The Honorable Cathy McMorris Rodgers

1. Dr. Cannon, 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 United Network for Organ Sharing (UNOS) system. 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?

This question falls outside of my area of expertise, so I am unable to offer specific solutions. I am confident that alternative solutions in the transplant system exist, whether that be in the private or public sector. I would suggest that HRSA seek guidance from best-in-class subject matter experts in each of the relevant domains (such as logistics, for example) as to how an ideal system would function, and then seek bids to implement that system. Contracts would need to have specific and enforceable performance clauses and be subject to competitive rebidding. This could be a slower process, but it would be worthwhile to ensure the redesigned transplant system functions properly.

2. Dr. Cannon, reports indicate that UNOS's technology platform is outdated, fragile, and unreliable for a system critical to saving lives.1 Despite this, it seems HRSA may extend the technology contract to UNOS, and UNOS claims no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. Shouldn't we be evaluating these options now to ensure we have the best system in place?

We should certainly be evaluating alternative options to UNOS' technology platform, including those offered by commercial vendors. I am not a technology expert, though I would view a claim that no organization other than UNOS can manage the technology underpinning the transplant system with skepticism. The transplant system is indeed complex, covering 104,251 candidates on the waitlist as of October 6, 2024. Commercial firms in the US routinely manage complex systems covering millions of people. If a company can individually target consumers with ads and content based on personal preferences and habits, there are likely commercial vendors capable of designing and managing a technology platform to implement an organ matching algorithm.

3. Dr. Cannon, we have received credible allegations of misconduct, mistreatment of patients and falsified records by Organ Procurement Organizations. Why do you think whistleblowers brought these concerns to the Committee rather than reporting them to the appropriate oversight body?

I believe whistleblowers would bring concerns to Congress rather than to the OPTN because they do not believe the system will take their complaints seriously and they likely fear retaliation. Whistleblowers might have such fear because many news reports have documented retaliation by high level OPTN officials (both past and current) that might dissuade future whistleblowers from taking concerns directly to the OPTN.

4. Dr. Cannon, what measures would you recommend to improve the transparency and accountability of OPOs across the U.S.?

Collection and public reporting of data on referrals of potential donors to OPOs would be a good start. This data would allow for better assessment of how OPOs are performing in converting potential organ donors into actual donors. This data would also allow for assessment of hospitals to ensure that they are referring potential donors in a timely and appropriate manner. This is currently a poorly understood area..

With regard to OPO accountability in areas beyond donor yield, the Membership and Professional Standards Committee (MPSC) of the OPTN is not equipped to oversee them. The MPSC is a volunteer body composed of professionals who hold full-time jobs, and is also tasked with monitoring transplant hospital performance. As such, the MPSC simply does not have the bandwidth to regulate OPOs properly. A better solution would be to create a professionally staffed oversight board within HHS whose sole mandate is to ensure OPO accountability and investigate potential violations of OPTN policy.

Greater specificity in the guidelines and rules by which OPOs must abide regarding organ allocation is also necessary. As I mentioned in my verbal testimony, 20% of deceased donor kidneys are now placed out of sequence, meaning that candidates with higher priority on the waitlist are being skipped[4]. While there can be very good reasons for this practice (for example, to allow for better matching of a higher-risk organ with an appropriate recipient while minimizing the amount of time it takes to place the organ, which directly impacts the likelihood that the organ will be viable for transplant), the manner in which it is being implemented is opaque and varies not only between OPOs, but also within an OPO. A better method would be to require OPOs who wish to develop an out-of-sequence offer algorithm to submit their plan to HHS for review and approval. This would ensure that the policies are appropriately vetted and would allow for OPOs to be held accountable for holding to the policies they put forward. An advantage of allowing OPOs to submit individual out-of-sequence allocation plans is that OPTN would be able to compare the effectiveness of multiple policy alternatives.

After an appropriate period, the OPTN should then evaluate the various policies in place and choose the best performing method, which could then become policy for all OPOs. Alternatively, the OPTN could devise a handful of out-of-sequence allocation schemes that are randomly assigned to OPOs, and then choose the best performing policy after an evaluation period. The

end result should be a unified policy for out-of-sequence allocation to which all OPOs are held accountable.

