

Responses to Questions for the Record:

**Questions 1-5 from The Honorable Chair Cathy McMorris Rogers:**

**1. Dr. Roach, the Securing the U.S. Organ Procurement and Transplantation Act aims to foster competition by allowing the Health Resources and Services Administration (HRSA) to select the best contractors for the Organ Procurement and Transplantation Network (OPTN) functions. However, I am concerned HRSA may not have a real chance to pilot technologies that could replace the UNOS system.**

While the Act aims to foster competition, we must approach the commercialization of kidney transplantation services with caution. There are valid concerns about HRSA's ability to pilot new technologies effectively, as well as the potential risks of prioritizing profit over patient care. To address these issues, we suggest:

- Establishing a kidney-focused innovation fund for HRSA to test new transplant matching technologies, with strict ethical oversight
- Creating a sandbox environment to pilot kidney allocation algorithms, ensuring that patient outcomes remain the primary focus
- Implementing a phased approach to technology adoption, with continuous evaluation of its impact on equity and access

We think that HRSA should support any new technology that can help patients get access to organs. However, it is HRSA's responsibility to ensure that these technologies are instituted in an evidence-based way and that patient safety is monitored.

**2. Are there alternative ways HRSA could test commercial solutions that would enhance competition? What specific benefits would this provide, and how could it improve the system's functionality or transparency?**

While exploring commercial solutions, it's crucial to maintain the integrity and equity of the organ transplantation system. HRSA could consider the following alternatives, with appropriate safeguards:

- Conducting limited regional pilot programs to test new kidney allocation technologies, with rigorous evaluation of patient outcomes and access
- Partnering with non-profit organizations and academic institutions for collaborative testing, to balance commercial interests with public health priorities
- Implementing a challenge-based approach that emphasizes ethical considerations and equitable access alongside technological innovation

It is crucial that any solution that is implemented be done with full transparency to the transplant community and to patients. It is important that we maintain trust in the organ allocation system.

**3. Dr. Roach, reports indicate that UNOS's technology platform is outdated, fragile, and unreliable for a system critical to saving lives.<sup>1</sup> Despite this, it seems HRSA may extend the technology contract to UNOS, and UNOS claims no other organization can manage the platform. However, I am aware of commercial solutions that could be quickly implemented. Should we be evaluating these options now to ensure we have the best system in place?**

While it's important to explore improvements to the current system, we must approach the evaluation of commercial solutions for kidney transplant management with caution. Any consideration of new technologies should prioritize:

- Patient outcomes and equitable access over profit motives
- Transparency in allocation algorithms to prevent bias or unfair practices
- Maintaining the ethical integrity of the organ donation and transplantation process

We believe that this is an opportunity to increase competition and therefore innovation. This innovation will hopefully result in more organs getting to the American people, and more efficient delivery of those organs.

**4. Dr. Roach, as a patient advocate, would you please elaborate on how you would like to see the makeup of the newly formed independent OPTN Board of Directors?**

It's important that the new OPTN board be independent and free of conflicts of interest. Ideally, the members should not have ties to UNOS or the previous OPTN. This is to ensure true reform and not a rehash of previous policies.

The newly formed independent OPTN Board of Directors should ideally include:

- Nephrologists and kidney transplant surgeons
- Kidney transplant recipients and dialysis patients
- Experts in kidney disease policy and ethics
- Representatives from organ procurement organizations specializing in kidney donation
- Data scientists with experience in kidney allocation algorithms
- Health Economists with experience in organ allocation
- Representation from the pediatric transplantation community

**5. Dr. Roach, how can we transform the OPTN to improve access to life-saving organs for rural or underserved communities?**

To improve access to life-saving kidneys for rural or underserved communities, we could:

- Implement telemedicine solutions for pre- and post-kidney transplant care. Patients typically must travel long distances for transplant evaluation, lab work, follow up, etc. Telehealth would help to minimize this travel, with patients needing to travel only when they truly need to be seen in person.
- Create targeted education about kidney disease, transplantation, and living donations in underserved communities. Education is inadequate about transplantation, especially in underserved communities. Many patients do not realize that transplantation is a viable option, or do not realize the full benefits of transplantation over other renal replacement therapies.
- Establish partnerships with rural healthcare providers to improve coordination of kidney care. These providers have unique knowledge of these populations and will be able to tailor outreach efforts to their needs.
- Ensure rural and underserved communities are represented in the OPTN Board, Committees, and Councils.

**The Honorable Raul Ruiz, M.D.**

**1. Because patients receiving organ transplants must be on immunosuppressing drugs to prevent organ rejection, serious infections are very common among patients with transplants. Growing antimicrobial resistance is making it extremely difficult and, in some cases, impossible to treat these infections, as our arsenal of effective antimicrobial drugs is running out. The development of novel antimicrobials is essential to successful organ transplants, and that is why I am a proud cosponsor of the bipartisan PASTEUR Act to strengthen antimicrobial R&D, and I urge Congress to pass this bill this year. Patients cannot wait any longer. Can you please share how you see antibiotic resistant infections threatening transplant patients and why you believe we must develop novel antimicrobial therapies?**

Antibiotic-resistant infections pose a significant threat to kidney transplant patients for several reasons:

- Immunosuppression makes kidney recipients highly susceptible to infections
- Resistant infections can lead to kidney rejection, graft failure, or death
- Limited treatment options for resistant infections can complicate post-kidney transplant care

Developing novel antimicrobial therapies is crucial for kidney patients because:

- It provides new options for treating resistant infections in immunosuppressed kidney recipients
- It helps preserve the viability of kidney transplantation as a life-saving procedure
- It contributes to better long-term outcomes for kidney transplant recipients

Supporting initiatives like the PASTEUR Act is essential to address this critical need and protect kidney transplant patients' lives.