

Biden to Spend \$5 Billion on New Coronavirus Vaccine Initiative Supported by Gates, Fauci and Republican Lawmakers

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The U.S. government will spend \$5 billion on a program to accelerate the development of new coronavirus vaccines and therapeutics, White House officials announced this week in an interview with <u>The Washington Post</u>.

Dubbed "Project NextGen," the new initiative will serve as the successor to the Trump administration's "Operation Warp Speed," launched in March 2020 to expedite the development of COVID-19 vaccines.

Similar to Operation Warp Speed, Project NextGen — with funding from the Bill & Melinda Gates Foundation and the <u>Rockefeller Foundation</u> — will encourage public-private partnerships.

<u>According to Reuters</u>, the project will be managed out of the U.S. Department of Health and Human Services (HHS), which will coordinate across various government agencies and private-sector actors, covering "all phases of development from lab research and clinical trials to delivery."

"Scientists, public heath [sic] experts and politicians have called for the initiative, warning that existing therapies have steadily lost their effectiveness and that new ones are needed," the Post reported.

The new initiative is based on a "roadmap" for the development of <u>new coronavirus</u> <u>vaccines</u>, formulated by the University of Minnesota and led by a former Biden administration official.

A 'roadmap' for 'better' coronavirus vaccines

Operation Warp Speed invested approximately \$30 billion in the development, manufacturing and distribution of COVID-19 vaccines, according to USA Today, with six drugmakers each receiving more than \$1 billion, along with a promise of a "guaranteed market" if they successfully developed a vaccine.

Project NextGen was originally to be named "Project COVID Shield," after some Republican lawmakers called for the launch of an "Operation Warp Speed 2.0" to build on the Trump administration's legacy.

However, "White House officials wanted some distance from the Trump effort as well as from COVID-focused branding, when much of the country had moved on from the pandemic," the Post reported, quoting two anonymous Biden administration officials.

The new initiative also will be "more modest," and have a "more open-ended mission," unlike Operation Warp Speed, which focused exclusively on COVID-19.

According to USA Today, the initial \$5 billion in funding "will be financed through money saved from contracts costing less than originally estimated."

Ashish Jha, White House coronavirus coordinator, said the new initiative has three primary goals: creating longer-lasting vaccines, accelerating the development of nasal vaccines and bolstering efforts to create "broader" pan-coronavirus vaccines.

The project also includes funding for more durable monoclonal antibodies.

The name "Project NextGen," made more sense, Jha said, as it is "a different time" with "a different set of goals." The new name "much more accurately captures what it is that we are trying to do," he said.

<u>Michael Osterholm, Ph.D., M.P.H.</u>, director of the Center for Infectious Disease Research and Policy (CIDRAP) at the University of Minnesota, is helping lead the effort.

In February, CIDRAP developed a "<u>roadmap</u>" for the development of "better" coronavirus vaccines. This "roadmap" serves as the basis for Project NextGen.

Osterholm was a member of the <u>COVID-19 advisory board</u> convened by then-president-elect Joe Biden's transition team. The board was dissolved when Biden took office in January 2021.

Jha told the Post, "It's been very clear to us that the market on this is moving very slowly. There's a lot that government can do, the administration can do, to speed up those tools ... for the American people."

Previously, during a July 2022 White House coronavirus vaccine summit, Jha said:

"We need vaccines that are more durable. Vaccines that offer broader and longer-lasting protection. Vaccines that can stand up to multiple variants. Vaccines that can handle whatever Mother Nature throws at us."

Osterholm characterized existing COVID-19 vaccines as "really good" but "not great."

"There is a substantial amount of work [to be done] to take these good vaccines and hopefully achieve better vaccines," Osterholm said.

Osterholm noted that SARS-CoV-2 is the third new coronavirus to appear in the past two decades — Middle Eastern respiratory syndrome (MERS) and severe acute respiratory syndrome (SARS) were the other two. According to Osterholm, it would be "great" to be prepared for a fourth new coronavirus when and if it appears.