Finally, transplant center feedback should play a role in OPO evaluation. Transplant centers are the ultimate "customers" for OPOs, yet there is currently no mechanism for transplant centers to address OPOs who fail to act as responsive partners. OPOs that persistently receive low ratings from their transplant center partners should be given an opportunity for performance improvement, and those which fail to improve should have their territory open to competitive bidding from more highly rated OPOs.

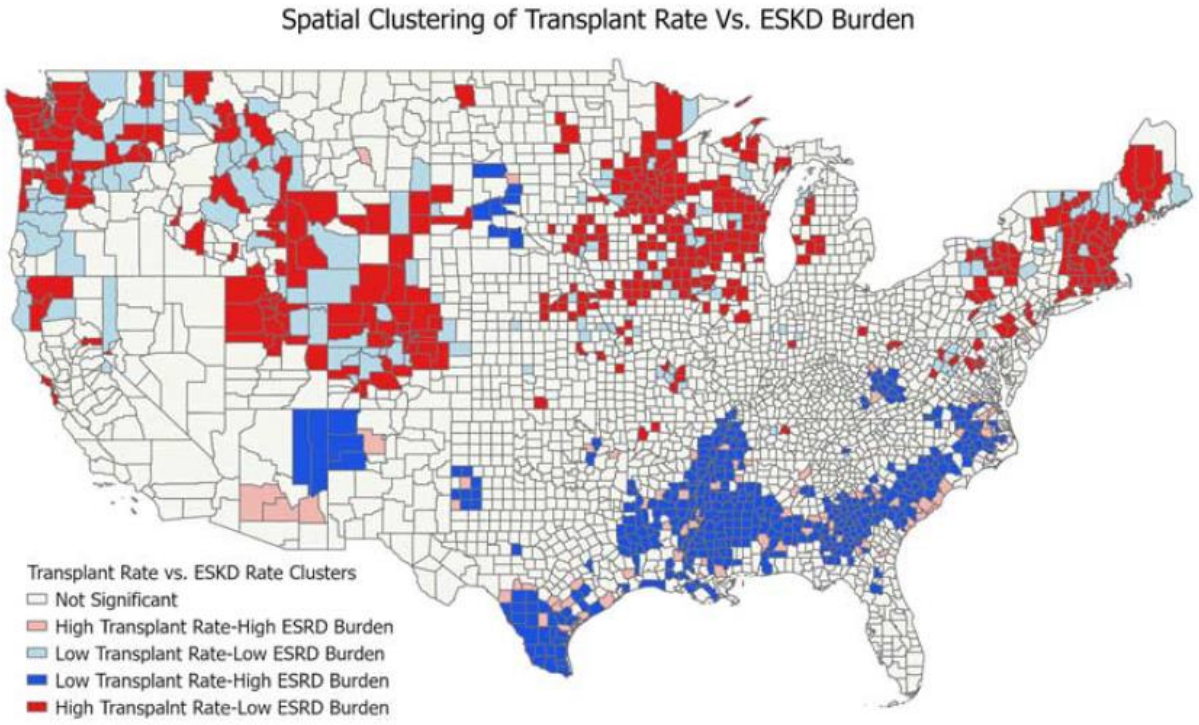
5. Dr. Cannon, given your experience at the University of Alabama at Birmingham, which serves a large rural population, what are the biggest barriers rural patients face when accessing organ transplants, and what changes do you hope the Modernization Initiative will bring to improve access for these communities?

Barriers in access to transplantation can be divided into two distinct phases: those that occur prior to being placed on the waitlist, and those that occur after being placed on the waitlist. Research shows that the majority of barriers occur in the pre-waitlist phase[5]. Over 20 years ago, the Institute of Medicine identified pre-waitlist barriers as including "inadequate health insurance coverage and inadequate access to primary care, proper diagnosis and treatment, and referral for transplant evaluation"[6]. Inadequate access to specialized care, lack of data, and misaligned policies can be added to this list of barriers. Below I address specific initiatives that I believe would improve access for disadvantaged communities:

