



\$6.5 billion proposed for new US health research agency

The Advanced Research Projects Agency for Health would fund high-risk, high-reward medical research, but its short-term planning could stymie basic research. Susan Jaffe reports.

During his first address to a joint session of Congress last month, US President Joe Biden drew little applause from Republicans in the physically distanced, masked audience. A rare exception to their steadfast silence came when he unveiled an ambitious plan to eradicate cancer.

To help reach this goal, Biden would establish a new biomedical research agency within the National Institutes of Health (NIH) called the Advanced Research Projects Agency for Health (ARPA-H). The agency would provide a fast track for transforming basic science into real-world applications. But it would also consume nearly all of the NIH funding increase Biden has proposed for the fiscal year starting Oct 1, 2021.

The prospect of funding opportunities from a new NIH agency has raised hopes as well as concern in the biomedical research community. Like other sectors in the USA, biomedical research has not yet fully recovered from the economic and health effects of the COVID-19 pandemic shutdown. Diverting funds to ARPA-H would be short-sighted, critics say, and possibly delay resumption of the full range of basic, clinical, and translational studies that the NIH supports. Biden sees the issue differently.

"We are going to have a singular purpose—to develop breakthroughs, to prevent, detect, and treat diseases like Alzheimer's, diabetes, and cancer", he told Congress. "I'll still never forget when we passed the cancer proposal in the last year I was vice president—almost \$9 million going to NIH". That proposal was the 21st Century Cures Act of 2016, which included a provision named

for Biden's son, Beau, who died from brain cancer in 2015. Then Biden departed from his prepared remarks to thank his most formidable adversary, the Senate's minority leader Republican Mitch McConnell.

"And, excuse the point of personal privilege, I'll never forget you

"We fully support the president's intention to do things in new ways to get to goal but not at the expense of basic research'..."

standing, Mitch, and saying name it after my deceased son. It meant a lot. But so many of us have deceased sons, daughters, relatives who died of cancer. I could think of no more worthy investment, I know of nothing that is more bipartisan. So, let's end cancer as we know it. It is within our power to do it."

Members of both political parties responded with an enthusiastic standing ovation. According to an overview of Biden's first budget proposal, the NIH would receive \$51 billion, or \$8.1 billion more than last year, and \$6.5 billion of that increase would be directed to ARPA-H.

"Aggressive approach"

"There's a lot of excitement about the clear recognition from the president that an investment in NIH is going to help people all across the country", said Tannaz Rasouli, senior director of government relations at the Association of American Medical Colleges (AAMC), which represents every accredited US medical school, more than 400 teaching hospitals and health systems, and more than 70 academic societies. This "is clearly personal to him", she said.

Although details have yet to be released, Biden has said ARPA-H would resemble the Defense Advanced Research Projects Agency (DARPA), created in 1958 in response to the Soviet Union's Sputnik satellite launch the year before. DARPA is part of the Department of Defense and has been credited with developing a precursor to the internet, miniature global positioning system receivers, precision weaponry, and other new technologies for the military.

ARPA-H "will help propel us forward in a way that is new to biomedical and health research", said Tara Schwetz, assistant director for biomedical science initiatives at the Office of Science and Technology Policy, which advises the president on scientific issues. "Housed within and complementary to NIH, ARPA-H will embrace a DARPA-like aggressive approach to fundamentally transform the application of biomedical and health research and accelerate the development of tangible breakthroughs for a range of diseases...as quickly as possible", she said.

Under ARPA-H, the federal government would "fund high-risk, high-reward projects with the expectation that if you don't show milestones quickly, they get unfunded", said Ross McKinney, a physician and AAMC's chief scientific officer. Funding that is contingent on results in a short time period could be a challenge for some academic researchers whose NIH grants cover several years of basic scientific exploration that sometimes hits a dead end, he said. "Basic science really takes time, and requires a certain amount of serendipity", he said. And without continued investments in basic science, he added, there is



nothing researchers can develop into new applications and “ARPA-H will not be effective”.

