

President Biden Proposes Advanced Research Projects Agency for Health (ARPA-H)

The president's request for fiscal year (FY) 2022 emphasized the Biden-Harris administration's strong support of and commitment to medical research and scientific innovation. While the president's complete budget will not be finalized by the start of the annual congressional appropriations process, typical during a presidential transition, the administration's proposal for discretionary funding in FY22 still provides useful insight into key administration priorities.

The administration proposed increasing the budget of the National Institutes of Health (NIH) to \$51 billion, a \$9 billion increase over FY21 levels (1). A significant portion of that increase would go to establishing the Advanced Research Projects Agency for Health (ARPA-H); President Biden first showed signs of supporting such an agency in 2019 on the presidential campaign trail. ARPA-H is envisioned to be housed within NIH and command a budget of \$6.5 billion to "provide significant increases in direct

Federal research and development spending in health" (2). ARPA-H's creation would be one of the largest increases in scientific research funding by the government in decades (3).

This new agency is believed to be charged with aggressively pursuing high-risk, high-reward technologies and therapies similar to the military's Defense Advanced Research Projects Agency (DARPA), after which it was modeled. While much still needs to be learned about ARPA-H as it is created, President Biden described the agency during his joint address to Congress on April 28, 2021, stating, "It would have a singular purpose: To develop breakthroughs to prevent, detect, and treat diseases like Alzheimer's, diabetes, and cancer" (4).

As ARPA-H is developed, ASN will advocate to the White House and NIH that sufficient resources be dedicated to programs within the agency that address kidney diseases and the needs of kidney patients. ASN will also

continue to engage the Biden-Harris administration and Congress to advocate for federal agencies and programs that promote translational research and prioritize medical and scientific innovation such as NIH and ARPA-H during the congressional appropriations process.

ASN will continue to provide updates on the policies and priorities of the Biden-Harris administration that affect kidney health professionals and the patients they treat. ■

1. <https://www.sciencemag.org/news/2021/04/biden-first-budget-request-goes-big-science>
2. <https://www.whitehouse.gov/wp-content/uploads/2021/04/FY2022-Discretionary-Request.pdf>
3. <https://www.statnews.com/2021/04/28/biden-pitches-new-health-agency-to-end-cancer/>
4. <https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/04/29/remarks-by-president-biden-in-address-to-a-joint-session-of-congress/>

Members of Congress Call for Organ Transplant System to Align with Patient Needs

By Zach Kribs

Members of the US Congress House Committee on Oversight and Reform called for urgency to increase the availability of organs for transplant and improve care for patients during a May 4, 2021, hearing on the US organ transplant system. Led by Committee Chair Raja Krishnamoorthi of Illinois and Ranking Member Michael Cloud of Texas, the hearing featured testimony from patients, organ donors, and transplant professionals and at times impassioned exchanges between members of the committee and Organ Procurement Organization (OPO) leadership.

"It is a very exhausting process waiting for a transplant," said Tonya Ingram, a hearing witness and patient on the waitlist for a kidney transplant. "Because of my rare blood type, being on the list could mean that I have to wait 10 years before I can receive a transplant. Ten years is a very long time for anyone...and to know that I won't have a kidney until then is a very daunting and heavy thing."

LaQuayia Goldring, a patient witness also on the waitlist for kidney transplant, provided testimony while receiving dialysis. "I can't miss dialysis, ever. Even when COVID-19 hit, I still had to come. And of course, I'm grateful for the opportunity to come to dialysis, and that it's keeping me alive, but it isn't easy."

The hearing follows recent finalization of the OPO Conditions for Coverage rule, which implements objective, verifiable, and standardizable metrics to assess the performance of OPOs. OPOs are a collection of 58 government contractors charged with the critical role of tracking potential organ donors, working with donors and donor families to obtain a consent-driven donation, and transporting the organ to the donor-recipient hospital.

"Given their central role in the transplant process, OPOs need to strive for perfection in their public mission," said Rep. Krishnamoorthi. "Unfortunately, they've been falling short. For years, OPOs have faced no outside incentive to perform. They evaded public scrutiny, refusing to reveal data showing their success and failure, hiding behind a wall of jargon and obfuscation. Each OPO enjoys a regional monopoly, under the law, with no competition, whatsoever."