1. We don't have an accurate estimate of how many patients are potentially in need of transplants and where they live. The United States Renal Data System (USRDS) is a population-based registry created by Medicare which tracks all patients with end stage renal disease (ESRD) in the United States. USRDS allows for accurate assessment of the ESRD burden and where the need for renal transplant is the greatest. It also allows us to identify areas where access to the waitlist is particularly challenging. No such data source exists for end stage liver disease, forcing researchers and policymakers to rely on surrogate measurements for disease burden, the adequacy of which are not verifiable[7]. This gap means that patients suffering from non-renal organ failure are essentially invisible to the organ transplant researchers and policymakers. Establishing a data system that captures all patients with organ failure would be an important step in ensuring that disadvantaged communities are recognized, and it would allow policymakers to take steps to alleviate disparities. As an example of how such a data system may prove beneficial, research has demonstrated that both distance to a transplant center and access to a gastroenterologist are important factors in access to liver transplantation[8, 9]. Accurate knowledge of disease burden would allow identification of geographic shortage areas where gastroenterology practice can be incentivized, similar to what is done in primary care. Similarly, the location of new transplant centers or satellite programs from existing

centers could also be informed by accurate knowledge of disease burden. This recommendation for collection of patient data along their entire journey, rather than just beginning with waitlist addition, was a key recommendation of the 2022 Institute of Medicine Report on how to improve the transplant system[10].

2. The OPTN has traditionally interpreted the Final Rule as limiting its purview to transplant candidates (those placed on a waitlist) and recipients, without considering the pre-waitlist population[10]. This has resulted in policies, particularly relating to organ allocation, that have disadvantaged regions where access to the waitlist is more difficult and disease burden is higher. The Institute of Medicine has stated that "this gap in oversight presents a significant challenge to ensuring fairness and equity in the organ transplantation system".



The mismatch between ESRD burden and kidney transplant rates is an example of inequities that may arise when policy is based solely on the waitlist population. In the figure above, the dark blue areas represent counties where transplant rates are low despite a high ESRD burden (low-outliers). Conversely, bright red counties represent areas where kidney transplant rates are high despite a relatively low ESRD burden (high-outliers). Compounding this disparity is the finding that the populations of the low-outlier counties generally have a lower sociodemographic status than the high-outlier counties[11]. Our research in end stage liver disease demonstrates a similar phenomenon where large population centers have high rates of waitlist access and liver transplantation relative to their disease burden[12]. Recently enacted organ allocation policies, which only considered those on the waitlist, will further exacerbate these disparities. In order to

remedy this situation, the OPTN should be mandated to consider the entire end stage organ failure population when making policy, not just those who have reached the waitlist. The 2022 IOM report concurs with this assessment, recommending "HHS should extend its regulatory oversight of the organ transplantation system beginning, at least, at the time a patient reaches end-stage organ failure and extending beyond 1 year posttransplant[10].

3. Nephrologists and dialysis centers are incentivized to refer chronic kidney disease patients for transplant evaluation. Similar incentives should be put into place to refer patients with non-renal organ failure for transplant evaluation. The Institute of Medicine recommends that "the Centers for Medicare & Medicaid Services should adopt payment policies that incentivize all providers—from primary and specialty care of patients with organ failure to referral for transplant, from care while awaiting a transplant to long-term posttransplant care—to improve equity in access to care and outcomes for patients"[10].

4. All patients with end stage renal disease are eligible for Medicare coverage, and the Comprehensive Immunosuppressive Drug Coverage for Kidney Transplant Patients Act of 2020 extended Medicare coverage to immunosuppressive medications indefinitely following transplant as well. Meanwhile, recipients of other organs sometimes must choose between paying for medications necessary to maintain their transplant and paying their utility or grocery bills. Extending Medicare benefits to patients in need of non-renal organ transplants would remedy this disparity.

5. The metrics by which the OPTN evaluates transplant centers are not aligned with the goal of providing transplants to as many patients as possible. Currently, transplant centers are compared based on waitlist mortality and post-transplant graft survival, among other measures. Centers which fall outside a very narrow range face sanctions by the OPTN. These measures provide a disincentive against listing and transplanting higher risk patients and hinder maximizing the use of available organs. OPTN regulatory metrics are cited as a factor in the higher kidney discard rate in the United States as compared to other nations[13]. To stay in the narrow outcomes window, transplant centers remove more patients from the waitlist and perform fewer transplants following an unfavorable evaluation[14, 15]. Rather than allowing the OPTN to continue comparing transplant centers against each other, the Modernization Initiative should promote performance metrics which are aligned with patients' interests. I would suggest the following actions:

1. Incentivize centers that place a higher proportion of referred patients on the waitlist.
2. Compare mortality in a center's waitlist population to the mortality of end stage organ failure patients who are not on the waitlist.
3. Compare post-transplant survival against the alternative of not undergoing transplant. In kidney transplantation, for example, the relevant comparison would be transplant vs. remaining on dialysis.

