Additional Questions for the Record
Greg Segal, Founder & CEO, Organize
The Honorable Cathy McMorris Rodgers

1. Mr. Segal, what do you believe are the most significant barriers preventing whistleblowers from reporting misconduct directly to the appropriate oversight bodies?

There is extensive documentation regarding the OPTN's systemic failure to meaningfully investigate claims of impropriety by its own members. As far back as 2006, the LA Times published an investigative story[1] highlighting that *"The little-known organization that oversees the nation's organ transplant system [the OPTN contractor — UNOS] often fails to detect or decisively fix problems at derelict hospitals — even when patients are dying at excessive rates"*, and further expounding that *"UNOS' failures in those cases are part of a larger national pattern of uneven and often weak oversight. At times, the group appears more intent on protecting hospitals than patients themselves"*, and that *"UNOS isn't just a regulator; it is a membership organization, run mostly by transplant professionals. Centers, in effect, oversee one another."*

The New York Times editorial board also wrote in 2019 that *"an astounding lack of accountability and oversight in the nation's creaking, monopolistic organ transplant system is allowing hundreds of thousands of potential organ donations to fall through the cracks"*[2], with the Washington Post similarly reporting that *"Enforcement of OPO safety standards is generally left to the United Network for Organ Sharing, an umbrella nonprofit that coordinates the system. It is difficult to determine how often problems occur because UNOS's records are hidden from scrutiny by the public or Congress."*[3]

This dynamic has continued on to the present day. In fact, the Senate Finance Committee published a bipartisan report in August 2022[4] essentially finding that UNOS has covered up untold patient harms – and even death – while actively fighting against Congressional or other oversight into these same problems. (It is also worth noting that – even though HRSA has titularly split the OPTN and UNOS boards – the current OPTN board is comprised entirely on people who either recently served on the UNOS board, and/or were selected by the UNOS/OPTN Nominating Committee to serve on the OPTN board going forward.)

The OPTN has not been subtle about this, as its past Executive Director even joked in emails obtained via subpoena that its patient safety protection process is *"like putting your kids' artwork up at home. You value it because of how it was created rather than whether it's well done."*[5]

[1] https://www.latimes.com/news/la-me-transplant22oct22-story.html
[2] https://www.nytimes.com/2019/08/20/opinion/erika-zak-organ-donor.html
[3] https://www.washingtonpost.com/national/health-science/a-human-heart-was-left-on-a-plane-revealing-how-organs-move-around-the-country/2018/12/14/3aabe696-ffb7-11e8-862a-b6a6f3ce8199_story.html
[4] https://www.finance.senate.gov/imo/media/doc/UNOS%20Hearing%20Confidential%20Memo%20(FOR%20RELEASE)%20on%20website.pdf
[5] https://www.usatoday.com/story/opinion/voices/2023/03/01/break-up-organ-donation-monopoly/11259464002/

It is also a well documented dynamic that OPTN board and committee members do not have to meaningfully disclose financial conflicts of interest. In fact, in September 2023, as part of its ongoing investigation into the organ donation industry, the Senate Finance Committee wrote that it "*has also heard testimony and received credible allegations that senior members of the current OPTN contractor, the United Network for Organ Sharing's (UNOS) patient protection and policymaking committees may harbor undisclosed for-profit interests and may be leveraging their UNOS leadership positions to self-enrich at the expense of patient care."*[6]

As a result, stakeholders, almost universally, have lost all faith that anything positive will come of filing a report regarding misconduct. Additionally, it is well-known – and now well-documented, including in reporting from the Richmond Times-Dispatch[7] – UNOS's own hometown newspaper – that UNOS/OPTN retaliates against whistleblowers for filing complaints in the first place.

Taken together, it is easy to understand why whistleblowers simply choose not to report abuses in the first place. After a decade of working with organ donation whistleblowers, I believe that this dynamic is very much by design; the OPTN does not even want there to be a record of any failings or misconduct in the first place, as it gives them plausible deniability of the widespread, systemic failures and abuses which are now being investigated not only by Congress, but also by the Department of Justice.[8]

It is now my measured belief that the best way to protect patients – and to ensure ongoing oversight of the organ donation system – that the Membership and Professional Standards Committee (MPSC) should be taken out of the OPTN completely, and given to an unbiased, unconflicted outside organization.

