ donation and transplantation opportunity. Every unused organ represents a lost chance at life for a waiting patient.

Two, mandate regular, easy-to-understand reporting on -- to patients on organ offers and declines made on their

behalf. This transparency will empower patients to make informed decisions about their care and give them a clearer understanding of their status on the wait list.

Three, require collection and public reporting of the data on the pre-wait listing experience. For many patients, the journey to the waitlist is fraught with obstacles. Understanding referral rates, evaluation timelines, and living donor processes can help identify and address disparities and access to transplantation. This data can also be used to ensure that all patients are treated fairly and equitably.

Further, we would like to highlight a few areas where continued focus is needed to better serve patients. We need a diverse and independent OPTN board that includes strong patient representation, bringing the lived experiences of those on the waitlist to the decision-making table. While institutional continuity is a valuable asset, this system has been run by a small group of the same people for many years, and it is time that a different and broader set of stakeholders have a space at that table.

Two, enhanced oversight of OPTN committees is essential. Many policy decisions are made at the committee level, but it has traditionally been an opaque process. HRSA needs to have and use its oversight powers to ensure that decisions are made in a timely, transparent, and patient-centric manner.

HRSA itself needs to ensure that decisions are made in a timely, transparent, and patient-centric manner. We must ensure that patient voices are heard and their needs prioritized in all policy decisions.

While we understand the need for a smooth transition, we urge HRSA to act with urgency in implementing reforms. Every day of delay means a lost opportunity for a patient waiting for a transplant. Time truly is of the essence.

And finally, in keeping with the need for transparency and accountability, a robust system for addressing whistleblower complaints at both the OPTN and HRSA levels is crucial to promote patient-centricity and maintain trust in the system. We believe regular, transparent updates to Congress, stakeholders, and, most importantly, patients on the progress of enhancing organ donation and transplantation would give hope to waiting patients and families, showing them that real change is happening. This communication should be made available to the widest possible audience.

In conclusion, we are encouraged by the steps taken thus far in implementing the Securing the U.S. OPTN Act. We must focus squarely on the patients. For too long the system has prioritized the stakeholders and the institutions at the top. Every policy decision, every system upgrade, and every new procedure must be evaluated based on its impact on those waiting for a transplant. HRSA's efforts to modernize our

organ donation and transplantation system are commendable, and we are cautiously optimistic about the positive impact these changes will have on patients' lives. However, for those in the waitlist optimism isn't enough. They need action, they need results, and they need them now.

Thank you for your time and critical attention to this critical issue. On behalf of the patients we serve, I welcome any questions you may have.

[The prepared statement of Dr. Roach follows:]

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

*Mr. Griffith. Thank you. I thank you all for your testimony. We will now move into the question-and-answer portion of the hearing, and I will begin the questioning and recognize myself for five minutes of questioning.

Dr. Karp -- and I am going to ask this of both you and Dr. Cannon and Mr. Segal -- you mentioned our committee staff and the work they were doing. And of course, oversight is important. And it has come to the committee's recent attention that there have been allegations of prospective organ donors, patients, waking up on the way to the operating room where their organs are expected to be removed, and yet they are still not brain dead, or still alive. Can you expand on that?

Can you tell me, have you -- we will start with you, Dr. Karp, but have you had any experience where this information was brought to your attention?

And I ask the three of you, because each of you mentioned it in one form or another, either in your opening statement or in your written testimony.

*Dr. Karp. I'm not aware of this particular --

*Mr. Griffith. Yes, mic. Yes.

*Dr. Karp. I'm not aware of this particular case. Of course, it's unbelievable to hear that. But it does happen not infrequently that I -- as a transplant surgeon, I also do donor operations. And so I go to a donor hospital, and it's

not infrequent that something comes up around the donor and whether or not the donor is dead.

And the problem is that we've got 40 years where there has been no oversight at all of the OPOs. And so what that has led to is poor education, poor standard of practice, poorly-trained people. And so in a situation like that you need to know what to do, and people don't know what to do in that situation. Unfortunately, they haven't been trained properly. And those types of problems could lead to something that you have described.

*Mr. Griffith. All right.

Dr. Cannon?

*Dr. Cannon. I've experienced this myself, unfortunately, as a donor surgeon. We went on a procurement, the donor had been declared brain dead. We were actually in the midst of the operation when the anesthetist at the head of the table said they thought the patient breathed, which would essentially negate the declaration of brain death.

What Dr. Karp said, no one really knew what to do. The staff on the ground called their administrator, whose recommendation was, "Oh, I think this is just a brainstem reflex, we recommend you proceed,'' which, of course, would have been murder if we had done so. So yes, we closed the patient, and we got out of Dodge, and wanted nothing to do with it.

So these things happen. I think --

*Mr. Griffith. Did the patient survive?

*Dr. Cannon. The patient was ultimately declared later, and they called us two days later. And of course, we wanted nothing to do with that because we couldn't trust the process. Every transplant surgeon has probably got a story of themselves or a colleague who's had something like this.

*Mr. Griffith. And I assume that did not happen in the state of Kentucky.

*Dr. Cannon. It did not. No, sir.

*Mr. Griffith. Thanks.

Mr. Segal?

*Mr. Segal. Yes, sir. I receive allegations like this with fairly alarming regularity. As I testified in my opening statements, when I receive these -- I'm not an oversight body, I don't investigate these fully myself, but I connect them with appropriate bodies, including this committee. And I sincerely hope if your committee has found these allegations credible, that there'll be opportunities to refer some of these cases to law enforcement. And certainly, I would appreciate the opportunity to work with this committee on solutions to ensure that the system is safe for patients.

What I will say, which I think is the biggest statement on the safety of the system, is I know many Organ Procurement

Organization coordinators who are no longer registered organ donors themselves because of what they have seen out in the field.

*Mr. Griffith. And I have referenced a minute ago the state of Kentucky. It is my understanding that perhaps you have had conversations with the attorney general of the state of Kentucky about a situation there involving somebody who was declared brain dead, and turned out they were not. Is that accurate?

*Mr. Segal. Yes, sir.

*Mr. Griffith. And there is documentation, the medical documentation, that they were found to be brain dead, but then they apparently woke up. And can you tell us a little bit more about what you have heard on that?

I understand you didn't do the full investigation, but you are working with the state of Kentucky -- the Commonwealth of Kentucky on that, is that correct?

*Mr. Segal. Yes, sir. I spoke to the Kentucky attorney general yesterday, who sprung into action and pulled a whole team together on this. And I understand that they are diving deeper into this specific allegation, and are even monitoring this hearing today.

*Mr. Griffith. All right, I appreciate that. I also heard that there might be a story where somebody actually mouthed the words, "Help me'' before somebody realized that

they weren't a potential donor. Is that accurate?

*Mr. Segal. Yes, that is an allegation I heard recently. I understand that that whistleblower has been in touch with your committee. What was relayed to me was that, yes, he was instructed to recover organs from someone who was mouthing the words, "Help me,'' decided not to proceed, and the person ended up surviving.

*Mr. Griffith. And you are not stating that as a matter of fact, you are stating it as an allegation that has been brought to you which you brought to our attention. Is that correct?

*Mr. Segal. Yes, that's correct.

*Mr. Griffith. That is what I understood. I have also heard allegations that in some cases there may be some medical personnel who don't put down the full story on the paperwork, so that it appears to be a classic heart attack where it might actually be an opioid overdose. Is that accurate?

*Mr. Segal. I've heard that allegation, as well, yes.

*Mr. Griffith. All right, and I am out of time. I am going to have a lot of questions, what we call questions for the record, because I originally, before I found out about these very serious and scary allegations, was going to work on the fact that it appears to me that perhaps the OPTN has ignored new technologies, as I mentioned in my opening, that

could extend the life of an organ. And they up to this point have ignored it. And the guy in my district has been working on this for a decade, trying to get their attention.

[The information follows:]

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

*Mr. Griffith. I now yield back and recognize Ms. Castor for her five minutes of questioning.

*Ms. Castor. Thank you, Mr. Chairman, and thank you for all of your testimony here.

Dr. Roach, thank you for your years of advocating for patients and bringing the patient perspective. I hear you when you say this whole process is entirely too opaque for patients. It mirrors what I hear from neighbors back home when they are faced with this very, very difficult situation.

When a patient is potentially eligible for an organ transplant, what are they doing at that time? Are they -- are they accessing this purely through their provider? And what information do they have early on?

*Dr. Roach. So when a patient is going through the transplant process, they're referred by their individual doctor to a transplant center, who then evaluates them. They're hopefully then put on a waitlist, or works with them to get things done that can get them on a waitlist.