Reuters quoted an unnamed HHS spokesperson, who stated:

"While our vaccines are still very effective at preventing serious illness and death, they are less capable of reducing infections and transmission over time. New variants and loss of immunity over time could continue to challenge our healthcare systems in the coming years.

"Project NextGen will accelerate and streamline the rapid development of the next generation of vaccines and treatments through public-private collaborations. The infusion of a \$5 billion investment, at minimum, will help catalyze scientific advancement in areas that have large public health benefits for the American people, with the goal of developing safe and effective tools for the American people."

The Post noted, however, that while the outbreak of new coronaviruses in recent decades has "spurred worries about the potential for future health crises," it might take years to develop a universal coronavirus vaccine, noting that such efforts have been unsuccessful for influenza despite decades of efforts.

Speaking to USA Today, Dr. Paul Offit, director of the Vaccine Education Center at the Children's Hospital of Philadelphia, expressed skepticism about Project NextGen's goals, noting that similar efforts to develop flu and HIV vaccines have been in progress for more than 40 years, without result.

Offit said that the effectiveness of nasal vaccines remains unclear, as they remain in the clinical trial stage at this time. Dr. John Moore, an immunologist at Weill Cornell Medical College in New York, expressed a similar view, saying "it's seriously naïve to believe that it will be easy to make [a nasal vaccine]."

He added that the emphasis on improving existing COVID-19 vaccines, which he described as "amazing," would likely undermine public trust in those vaccines.

Moore told USA Today that "an initiative like this is much needed and should have been put in place much sooner," adding that "Anyone familiar with vaccine development knows that translation into a practical product is a much harder and more expensive process" than the creation of a basic vaccine.

"A lot of designs that look good in the early stages fizzle out because they cannot be manufactured efficiently under the conditions required for human trials," Moore said.

According to Jha though, the new project and its investment in a new generation of coronavirus vaccines "will have very large benefits for other respiratory pathogens we deal with all the time, like flu and RSV."

Gates, Rockefeller Foundations behind Project NextGen

On Feb. 21, CIDRAP published its "<u>roadmap for advancing better coronavirus vaccines</u>" — with \$1 million in support from the Gates and Rockefeller Foundations, "To help jump-start the search for better vaccines [and] develop broadly protective vaccines."

According to the project description, the funding was used to assemble "an international collaboration of 50 scientists who mapped out a strategy to make the new vaccines a reality."

Osterholm stated at the time, "If we wait for the next event to happen before we act, it will be too late."

Bruce Gellin, M.D., M.P.H., chief of Global Public Health Strategy at The Rockefeller Foundation, said that there is an "urgency" to take the next steps, calling for an "equivalent" to Operation Warp Speed.

According to CIDRAP, Gellin "has led several federal vaccine initiatives and has been a technical advisor for groups including Gavi, the Vaccine Alliance, COVAX, and the World Health Organization."

The Gates Foundation is a partner of <u>Gavi, The Vaccine Alliance</u>, which, in turn, closely collaborates with the <u>ID2020 Alliance</u>, which promoted the <u>development of digital ID</u>. <u>Microsoft is a founding member</u> of the ID2020 Alliance, as well as Gavi, the BMGF, the World Bank, Accenture and the <u>Rockefeller Foundation</u>.

CIDRAP received the \$1 million grant in April 2022, and by October 2022, had developed a draft version of its "roadmap." According to Osterholm, it draws on a similar "roadmap strategy" employed by CIDRAP for previous projects, including the <u>improvement of seasonal flu vaccines</u> and the development of a universal flu vaccine.

For the new "roadmap," these efforts culminated in a <u>92-page report</u>, and <u>accompanying summary</u>, published in Vaccine journal. The project is divided into five core areas: virology, immunology, vaccinology, animal and human models for vaccine research, and policy and funding.

In an accompanying commentary published in the <u>same issue of Vaccine</u>, Dr. Margaret Hamburg, a former FDA commissioner who is co-president of the InterAcademy Partnership, and Dr. Greg Poland, director of the Mayo Clinic's Vaccine Research Group, said that COVID-19 vaccines have been effective in preventing serious disease.