Additionally, Congress needs to exercise enhanced oversight of both HRSA and CMS to ensure that they are fully investigating all credible allegations they receive, given that both agencies historically have been captured by their own organ donation contractors.

Consider, for example, the 2012 case of two Alabama OPO executives being sent to federal prison for a kickback scheme. This was something first reported to OPTN/UNOS (see 2022 Senate Finance Committee report[9]), yet neither OPTN/UNOS nor CMS took action. It was the FBI and Department of Justice that ultimately took action, sentencing the two OPO executives to Federal Prison.[10] (It is also important to note that, in addition to OPTN taking no action on this allegation, that one of the

[6] https://www.grassley.senate.gov/imo/media/doc/wyden_grassley_cardin_young_to_jan_finn_-_opo_conflict_of_interest.pdf

[7] https://richmond.com/news/state-regional/government-politics/insiders-say-richmond-s-organ-transplantation-network-dismisses-whistleblower-concerns-resists-change/article_6bf09988-10a9-11ee-b47a-a3789114d0c7.html

[8] https://www.washingtonpost.com/health/2024/02/26/organ-transplant-investigation/

[9] https://www.finance.senate.gov/imo/media/doc/UNOS%20Hearing%20Confidential%20Memo%20(FOR%20RELEASE)%20on%20website.pdf

[10] https://archives.fbi.gov/archives/birmingham/press-releases/2012/former-alabama-organ-center-executive-sentenced-for-fraud

whistleblowers was also subjected to intense retaliation, with CBS News reporting that he and his parents were threatened with being "cremated alive."[11])

2. What measures would you recommend to improve the transparency and accountability of OPOs across the U.S.?

CMS should move urgently to:

- Enforce the 2020 OPO Final Rule, without dilution or delay, including by closing the pancreas loophole in line with Senate Finance Committee recommendations[12], and publishing Criteria for Competition that awards donation service areas (DSAs) to OPOs with a data-driven track record of effective, equitable, and safe care delivery, as well as any other additional steps necessary to ensure that the OPO rule is fully enforceable;
- Require clinical licensure for all OPO staff interacting with patients;
- Require all OPO staff, executives, or board members to publish all financial and fiduciary relationships they maintain with any other companies, entities, or individuals with whom their OPO – or any other OPTN member – conducts business (e.g., tissue processing firms; aviation companies; medical device companies) so that any potential conflicts are easily accessible for public scrutiny;
- Update its OPO Site Surveys and Conditions on Coverage, which, historically, have clearly been insufficient to identify and redress the widespread abuses and patient safety failures in the OPO industry (consider: if Site Surveys have not caught the credible allegations unearthed in the E&C Committees investigations, then they are clearly not fit for purpose; my understanding is that these surveys relate more to the existence of certain processes and protocols, rather than any actual evaluation on whether such protocol are followed or, more broadly, whether they are sufficient to ensure patient safety);
- Move away from cost-reimbursement basis for OPOs[13], which is an arcane financial reimbursement structure which creates perverse incentives for OPOs, often at the direct expense of patient care;
- Disallow OPO-run "organ recovery centers", which essentially operate as unlicensed private surgical facilities, and over which CMS has no jurisdictional oversight authorities;
- Publish OPO process data for evidence of effective and equitable performance;
- Issue waivers to hospitals who request to work with higher performing OPOs instead of lower performing OPOs. (Note: CMS has received two such requests in the last two years — one from North Carolina and one from Ohio — and has not issued decisions, despite a clear case that these hospitals are seeking to better serve patients. This is fundamentally at odds with bipartisan pushes for competition and the President's Executive Order on Competition, and leads to continued entrenchment of unaccountable monopolies at the expense of patient care); and

[11] https://www.cbsnews.com/news/whistleblower-threatened-with-being-cremated-alive-after-exposing-mortuary-kickback-scheme/

[12] https://www.finance.senate.gov/imo/media/doc/060624_wyden_grassley_cardin_young_pancreata_letter_to_cms_final.pdf

[13] https://www.bridgespan.org/getmedia/aea38d49-f013-4729-aa26-404d20a1f889/bridgespan-opo-report-final-august-2023-update-appendix-a.pdf

- Invoke Urgent Need for the Kentucky OPO (which recently merged with another OPO, though kept much of the dangerous Kentucky leadership in place), as well as other OPOs where there are proven instances of unsafe conditions which harm patients.

