RFK Jr. will require shift in how new vaccines are tested, HHS says

washingtonpost.com/health/2025/04/30/rfk-jr-vaccine-testing

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Exclusive

RFK Jr. will order placebo testing for new vaccines, alarming health experts

The potential change outlined in a statement would require all new vaccines to undergo placebo testing, sparking concerns among medical experts.

Updated
May 1, 2025 at 2:12 p.m. EDTtoday at 2:12 p.m. EDT

10 min

A health-care worker fills a syringe with the Pfizer coronavirus vaccine. (Lynne Sladky/AP)

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Health and Human Services Secretary Robert F. Kennedy Jr. intends to shift the way vaccines are tested, a move that the agency said will increase transparency but that medical experts fear could limit access to vaccines and undermine the public's trust in immunization depending on its implementation.

The potential change outlined in a statement says all new vaccines will be required to undergo placebo testing, a procedure in which some people receive the vaccine and others receive an inert substance — such as a saline shot — before the results are compared.

"All new vaccines will undergo safety testing in placebo-controlled trials prior to licensure — a radical departure from past practices," an HHS spokesperson told The Washington Post in response to questions about Kennedy's comments on the measles vaccines and general vaccine policy.

Vaccines for new pathogens are often tested this way. But for well-researched diseases, such as measles and polio, public health experts say it makes little sense to do that and can be unethical, because the placebo group would not receive a known effective intervention.

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HHS did not clarify how the change will be implemented and for which vaccines the testing would apply, nor did it define what the department meant by "new vaccine." But the government indicated it wouldn't apply to the flu vaccine, which is updated year to year and which HHS stated "has been tried and tested for more than 80 years." In response to questions about whether other vaccines previously safety tested would be newly scrutinized, the department focused on its concerns around the coronavirus vaccine but did not address other immunizations.

Kennedy has long disparaged vaccines, said they are not adequately safety tested and previously called for placebo testing for vaccines that are approved for use.

"Secretary Kennedy is not anti-vaccine — he is pro-safety, pro-transparency, and pro-accountability," HHS said in a statement.

The HHS statement raised concerns among medical and public health experts who said the move could be a significant shift in how the country has ensured the safety of vaccines for decades, as well as cast doubt on vaccines that are safe, effective and key to public health. The potential change comes as public trust in vaccines continues to decline amid a growing measles outbreak and worries over Kennedy's mixed messaging about immunizations.

Medical and public health experts also expressed dismay that the testing change could require coronavirus vaccines, and potentially others, to undergo costly and, in their view, unnecessary studies that would probably limit vaccine production and access — and leave more Americans at risk of preventable disease.

"You are watching the gradual dissolution of the vaccine infrastructure in this country," said Paul Offit, director of the Vaccine Education Center at Children's Hospital of Philadelphia. "The goal is to make vaccines less available and less affordable."

In recent weeks, the Trump administration has injected uncertainty into the annual process for approving an updated coronavirus shot traditionally offered in the fall, indicating there may need to be more data.

"Except for the COVID vaccine, none of the vaccines on the CDC's childhood recommended schedule was tested against an inert placebo, meaning we know very little about the actual risk profiles of these products," HHS said in its statement.

Vaccine and public health experts said the statement from HHS is a combination of misinformation and exaggeration or misrepresentation of scientific studies.

"To make a blanket statement like that, I think that would go against the science," said Sean O'Leary, a pediatric-infectious-diseases physician and chair of the American Academy of Pediatrics' committee on infectious diseases.

The move came as Kennedy urged parents this week to "do your own research" and said that "making sure the vaccines are safe" is one of his top priorities, during an interview with Phil McGraw, who is known as Dr. Phil.

Since Kennedy became HHS secretary, the department has appointed a vaccine skeptic to investigate the debunked link between vaccination and autism. Peter Marks, the nation's top vaccine regulator, resigned under pressure. And Kennedy has not spoken as forcefully for vaccination amid an ongoing measles outbreak as the first Trump administration did.

The HHS statement and others from Kennedy casting doubt on vaccine safety are part of his long-running effort to decrease confidence in immunizations, said David Gorski, a Wayne State University School of Medicine professor of surgery and oncology and managing editor of Science-Based Medicine, which debunks misinformation in medicine.

“Instead of just an anti-vaccine activist … saying this stuff, now the federal government, HHS and FDA is now saying this stuff. That matters,” he said.

‘Undermines real transparency’

Kennedy has previously claimed that vaccine testing studies are not long enough to capture potential safety issues, although vaccines are continuously and rigorously monitored.

“A lot of the injuries that come from medication are autoimmune injuries and allergic injuries and neurodevelopmental injuries that have long diagnostic horizons or long incubation periods, so you can do the study and you will not see the injury for five years,” Kennedy said in a 2021 interview. Waiting to conduct a multiyear study as per Kennedy’s suggestion would slow the development of vaccines and their release.