During the time that they're on the waitlist, one of the things that we would like to see that isn't happening is that patients -- if a patient is declined offers, if a patient is -- sometimes patients don't even know that they've been removed from the waitlist. We think it's important that when patients are on the waitlist, that their process is fully transparent, that they're aware of what's going on with them,

and we're aware of their status on the waitlist. When -- thank you.

*Ms. Castor. Are they -- are they able to access that information through the transplantation network, or do they have to go through their provider at all times?

*Dr. Roach. I mean, usually they have to go through their provider. There's no way for them to independently access that information in most -- for most centers.

*Ms. Castor. But I imagine that is particularly difficult for a lot of folks. It is hard just to make an appointment for -- with a -- with a doctor these days. How is the average person really supposed to understand where they are on a waitlist, and the timing, and potential, and the -- just the uncertainties of it all?

*Dr. Roach. So a lot of times they don't. A lot of times some patients are not aware of where they are. There have been steps that have been taken, according -- some models that have been put out to try and increase that transparency and increase the number of notifications that they're getting.

It increases burden on the transplant centers, but I think it's for something that is potentially worth it to have patients be aware of where they are in this process.

*Ms. Castor. And then I imagine it is even worse if you are -- depending on your social determinants, your

socioeconomic status and disparities. How -- do you see fixes in the reform legislation and what HRSA is doing that will tackle that problem, too?

*Dr. Roach. Well, I think having more transparent data, I think making the data available, I think making the data transparent, I think more communication with patients so that you can understand where the patients are coming from and what their lives are actually looking like, and come up with shared decision-making with the patients -- do you want to be more aggressive with what type of organs you accept? Would I like to -- am I having offers that aren't -- just conversations, spurring more conversations with their doctors.

And I think that also the data can help us see certain groups of patients aren't getting transplanted, aren't getting referred, aren't making it to the waitlist at higher levels as other populations. And so I think having more data and being more transparent, I think, would help with that, as well.

*Ms. Castor. In fact, Dr. Karp, you have done -- you have published research on the need for better data and how improvements in that area will help boost organ donation and procurement. Where in the OPTN system are the greatest needs for the improvements in data collection and reporting and reforms here?

*Dr. Karp. I think by far the need is to identify the underperforming OPOs, understand why they are under-performing, and address that directly.

We published just about a year ago that there are large hospitals in the United States that don't have any donors. The VA system doesn't have hardly -- has less than 10 donors a year. That's just crazy, and that needs to be addressed. And if you had the data, you could identify hospitals, hospitals in the VA system, and say, "Why haven't you had any donors for the last 20 years,'' and then you go into those hospitals and you fix it. It's not rocket science.

*Ms. Castor. Why doesn't the VA do that?

*Dr. Karp. That's a good question. I don't know that I know the answer to that, but a colleague of mine, Ray Lynch, is looking into that, and has got some really good ideas around that. And that's something that I think will get better.

*Ms. Castor. Is there information that the OPTN and Federal agencies should be collecting that will enhance their oversight capacity?

*Dr. Karp. Absolutely. So you need to start at the beginning. If a patient comes in with a likelihood of dying, that needs to be reported. The information that goes from the hospital to the OPO needs to be reported. The response of the OPO to that information all needs to be reported. If

you had that, you basically have the map, and then you just go to the place where there's a problem. But we don't have that, and that's the tragedy.

*Ms. Castor. Thank you very much.

I yield back.

*Mrs. Lesko. [Presiding] Thank you. Now I recognize the chairwoman of the Energy and Commerce Committee, Mrs. McMorris Rodgers.

*The Chair. Thank you, Madam Chair.

Right now more than 100,000 Americans, including more than 1,500 in my home State of Washington, are on the organ waiting list. As I mentioned in my opening statement, transitions like this can be challenging, but I remain committed to ensuring the success of the OPTN Modernization Initiative.

Mr. Segal, given your experience, would you briefly share your view as to why, after decades, we continue to experience these long waiting lists?

*Mr. Segal. So I'm going to --

*The Chair. Oh, and just, if you could, do it briefly because I do have some other questions.

*Mr. Segal. Absolutely. I'm just going to build on Dr. Karp's --

*The Chair. Yes, okay, great.

*Mr. Segal. -- answer is that there has never been any

accountability for OPOs.

More than 95 percent of Americans support organ donation. That actually polls higher than puppies and ice cream. And yet the OPTN's own research has found that OPOs only recover organs from one out of five potential donors. They are monopolies, and they've never had any enforceable regulations, and their performance has greatly suffered.

*The Chair. Thank you.

Dr. Karp, Dr. Cannon, do you have anything to add?

*Dr. Karp. I agree with him.

*Dr. Cannon. I do, too.

*The Chair. Okay. Dr. Karp, given your experience on executive committees like the Membership and Professional Standards Committee, MPSC, can you speak to the mechanisms that currently exist to hold the OPTN accountable?

And do you have examples of the system working or failing, falling short?

And additionally, how would you envision a well-functioning MPSC?

*Dr. Karp. I don't know the mechanism by which we hold the entities accountable, and I was on the MPSC for two years.

The problem is that a lot of it gets buried before it even gets seen. And when I would hear about things peripherally and say, "Hey, I just heard about this, why

didn't it come to the committee,'' I would be told, "Well, we just took care of that,'' or, "We have to protect the identity of the Center,'' neither of which made any sense, because we were the oversight body and we were the ones that were supposed to be deciding what should happen. And it never got to us. It never got to me.

*The Chair. Okay. A couple of -- thank you. A couple of weeks ago, on August 29, HRSA announced that, for the first time in its 40-year history of the OPTN, the OPTN Board of Directors, the governing board that develops national organ allocation policy, is now separately incorporated, independent from the board of a long-time OPTN contractor, UNOS.

HRSA has awarded an OPTN board support contract to American Institutes for Research to support the newly-incorporated OPTN Board of Directors. I would like to hear each of your thoughts on this development, and I will just start with Mr. Segal and move down.

*Mr. Segal. So in theory it's a good thing that the board has been separated. In practice, what has happened is every current member of the OPTN board either is a legacy UNOS board member or was selected to be a UNOS -- an OPTN board member by UNOS. So I think it's important to recognize there can be structural conflicts, and HRSA has taken a step towards mitigating those. But people have conflicts as well,

and the entire current composition of the OPTN board is people that were selected by UNOS.

*The Chair. Thank you.

Dr. Cannon?

*Dr. Cannon. I agree with Mr. Segal. It's the same industry insiders who continue to run and be on these boards. We've sort of failed to elect the right board members, and I'd suggest it'd be better if independent and highly-vetted individuals are appointed with strict conflict of interest oversight.

*The Chair. Thank you.

*Dr. Karp. I agree it's necessary, but it's not sufficient, and the board needs to be replaced.

*The Chair. Yes, doctor.

*Dr. Roach. I can't -- I'm not going to comment on specific members or conflicts, but I do think that the current board hasn't met the needs of patients. And so I think there needs to be different representation.

*The Chair. Thank you. Thank you. Well, I really appreciate you all being here and sharing your insights. So we're going to stay committed to getting this oversight accomplished and getting us back on track.

I yield back.

*Mrs. Lesko. Yes. Now I would recognize the ranking member of the full Committee of Energy and Commerce, Mr.

Pallone, for five minutes of questioning.

*Mr. Pallone. Thank you, Madam Chairwoman. The testimony from today's panel makes it clear why congressional action was necessary to provide HRSA with new authorities to modernize the structure and operation of the OPTN through passage of the bipartisan Securing the U.S. Organ Procurement and Transplantation Network Act, but -- and statutory language dating back to the creation of the OPTN all but guaranteed that a single contractor, in this case UNOS, would be awarded the entire OPTN contract in perpetuity, preventing any opportunity for competition or incentive to innovate. And allowing OPTN management to be broken up into multiple contracts lets HRSA make awards based on which applicant will provide the highest quality service for each part of the system.

So let me ask Dr. Karp, what have been some of the drawbacks of having UNOS manage all facets of the OPTN?

*Dr. Karp. The transplant system has just gotten way too big. There is not enough expertise on logistics. There's not enough expertise on policy. There's not enough expertise on ethics. And so this small group is trying to manage this enormous system, and they're just overmatched.

*Mr. Pallone. All right. So one of the first steps towards implementing reforms, HRSA issued contract solicitations to conduct full reviews of key functions of the

OPTN, and so let me go to Dr. Roach.