HRSA should move urgently to:

- Reform the OPTN board structure, moving to a system of Administration appointments for OPTN board members made in patients' interests – rather than industry-run elections that protect industry's interests – in line with other national policymaking bodies (e.g., the Federal Reserve);
- Dramatically limit the overall scope of the OPTN board, including – and most urgently – by removing the MPSC from the OPTN;
- Finalize the Ventilated Patient Form (VPF) it has proposed via Secretarial Data Directive in February 2024[14];
- Build internal staff capacity for financial oversight of OPTN and OPTN-related contractors and its various stakeholders within HRSA, including through coordination with the Office of the Inspector General (OIG) and the Department of Justice; and
- Publishing clear prohibitions for any key personnel or "subject matter experts" for any OPTN contractors – current or future – on maintaining business relationships or other real or perceived conflicts of interest. For example, the OPTN, via one of its contractors, has engaged an industry consultant, Dennis Wagner,[15] as part of its "Expeditious Task Force", with no public disclosures regarding who Wagner's consulting clients are, as well as whether they financially benefit from the work Wagner is pushing under the banner of the OPTN.

3. Mr. Segal, could you please share known instances of whistleblower retaliation? Please provide as much detail as possible.

This is an incredibly important question, and also a delicate one as providing as much detail as possible could inadvertently expose the identity of some of the whistleblowers, and ultimately expose them to further retaliation.

That said, I would greatly appreciate the opportunity to meet with Committee staff directly to discuss these many, many instances of retaliation, as well as to provide extensive supporting documentation where it exists – including behaviors I believe may constitute attempts to intimidate federal informants, which may constitute a federal crime.

4. Mr. Segal, with the recent contract awarded to The American Institutes for Research (AIR) to manage the independent Organ Procurement and Transplantation Network (OPTN) Board, there has been debate within the community about how the board should be formed. During a staff briefing, HRSA mentioned that some surgeon groups are advocating for elections rather than appointments. Could you please share your views as a patient advocate as to how the board should be formed?

[14] https://optn.transplant.hrsa.gov/news/hrsa-directive-to-expand-optn-data-collection/
[15] https://yesandleadership.com/about-us

It is beyond clear that the current board structure is dysfunctional. In fact, the former OPTN Executive Director himself – in emails unsealed by a federal judge – characterized the OPTN as "not having a real board"[16], and further likened the OPTN to an "overgrown homeowners' association."[17]

The single best first step HRSA can take to ensure the OPTN board operates in patients' interest is to move to board appointments, rather than industry-led elections. It is in no way surprising that industry has opposed this, given the extensive documentation – both via investigative reporting as well as Congressional investigations – that the OPTN has acted as a cover-up arm for industry stakeholders.

It is also telling that, in its opposition to board appointments, industry actors (e.g., the American Society of Transplant Surgeons, ASTS) have relied heavily on fearmongering and misinformation, rather than engaging in a good-faith, intellectually honest policy debate. (For example, ASTS baselessly asserted that board appointments would somehow mean doctors and other clinical experts would no longer be represented on the board; in actuality, board appointments would not, in any way, change the composition of the OPTN board (i.e., doctors would still have the exact same representation), it would simply mean that the Administration is able to appoint *which* doctors serve in OPTN roles.)

Not only would board appointments ensure that the most competent, responsible, and pro-reform stakeholders serve on the OPTN board (rather than, as historically been the case, the most protectionist and obstructionist), but this structure would also change the incentives for actors across the entire industry.

Specifically, because many industry professionals want to, eventually, join the OPTN board, many begin to 'audition', so the speak, for the role, by working in concert with other industry leadership to obstruct or oppose any reforms, knowing that engaging in this behavior may ultimately see them rewarded by OPTN leadership by nominating them for the OPTN board. Should HRSA move to a system of board appointments, however, this would fundamentally change the incentive structure for industry actors to behave in pro-patient ways, for which HRSA, presumably, may decide to reward them with an appointment to the OPTN board.