Now as head of HHS, Kennedy has said he wants to restore “gold standard” science to the federal health agencies and look at the data.

“HHS is now building surveillance systems that will accurately measure vaccine risks as well as benefits — because real science demands both transparency and accountability,” an HHS spokesperson told The Post.

Medical experts dismissed the idea that a new system was needed, saying the current system adequately tracks adverse events associated with vaccines.

Sen. Bill Cassidy (R-Louisiana) received a list of commitments from Kennedy before voting to confirm the secretary. That included a commitment to work within the “current vaccine approval and safety monitoring systems” and giving a 30-day notice to the Senate health committee if the agency seeks to make changes to any federal vaccine safety monitoring programs, Cassidy said in a Feb. 4 speech on the Senate floor.

In a statement to The Washington Post Thursday, Cassidy raised concerns about HHS’s intended shift.

“The first vaccine for a disease is already proven safe through a placebo-controlled trial,” Cassidy said. “Updating that vaccine does not require a new placebo-controlled trial to determine its safety. To require a placebo group would deny those patients access to the vaccine that has already been found safe.”

“Claiming vaccines have risks the data doesn’t show or trying to overstate vaccine risks is not transparency,” said Dorit Reiss, a professor at the University of California College of the Law at San Francisco who tracks public health vaccine law. “It’s misinformation, and it undermines real transparency and informed consent.”

Additionally, many vaccines have been tested against placebos, the experts said. And while HHS said the trials would be for “new vaccines,” if Kennedy tries to test vaccines that have already been approved, such as the measles vaccine, against a placebo, that would mean in practice some children would not get vaccinated against the infectious disease while their neighbors did — a quandary that physicians say leaves them susceptible to diseases when there is a vaccine that works.

Stanley Plotkin, a pioneer in the field who developed the rubella vaccine, said that when scientists test vaccines against a new disease, they typically look for evidence that the vaccinated individuals do not get a disease, compared with those who received a placebo. This is how the coronavirus vaccines were tested, in 30,000-person trials in which half of the participants received saline shots.

But when a disease is already well understood, scientists can look for evidence that vaccines induce a biological response that has been scientifically shown to protect against the disease — what scientists call “a correlate of protection.”

In the case of diseases that cause serious illness and can even be fatal, if there are existing interventions, the use of placebos is often not considered ethical.

“Ethics must be taken into account when you set up a study,” Plotkin said. “Can I ethically agree to having people acquire the disease because they receive a placebo?”

Coronavirus vaccine in play?

The administration has taken aim at reexamining the coronavirus vaccine.

When asked by CBS News on Tuesday whether the Food and Drug Administration plans to green-light updates to the coronavirus shots, FDA Commissioner Marty Makary said the agency was “taking a look.”

“We have a bit of a public trust problem,” Makary said. “I think there’s a void of data. And I think rather than allow that void to be filled with opinions, I’d like to see some good data.”

In a statement, HHS affirmed Makary’s comments: “Using the COVID pandemic as an eternal justification for blanket approvals of new products will not happen under the leadership of Commissioner Makary.”

Additionally, the Trump administration is seeking for the drug manufacturer Novavax to commit to conducting a new clinical trial on its coronavirus vaccine after it gets approved. The company’s shot has been available under emergency use authorization and is the only vaccine that uses a more traditional protein base instead of messenger RNA — an appealing option to some who have reactions to mRNA shots.

The FDA was on track to grant full approval to the vaccine April 1, according to two people familiar with the matter who spoke on the condition of anonymity to share internal deliberations. Top Trump FDA officials told agency regulators to pause the approval, these sources said — which some vaccine experts say amounts to political interference into decisions typically made by career staff tasked with reviewing the data.

“To be clear, this is a new product that Novavax is trying to introduce to the market with a study of a different product from 2021. New products require new clinical studies,” Makary wrote Saturday in a post on X. Several vaccine experts dismiss the notion that the vaccine constitutes a new product.

Such a move would be costly and suggests a potential shift in how the agency may approach coronavirus vaccines going forward. Typically, Pfizer and Moderna get instructions from the FDA on how to update their vaccines in June. It’s unclear whether they will need to run new clinical trials for their vaccines, which would be unlikely to occur before the annual coronavirus shot in the fall.

“While we cannot comment on this specifically, we look forward to continued collaboration with the Administration and teams across HHS,” said Chris Ridley, a spokesman for Moderna.

Medical experts The Post spoke to predicted that the change by Kennedy could limit new vaccines approved under his watch, as well as slow investment by pharmaceutical companies. Ultimately, that would result in fewer vaccines available.

“It’s just not correct. They obviously don’t understand how vaccines are approved and how one obtains safety data,” said Michael Osterholm, a University of Minnesota infectious-disease expert who advised President Joe Biden’s transition team, adding that the change threatened the existence of coronavirus vaccines.

Caitlin Gilbert and Fenit Nirappil contributed to this report.