As a patient advocate, what are you watching for as HRSA is issuing these transitional contracts to examine current OPTN functions and propose improvements, if you would?

*Dr. Roach. Yes. So we are making sure HRSA should be prioritizing patient-centricity. So every decision should be evaluated based on the impact on those waiting for transplants. We're looking for transparency, regular, clear communication with the public in both the public and stakeholders. We're looking for data-driven decision-making, so utilizing comprehensive and accurate data to guide policy. We want equity. We want flexibility. So we want a system that can adapt to future technological advances. And we want stakeholder engagement, so continuously involving patients, doctors, medical professionals, donors, and other stakeholders in the planning process.

*Mr. Pallone. Well thank you. But Dr. Roach, how -- just in general, how would increased competition for OPTN operations benefit patients?

*Dr. Roach. I think that if you have competition, people are more willing to introduce new technologies, people are more willing to do things in a different way that could benefit patients. Having 1 person do the same thing for 40 years, does it give them impetus to change for new technologies to benefit patients? I think that there could

be some cost savings by introducing competition. So I think that, overall, it would be good for patients.

*Mr. Pallone. All right. Now, how -- let me ask you one more question. How can multi-vendor infrastructure make the OPTN more functional and responsive to patient needs, if you will?

*Dr. Roach. Well, I think that it allows for different expertise to be brought in, so different aspects of organ donation and transplantation you can bring in multi-vendors. People that have expertise in one area might not have it in another, so having multiple vendors to do that, I think, will benefit patients. I think it will just foster innovation, I think, which can only be good for patients, new technologies, new methods and things. And I think that -- yes. So I think -- and I think that competing on performance will also only help patients.

*Mr. Pallone. Okay. Well, thank you.

You know, obviously, the bipartisan law directs HRSA to make significant changes to how the OPTN has been structured and managed for decades, and I am just hoping that we continue to conduct bipartisan oversight as this implementation continues, and also support the funding level that the agency needs to successfully implement the law and create an OPTN that prioritize patient safety.

But thank you, I thank the panel.

Thank you. I yield back, Madam Chair.

*Mrs. Lesko. Now I call on myself for five minutes of questioning until some other members arrive.

You know, your testimony about donors that are still alive and the one yelling, "Help me,'' or mouthing, "Help me,'' is absolutely terrifying. And I used to serve in the Arizona state legislature before coming to Congress, and I think every year out on the lawn at the state capitol the Arizona Donor Network had a big event and -- to encourage people to sign up for the donor list. And if word got out to more people that these type of things were happening, I think there would be less donors to sign up. So we need to continue to work to try to improve this.

So my question to each one of you. We have four minutes left. In one minute each, if you stood in an elevator with a Congress member, tell that Congress member, me, what we can do as Congress members. We have already passed a law. What can we do to change this?

*Mr. Segal. I think a very good first step is, as a few of us have testified, de-conflicting the OPTN board and moving to board appointments, including -- because, as Dr. Karp testified, the MPSC has always been a captured body. That is the organization that's supposed to investigate these patient safety claims. If there were a functioning MPSC and they were meaningfully investigating these claims, including

so that people felt comfortable even bringing these claims to the MPSC in the first place, that would be an excellent deterrent.

And the other point that I will make is there is no clinical licensure requirements that CMS, Center for Medicare and Medicaid Services, has ever imposed on OPO staff that are interacting with donor patients. I will tell you I had an Uber driver when I was in Los Angeles a couple of weeks ago who asked me what I did a couple of months ago, and I said something about organ donation, and he told me that he, in his -- as a side job from his Uber job does organ recoveries for the local OPO there. And it just was astounding to me that my Uber driver is part-time doing organ recoveries. And I think we need to professionalize this.

*Mrs. Lesko. Sir?

*Dr. Cannon. We need to recognize the work that the best-performing OPOs do. Until recently we haven't even been able to know that because the metrics were captured. But now, with the CMS work, we can. And spread the best practices of the OPOs who are out there really doing the job well, and quit shielding the ones who are under-performing. Right now the system is meant to protect institutions, transplant centers, and OPOs. All metrics and all regulation needs to be centered on patients and what's best for them.

The MPSC has had the same problem. They impose metrics

on transplant centers that aren't patient-centric, and they don't -- and they have said they don't have the staff, the time, or the energy in order to investigate every complaint. And that needs to be changed.

*Mrs. Lesko. Thank you.

*Dr. Karp. I'll be quick. People and process. You got to get the right people in place, and you have the right process. And we're working towards that because the day-to-day, minute-to-minute decisions, you can't legislate those. But you have to set -- get the right people in place and get the right process in place so that complaints can be addressed and the system can improve itself.

*Mrs. Lesko. So we have already passed law, and it seems like things aren't changing. And so, I mean, we have funding. We -- but I would hate not to fund something as important as this. So that is why I am trying to get to the root. Like, what do we do next besides complain, have hearings?

You, sir.

*Dr. Roach. So yeah, I would -- I mean, I would just continue to put pressure on both CMS and HRSA, actually, to hold the OPOs and OPTN accountable, make sure the data is being published, everything is transparent. I feel like transparency is very important for this so that patients, our patients and everyone else, can see what's going on.

And I think that -- I just think continued pressure, and also just make sure that they have the funding to have their oversight and continue to be able to hold these organizations accountable.

*Mrs. Lesko. Thank you, all of you. This is very interesting. And I am kind of thinking, like, well, we need to publicize it, but we kind of don't want to publicize it because then we would hurt the number of people that are actually going to donate their organs. So we are kind of -- this is a problem. And I thank you for being here and testifying.

And with that I yield back. Next I recognize Representative Schakowsky for her five minutes of questioning.

*Ms. Schakowsky. Thank you, Madam Chair.

So in Illinois, my state, approximately 28 people die every month who are waiting for an organ transplant, and nearly 4,000 people are on a waiting list in Illinois. And this is a real problem right now for so many people.

I am really glad that the Congress actually took action and passed some legislation that I understand is really just now going into effect and being implemented. And one of the major changes has been to create an independent board of directors. So I wanted to ask Dr. Cannon.

How do you anticipate that this change is going to at

least begin to make the kind of changes that we need?

*Dr. Cannon. Right now it's not, because we have the same people on the board. You have -- as Dr. Karp said, you have to have the right people in, and you have to have oversight. HRSA needs to do their job and tell the OPTN to do theirs.

So we need to start with appointed board members who are patient-centric and do not have significant conflicts of interest, and then it can start to do its job.

*Ms. Schakowsky. So none of this has happened right now. We passed a law, and so far there is no change in the personnel?

*Dr. Cannon. As Mr. Segal noted, no, ma'am. The -- much of the independent OPTN board has previously served in the UNOS and oversight board. The current --

*Ms. Schakowsky. And what would you recommend that we be doing now to move things along?

*Dr. Cannon. We need to be appointing truly independent board members to both the OPTN and the contractor.

*Ms. Schakowsky. Okay. Well, we better get going on this.

I want to ask Dr. -- what is it, Karp -- a question. Where are you? Okay, there you are.

I know that 80 percent of organ transplant patients are in urban areas. And I wanted to ask you, what are we doing

to make sure that we can reach people outside of the urban areas, and make sure that they become eligible and get treated?

*Dr. Karp. Yes, it's such an important question, and it's something that I wrestle with on a regular basis.

We had a transplant center in the eastern part of Tennessee that closed, served a rural population, and that population is highly disserved. And so this has to be part of a national policy that we need to have these smaller centers, we need to keep them open. We need to understand that they're just honestly not going to be able to give the same type of -- the same degree of care, potentially, as a major urban center, but they're very important, and they need to stay open. And that's something that, really, the OPTN and UNOS hasn't given any thought to, honestly. And it's very upsetting.

*Ms. Schakowsky. We need to work on that. Thank you.

Mr. Segal, I wanted to -- I have a question for you. What has OPTN done to protect the privacy of the patients? There was a big breach that happened last year, and there were -- how many thousand -- 1.2 million patients had their information -- was released. So what can we do?

*Mr. Segal. Sure, thank you for the question. And I'll add a little bit of context to what this information is. It includes Social Security numbers, your sexual history, your

mental health history. This is about as sensitive data as you could possibly imagine.

UNOS has been in place as the contractor overseeing this since 1986. There was a United States Digital Service report that was published in 2021 that found enormous deficiencies in UNOS's technology, so much so that the Senate Finance Committee actually wrote to the Biden Administration, urging them to address this as a matter of national security.