Additionally, HRSA, via AIR, should move urgently to publish clear guidelines to prohibit financial or structural conflicts of interest for any OPTN board members. More specifically, HRSA should reference its own policy on conflict of interest and federal financial assistance[18], which applies to cooperative agreements. OPTN Board Members can reasonably be considered officers or agents of that nonprofit organization under HRSA's designation of that organization as the OPTN Board.

As further context, HRSA established its Federal Financial Assistance Conflict of Interest Policy (COI Policy) pursuant to 45 CFR §75.112. The policy:

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[16] 1:19-cv-01783-AT Callahan et al v. United States Department of Health and Human Services et al, Document 357-1, page 190

[17] Senate Finance Committee investigation findings. Accessible online at: https://www.finance.senate.gov/download/other-documents-related-to-the-staff-memo-on-organizational-failures-of-the-united-states-organ-procurement, Document 149

[18] https://www.hrsa.gov/grants/standard-terms/conflict-interest-policy

- Address conditions under which outside activities, relationships, or financial interests are proper or improper;
- Identifies when and how a non-federal entity (NFE) must provide written notification of such outside activities, relationships, or financial interests to HRSA or, in the case of grant subrecipients, to the pass-through entity;
- Describes a process of review of such disclosures; and
- Discusses the means by which financial conflicts of interest may be addressed.

This COI Policy applies to all NFEs receiving HRSA financial assistance, including cooperative agreements, either directly (from HRSA) or indirectly (i.e., through a subaward from a pass-through entity).

The COI policy defines conflict of interest as **a significant financial interest that could directly compromise or bias professional judgment and objectivity related to the management of federal financial assistance.** The policy offers other helpful definitions, including:

- **Affiliate:** Persons are affiliates of each other if, directly or indirectly, either one controls or has the power to control the other or a third person controls or has the power to control both. Such control may – but is not required to be – evidenced by: Interlocking management or ownership; Identity of interests among family members; Shared facilities and equipment; Common use of employees; or A business entity, which has been organized following the exclusion of a person that has the same or similar management, ownership, or principal employees as the excluded person.
- **COI Point of Contact:** The individual designated by the NFE as having responsibility for disclosing in writing to HRSA and resolving a potential COI. This should ordinarily be the Project Director as the Authorized Representative of the NFE.
- **Non-Federal Entity**: A state, local government, Indian tribe, institution of higher education (IHE), or nonprofit organization that carries out a federal award as a recipient or subrecipient.

A NFE receiving federal assistance from HRSA must comply with the HRSA written policy on conflict of interest. If an NFE conducts activities supported by grant funding through subrecipients (including subawards), the NFE must take reasonable steps to ensure that these organizations or individuals also comply with this conflict of interest policy and notify the NFE receiving federal assistance directly from HRSA of any actual or perceived conflicts of interest.

This policy addresses potential situations that may trigger **actual or perceived individual or organizational** COIs and how the NFE should address them:

- **Individual COIs in the selection, award and administration of contracts by NFEs**. The NFE must maintain written standards of conduct covering conflicts of interest and governing the actions of its employees engaged in the selection, award and administration of contracts. No employee, officer, or agent of the NFE may participate in the selection, award, or administration of a contract supported by a federal award if he or she has a real or apparent conflict of interest. The NFE's standards of conduct must provide for disciplinary actions to be applied for violations of such standards by officers, employees, or agents of the NFE.

- Such a conflict of interest would arise when "the employee, officer, or agent, any member of his or her immediate family, his or her partner, or an organization which employs or is about to employ any of the parties indicated herein, has a financial or other interest in or a tangible personal benefit from a firm considered for a contract."