After funding ARPA-H, approximately \$1.6 billion of the proposed \$8.1 billion increase would be directed to the NIH. Details on how that money will be distributed will come when Biden releases his full budget later this month, an NIH spokesperson said. Once the full budget is available, Congress debates and makes changes before approving and sending it to the President for his signature. A key point likely to come up is how ARPA-H would differ from the NIH’s National Center for Advancing Translational Sciences, which appears to have a similar mission.

Although Representative Tom Cole, an Oklahoma Republican, said Biden’s overall request for the NIH “looks pretty good”, he hopes the proportion earmarked for ARPA-H will change during negotiations between the White House and Congress, which finalises the budget. He wants to reduce ARPA-H funding and “redistribute those dollars to other NIH functions”, such as expanding the availability of research grants. Cole is the senior Republican on one of the committees that oversees the NIH.

“We fully support the president’s intention to do things in new ways to get to goal but not at the expense of basic research”, said Eleanor Dehoney, vice president of public policy and advocacy at Research!America, an

alliance of research institutes, medical centres, scientific societies, and patient advocacy groups. “If you pit those two against each other, you are pitting short-term gains against ongoing progress and the possibility of continued gains.”

Pandemic recovery

Dehoney, along with Cole and other NIH supporters, is concerned that the \$1.6 billion increase for the NIH will not stretch far enough to help researchers recover from the effect of the pandemic while also keeping the trajectory of its budget increases well above inflation.

The pandemic relief packages Congress passed earlier this year and in 2020 provided funding for the NIH, the Centers for Disease Control and Prevention, and other federal agencies for the public health emergency response and kept many businesses from closing. But that aid did not address NIH work that was disrupted by the pandemic, said an NIH spokesperson.

“So much of our research enterprise, not just at NIH in our laboratories in Bethesda [MD, USA] but all over the country—since that’s where most of NIH’s dollars go—has been very much scaled back”, said NIH Director Francis Collins during a congressional hearing last July. “And people were still able to do science and many of them have worked incredibly hard doing what they can do. But if you need a lab bench and you need some equipment and some supplies, you can’t do that at your dining room.”

Universities and medical centres, which are major NIH grantees, have suffered research setbacks due to the pandemic, he continued. “We have estimated just on the basis of the research that’s been lost, something in the neighbourhood of \$10 billion of federal funds that may be necessary...if we’re going to bring these institutions back up to where they need to be”, Collins said. The NIH has since updated that estimate to \$16 billion, according

to an NIH spokesperson. Most of the laboratory and clinical research done at the NIH was affected in some way because of the pandemic, according to an NIH spokesperson. “As a result of NIH focusing intramural resources on SARS-CoV-2 research, many of our clinicians could not initiate new, non-COVID-related protocols, and recruitment of volunteers into ongoing protocols was curtailed significantly, particularly in the first half of 2020.”

Cole has co-sponsored the bipartisan Research Investment to Spark the Economy (RISE) Act, which would provide a one-time infusion of \$25 billion to restore the US scientific research enterprise to pre-pandemic levels. The NIH would receive \$10 billion. In an initiative led by Research!America, more than 200 academic research centres, health-care systems, scientific and medical societies, and patient advocacy groups have urged Biden to support the bill.

The legislation underscores the unmet needs at the NIH as a result of the pandemic, while the president’s NIH budget attempts to set a course to meet future challenges. Reconciliation might depend on yet another, seemingly unrelated factor: Democrats’ plan to include a provision in the budget that would rescind the Hyde Amendment, which prohibits government-funded abortions (unless the pregnancy endangers a woman’s life, or resulted from rape or incest). Opponents say the restriction discriminates against low-income women who otherwise cannot afford the procedure. Biden agrees.

“You’re not going to have any support on the Republican side for biomedical research if you do this”, said Cole. Democrats might have enough votes in the House of Representatives to overcome Republican opposition, Cole predicted, but not in the Senate, where Democrats maintain a majority of just one vote.

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