



# NATIONAL KIDNEY FOUNDATION®

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December 2, 2025

The Honorable Robert F. Kennedy  
Secretary of the U.S. Department of Health and Human Services  
Hubert H. Humphrey Building  
200 Independence Avenue SW  
Washington, DC 20201

Re: Expanding Organ Access to Patients and Restoring Trust; Department of Health and Human Services Announcement of Organ Procurement Oversight Reforms, September 18, 2025

*cc: The Honorable Jim O'Neill, Deputy Secretary of the U.S. Department of Health and Human Services;  
The Honorable Dr. Mehmet Oz, Administrator, Centers for Medicare and Medicaid Services;  
Stefanie Spear, Senior Counselor, Office of the Secretary, U.S. Department of Health and Human Services  
John Brooks, Chief Policy and Regulatory Officer, Centers for Medicare and Medicaid Services;  
Meghan O'Toole, Senior Advisor, Centers for Medicare and Medicaid Services;*

Dear Secretary Kennedy,

On behalf of the National Kidney Foundation (NKF) and the 37 million Americans living with kidney disease, thank you again for your remarks at the September 18 briefing outlining HHS's vision for expanding kidney availability through xenotransplantation, regenerative medicine, and advanced biomanufacturing. Your leadership offers real hope to the more than 550,000 patients receiving dialysis, to the more than 90,000 patients currently waiting for a kidney transplant, and to the thousands who die each year while on the waitlist.

The NKF has a long history of supporting innovations that increase organ supply and advance equity in transplantation. Our Externally-Led Patient Focused Drug Development meeting on kidney xenotransplantation provided the first national platform to bring patient perspectives directly into regulatory and clinical development discussions, and we are proud that this work helped shape early expanded-access xenotransplantation efforts.

We share your belief that progress will require collaboration across patients, clinicians, scientists, regulators, and public agencies. NKF stands ready to connect its national network of nephrologists, transplant surgeons, engineers, researchers, patient advocates, and innovation partners to help accelerate development, ensure safety and trust, and promote equitable access.

We also commend HHS's commitment to strengthening and modernizing the Organ Procurement and Transplantation Network. Improving accountability, transparency, and oversight is essential to restore public confidence and ensure every potential organ is used to save or improve a life.

We respectfully request a follow-up discussion with HHS to identify next steps for collaboration and continued progress.

Thank you for your continued leadership and commitment to patients.

Sincerely,

Kevin Longino  
CEO and Transplant Patient



December 2, 2025

Dr. Martin A. Makary  
Commissioner of Food and Drugs  
U.S. Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

Re: Expanding Organ Access to Patients and Restoring Trust; Department of Health and Human Services Announcement of Organ Procurement Oversight Reforms, September 18, 2025

cc: *Dr. Vinay Prasad, Director, Center for Biologics Evaluation and Research, U.S. Food and Drug Administration; Vijay Kumar, Acting Director, Office of Therapeutic Products, Center for Biologics Evaluation and Research, U.S. Food and Drug Administration;*

Dear Commissioner Makary:

On behalf of the National Kidney Foundation (NKF), thank you for the FDA's leadership in advancing kidney xenotransplantation research into clinical evaluation. For the more than 90,000 Americans waiting for a kidney transplant, the FDA's progress represents not only scientific advancement, but renewed hope.

The NKF has worked for many years to ensure that patient perspectives inform this field. Our Externally-Led Patient Focused Drug Development meeting on kidney xenotransplantation<sup>1</sup> brought forward essential insights regarding patient expectations, willingness to participate in trials, risk tolerance, and quality-of-life goals. We are proud that this work helped support the early compassionate-use xenotransplants and contributed to shaping the considerations now guiding clinical trial design.

As xenotransplantation moves into broader clinical study, continued attention to patient experience, informed consent clarity, post-transplant monitoring, and long-term safety will be critical. NKF stands ready to assist with:

- Patient education and community engagement
- Facilitated listening sessions with transplant candidates and caregivers
- Clinical and ethics advisory input from our transplant and nephrology networks
- Support in communicating trial findings in clear, trustworthy, and accessible ways

We deeply value the FDA's commitment to robust ethical and safety standards. Maintaining public confidence will determine the success of this innovation pathway as much as the science itself.

We respectfully request a follow-up meeting with FDA leadership to discuss structured collaboration opportunities that would ensure patient voice, safety, and equitable access remain centered throughout clinical development.

Thank you for your continued dedication to patients and innovation. Thank you for your continued leadership and commitment to patients.

Sincerely,

Kevin Longino  
CEO and Transplant Patient

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<sup>1</sup> [https://www.kidney.org/sites/default/files/2024-11/NKF\\_Xeno%20VoP\\_Final.pdf#](https://www.kidney.org/sites/default/files/2024-11/NKF_Xeno%20VoP_Final.pdf#)



December 2, 2025

Dr. Alicia Jackson  
Director  
Advanced Research Projects Agency for Health (ARPA-H)  
U.S. Department of Health and Human Services

Re: Expanding Organ Access to Patients and Restoring Trust; Department of Health and Human Services Announcement of Organ Procurement Oversight Reforms, September 18, 2025

*cc: Megan Frisk, Acting Chief of Staff, Advanced Research Projects Agency for Health, U.S. Department of Health and Human Services;*  
*Rebekah Cecil, Deputy Chief Operations Officer, Advanced Research Projects Agency for Health, U.S. Department of Health and Human Services;*  
*Dr. Jonah Odum, Program Manager of Scalable Solutions, Advanced Research Projects Agency for Health, U.S. Department of Health and Human Services;*

Dear Dr. Jackson:

The National Kidney Foundation (NKF) appreciates ARPA-H's leadership in advancing regenerative medicine and the development of patient-matched organs. For millions of Americans living with kidney disease, the vision of engineered or bioprinted transplantable kidneys represents a future no longer constrained by organ scarcity.

We were encouraged by ARPA-H's Personalized Regenerative Immunocompetent Nanotechnology Tissue (PRINT) program and its focus on scalable, immunocompatible organ manufacturing. This aligns closely with NKF's mission to eliminate preventable kidney failure and ensure every patient who needs a transplant can receive one.

NKF's national network and Innovation Fund are actively advancing technologies that complement ARPA-H's goals, including increased use of perfusion in transplant and new organ preservation solutions, cell-based therapies, transplant readiness tools, and patient-centered evaluation frameworks. We see significant opportunity for partnership to accelerate translation and support real-world deployment.

We would welcome the opportunity to collaborate by:

- Facilitating advisory input from our transplant surgeons, nephrologists, and regulatory specialists
- Convening patient and caregiver focus groups to inform development and trial design
- Supporting communication and trust-building with the patient community

The future of kidney transplantation will not be achieved by science alone; it will require patient trust, clinician engagement, and equitable access planning from the start. NKF is prepared to play this role. We respectfully request a follow-up meeting to discuss coordination between ARPA-H, NKF, and our Innovation Fund partners.

Thank you for your leadership and commitment to transformative kidney innovation.

Sincerely,

Kevin Longino  
CEO and Transplant Patient