



## US election 2020: research and health institutions

How will the NIH, CDC, and FDA change if President Donald Trump wins a second term or if his Democratic challenger, Joe Biden, defeats him? Susan Jaffe reports from Washington, DC.

### NIH

This report is the second of three in a series exploring the health and science issues in the campaign for the US presidency

For **Trump's priorities** see <https://www.donaldjtrump.com/media/trump-campaign-announces-president-trumps-2nd-term-agenda-fighting-for-you/>

For **Biden's priorities** see <https://joebiden.com/joes-vision/>

For more on **Trump and the CDC** see *World Report Lancet* 2020; 396: 875

Although President Donald Trump has not outlined any specific plans regarding the National Institutes of Health (NIH) should he win re-election, it is not difficult to figure out what is in store for the largest public funder of biomedical research in the world.

In each of Trump's 4 years in the White House, his administration has proposed cuts in NIH funding, and each year Congress approved increases instead. "There's been a fairly unified message from Congress that these kinds of funding reductions are unacceptable", said Matt Hourihan, director of the Research and Development Budget and Policy Program at the American Association for the Advancement of Science, which represents 250 scientific societies and academies serving 10 million members. Some relatively small Trump initiatives, such as paediatric cancer and neonatal research, do little to offset the president's overall budget reductions, he said. The Trump administration has requested US\$39.1 billion for the NIH for the fiscal year ending September, 2021, which is 16% less than last year's \$41.7 billion final budget and 13% lower in inflation-adjusted dollars than what it received in 2003.

One exception to Trump's consistent NIH funding cuts is his agreement with Congress on three emergency aid packages so far this year in response to the COVID-19 pandemic, including a total of \$3.59 billion for the NIH. But that assistance is restricted to work related to the virus.

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Competition for NIH research grants "is so great that it discourages young scientists", said Mary Woolley, president and chief executive officer of Research!America, an alliance of research institutes, medical centres, scientific societies, and patient advocacy groups. "We have to do better than fund one in five proposals."

If Trump wins re-election, it is unlikely that he will dramatically change course, said Jennifer Zeitzer, public affairs director at the Federation of American Societies for Experimental Biology, which represents 29 professional scientists' associations. "Everything that we've observed in the last 3 years, and however many months it's been, suggests that Trump 2.0 would probably be a lot like the first Trump administration, with the same level of unpredictability in the administration's policies, and the back-and-forth support for science on one hand and then willingness to criticise the scientific process on the other hand", she said.

At the request of the Trump administration, the NIH is part of Operation Warp Speed, an unprecedented multi-agency effort to accelerate development of a COVID-19 vaccine,

said Zeitzer. But at the same time, Trump claimed the vaccine would be ready by election day, Nov 3—an unrealistic assertion demonstrating that he does not appreciate "that science takes time", she said.

Trump's campaign website includes a list of priorities for his second term, posted in late August, that contain brief phrases and still lack specifics. There is no reference to the NIH, Centers for Disease Control and Prevention (CDC), or Food and Drug Administration (FDA), nor is medical research mentioned. A campaign spokeswoman and the White House press office declined to answer questions for this article.

Former Vice President Joe Biden has had a long-standing interest in medical research. President Barack Obama appointed him to lead the Cancer Moonshot Task Force, which produced a report in October, 2016, outlining public and private sector commitments to speed up cancer prevention, diagnosis, and treatment.

As president, Biden has promised to provide \$300 billion over 4 years to promote research and development and create jobs across the economy, including direct funding to the NIH, according to the campaign. He would create an Advanced Research Projects Agency for Health within NIH's parent agency—the Department of Health and Human Services—modelled after the Defense Advanced Research Projects Agency.

Biden also proposes giving the NIH \$50 billion over a 4-year period to invest in cures for cancer, diabetes, Alzheimer's disease, and Parkinson's disease. "No drug company has the capacity to do it", he said at a rally in Florida last week. "If we do not find an answer to Alzheimer's, then in the next 19 years, every single solitary bed that exists in the United States of America



Carlo Barria/Reuters

now will be occupied by an Alzheimer's patient."

