

Energy and Commerce Committee

Subcommittee on Oversight and Investigations

"A Year Removed: Oversight of Securing the U.S. Organ Procurement and Transplantation Network Act Implementation"

September 11, 2024

Documents for the Record

1. Staff - ADA Statement for the Record
2. Staff - OPTN Patients Affairs Leaders Call for Formica Resignation
3. Burgess – Article concerning Mr. Segal and Non-profits

September 10, 2024

The Honorable Morgan Griffith
Chairman
Subcommittee on Oversight and Investigations
Energy and Commerce Committee
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Kathy Castor
Ranking Member
Subcommittee on Oversight and Investigations
Energy and Commerce Committee
2322A Rayburn House Office Building
Washington, DC 20515

Dear Chairman Griffith and Ranking Member Castor,

On behalf of our 159,000 members, the American Dental Association (ADA) is writing about the September 11, 2024, Subcommittee on Oversight and Investigations hearing titled, "A Year Removed: Oversight of Securing the U.S. Organ Procurement and Transplantation Network Act Implementation." The ADA appreciates the opportunity to contribute to this important discussion and emphasizes the essential role that dental services play in the success of organ transplants and patient outcomes.

The ADA has supported the inclusion of dental services as part of the comprehensive medical care necessary for successful organ transplants. As we noted in our previous comments submitted to the Centers for Medicare & Medicaid Services (CMS), oral health can be intrinsically linked to overall health. Failure to address dental infections prior to organ transplant procedures can significantly compromise the success of the surgery and the patient's long-term health. Studies have demonstrated that some oral infections can lead to systemic infections that affect surgical outcomes and patient recovery.¹

We commend Congress for passing the bipartisan Organ Procurement and Transplantation Network Act, which provides critical improvements to the system. However, challenges remain in ensuring that patients undergoing organ transplants receive the necessary comprehensive care, including dental services. Primarily, many individuals who await transplants are not able to proceed due to presence of dental infection that must be treated by dental providers to mitigate the risk of immunosuppression and transplantation rejection. The ADA has previously endorsed CMS rules to pay for dental examinations as part of a pre-transplant medical workup, as well as necessary dental treatments to eliminate oral infections prior to surgery (CMS-1770-P, 2022).²

We urge the full committee to prioritize the inclusion of dental care as an essential element in patient care. Dental care plays a pivotal role in reducing complications and improving the quality

¹ Scannapieco FA, The oral microbiome: its role in health and in oral and systemic infections. Clin Microbiol Newsl. 2013; 35: 163-169

² Federal Register, [Medicare and Medicaid Programs; CY 2023 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies](#), November, 18, 2022.

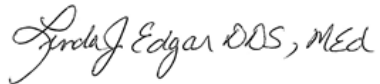
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of life, especially for transplant patients. As we noted in previous comments to CMS,³ comprehensive dental care is critical not only to the success of the surgical procedure but also to the patient's long-term health outcomes.

We appreciate your attention to these issues and are available to provide further information as needed. Please contact Mr. Chris Tampio, tampioc@ada.org or 202-789-5178 for further discussion.

Sincerely,



Linda J. Edgar, D.D.S., M.Ed.
President



Raymond A. Cohlma, D.D.S.
Executive Director

LJE:RAC:ct

³ American Dental Association, [Calendar Year \(CY\) 2023 Proposed Rule: Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies](#), September 2, 2022.

Dear _____,

As volunteer leaders of the Organ Procurement and Transplantation Network (OPTN) Patient Affairs Committee, the only committee inside the OPTN whose role is to represent the voice and interests of patients, we were appalled to learn that the president of the OPTN, Dr. Rich Formica, has declined the Congressional request to appear at the September 11th hearing, "[Oversight of Securing the U.S. Organ Procurement and Transplantation Network Act Implementation.](#)"

The Securing the U.S. OPTN Act passed Congress unanimously last year, and lives depend on its successful implementation. We are grateful to the Energy & Commerce Committee for its leadership in passing this bill into law, and in its vigilant and bipartisan oversight.

This utter disregard for Congress, and the level of arrogance demonstrated by his refusal to appear, leads us to the conclusion we have feared for months: that despite rhetoric to the contrary, the President of the OPTN is against Congressional efforts to modernize the U.S. transplant system, and as a result, apparently has no qualms sentencing thousands of patients to death in this outdated and archaic system.

We shouldn't be surprised. This is the individual who has been called out in [investigative reporting](#) and in the [Committee's bipartisan investigation](#) for retaliatory behaviors against patients and professionals who speak out against the status quo, yet has faced no investigation into these behaviors.

This is the individual who wrote a misleading letter to the organ donation and transplantation community in an effort to subvert basic government oversight; a letter so egregious that it prompted an immediate response and correction from [bipartisan Members of the Senate Finance Committee](#).