And I think the problem is that not only is UNOS, by virtue of their monopoly status, never had to get better or do better, they just aren't the provider to do it, but they have lobbied aggressively against the reforms that would enable competition. And I forget which of my panelists along with me made the point that they've done everything they can to undermine potential competitors, including by making transitions as difficult as possible.

*Ms. Schakowsky. Okay, we have a lot of work to do.

And with that I yield back.

*Mrs. Lesko. We sure do have a lot of work to do.

I would recognize Dr. Burgess for five minutes of questioning.

*Mr. Burgess. Thank you, Madam Chair, and thanks to our witnesses for being here. I apologize for being out of the room for some of this. So if anything I ask is duplicative, I ask your forbearance. We have got three hearings going on

in three different rooms, three different buildings, which is sort of par for the course up here.

Mr. Segal, I appreciate you being here. I appreciate all of you being here, and I appreciate your testimony. Mr. Segal, as I read through your testimony, I mean, some of the most startling allegations that were brought to you by whistleblowers -- and I -- again, I apologize for not being here when you submitted your testimony. But rampant Medicare fraud, unsafe patient care, harvesting of organs from patients who whistleblowers believe would otherwise have survived? I mean, this is all pretty -- really serious stuff that the committee and the agency really should want to drill down on, and I appreciate you bringing these forward. And it has not been without some personal cost to you. Is that not correct? Do I understand that correctly?

*Mr. Segal. Yes, sir. That's correct.

*Mr. Burgess. And there has been -- I mean, you referenced in your testimony that you actually became under some criticism from outside sources who published op eds and suggested that there may be things wrong with you, rather than with the system. Is that a fair assessment?

*Mr. Segal. That's correct. And there have been times when I felt at fear for my personal safety.

*Mr. Burgess. So in light of that, Madam Chair, I -- and it took me some time to find this. It wasn't intuitively

obvious to the casual observer. But I wanted to submit for the record the op ed that was written criticizing Mr. Segal for bringing forward to Congress what I consider very, very serious allegations, and one which this committee, in particular -- I have been on this committee a long time, and these are some of the most serious allegations that I have seen.

Look, we all are concerned about the fact that we can't really pay for all the Medicaid and Medicare that we have promised people. And then you talk in here about rampant Medicare fraud. I mean, we should be interested in that. Every dollar that we spend inappropriately in Medicare, every dollar that we spend that we shouldn't have to spend, there is actually -- because of interest rates being so high, it actually costs a dollar and a half. So, I mean, the problem got magnified over the past several years because of the effects of inflation. But then the damage to patients, the damage to the credibility of the system in which you all work, I mean, that's just -- I almost don't know how you recover from that.

Now, it does seem to me that HRSA seems to pop up in all the wrong places in oversight work that this committee does, whether it be 340B, whether it be Federally Qualified Health Centers. HRSA doesn't really seem to be doing the job of oversight that the agency should. So do you all have any

suggestions for us about how we might -- I don't want to make HRSA overbearing in your daily lives, but at the same time it seems like they need to be doing a better job.

So I will just open it up to the entire panel, starting with you, Mr. Segal, and we will work our way down.

*Mr. Segal. Sure. So I think we've talked through a bunch of the things today that I think HRSA can do, including -- and especially moving to board appointments for the OPTN to get the right people, unconflicted people, in place.

I'll also point out --

*Mr. Burgess. Let me just ask you, is it HRSA that makes the appointments?

*Mr. Segal. So there have never been board appointments. This is a major seismic shift reform that we're advocating for that we think would help durably improve the system, rather than rely on Congress to hold a hearing every time there's a problem.

*Mr. Burgess. Good.

*Mr. Segal. One of the other very important things -- and I'll leave time for the other panelists -- is OPOs -- you had mentioned Medicare fraud, picking up on my mentioning of Medicare fraud.

OPOs are one of only two major programs left in health care that operate on what's called a cost reimbursement basis. They're essentially fully reimbursed for all costs,

even costs unrelated to patient care. And even if a provider is very poorly managed -- most of health care used to work this way, you probably know this, we moved away from it in most other places because there was a lot of Medicare fraud, and we have left OPOs with this system, and I think we need to move away from it.

*Mr. Burgess. Dr. Cannon?

*Dr. Cannon. You have some very good and dedicated people within HRSA who want to make this reform work, but they're being hindered by others inside the agency. So find those who want change, empower them, and clean house with the ones who don't.

*Dr. Karp. Having served on the board, I can say that my feeling was always that HRSA was just overmatched. You have 40 board members, you have a multi-million-dollar organization basically dictating to one or two regulators what the policy should be, and they were just overwhelmed.

*Mr. Burgess. I see.

Mr. Roach, Dr. Roach?

*Dr. Roach. And I'd just say quickly I agree with everything they said. There's dedicated people in HRSA. Make sure we support them, give them the oversight.

And also, just transparency, transparency, transparency. That's one of the things that we want for our patients.

*Mr. Burgess. All right. Well, it is just criminal

that organs are not being used when the waiting lists are so long, and then we all know that lives are lost.

So thank you, Madam Chair. I will yield back.

*Mrs. Lesko. Yes. And without objection, your article will be recorded.

[The information follows:]

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

*Mrs. Lesko. And now I call on Mr. Tonko for five minutes of questioning.

*Mr. Tonko. Thank you, Madam Chair, and thank you to the witnesses for being here today.

I am glad the subcommittee is holding this hearing, because the OPTN system is too important for so many people to tolerate persistent inefficiencies. For many it is a matter of life and death. The transplant waiting list has more than 100,000 patients, and studies show that the number of available organs is likely much higher than the number procured for transplant.

One of my constituents, Keith Plummer from Saratoga Springs, New York, shared this, and I quote, "There is nothing more disheartening than to be called for a transplant and have it canceled due to complications. We want -- we went through this three times when UNOS changed boundaries for centers to draw organs. This dropped me from top 3 on the list down to 180 to 200. This drop translated into adding about four years to my waitlist time. That is when my daughter stepped in and we did the paired exchange to get me a kidney. Under the old system we lost about 20 percent of the kidneys harvested, but with the changes that number appears to be dropping. With the new system patients have much more transparency as to how the list works and where they stand on it. These are little things, but so important

when waiting for the gift of life."

So Dr. Karp, what are the major challenges to procuring enough organs to meet the needs of transplant-eligible patients?

And how can we begin to address some of those given challenges?

*Dr. Karp. I think there are two major issues. One is the performance of the Organ Procurement Organizations. And as we know, as you have quoted the research, there are many more organs out there. We need to find them. We need to hold the OPOs accountable for getting them.

The other piece is on the discards. And so the discards are tricky because I don't want a regulator getting in -- somebody other than a physician getting involved in that very personal decision between the doctor and the patient about whether or not to accept an organ. But there are centers who routinely will use organs that are, let's say, have higher risk. And those centers need to be preferentially offered those kidneys. Right now there's a list of 100 centers every time there's a kidney available. And the OPOs have to go through every one of those centers to get a decline, knowing that most of those centers would never use a kidney like this.

And so the efficiency in the system is something that needs to be addressed, and we know how to do that. We just

have to do it.

*Mr. Tonko. And Dr. Karp, how could more timely and better information for health care providers and patients minimize inefficiencies or waste in the system?

*Dr. Karp. I can tell you just about a month ago that I had accepted a liver from Chicago, and was told the organ was going to get there at a certain time. And I'm waiting and waiting and waiting, and the organ doesn't show up. It doesn't show up. And I call up and they say, "Well, the courier never showed up.''

I said, "Well, what are we going to do now? Well, we'll find a new courier.'' That was three hours later. So I think as was mentioned by -- maybe by Ms. Castor that we have -- we can find out where our socks are, but we don't know where our kidneys are, that's crazy.

*Mr. Tonko. Okay, and I thank you for the answer.

I am also interested in how communication and coordination with patients can be improved. So Dr. Roach, what do you hear about patients' typical experiences trying to access information about their health care from the OPTN network?

*Dr. Roach. I mean, I think that there's very little communication between the networks and the actual patients. Like I said before, we have patients have organs declined on their behalf. They have no idea that that's happening. And

I just think that more transparency would allow for a better conversation between a physician and a patient. They could talk about what types of organs they're willing to look at, they can go maybe look at other centers. And I just think that the transparency is so important to having honest communication between a physician and the patient.

And then also, I just think that we just need to make sure that, yes, we want efficiency in the system to make sure that organs are getting transplanted, but we want to make sure that we also just monitor that to make sure that certain types of patients aren't being disadvantaged by taking order -- allocations out of sequence in order for -- in order to increase efficiency. We definitely want more organs transplanted, but we just want to make sure that it's done in a transparent manner, and that there's data on the types of people that are getting transplants.