- **Individual COIs in situations that <u>raise concerns about the appearance of a loss of impartiality</u>.**
  - A potential COI is presented where the employee, officer, or agent of the NFE is involved in a particular matter involving specific parties and the employee, officer, or agent of the NFE knows (or should know) that: the matter is likely to affect the financial interests of a member of an employee, officer, or agent of NFE's household; or one or more of the parties to the matter is or is represented by one of the following:
    - A person or organization with whom the employee, officer, or agent of the NFE has or seeks a business relationship;
    - A person who is a member of an employee, officer, or agent of the NFE's household;
    - A person who is a relative with whom the employee, officer, or agent of the NFE has a close personal relationship;
    - A person or organization for whom the employee, officer, or agent of the NFE's spouse, parent, or dependent child is serving or seeking to serve as an officer, director, trustee, general partner, agent, attorney, consultant, contractor, or employee;
    - Any person or organization for whom the employee, officer, or agent of the NFE has, within the last year, served as officer, director, trustee, general partner, agent, attorney, consultant, contractor, or employee; or
    - An organization, other than certain political organizations, in which the employee, officer, or agent of the NFE is an active participant.

- **Organizational COIs in procurement actions presenting organizational COIs in relation to a parent, affiliate or subsidiary organization that is not a state, local government or Indian tribe**. If the NFE has a parent, affiliate, or subsidiary organization that is not a state, local government, or Indian tribe, the NFE must also maintain written standards of conduct covering organizational conflicts of interest. The NFE must disclose in writing to HRSA (or to the pass-through entity, in the case of a subrecipient) any potential organizational COI supported by a federal award, including what measures were taken by the NFE to resolve the potential organizational COI.
  - A potential organizational COI is presented where, "because of relationships with a parent company, affiliate, or subsidiary organization that is not a state, local government, or Indian tribe, an NFE is <u>unable or appears to be unable</u> to be impartial in conducting a procurement action involving a related organization."

In such situations, a potential COI should be considered by the NFE as to whether it is truly a COI or a perceived COI. In either case, the NFE should take steps to mitigate the situation. To determine if a perceived COI should be addressed, <u>NFEs should consider whether a reasonable person with knowledge</u>

of the relevant facts would question the NFEs impartiality if the NFE participated in the matter. If the NFE concludes that the NFE's impartiality would be questioned, the NFE should not participate in the matter.

NFEs must disclose in writing to HRSA (or to the pass-through entity, in the case of a subrecipient) any potential COI supported by a federal award, including what measures were taken by the NFE to resolve the potential COI – *organizational or individual*. NFEs that are nonprofit organizations must provide COI disclosures to HRSA within 30 calendar days of discovery of the potential COI, and in accordance with the terms and conditions of their award. All COI disclosures, including potential COI disclosures, must be in writing by email using a provided template, from the Authorized Organization Representative (AOR) of the NFE. NFE must provide HRSA with any information regarding its plan and/or measures taken to eliminate, mitigate or otherwise resolve the COI.

This COI Policy applies to all NFEs receiving HRSA financial assistance, including cooperative agreements, either directly (from HRSA) or indirectly (i.e., through a subaward from a pass-through entity).

The COI policy defines conflict of interest as a significant financial interest that could directly compromise or bias professional judgment and objectivity related to the management of federal financial assistance.

5. Mr. Segal, what key factors do you believe will ensure that the independent board holds the maximum amount of credibility?

Currently the OPTN does not have an independent board in any real sense of the word, as all board members either were members of the UNOS board earlier this year or were chosen through a nominating process by that same UNOS board.

To move to a board that is independent of industry interests, as alluded to earlier, the key factors to ensure – for the first time – that the OPTN board maintains any credibility, are:

- Board appointments, including with HRSA maintaining the authority to remove any OPTN board member at any time for impropriety, which ensures that OPTN board members are answerable to their actions (as a reminder, the current OPTN president, Dr. Rich Formica, refused to testify in front of the Committee);
- Transparency regarding – and, as appropriate, prohibitions against – any financial conflicts of interest; and
- HRSA modernizing its requirements for the relevant skills to serve on the OPTN board (e.g., to include skills such as patient safety; cybersecurity; oversight/forensic accounting; health equity), to ensure that the skills resident on the OPTN board are fit for modern day realities; and
- Dramatically limited scope of the OPTN board to remove structural conflicts in the first place (e.g., no longer allowing industry to run the MPSC).

6. Mr. Segal, I understand that the majority of individuals who work with and for the OPTN are serving with their best intentions for a very difficult and emotional mission. However, I remain concerned over the current state of OPOs across the United States is safe for Americans. What can be done to improve patient-safety concern?