The rule, staunchly supported by ASN, was established under the joint leadership of both the Trump and Biden administrations and many members of Congress. Rep.

Cloud remarked that it was "refreshing" to work with congressional colleagues in a bipartisan manner, noting that "finalization and implementation of this rule [are important steps]" and that Congress "must scrutinize the system in its entirety, in order to truly bring about meaningful reform," as "OPOs are not the only actor in the system and, certainly, not the only problem."

In written testimony provided to the committee, ASN President Susan Quaggin, MD, FASN, stated: "Improving our organ transplant system will require improvement of many different, interconnected, and too often fragmented, systems, including OPO performance, streamlining government oversight of the US transplant system, cutting 'red tape' surrounding the regulation of transplant centers, and above all else, ensuring that the US organ transplant system is built around and aligned with the needs of patients first."

Putting patients first, in particular patients of color who are disproportionately affected by the failures of the current system, was a persistent theme throughout the hearing. "As a former transplant nurse ... I personally treated and counseled patients suffering through chronic and severe illnesses," said Rep. Cori Bush of Missouri. "Black and Brown patients are more likely to suffer from illnesses like kidney failure and less likely to get an organ transplant. For them, the promise of receiving an organ is, too often, delayed or denied because there aren't enough organs available. I've watched this system fail dying patients time and time again. I've watched the system fail young people, older adults and far too many Black and Brown people. Our failing organ donation system is a death sentence for thousands. My time treating transplant patients has stayed with me, and I cannot overstate the urgency of this issue. We must do everything in our power to fix this system."

"Black Americans are three times more likely than white Americans to have a kidney failure, said Rep. Hank Johnson of Georgia." Despite this, Black kidney patients are less likely to be identified as transplant candidates, less likely to be put on a wait list, and less likely to receive a transplant."

The move to increase transparency and accountability was applauded by many, including US House Committee on Oversight and Reform Chairwoman Carolyn Maloney of New York. Rep. Maloney expanded on the need for transparency in the transplant system, highlighting that

"UNOS [United Network for Organ Sharing], the entity that manages the US transplant list, under contract with the government, stores valuable OPO data. But UNOS prohibits OPOs from sharing performance data with the public and only allows some data to be distributed publicly." Maloney stated simply that "Because OPOs provide a public service, their data should be public."

Rep. Katie Porter of California, a longtime champion for reforming the transplant system, also expanded on the importance of transparent and standardizable data, bringing out her signature whiteboard to illustrate her point to Association of Organ Procurement Organizations (AOPO) CEO Steve Miller. Highlighting pitfalls of the now-replaced metric, which allowed OPOs to define the denominator to which they are held accountable, Porter criticized AOPO for "defending a system in which OPO B looks like [it's] much worse than OPO A. But in reality, it could just be the case that OPO B is going after every possible donor, regardless of race, regardless of whether it's hard, regardless of whether [it] may not get turned down, regardless of whether or not it might be easy."

Members of Congress made it clear that the hearing was only the start of their work to reform the transplant system for patients. Porter stated: "Thousands of patients waiting on a life-saving organ cannot wait while the AOPO lobbies and tries to stop rules and procedures, just to make it simply clear whether an OPO is doing the life-saving work of retrieving organs and putting them into patients in need." Krishnamoorthi warned that any effort to avoid congressional scrutiny would not succeed, stating, "This committee is on the case, and we're not going away. We're actually going to accelerate our efforts and we're going to pursue this, as far as we can."

As to what the result of increased congressional oversight and access to transplants would mean for patients, Ingram said, "For me, it kind of boils down to the simple fact of keeping people alive and just ... what that holds. Like, we get to sit here right now, and this is living ... Essentially the gift of being able to have an organ is to be able to engage in and live this beautiful full life."

A full recording of the hearing can be found on the Oversight and Reform Committee's website at <https://oversight.house.gov/legislation/hearings/the-urgent-need-to-reform-the-organ-transplantation-system-to-secure-more>. ■