## CDC

The Trump administration has also proposed cuts in federal funding for the CDC that Congress has rejected in favour of increases for the past three budgets. It has a current budget of about \$8 billion and some 13 000 employees in the USA and around the world, along with 10 000 contractors. The agency also received additional emergency funding to respond to COVID-19. The administration's budget proposal for the 2021 fiscal year calls for a 9% reduction.

The Trump campaign has pledged to develop a vaccine by the end of this year and "return to normal in 2021", although CDC Director Robert Redfield has said a vaccine will not be ready until spring 2021. In addition to the lack of details on how to reach those goals, Trump has minimised the seriousness of the virus and flouted the precautions that the CDC and other agencies have recommended. The agency has also been tarnished by media reports of efforts to deflect criticism of the president's pandemic response by manipulating CDC guidance and keeping its career scientists from appearing at press conferences.

Unless the Trump administration makes some changes to restore the CDC's scientific integrity and respect, scientists will leave and the agency will have difficulty hiring new people, said James Curran, dean of the Rollins School of Public Health at Emory University in Atlanta, GA, which is also home to CDC headquarters. Curran was also an associate director at the CDC, where he led the HIV/AIDS Division.

A Biden administration will "listen to science" and "ensure that public health decisions are informed by public health professionals", according to the campaign.

Instead of letting individual states decide how to respond to the pandemic, Biden's national response plan would "direct the CDC to provide

specific evidence-based guidance for how to turn the dial up or down relative to the level of risk and degree of viral spread in a community, including when to open or close certain businesses, bars, restaurants, and other spaces; [and] when to issue stay-at-home restrictions".

Curran says that whoever wins the presidency needs to "restore the CDC and improve it by letting them know that they will have an opportunity to do the best science and make the best recommendations from that science, and be ready to defend them".

## FDA

Experts suggest that the scientific integrity and independence at the FDA is at stake in the election.

The presidential candidates have very different visions for the FDA, said Daniel Carpenter, a professor of government at Harvard University who has studied the agency. "I think Biden is more trustful of civil servants and government scientists", he said. If Biden wins, Carpenter thinks we are likely to see "appointments to the FDA that strengthen public health" at all levels of the agency.

The COVID-19 pandemic has revealed how the Trump administration has attempted to commandeer the FDA. After Trump touted the benefits of the anti-malarial drug hydroxychloroquine to treat COVID-19, the FDA issued an emergency use authorisation for the drug it later had to withdraw when studies showed the drug was ineffective and, for some patients, dangerous.

On the eve of the Republican convention in August, Trump disregarded objections from the NIH and announced that the FDA would permit the use of convalescent blood plasma to treat the virus under an emergency use authorisation. At a White House press conference, he claimed the "historic" action would reduce COVID-19 fatalities by 35%. Trump called it "a tremendous number", but it was also wrong.

FDA Commissioner Stephen Hahn reiterated the president's claim, but



later conceded it was exaggerated and removed a public relations official at the FDA (appointed by the White House) who was involved in the error. The FDA's parent agency, the Department of Health and Human Services, also cancelled the contract of an FDA media consultant who had advised Hahn to correct his misstatement, according to *The Washington Post*.

In addition, under the delayed FDA guidance for vaccine manufacturers, an emergency use authorisation for their products requires them to monitor patients for 2 months after their final dose. The decision is one reason why Trump is unlikely to keep his promise of a vaccine before voters go to the polls on Nov 3.

Eventual vaccine approval must be free of unsupported promises and intervention from political appointees, said Carpenter. "If people feel it was railroaded through by Trump, you'd have a huge adherence problem", he said.

Biden, according to his campaign, would "Put scientists in charge of all decisions on safety and efficacy; publicly release clinical data for any vaccine the FDA approves; authorize career staff to write a written report for public review and permit them to appear before Congress and speak publicly uncensored". These steps should ensure that politics "play no role in determining the safety and efficacy of any vaccine".

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