*Mr. Tonko. Well, I understand it is difficult for many to navigate the current organ transplantation system, especially those who are suffering from organ failure. But Dr. Roach, what are the specific challenges in keeping patients informed about their eligibility status or updates on their waitlist position?

And how can a reform system overcome those challenges?

*Dr. Roach. Well, I think that some of the challenges are means of communication. I think some patients -- I think

we have to use different types of technology to make sure that we have patients able to access their information. I think we need more communication. I think we need more frequent communication. Sometimes it's hard to get patients to come in to talk about it.

And so I think just being able to reach out more, some patients have -- are able to look at their computer, some patients aren't, and things like that. And so I just think that more frequent communication, more transparency is what's helpful.

*Mr. Tonko. Thank you so much.

And Madam Chair, I -- oh, Mr. Chair now -- I yield back, but also would express to the subcommittee that I hope we can move the Charlotte Woodward Organ Transplant Discrimination Prevention Act, which is incredibly important to many. Thank you --

*Mr. Griffith. [Presiding] I thank the gentleman --

*Mr. Tonko. -- and I yield back.

*Mr. Griffith. -- and now recognize Mr. Palmer for his five minutes, and have to say a public thank you. He let me go in front of him on Energy, which allowed me to get my questions done and get back up here. So thank you, sir.

*Mr. Palmer. It has been a busy day, Mr. Chairman.

*Mr. Griffith. It has been. Yes, sir. Thank you.

*Mr. Palmer. So I appreciate the witnesses being here

this morning.

I have got some concerns about the oversight and accountability for the Organ Procurement Organizations and, Dr. Cannon, in particular, in regard to the impact on rural communities.

You are -- you have done a great job at the University of Alabama Birmingham, and I appreciate you being here. But do you have any insights into what we could do to improve oversight and accountability?

*Dr. Cannon. We need to start by recognizing that these people exist and are important. I mean, people from rural areas, rural states like where you and I are from, have routinely been dismissed. They've been called "imaginary patients.'' The MPSC once voted to change its charge to include taking care of patients who have not made the waiting list, but all patients with organ failure. They voted unanimously to approve this, and were then told by the board that they couldn't do it, and they had to revote.

You need a system that recognizes all patients with organ failure to start because, really, those most penalized and facing challenges in access to the waitlist are rural patients.

*Mr. Palmer. Do we -- what is the situation in regard to the availability of organs?

Do we have enough organs available to meet the needs of

the population, whether it is urban or rural?

*Dr. Cannon. We don't have enough organs available right now. Through the use of new technology and also improvements in OPO performance, I think we could. We need to support new technologies like normothermic perfusion. That's greatly increased access for our patients. And we need to stop having allocation policies written by special interests that favor larger urban centers.

*Mr. Palmer. When you say that the policies are written by special interest groups, is there a role for Congress in addressing that?

*Dr. Cannon. Yes, there is. The role, I think, would be to make sure the board is independent and not driven by special interests, as I believe we've all said up here so far. Yes, sir.

*Mr. Palmer. Yes. Well, I grew up in Hackleburg, Alabama. I don't know if you have ever had a patient from Hackleburg. And I am a potential organ donor at some point at the end of my life. And I would like to think that there was no politics, there was no special interest, that if someone from where I grew up needed an organ they would be able to get it, that their probability of survival would be as good as anybody else.

And I do appreciate what you are doing through the University of Alabama.

Dr. Karp, Federal authorities are actively investigating OPO organizations in at least five states, and one piece of the investigation appears to be whether any of the non-profit OPOs have violated the Federal False Claims Act by knowingly billing Medicare for unallowable costs. And this is a big issue with me, because we are sending out about $100 billion a year in improper payments on Medicare alone, and another 50 billion on Medicaid. How does this fraud affect patients, and what does the OPTN do to prevent fraudulent claims?

*Dr. Karp. I can't comment on this particular case, but of course the -- I can't comment on this particular case, but, of course, taking money out of the system is a disaster. These transplants are expensive. They save an enormous amount of money, I would mention, compared to dialysis, a kidney transplant for example. But taking money out of the system and -- is terrible.

*Mr. Palmer. I think this is something, Mr. Chairman, that we need to look into again, and follow up on this.

Mr. Segal, given your advocacy for transparency and equal access in organ procurement system, how can the modernization initiative specifically address disparities that rural patients face in accessing organ transplants?

And what role should accountability and transparency play in ensuring that treatment for all patients, regardless of where they live?

And is there -- and do you have any recommendations for Congress? I mean, that is why we are here discussing this with you guys.

*Mr. Segal. Yes, thank you for the question. I'll pick up on something that Dr. Karp said in his opening testimony.

There are enough organs available, theoretically. Certainly not currently actualized by the current system, but theoretically, to eliminate the waiting list for every organ category other than kidney. But what we -- and to -- it would significantly decrease the need for kidney transplants.

The best way to address inequities is to increase the pie. There are enough organs for all of the patients, other than for kidneys, and we need to stop getting in fights over who has access to them, but make sure there are enough organs available for all of them.

And the biggest choke point has been the complete failure of CMS to regulate and oversee OPOs to ensure that they are capturing anywhere close to the potential of the organs that are available.

*Mr. Palmer. Mr. Chairman, this -- it is really disappointing to me, considering the loss of access to health care in rural areas, and then you compound that with, I think, the prejudice that exists in organ transplant opportunities. So I think it is something that we need to continue to look into.

And again, I thank the witnesses for being here, and I yield back.

*Mr. Griffith. I thank the gentleman for his comments and his questions, and now recognize Dr. Ruiz for his five minutes of questioning.

*Mr. Ruiz. Thank you, Mr. Chairman.

Access to health care in our country continues to be plagued by economic, racial, and geographic disparities. Unfortunately, this is also the case with the Organ Procurement and Transplantation Network, or the OPTN.

Marginalized patient populations faced increased barriers to access to the National Organ Transplantation System. For example, according to data from the Health Resources and Services Administration, in 2020 about 30 percent of Hispanic patients on the waiting list received organ transplants, compared to 48.8 percent of White patients on the list. Additionally, White patients were much more likely than Black patients to receive an organ transplant from a living donor.

Dr. Roach, the Kidney Foundation has actively promoted equity in kidney care. What are some of the specific obstacles that patients of color face in the transplant process that lead to these disparities?

*Dr. Roach. So there's a number of -- so you mentioned the decreased transplantation. But I would say that even

getting to the waitlist and getting referred to a transplant center. There's significant data showing that Black and Hispanic patients aren't referred as -- to transplant centers at a high level. So just getting on the waitlist is the first obstacle.

And then, once they're on the waitlist, you're right, they get transplanted at a lower rate. There's been efforts to try and change that, but we don't think there's been enough. We don't -- and we think that more has to be done to encourage that.

I think one of the ways to do that is to increase organ donation from Black and Hispanic donors. I think that a lot of times the OPOs have been overlooking those potential donation possibilities, not approaching patients, not -- again, not maximizing the amount of organs that we get.

And then I also think -- this isn't specifically about this, but I think that one of the things that we espouse is living donation, and that we encourage and -- Black and Hispanic patients donate at a lower rate for living donation, too. Living donors, kidneys typically last longer because a lot of times they're related to the patient and they're also living.

But there's lots of barriers for patients -- for donors to be able to give that gift of life to someone they know or to someone they don't know in an altruistic thing, lost

wages, transportation. And we need to support that, too.

*Mr. Ruiz. How about in rural communities, regardless of race, what are the barriers there?

*Dr. Roach. So rural communities are -- you have to transport yourself to a transplant center. It's difficult.

*Mr. Ruiz. Is OPTN well represented in rural communities?

Are they even seeking to recruit potential organ donations in rural areas?

*Dr. Roach. I think that it has been -- it has not been an area of focus in the past. I think that -- I think it could be improved. So, yes, I definitely think --

*Mr. Ruiz. In your opinion is more data needed to measure the impact of these disparities on patient care?

*Dr. Roach. Yeah, we're always in favor of more data, more transparency.

I do think that, as we implement these changes, we need to make sure that we're evaluating them for the effect on marginalized populations, whether they're Black, Hispanic, rural patients. Pediatric patients are another area that we need to make sure -- because they have specific needs.

So more data, and we need to be monitoring this closely as these changes are made.

*Mr. Ruiz. Okay. How about internet connectivity and other factors for rural areas?