As someone who speaks with brave, frontline OPO employees every day, I greatly appreciate the framing of this question. Most frontline staff are good, hardworking people with the right intentions. However, these same people are placed in impossible positions, and are often given explicit direction by their leadership to engage in unsafe or unethical behaviors.

To improve patient safety, CMS should move urgently to:

- Require clinical licensure for all OPO staff interacting with patients;
- Work with Department of Labor to investigate OPO working conditions, including the regular practice of deploying coordinators on 24- or even 30-hour shifts multiple times per week;
- Create safe pathways for whistleblowers to report complaints directly to CMS and, jointly to a non-OPTN body managing the MPSC (with law enforcement brought in as appropriate), rather than to the OPTN, and with the commitment that CMS will meaningfully investigative all credible claims;
- Disallow any OPO executives, staff, or board members from maintaining relationships with any companies or other entities with which they, or other OPTN members, conduct business (e.g., if an OPO executive has a financial relationship with a particular medical device company or organ perfusion technology, that may unduly influence that executive's decisionmaking); and
- Disallow private, OPO-run organ recovery centers (ORCs), which are essentially unlicensed, privately-run surgical facilities in which OPOs conduct organ harvests, but over which CMS appears to have no jurisdictional authorities.

Additionally, HRSA should move urgently to remove all MPSC activities from the OPTN.

7. Mr. Segal, the Securing the U.S. Organ Procurement and Transplantation Act aims to foster competition by allowing HRSA to select the best contractors for OPTN functions. However, I am concerned HRSA may not have a real chance to pilot technologies that could replace the 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?

The concern that HRSA may not have a "*real chance to pilot technologies that could replace the UNOS system"* is a real one, and it is incredibly important for the Committee to exercise the proper oversight over HRSA to ensure that this is rectified. There certainly are commercial solutions available that could be piloted, although among the main roadblocks in properly evaluating and implementing new potential solutions is the lack of relevant expertise at HRSA, as well as serious concerns related to the motivations of much of the current HRSA civil service.

Specifically, from 2019-2021 the United States Digital Service (USDS) undertook an analysis of the OPTN technologies systems, as well as HRSA's ability to manage the OPTN, and ultimately published a

damning report, which it titled "Lives Are At Stake." A version of this report, with HRSA's redactions, has been made public by the Senate Finance Committee.[19] However, what HRSA chose to redact[20] is perhaps even more telling, including the following assessments:

- "Lack of technology expertise in the government program office that administers the OPTN contract is creating missteps in overseeing parts of the OPTN contract."

- "In the face of their inability to encourage competition in this space, HRSA has tried many things over the years to encourage more transparency and accountability from UNOS through the OPTN contract. All of these attempts have been met with hostility from the contractor – UNOS has at times even threatened to walk away and continue operating the OPTN without a contract, despite the fact that it would be illegal for them to operate such a network independent of a government contract. This is a fear that the HRSA HSB team has been living with, keeping them hesitant about pursuing avenues for real change in this program."

- "Unfortunately, there has been no one on the government side of the program administration that has the technical background or experience to cut through these tactics from UNOS. When they sensed something was not quite adding up in what they were seeing or hearing from UNOS, they did not have the right technical vocabulary to engage in meaningful questioning of the contractor or deliverables. While HRSA OIT did engage during some of the vendor demo sessions, they were often unprepared and subsequently unable to offer the program team good counsel on technology issues and vendors' technical capabilities."

- "This lack of technology engagement by federal program staff is most alarmingly evident in the fact that they are neither users of the current IT systems operated by UNOS, nor have they ever requested access to them. In fact, until the December 10, 2020 UNOS market research session, no one in the government had ever seen a demonstration of the current system functionality. The government's only understanding of the OPTN systems was through the status reports required by contractual deliverables and what information they have picked up through their own attendance at OPTN committee meetings. They knew incredibly little about the functionality or other specifics of the system."