Hamburg was a participant in the Nuclear Threat Initiative's (NTI) monkeypox pandemic simulation in March 2021, based on a remarkably prescient "fictional" monkeypox outbreak in May 2022. She is a board member of the Nature Conservancy and vice president of NTI's Global Biological Policy and Programs and is on the board of Gavi.

However, according to Hamburg and Poland, there are some problems with the current vaccines, including "notable reactogenicity" in certain individuals, a short duration of protection, and technical requirements that make them difficult to store and administer in remote locations and areas with low resources.

They said the next-generation vaccines may offer additional benefits such as "new methods"

of delivery — transdermal patches, oral or intranasal vaccines — which are easy to distribute and apply, stimulate mucosal immunity, and potentially block transmission," adding that this is superior to the current strategy of "chasing" new variants and developing boosters.

Hamburg and Poland said that a universal coronavirus would be easy to stockpile, but the road to the development of such a vaccine could take a "tiered approach," starting with the creation of a "variant-proof" COVID-19 vaccine, followed by developing vaccines that offer broader protection against various coronavirus families.

Members of CIDRAP said in February that funding would be a challenge for the initiatives set forth in their "roadmap," due to "shrinking support for large-scale vaccine investments, now that the emergency phase of the COVID-19 pandemic has mainly passed."

The federal funding earmarked for Project NextGen would, however, appear to address this issue.

Other challenges the CIDRAP team identified included the "lack of corporate incentives, uncertainty around public demand for a broadly protective vaccine, and the feasibility of expanding vaccine production capacity."

Gellin, however, said in a Feb. 21 <u>University of Minnesota press release</u> that: "Time and time again, we have seen that investment in science brings solutions. The COVID-19 pandemic galvanized the research community and advanced vaccine R&D efficiently and through broad collaborations," essentially previewing Project NextGen.

On April 20, CIDRAP will hold a one-hour "scientific webinar," open to the public, presenting their "roadmap."

Republican lawmakers, Fauci pressed for 'Warp Speed 2.0'

Political wrangling delayed the funding of Project NextGen, according to the Post, which reported that Republicans insisted that funds were left over from prior COVID-19 aid packages.

Ultimately, HHS "shifted funds intended for coronavirus testing and other priorities" into the new initiative.

<u>Dr. Anthony Fauci</u> was one of the voices who "spent months pressing Congress for billions of dollars that could be used to develop next-generation vaccines and treatments," the Post reported, adding that these arguments "largely fell flat" in the face of Republican opposition.

However, according to the Post, "Even some of the Republicans who blocked the White House's coronavirus funding requests last year said they wanted a 'Warp Speed 2.0' to rush updated vaccines and treatments that would better fight the virus."

In August 2022, former Sens. Richard Burr (R-N.C.) and James Inhofe (R-Okla.) <u>wrote to President Biden</u>, stating "Operation Warp Speed was the most successful public health program since small pox. It saved millions of lives, and it should be resurrected as soon as possible."

Dawn O'Connell, assistant secretary for Preparedness and Response at HHS, told the Post that the Biden administration learned lessons from Operation Warp Speed, including how to speed up vaccine development, and that these lessons would be applied to Project NextGen.

"We've learned a lot in these three years," O'Connell said. She added that some of the lab work related to Project NextGen has begun, and that the government has launched efforts to identify potential partners in the private sector.

"We've begun surveying the landscape out there — assessing what vaccine candidates are available, [and] moving through what exciting technologies are there," she said.

According to the Post, O'Connell and her team informed companies working on the development of monoclonal antibodies that the government may soon make new investments in the technology.

Jha, however, refused to set a timetable for when new products developed under the aegis of Project NextGen would be available to the public, the Post reported.

"The timelines are really going to be predicated on how quickly the scientific advancements continue, and how quickly we can study and measure the efficacy and safety of these products," Jha said.

Project NextGen is also still without a leader, with the White House "still considering candidates," according to the Post, which noted that the process is slowed down by "Democrats' desire to avoid questions of conflicts of interest that dogged Operation Warp Speed, after Trump officials selected Moncef Slaoui, a pharmaceutical industry executive with significant stock holdings, to lead that program."

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