*Dr. Roach. So we believe that Internet connectivity is a very important aspect to receiving care. It improves the ability to get telehealth, it improves the ability to communicate about your status on the waitlist. So I think it's essential that we are ensuring that these people are getting access to broadband. We think telehealth is the way to improve care and to reach more populations and have them more -- have access to all types of care, including transplant.

*Mr. Ruiz. As part of its modernization initiative, HRSA has announced that it has begun requiring data reporting on demographic-specific outcomes in an effort to boost accountability and enable more equitable practices that better serve all patients.

Dr. Karp, what specific steps should HRSA take to make sure that a reformed OPTN is properly equipped to address health disparities and inequities?

*Dr. Karp. Yes, so I'll say that the OPTN UNOS made a decision probably a couple of years ago that they were going to look at equity to transplant access as after you got onto the list. As my colleagues have said, that's absurd. And so you need to understand that that is not what equity is.

And then the data, the data, the studying and making sure that there is actually access, equal access, which right now there is not.

*Mr. Ruiz. Okay. Well I appreciate it, and I yield back my time. Thank you.

*Mr. Griffith. The gentleman yields back. I now recognize the gentleman from North Dakota, Mr. Armstrong, for five minutes of questioning.

*Mr. Armstrong. Mr. Segal, you come from a patient family. Can you tell us why so many patient safety lapses are never reported to the OPTN?

*Mr. Segal. I think the biggest issue is that whistleblowers rightfully have no confidence that the OPTN would do anything with allegations that are brought to them. And I have a lot of friends who have tried to bring allegations and have suffered severe retaliation.

*Mr. Armstrong. What kind?

*Mr. Segal. I saw career-limiting and, in some cases, career-ending. I have a very good friend who brought a claim to the MPSC about -- MPSC being the body that is supposed to evaluate this -- about inappropriate practices by two surgeons. They were pushed out of their job shortly after making that claim. And then, within just a few weeks, the two surgeons about whom he brought that claim were promoted to serve on the MPSC. And people see this happen and decide it is not worth it to bring the claim next.

*Mr. Armstrong. What is the OPTN's whistleblower protection policy?

*Mr. Segal. So the OPTN recently finalized their first-ever whistleblower protection policy, and they have celebrated it as a win. But what it does is it protects the OPTN, rather than protecting the whistleblowers.

And I'll just bring this into Technicolor. If you bring a claim to the OPTN, it is reviewed by the OPTN president. That is currently Dr. Rich Formica. Dr. Rich Formica has been --

*Mr. Armstrong. He refused to testify today, right?

*Mr. Segal. He had something more important to do today, apparently.

He has been written about in investigative journalism as having been one of the perpetrators of retaliation. So if I were going to bring a claim to the OPTN about being retaliated against, it would be reviewed by the person who's leading the retaliation. This is absurd, to use Dr. Karp's word.

*Mr. Armstrong. And we have serious witnesses, this is a serious hearing, this is a serious committee. And we can talk about efficiency in the system, transparency of the process, you know, interagency coordination, better data management. But we are kind of burying the lead here a little bit.

I mean, we have -- and to be clear, these are allegations. But, like, we have allegations of overdoses

being treated as heart attacks, people being wheeled in while they are still alive. You said you fear for your public -- you, like, fear for your physical -- like, I travel back and forth to North Dakota a lot. And the one thing I don't do is work on airplanes. So I read fiction novels and watch, like, streamed movies. Like, this -- like, these things are -- like, it is like a bad Netflix movie.

And I mean, do we think -- I mean, these are -- and again, I want to be clear, I spent 10 years of my life in a courtroom. Allegations are not proof. I mean, we know all of that. But do we think these are isolated -- is it possible this stuff is actually happening?

*Mr. Segal. I will say the Washington Post earlier this year ran a front page story. The Department of Justice doing is doing a sweeping investigation into the organ donation system.

I think one of the frustrations that I've had, candidly, over the last 5 years, 10 years doing this advocacy is that this has been viewed largely as a policy problem. And I think this is a problem of systemic corruption which is enabled by monopolism and opacity.

*Mr. Armstrong. So why the corruption? I mean, like, I understand the framework in which it can occur. What is the motivation?

*Mr. Segal. There was a -- there was a two executives

from the -- actually, the Alabama OPO that were sent to Federal prison in 2012 for 14 months for a kickback scheme with a local funeral home. The whistleblower, actually, CBS news did a story about him. He said that he and his threatened -- and his parents were threatened with being "cremated alive.'' The OPO executive who was sent to Federal prison -- this is from memory, this is directionally right, it may not be the exact words, but he said, "There's too much money and there is too much unregulated in the system.''

As I mentioned to Congressman Burgess, OPOs are one of the only systems left in -- programs left in Medicare that operate on a cost reimbursement basis. They have unlimited taxpayer resources, and OPO executives do not have to disclose if they have financial interests in any of the ancillary businesses OPOs participate in, which is tissue banks, tissue processing. You know, they recover skin, eye, tissue, bones. I think it's unfortunate they're called Organ Procurement Organizations when they recover all of these things. And they do not have to disclose if they have a financial interest in any of the ancillary businesses.

*Mr. Armstrong. So the motivation is money.

Look, we do this a lot. We could talk about increased efficiencies, transparency, you know, data management, and everybody is there. There is some times where we can do things and tweak things and make it better. And there is

sometimes we need to tear things down to the studs and rebuild it.

And Dr. Cannon, you have been just watching, and it is like -- you get 22 seconds. What do we do? Like, this is bad.

*Dr. Cannon. You do just what you said. You tear it down to the studs and rebuild it.

*Mr. Armstrong. Like, increased efficiency isn't solving this problem.

*Dr. Cannon. No.

*Mr. Armstrong. Better data collection amongst agencies isn't solving this problem.

*Dr. Cannon. We need all those things. We need the transparency.

*Mr. Armstrong. Well, for sure.

*Dr. Cannon. But the system needs to be rebuilt from the ground up. We've got a 40-year-old system that really hasn't changed.

*Mr. Armstrong. And obviously, motivates bad actors to do really, really bad things in some of the most helpless situations patients and families could find themselves in.

I yield back.

*Mr. Griffith. The gentleman yields back. I now recognize Mrs. Cammack for five minutes -- her five minutes of questioning.

*Mrs. Cammack. Well, thank you, Mr. Chairman. Thank you for our witnesses for appearing before us today. So much that we could dig into. And I want to thank my colleague from North Dakota for basically teeing this up.

So, according to HRSA, 17 people a day are dying waiting for an organ transplant. But of course, this number fails to represent those individuals who were never allowed on the waiting list to begin with. So I know we have been in and out a little bit today, but I think this is something that should be addressed, and that is, for those patients that have disabilities -- and I had a particular situation in my district with one of my constituents, Zion Sarmiento, who was born with Down syndrome, and he was desperately in need of a heart transplant, but was denied by several hospitals citing directly and indirectly that his intellectual disability devalued his life. He passed away at less than four months old since he was denied a heart transplant.

This legislation is about holding the transplant system and its participants accountable to the American people where it serves, but we can't forget those that are also left behind in the process. So I would strongly urge my colleagues to support final passage of the House bill to end discrimination based solely on a disability, the Charlotte Woodward Organ Transplant Discrimination Prevention Act, which passed out of this committee earlier this year by

unanimous vote.

And I am going to start with you, Dr. Cannon. In 2019 the National Council on Disability released a report on organ transplants and individuals with disabilities which found that people with disabilities are frequently denied access -- and that is a nice way of putting it -- denied access to organ transplants based on transplant centers' written and unwritten policies excluding people with disabilities as candidates, and in some cases just outright refusing to evaluate a patient's medical suitability for organ transplants because of their disability. Does your transplant center or hospital have a non-discrimination policy that explicitly covers individuals with disabilities?

*Dr. Cannon. We don't have this policy explicitly, but I can tell you we will bend over backwards to do everything we can for a patient with a disability.

You know, the issues at play is we want to make sure the patient is going to be able to take care of themselves, that they have the support in place, and we want to make sure that we do that. We have extensive social work support to help patients provide support for themselves. So yeah, we are 100 percent built around trying to help patients overcome the many barriers they face in --

*Mrs. Cammack. But, Doc, why don't you have that policy?

*Dr. Cannon. You know, we probably should have the policy written down. We don't have it written down because it's what we do day to day, and we believe in it. So I guess we haven't felt the need to write it because we do it. But you're right, that's an oversight. We should.