- "HRSA lacked the willingness to fight with UNOS, even when they needed to. We saw this during the market research process, where they expressed fear in just requesting a demo from UNOS, even though there was no feasible way to determine the viability of other vendors without seeing the technology and capabilities of the current systems. This fear was around how UNOS would react to the request, knowing that the RFI was aimed at replacing the current technology. It was only with pressure from the HHS Immediate Office of the Secretary (IOS) that market research demos even occurred."

[19] US Digital Service report, Lives Are At Stake. Accessible online at: https://58425eca-649a-42d4-b265-d1e1743b6c48.filesusr.com/ugd/581bc3_11444ae6eeba4a65a3894a01d9095bed.pdf
[20] Unredacted report to be shared directly with Committee

- "Based on the critical need to modernize the core functionality of the OPTN IT Systems and the reality of the NOTA, we recommend the following three actions:

  1) Properly staff and support the program move into the new Office of Organ Policy in the Office of the Assistant Secretary for Health (OASH) at HHS with the right mix of skills and authority."

Additionally, while HRSA's political leadership has undertaken an important step in launching the OPTN Modernization Initiative, it is very important to understand that many of HRSA's civil servants appear to be captured by industry, and to be working actively to undermine the Modernization Initiative's success.

For example, just two days after HRSA Administrator Carole Johnson announced HRSA's OPTN Modernization Initiative – which was met with broad acclaim from patient groups and bipartisan members of Congress, HRSA staff member Marilyn Levi joined an OPTN/UNOS board meeting, deriding the HRSA Administrator as well as senior members of Congress, and encouraged industry to fight against these reforms. Specifically, Levi said[21]:

- *"When you're in government and you're dealing with new administrations, they all want to reinvent the wheel. It's actually been kind of a very frustrating process even for me, is you work on something, you work on something, and then suddenly there's a change in administration, a new President, they bring in their own people, and suddenly you have to start over again and try to explain. The problem is then we are also at mercy of the media, and they get little pieces and they just run with it, and they don't sometimes they don't know what they're talking about quite frankly…. Elizabeth Warren, I mean, I can't even talk about her. The kinds of lack of knowledge and lack of understanding, the lack of going to the right people to get the right information is astonishing."*

Levi went on to encourage OPTN board members to fight against the Modernization Initiative in Congress as well as with op-eds, which they have done aggressively. Additionally, and perhaps even more concerning, I have reason to believe that other senior HRSA civil servants are leaking sensitive information to UNOS and other industry actors, including, in some cases, market-moving information. I would be grateful for the opportunity to share all of the information I have with Congressional investigators so that they may dive deeper into whether there is an inappropriate – or, even potentially illegal – coordination between HRSA and UNOS.

Related, UNOS's hiring of Ankit Mathur, the former #2 at the United States Digital Service, has raised serious questions over whether he was privy to sensitive OPTN contracting information before he left government, as well as whether he has shared such information with UNOS.[22] By all appearances, UNOS's press release announcing Mathur's hiring seems to explicitly suggest that he will be undertaking activities at UNOS which appear to be in direct violation of his Post Employment Guidance (PEG).

[21] Audio shared with Committee
[22] https://aboutblaw.com/bfcb

8. Mr. Segal, reports indicate that UNOS's technology platform is outdated, fragile, and unreliable for a system critical to saving lives. 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?

Every day HRSA allows UNOS to operate the technology system poses a dangerous threat to sensitive patient data, including patients' social security numbers, sexual and mental health history, and next of kin information. In fact, UNOS is already the subject of at least 10 lawsuits from patients over a recent data breach, which affected as many as 1.5 million patient records.

Additionally, in February 2022, the Senate Finance Committee wrote to senior officials at the White House Office of Management and Budget (OMB), the Department of Homeland Security (DHS), and the Department of Health and Human Services (HHS) that it has "no confidence in the security of the [OPTN technology] system", and urged the Administration to take "immediate steps" to protect the system from "cyber attacks" and "hackers."[23]

It is my understanding that, until this intervention, UNOS has been using a security algorithm from 1996 to protect all sensitive patient data (for context, that implies that UNOS deployed a very primitive security system decades ago, and then did not bother to update it until the Federal Government forced them to do so amid serious concerns for national security).