This is the individual who as recently as March of this year, served on the board of the United Network for Organ Sharing (UNOS), about which the [Committee](#) wrote:

"UNOS has been the sole organization managing the OPTN, during which time concerning reports have emerged that the organ donation system has become [unsafe](#), [inequitable](#), [self-dealing](#), and [retaliatory](#)."

And now this is the individual who has put his own personal interests in front of the patients he is supposed to represent, and does not have the courage to show up and be held accountable.

We wish patients had an option to decline the burden organ failure brings, but they do not.

The fact that Dr. Formica can't concern himself to respond to a request from the U.S. Congress to appear today speaks louder than anything we can share with you.

A system led by a person so callous to demonstrate such disregard for patients and Congress deserves no national policymaking role in the transplant system. As a result, we demand Dr. Formica's immediate resignation from his OPTN role.

Yours sincerely,

Molly McCarthy

3-time Kidney Transplant Recipient

Chair of the OPTN Patient Affairs Committee

with

Garrett Erdle

Living Kidney Donor

Immediate Past Chair of the OPTN Patient Affairs Committee

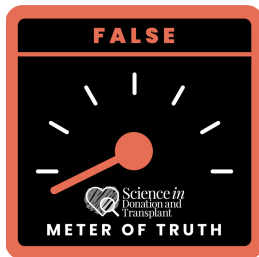
and

Lorrinda Gray-Davis

Liver Transplant Recipient

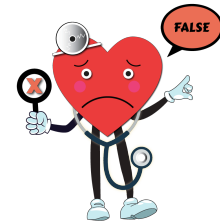
Vice Chair of the OPTN Patient Affairs Committee

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Greg Segal stated on December 2, 2020, in an op-ed article

“In the last year, I’ve lost three people I love to the organ donation shortage. [...] And, frankly, I am exhausted of the government contractors responsible for their deaths fighting with their constituents rather than for them.”



In a recent op-ed in the [Albuquerque Journal](#), Greg Segal, founder of Organize.org, writes of three people’s personal loss this past year waiting for transplants. Segal claims Organ Procurement Organizations (OPO’s), nonprofits whose sole reason for existing is to facilitate life-giving transplants, are “responsible for their deaths...”. Segal offers no evidence, only hyperbolic conjecture, which does not back up this horrific claim.

Organize.org and primarily from its founder Greg Segal.

Again, we understand Mr. Segal's pain and frustration. The donation community worked hard to get his father and all other fortunate recipients life-saving transplants. Contrary to Mr. Segal's allegation that the opponents to the new federal regulations are "moneyed interests," the donation community is comprised of non-profit organizations, volunteers, and transplant physicians. In contrast, let's look at Mr. Segal's newfound interest in the donation system. Organize.org is only the front-man in Segal's efforts to take control of the nation's life-saving organ procurement and transplant system.

Organize.org is a non-profit corporation controlled by Segal, whose original goal was to build a donor information network and sell it to the federal government and procurement organizations. His early efforts faced resistance. A national online registry was already being created through donation-related organizations and volunteers, and Mr. Segal badly wanted in.

Organize created private listings of potential organ donors, mainly by encouraging young people to express their general donation approval and posting their Facebook wishes. Organize then promised to sell its ability to scrape Facebook data to share it (for a fee) with organ procurement organizations. Their efforts fell short of registering organ donors. The actual donor registry information, comprised of legally enforceable 'documents of gifts,' was already available to OPOs from secure state registries for free.

Segal writes that no OPO has been decertified. Low-performing OPO's need assistance, not destruction. We don't close low-performing hospitals. We help them do better.

Segal wants to add "forced competition" between OPO's, bringing chaos to the complex system that makes organ donation and transplants possible—spoken like a genuine venture capitalist with no professional experience in organ donation and transplantation.

Segal claims the historic rise in organ donations "is almost wholly attributable to the drug epidemic." At the same time, Segal cites no source for this claim. We suspect this claim comes from an article by the same person who utilizes inaccurate death certificate data to support claims that tens of thousands of organs go unrecovered, Dr. David Goldberg.

According to the letter in *The New England Journal of Medicine* on February 7, 2019, [Organ Donation and Drug Intoxication—Related Deaths in the United States](#), "The increase in the percentage of donor organs recovered from persons who died from drug intoxication ... is greater than would be expected from the increase in the rate of drug intoxication-related deaths alone." This statistical fact, coupled with the common practice of reporting deaths of drug-users, and even former drug users as "opioid deaths" refutes Segal's claim."

As an April 10, 2020 letter in *Clinical Transplantation* states: "The authors [Goldberg et al.] anchored their analysis on a logical fallacy—that "drug-related" deaths



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The increase in opioid deaths hardly supports Segal's exaggerated claim that record donations and transplants are "wholly" due to drug addicts dying. He discounts all systems improvements made by nonprofit Organ Procurement Organizations. Segal claims an unnamed data scientist as the source of the claim. If this claim is valid, it is incumbent on Segal to name the person.

As with most things, Segal uses hyperbole, contrived data, and lousy sourcing to make unfounded attacks on the organ donation system in our nation.

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