*Mrs. Cammack. I would encourage you to do it. Would you commit right now to actually putting that policy in place?

*Dr. Cannon. Absolutely.

*Mrs. Cammack. I think that the parents of Baby Zion would feel better knowing that there was some progress in Washington being made on this. So I thank you for your commitment to that.

Dr. Karp, same question to you.

*Dr. Karp. Yes, I can tell you that I personally performed a combined heart-liver transplant in a patient that had Down syndrome, and I'm very supportive of this. I think our overall institutional policy is not to discriminate on the basis of disability.

*Mrs. Cammack. Is it a written policy?

*Dr. Karp. I'm sure it is a written policy. I can get it to you. I can't remember the last time I actually saw it, but I would be shocked if that wasn't a written policy of the of the university and the medical center.

*Mrs. Cammack. Okay, all right. Well, I would

appreciate you following up on that.

And I want to turn to a Florida-specific issue. Now, more than 5,000 Floridians are currently on the waiting list for an organ transplant, and 48 of them die every month. As we are hearing this, death is not because American organ donors aren't stepping up -- they certainly are -- but because of the failures of the taxpayer-funded contractors. Last month there were particularly alarming reports in Vox highlighting the over 3 years, 7,000 American -- that over the last 3 years, 7,000 Americans' pancreases, the organ that produces insulin, have been cut out from generous American organ donors, and the Federal Government does not know where they went. This seems to be a chronic repeating issue in the Federal Government.

Now, this week I received a letter from a Florida woman who has been waiting four years for a pancreas transplant. You can imagine her horror when she reads reports like that, that the government has lost 7,000 pancreases. So we know that they are getting stuck in a freezer, but then we can't find them. This is absurd.

Dr. Karp -- Mr. Segal, actually, you testified that many whistleblowers have come to you. Have you heard about this practice?

*Mr. Segal. Yes, ma'am. And actually, I've shared with this committee a picture that I received from a whistleblower

at an OPO, which was boxes of pancreases just sitting in freezers. And I can tell you whistleblowers at that OPO -- CMS tells OPOs that they need to recover pancreas for research. They haven't defined "research.'' The joke at that OPO is that they're conducting research on the efficacy of garbage disposal A versus garbage disposal B.

*Mrs. Cammack. Wow, that is disgusting.

*Mr. Segal. I agree.

*Mrs. Cammack. Dr. Karp, I have follow-up questions, but I will submit them in writing and would appreciate a response.

[The information follows:]

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

*Mrs. Cammack. Thank you, Mr. Chairman. My time has expired, I yield.

*Mr. Griffith. I thank the gentlelady for yielding back. I now recognize the chairman of the Health Subcommittee, Mr. Guthrie, for his five minutes of questioning.

*Mr. Guthrie. Thank you very much. I appreciate the recognition. Thank you for you all being here. This is very serious, the situation.

I can give you a couple of examples I personally experienced. My mom had end stage liver failure at Vanderbilt, and had great care, just had end stage liver failure, but she was called for a transplant. And it is interesting to -- when you don't know what that situation is. The surgeon actually saw us in Nashville -- I live in Bowling Green, so I am an hour away -- and was going to get on an airplane and fly to Chattanooga and harvest the liver and bring it back -- I hate to use the word "harvest,'' that is what people use -- and he got there and said the liver wasn't as good as he thought it was. So my mom was actually wheeled into surgery and came back. You know, she never got taken care of and, unfortunately, didn't get called again for a liver. So -- but that experience.

The other one, I have a good friend of mine in Huntsville, Alabama, from Birmingham, who was in a car wreck,

50 years old. You wouldn't know he had a -- he didn't have a scratch on his body, and -- but his family decided that they were going to give his organs, which they should have done, I am glad that they did. And he was probably kept alive for a couple of days until all the planes were flying into Huntsville to take care -- to help people survive. And so it is important what happens.

But so Dr. Cannon and Dr. Karp, I know there has been some references here, and people call us, you know, after we know this hearing is going to happen, and just -- the two of you, since you are transplant surgeons, what -- who determines when somebody is clinically dead, where they can donate organs?

And how is that -- how do you -- I mean, you hear some things -- hear stories that people were clinically dead and they weren't, but how do you -- who verifies that, and how do you verify that, and what's the criteria for that?

Dr. Cannon and Dr. Karp?

*Dr. Cannon. Typically, each state will have a Determination of Death Act. They tend to be sort of based on a uniform determination of death. Most donors are declared brain dead. So there are specific criteria that came out of the Harvard Commission back in the 1980s. This will generally involve a clinical exam by two independent physicians.

Generally, if I'm going to be involved in a donor -- and most other surgeons I know, as well -- we'd like to see a -- what's called a confirmatory test, so not dependent upon a doctor or something, what's called an apnea test, or perhaps a study showing no blood flow to the brain.

That policy is not uniform across states, whether a confirmatory test is required. But that's who initially makes the determination of death.

*Mr. Guthrie. Dr. Karp?

*Dr. Karp. Yes, and then that -- so that irreversible cessation, so lack of blood flow to the brain is one criteria. The other one is irreversible cessation of cardiac arrest and respiratory function. And so that first one, the first brain death criteria, is usually made by tests and studies. The second determination can be sometimes made actually in the operating room, when the patient has decided to do a donation, they go to the operating room with -- support is withdrawn, and then a physician at the bedside makes a determination that cardiorespiratory failure has occurred, and then the patient is declared dead, and then the organ procurement occurs.

*Mr. Guthrie. Okay. So Dr. Cannon, you said two independent. Is -- that is Alabama's law, two independent -- independent of what? Like, it is not the transplant surgeon that makes the decision?

*Dr. Cannon. No, sir. They're completely uninvolved. So they don't work for the OPO, they don't work for the transplant center. In fact, by law, they really should have nothing to do with the organ procurement. So it tends to be probably the doctor taking care of the patient and then brought in another as a consultant when declaring brain death. It's usually a single physician for the donation after cardiac death that Dr. Karp referred to.

*Mr. Guthrie. So what does the Organ Procurement Organization have to do with the declaration of death?

*Dr. Cannon. Really, nothing. They should not -- they take over the patient's management once they are declared brain dead, or they take over the patient once they are rapidly declared dead by cardiac means. But really, the OPO is not the one determining death.

*Mr. Guthrie. Dr. Karp, in Nashville?

*Dr. Karp. That is, in fact --

*Mr. Guthrie. I don't think your microphone is turned -- yes, there you go.

*Dr. Karp. So that is, in fact, true. In practice what happens is that, once the brain death is -- occurs, the care of the patient then is overtaken by the OPO. And so if there were to be something where a patient would mouth something or move a foot or something like that, which does happen, it's the OPO representatives who are with the patient at that time

that really need to let people know, hey, something's going on here, and then we have to go back to the drawing board, basically, start all over again.

*Mr. Guthrie. Okay. So you are saying there could be an incidence where, after all the declaration, that somebody for some reason isn't technically dead or --

*Dr. Karp. Yes. So I want to make it clear that that's very, very rare. But there are times when we feel that a patient is dead, and something happens that makes us wonder about that. And if I'm doing the donor or if one of my colleagues is doing the donor, everything stops immediately. If anybody says, "Wait, I'm uncomfortable with this,'' everything stops. And I have personally made sure that that happens. My colleagues do the same thing, and everybody in our group does exactly the same thing.

*Mr. Guthrie. Okay. Well, thanks. So I didn't realize that. So I appreciate your testimony. I have about 10 seconds left, so I will yield back and thank you for your testimony.

*Mr. Griffith. I thank the gentleman and now recognize Dr. Bucshon for his five minutes of questioning.

*Mr. Bucshon. Well, thank you. Thanks for allowing me to participate in this hearing.

I was a cardiothoracic surgeon prior to coming to Congress. I didn't do transplants, but I did my residency,

of course. I am a proud sponsor of H.R. 2544, along with my colleague, Robin Kelly, the Securing the U.S. Organ Procurement and Transplantation Network Act. And I was thrilled when it was signed into law.

Getting legislation through Congress isn't easy, but this is transformational. I really believe that. Well, it is an accomplishment we are celebrating. The job of Congress doesn't end when a bill becomes law. In fact, in many ways it starts. We then have to have the responsibility to ensure the law is implemented as intended.

I want to express my appreciation for the people at HRSA for the work they are doing on implementing -- implementation of the law thus far. It is a difficult job. Modernizing a system that has been in place for four decades is tough, and I have had multiple conversations with HRSA administrator Carole Johnson, and her staff has been available to answer questions about their process.