UNOS does not care about patients, nor does it care about protecting our sensitive health data. Any steps HRSA can take to remove UNOS immediately are vitally important, including, as alluded to in a previous answer, by bringing on meaningfully qualified technology professions to run OPTN oversight, rather than continuing to allow the same captured civil servants to undermine reforms and, seemingly, to leak government information to industry.

9. Mr. Segal, given your advocacy for transparency in the organ procurement system, how can the Modernization Initiative specifically address the disparities that rural patients face in accessing organ transplants? What role should accountability and transparency play in ensuring fair treatment for all patients, regardless of where they live?

Rural patients face severe disparities in access not only to organ transplants, but also to donation care from OPOs. It should also be noted that – despite UNOS's attempts to minimize these disparities or to otherwise explain them away – these disparities seem to result directly from entirely informed decisions UNOS made that were animated by an active antipathy to rural and minority patients, or, at best, a shocking and reckless indifference to the harm that their policy decisions would case these patients.

For example, in emails unsealed by a Federal Judge, a then-UNOS board member, Alexandra Glazier, wrote to then-UNOS CEO Brian Shepard, defending a UNOS policy decision that would cause significant

[23] Available online at: https://www.grassley.senate.gov/imo/media/doc/wyden_and_grassley_to_omb_-_optn_tech.pdf

harm to rural Americans by restricting their access to lifesaving liver transplants. Glazier's justification for why rural Americans do not deserve the same access to lifesaving care as urban Americans was simply that these patients are "dumb fuck[s]" for where they live.[24] Shepard also additionally commented that, under UNOS's leadership, *"Only people who have means can get transplant So [policy considerations pertaining to organ allocation are essentially about whether UNOS should] give txs to those of us who have to live near poor people."*[25]

(It should also be noted that the OPO Glazier runs, New England Donor Services, is considered underperforming [Tier 2] by CMS, and was previously investigated by the House Oversight Committee for "shocking mismanagement" and what Rep. Katie Porter called "patient abuse.")

In addition to, first and foremost, replacing UNOS with competent, good faith OPTN contractors who do not share UNOS's disdain for rural Americans and poor people, the best way to address disparities these disparities is through:

- Strict enforcement of the OPO Final Rule, without dilution or delay, which HHS estimates will lead to more than 7,200 additional lifesaving organ transplants every year;
- Publish OPO process data, in line with every other mature international transplant system so that there is evidence of effective and equitable patient care. OPO process data specifically refers to such data as how many referrals OPOs received from each hospital; and how quickly they responded to the referral, if at all) (given that OPOs are far less likely to even respond to cases at rural and/or minority-serving hospitals, much of the disparities in access to donation care is enabled by the opacity in which CMS has allowed OPOs to operate); and
- Publishing pre-waiting list data for transplant candidates, so that transplant centers can no longer discriminate against certain patient populations in terms of who they place on the transplant list in the first place without scrutiny from the public, their regulators, or Congressional oversight bodies.

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 that we must develop novel antimicrobial therapies?

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[24] 1:19-cv-01783-AT Callahan et al v. United States Department of Health and Human Services et al, Document 357-1, Page 6.
See also Washington Post, accessible at: https://www.washingtonpost.com/health/liver-transplant-lawsuit/2021/12/21/2443f904-61b9-11ec-bf70-58003351c627_story.html
See also STAT News, "The organ procurement system is failing people of color like me. It's time for reform", accessible at: https://www.statnews.com/2022/04/07/organ-procurement-system-failing-people-of-color/

[25] 1:19-cv-01783-AT Callahan et al v. United States Department of Health and Human Services et al, Document 357-1, Page 1.

This is such an important issue, and one that is also personal for me, given that my own father – like all transplant patients – takes immunosuppressing medications every day, which greatly increase his risk for serious infection, and have otherwise worsened his quality of life. People generally think of transplant as a cure for organ failure, and, by extension that the patient is somehow 'cured' post-transplant.

While transplants are obviously lifesaving, though, my father – like all other transplants – have simply transitioned from being a pre-transplant patient to a post-transplant patient, which is fraught with risks and complications, most of which result from taking daily immunosuppressing medications.

I am a major proponent of any and all efforts to fund and to de-risk new antimicrobials, and am deeply grateful for your leadership on this important issue.