6. Dr. Cannon, during the hearing you stated, "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." Could you elaborate on who these insiders are and provide suggestions for ensuring independent, highly-vetted members on the newly formed OPTN board?

Under the current system, OPTN board members are elected by member *institutions* (such as transplant centers and OPOs)**.** Volunteer board members have selflessly given countless hours of their time to work on the board, and I do not wish to demean their services. The reality, however, is that a board elected by *institutions* will be systematically biased to promote the interests of those institutions. I don't think the public would find it acceptable for the leadership of the Nuclear Regulatory Commission to be selected by our nation's nuclear power plant operators. Why should the relationship between the transplant system and our regulator be any different? In order for the top-level leadership of the OPTN to be responsible to the public rather than the industry, they need to be chosen in the same manner used for other federal regulatory bodies—by administrative appointment. OPTN policy will always need to be informed by subject matter experts who should fill the committee structure; however, leadership at the top should be an administrator and/or board chosen specifically as public servants. The OPTN President and Executive Committee should not concurrently hold leadership roles in a transplant center, OPO, or any other industry group during their term of service. Policies regarding eligibility for office and conflict of interest should mirror standards for other federal regulatory commissions.

7. Dr. Cannon, how do you believe the OPTN board's decision-making processes could be improved to prioritize patient outcomes and safety over institutional or industry interests?

I believe *appointment* of top level OPTN leadership rather than election by member institutions is the most important change that can be made to improve the OPTN decision-making process, as stated in further detail in response to the previous question. This will make it explicit that OPTN leadership serves the public rather than its institutional members.

8. Dr. Cannon, given the complex nature of organ procurement and allocation, what specific reforms would you propose to improve collaboration between OPOs and transplant centers?

-Revise regulatory metrics to promote shared goals:

1. Our current system of regulatory metrics for transplant centers and OPOs is misaligned and creates conflict between the two groups. OPOs are graded by maximizing placement of organs by any means necessary, while transplant centers are graded on post-transplant survival, as I discussed in question 5. A better system would be to create a set of shared, system-wide goals that align transplant centers and OPOs to create the most effective possible system.

-Improve the organ offer process:

1. The information presented for any individual organ offer varies widely by OPO, or even by which individual OPO personnel are assigned to a case. Creating a set of best practices for organ offer presentation would improve mutual trust within the system and ensure that the most relevant information needed to make an informed decision on acceptance is readily available.

2. Mandate expanded use of offer filters so OPOs and transplant centers are not burdened with allocating organs to a center is highly unlikely to accept. Very granular criteria need to be made available when setting filters to allow centers to filter out offers they would not accept without missing out on offers in which they would be interested. Filters should be mandatory for combinations of donor characteristics that a center has never accepted for transplant. Centers could be given an opportunity to change behavior by requesting a filter be removed; however, this would need to be followed by an evaluation period to demonstrate the center has indeed been willing to accept this type of organ. Advanced analytics and AI can be useful for creating filters. UNOS has started this work and we've found it beneficial, and it should certainly be expanded. A shortcoming of the current offer filter system is that centers can only create filters that apply to all their patients on the list. Offer acceptance criteria for individual patients are much less granular. It would be beneficial to allow for more granular offer acceptance criteria when listing patients. This would allow centers to have an *a priori* conversation with patients on which types of donors would be most suitable for them, and offer filters could then be set to reflect the shared decision making between patients and transplant centers. This would also increase the efficiency of the allocation process and reduce out-of-sequence allocations.

-Increase collaboration in quality improvement and educational offerings:

1. Including transplant centers in OPO quality improvement efforts would allow OPOs and transplant centers to better understand one another's needs and create a culture of shared system improvement. These efforts are currently underway in some of the OPOs with whom we frequently partner and ideally would be expanded.
2. Prior collaborative efforts such as the Organ Donation Breakthrough Collaborative and Collaborative Innovation and Improvement Network (COIIN) have been successful and have fostered partnership between transplant centers and OPOs. Future efforts at joint performance improvement should be prioritized.