It is unfortunate they wouldn't make themselves available to provide updates on their work for us here today for procedural reasons, and as this is a hearing for Congress to learn about how HRSA is working to implement the law, it would have been ideal to have them here. And even though I won't be here next Congress -- I am leaving Congress -- it is my hope that the subcommittee will hold another oversight hearing and ensure that HRSA testifies.

In the meantime, stakeholders have thoughts about how things are going, and they do play an important role. The OPTN was, after all, always intended to be a public-private partnership that promotes organ transplantation, as President Reagan highlighted when the National Organ Transplant Act, or NOTA, passed in 1984.

So Dr. Karp, some of this has been asked, but I am going to dig deeper. There has been a lot of discussion among stakeholders about the need for the OPTN board to be "independent.'' What is the -- what does board independence mean to you?

And what types of people specifically and what professional backgrounds should they have to be on this board, in your opinion?

*Dr. Karp. This is a very complex space, and the experts need to be highly involved driving the policy, and they need to make policy recommendations.

But there has to be governmental oversight. We have seen what happens when there is ineffective government oversight. That's what's gotten us where we are today, which we all, I think, agree is a disaster.

So there needs to be -- the policy-making needs to be -- needs to come with direction from government, with direction from HHS, with direction from HRSA. It needs to be made within the community, and it needs to go back to HRSA and

back to HHS to make sure that that, in fact, is policy consistent with the national need.

*Mr. Bucshon. I mean, is HRSA making any progress on that issue at this point?

*Dr. Karp. You know, they're -- I believe they're trying. I think it's a tall order.

I think the first thing, as we've talked about, is replacing the people. Without replacing the people, this is going to fail. And so I would encourage HRSA to commit to replacing the board with people that are reform-minded, that understand the issues with the system.

*Mr. Bucshon. Right. Dr. Cannon, can you go into more detail about specific modifications you believe are necessary for NOTA to result in impartial, data-based, transparent policy?

And I know we have talked about some of it, but if you have some things that you haven't been able to say in that vein, please give us your comments.

*Dr. Cannon. You need to allow HRSA to actually collect the data themselves, and not be dependent upon the OPTN to provide it for them in their oversight of them.

And I really think the metrics by which centers in particular are measured need to be aligned with patient interests. Right now, for example, there's kidneys that are definitely going to be associated with better survival than

dialysis. But transplant centers can't use them. That's why they're discarded, because you'd be flagged by the MPSC for the outcomes, because we're not comparing transplant to the alternative, which is lack of a transplant. We're comparing it to other centers with very highly, highly selected patients. There's more patients out there we can transplant.

*Mr. Bucshon. Yes. I mean, in my experience in medicine in general, right, there is -- it is all -- there is always risk-benefit, right? And if you don't balance those two, if you only consider risk and you don't look at the benefit side of this, even though the benefit may not be 100 percent perfect -- nothing in medicine is 100 percent, as we all know. So I understand where you are coming from on that, and I think we need to do better.

I do want to close on a -- with a message of hope, though. I think we all share the common goal to use the Organ Procurement Transplant Network to save lives, right? We all see the potential that organ donation provides to humanity as a whole, and we see opportunities to create a system that allows every donated organ to save a life. We should have really minimized the waste of organs that are not transplanted, even ones that might not be perfect but may be better. I am confident that those who volunteer their time and effort to advocate for transplant issues do so because they see the potential and the opportunity exists.

The United States is home to some of the greatest transplant surgeons and transplant hospitals in the world. Furthermore, we need -- we innovate like any other nation in the world. I strongly believe that. And so I encourage each of you to keep in mind as you go about your work and continue to be involved in advocacy. We must work together to harness this potential.

You can tell this is an issue for me, very emotional. It is about patients, right? It is about people. And we need to do better.

I yield.

*Mr. Griffith. The gentleman yields back. I now recognize the gentlelady from Michigan, Mrs. Dingell, for five minutes of questioning.

*Mrs. Dingell. Thank you, Mr. Chair, and thank you for allowing me to waive on. And I want to thank Dr. Bucshon for his leadership.

And I promise you that we are going to stay on it and get your advice -- as he is leaving. We need his advice. He cares a lot about this.

I am having a hard time understanding why Organ Procurement Organizations in our country are being maligned when they have, in fact, increased the number of organs made available for transplant for the last 13 consecutive years. In fact, according to the Organ Procurement and

Transplantation Network data, the number of deceased donors has grown by 52 percent over the past 5 years, but the number of transplant recipients has only grown by 26 percent over that same period. And I am disappointed that an IPO is not being represented today. They are a critical link in our country's organ donation and transplantation system.

And look, we want to keep this safe. We all do. We all -- and there are a lot of good, well-intentioned people. So we have got to understand the system. But I believe, like the doctor does, with hope, and that there are more good people with good intentions than there are evil.

Gift of Life Michigan is the OPO that serves my district in Michigan, and I met with them last month, as did all of my state legislators. And the state legislators and I meet with them regularly, as does my staff, asking questions, giving oversight, probably, in some ways trying to understand issues. Gift of Life recovered 1,372 organs in 2023 that were transplanted, which is an increase from the 1,050 organs that they transplanted in 2022.

At a national level, Congress and the Administration continue to take significant action to reform the OPTN and modernize its operations to best serve the needs of patients. From the passing of -- Dr. Bucshon just talked about -- of the bipartisan Securing the U.S. Organ Procurement and Transportation Network Act to Health Resources and Services

Administration, HRSA, implementing reforms in conjunction with its Organ Procurement and Transplantation Network Modernization Initiative -- these are mouthfuls -- announced in March 2023, and they have been soliciting stakeholder feedback throughout the process. The five areas of focus for the initiative are technology, data transparency that you have all talked about, governance, operations, and quality improvement, and innovation.

In March 2024 Congress passed and President Biden signed into law a funding package that included an additional $23 million for the HRSA OPTN Modernization Initiative. And it is important that adequate resources for the program to -- are there to ensure that HRSA can fully implement the reforms mandated by Congress, correcting the inefficiencies and mismanagement that you all have talked about for OPTN that have persisted for decades. We have got to keep working together because we all have the same goal.

Having said that, I am going to transition to a specific transplant issue that I have been hearing about as I talk about this regularly -- to supplemental oxygen as these patients have reached out. I have heard from physicians at academic institutions who work on transplant teams that access to supplemental oxygen has become a barrier to appropriate medical care for patients awaiting lung transplantation. Some patients who are awaiting a lung

transplant were unable to make physician visits due to flow rate and portability problems with their oxygen, essentially preventing them from being candidates for a lung transplant.

Dr. Karp or Dr. Cannon, but any of you who want to answer this, are you aware of challenges that access to supplemental oxygen is causing Medicare beneficiaries awaiting lung transplants?

*Dr. Cannon. I mean, as a liver transplant surgeon, I unfortunately have no idea. I can't answer your question. I'm sorry.

*Dr. Karp. I'm also not aware of that.

*Mrs. Dingell. So nobody. Any of you? Okay. That is a problem, too, because I have heard it at three different places.

So we have got to keep working on all of this. Thank you for all your time and work on these important issues.

And Mr. Chairman, I will yield back the balance of my time.

*Mr. Griffith. The gentlelady yields back.

If you don't object, I am going to just -- I am going to throw this out there. I will follow it up with a question for the record.

But I mentioned in my opening that if we can track a pair of socks sent by Amazon, we ought to be able to track the organs. And while I was sitting here I thought about the

mussels in one of my rivers back home. We have a diversity of mussels, and some of them are as small as about half the size of my pinkie, the spats, and they mark those with an electronic marker. I am just curious. What would be the problems with doing that with organs so they don't end up in a freezer not being used? Because once you mark them and you put them into that computer system, then we would have a national system of tracking where these organs are.

I will get the answer later. I just want to throw that out there because I figured trying to put that into a question form, if you didn't know what I was asking, would be hard.

[The information follows:]

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

*Mr. Griffith. I appreciate it.

Seeing there are no further members wishing to ask questions, I would like to thank our witnesses again for being here today. I appreciate your time.

I ask unanimous consent to insert in the record the documents included on the staff hearing documents list.

Without objection, that will be the order.

[The information follows:]

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

*Mr. Griffith. Pursuant to committee rules, I remind members they have 10 business days to submit additional questions -- that would be the questions for the record -- and I ask that the witnesses submit their responses within 10 business days upon your receipt of those questions.

Without objection, the subcommittee is adjourned.

[Whereupon, at 12:35 p.m., the subcommittee was adjourned.]