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

I believe effective transformation of the OPTN into a public-serving body that promotes improved access to organ transplant for all can be achieved by the following broad areas of reform which I discussed in greater detail in response to your earlier questions:

1. Expanding the OPTN's mission
    a. The OPTN should recognize all patients with organ failure as the constituents it serves. Recognition of this broader mission will require unified data collection at all points along a patient's journey, from diagnosis with end stage organ failure through referral, placement on the waitlist, transplant, and beyond. We cannot adequately serve all patients with organ failure until they are no longer invisible to the system.
2. Aligning the interests of system participants with those of patients through realigned performance metrics

a. The current performance metrics are a disincentive to transplanting higher risk patients and minimizing discard of potentially viable donor organs. There are many patients who would benefit from transplant who are never given an opportunity, and many organs that could extend life that go unused because their expected outcome does not meet the high bar we have set for ourselves in terms of outcomes. The appropriate comparison for any medical intervention is how the patient is expected to fare if that intervention were withheld or an alternative treatment was provided. Transplant-related metrics should be no different. For example, the appropriate yardstick by which survival following kidney transplant is measured should be survival on dialysis. A center should never be in the position of having to withhold transplant from a patient who would benefit because the regulatory standards state that the patient's benefit is not good enough. Proper alignment of metrics at all levels across the system to promote greater access to transplant is, in my opinion, the most important reform we can undertake.

3. Governance that is accountable to the public
    a. The system of regulatory oversight by an OPTN president and top-level leadership chosen by the very institutions the OPTN is supposed to oversee has failed. The OPTN president and executive committee should be appointed rather than elected by member institutions.

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 research and development and I am working for 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 that we must develop novel antimicrobial therapies?

I have asked my colleague at UAB Dr. Jeremy Walker, who is an expert in immunocompromised infectious disease, to shed further light on the scope and severity of the problem:

"Antibiotic resistant infections are an important consideration in Solid Organ Transplant. We see infections with 5 of the top 12 bacteria highlighted by the World Health Organization as major threats to human health, including all three pathogens labeled as critical priority (carbapenem resistant Acinetobacter and Pseudomonas as well as multi-drug resistant (MDR) Enterobacteriaceae, vancomycin-resistant enterococcus, and staphylococcus aureus). Of the high priority pathogens, VRE is of particular concern amongst those undergoing liver transplantation and we have seen complicated and life-threatening infections from this entity. Treatment of VRE can be further complicated by the toxicity of some of the available agents (such as linezolid),

which suppresses the bone marrow and can be challenging to use alongside our immune-suppressive agents. This further highlights the challenge of treating this population because we not only have to find an effective agent, but also one that can be safely given alongside the comorbidities and other treatments the patient requires. Patients may be forced to choose a therapy that we know will have side effects, but is our only option to gain control of the infection.

There is data that reports incidence of multi-drug resistant pathogens in 20-25% of liver transplant recipients. This has been associated with increased mortality. Similar findings have also been seen in other solid-organ transplantation. VRE and MDR Enterobacteriaceae have the highest burden in our population, although Acinetobacter and pseudomonas are also seen. In addition to bacterial pathogens, we also see severe fungal infections following transplantation. Thoracic organs have more invasive mold infections such as aspergillus, but in liver transplantation the main fungal infection of concern is candida. This can be a very challenging infection to treat and has significant mortality amongst transplant recipients. We are also seeing increasing drug resistance for candida species and increasing spread of C. auris, a pathogen with known high resistance levels across the southeast. It is heartbreaking when we are using the strongest antibiotics, we have available to clear an infection and yet it remains refractory to our best available options. It is imperative that we continue to pursue novel antimicrobials to be able to maintain therapeutic options for these resistant pathogens we are seeing spread at high rates amongst our population. “

From these words and our front-line experience, it is clear to me that novel antimicrobials will be a critical component to ensuring the survival and thriving or our transplant recipients.

I would like to thank all of the members of this committee for their interest in this vitally important manner, and for allowing me the opportunity to speak with you.

Sincerely,

Robert M. Cannon

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