Trump’s Team Cited Safety in Limiting COVID Shots. Patients, Health Advocates See More Risk.

Under the new guidance, vaccines will be available for high-risk individuals and seniors, but not healthy children and younger adults.

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Larry Saltzman has blood cancer. He’s also a retired doctor, so he knows getting COVID-19 could be dangerous for him — his underlying illness puts him at high risk of serious complications and death. To avoid getting sick, he stays away from large gatherings, and he’s comforted knowing healthy people who get boosters protect him by reducing his exposure to the virus.

Until now, that is.

Vaccine opponents and skeptics in charge of federal health agencies — starting at the top with Health and Human Services Secretary Robert F. Kennedy Jr. — are restricting access to COVID shots that were a signature accomplishment of President Donald Trump’s first term and cost taxpayers about $13 billion to develop, produce, and distribute. The agencies are narrowing vaccination recommendations, pushing drugmakers to perform costly clinical studies, and taking other steps that will result in fewer people getting protection from a virus that still kills hundreds each week in the U.S.

“There are hundreds of thousands of people who rely on these vaccines,” said Saltzman, 71, of Sacramento, California. “For people who are immunocompromised, if there aren’t enough people vaccinated, we lose the ring that’s protecting us. We’re totally vulnerable.”

The Trump administration on May 20 rolled out tougher approval requirements for COVID shots, described as a COVID-19 “vaccination regulatory framework,” that could leave millions of Americans who want boosters unable to get them.

The FDA will encourage new clinical trials on the widely used vaccines before approving them for children and healthy adults. The requirements could cost drugmakers tens of millions of dollars and are likely to leave boosters largely out of reach for hundreds of millions of Americans this fall.

Under the new guidance, vaccines will be available for high-risk individuals and seniors. But the

FDA will encourage drugmakers to commit to conducting post-marketing clinical trials in healthy adults when the agency approves COVID vaccines for those populations.

For the past five years, the shots have been recommended by the Centers for Disease Control and Prevention for everyone 6 months and older. They have been available each fall after being updated to reflect circulating strains of the virus, and the vaccines have been shown to be safe and effective in clinical trials.

Vinay Prasad, who leads the FDA's division overseeing vaccines, cited "distrust of the American public" as he announced the new guidelines at a May 20 briefing.

"We have launched down this multiyear campaign of booster after booster after booster," he said, adding that "we do not have gold-standard science to support this for average-risk, low-risk Americans."

The details were outlined in a May 20 article in The New England Journal of Medicine, written by FDA Commissioner Marty Makary. He and Prasad later followed up with the briefing, which appeared the same day on YouTube.

The added limits on access aren't the result of any recent data showing there are new health risks from the COVID vaccines. Instead, they reflect a different regulatory stance from Kennedy, who has a history of anti-vaccine activism, and Makary, who has questioned the safety data on COVID mRNA shots.

Announcing a major regulatory change in a medical journal and YouTube video is a highly unusual approach that still leaves many questions about implementation unanswered. It remains unclear when the changes will go into effect or whether there will be any public comment period. The changes were announced by the administration before an FDA advisory committee meeting on May 22 to consider the 2026 COVID vaccine formula.

It's a sharp reversal from the first Trump administration, which launched Operation Warp Speed — the effort that led to the development of the COVID shots. Trump called the vaccines the "gold standard" and a "monumental national achievement."

Concerns About Higher Transmission

The announcement is rattling some patient advocacy groups, doctors, nursing home leaders, and researchers who worry about the ramifications. They say higher-risk individuals will be more likely to get COVID if people who aren't at risk don't get boosters that can help reduce transmission. And they say the FDA's restrictions go too far, because they don't provide exceptions for healthy individuals who work in high-risk settings, such as hospitals, who may want a covid booster for protection.

The limits will also make it harder to get insurance coverage for the vaccines. And the FDA's new stance could also increase vaccine hesitancy by undermining confidence in COVID vaccines that

have already been subject to rigorous safety review, said Kate Broderick, chief innovation officer at Maravai Life Sciences, which makes mRNA products for use in vaccine development.

“For the public, it raises questions,” she said. “If someone has concerns, I’d like them to know that of all the vaccines, the ones with the most understood safety profile are probably COVID-19 vaccines. There is an incredible body of data and over 10 billion doses given.”

Some doctors and epidemiologists say it could leave healthy people especially vulnerable if more virulent strains of COVID emerge and they can’t access covid shots.

“It’s not based on science,” said Rob Davidson, an emergency room doctor in Michigan and executive director of the Committee to Protect Health Care, which works to expand health care access. “It’s what we were all worried would happen. It risks peoples’ lives.”

Current federal regulators say there is no high-quality evidence showing that vaccinating healthy people, including health workers who are near or around immunocompromised people, provides an additional benefit.

“It is possible, actually, that such approvals and strategies provide false reassurance and lead to increased harms,” Prasad said.

The COVID vaccines underwent clinical trials to assess safety, and they have been subject to ongoing surveillance and monitoring since they obtained emergency use authorization from the FDA amid the pandemic. Heart issues and allergic reactions can occur but are rare, according to the CDC.

On a separate track, the FDA on May 21 posted letters sent in April to makers of the mRNA COVID vaccines to add information about possible heart injury on warning labels, a move that one former agency official described as overkill. The action came after the Permanent Subcommittee on Investigations, a panel of the Senate Homeland Security and Governmental Affairs Committee, held a hearing on alleged adverse events associated with COVID vaccines.

Limiting boosters to healthy people goes against guidance from some medical groups.

“The COVID-19 vaccine is safe, effective, and the best way to protect children,” Sean O’Leary, chair of the Committee on Infectious Diseases at the American Academy of Pediatrics, said in an email. “Young children under 5 continue to be at the highest risk, with that risk decreasing as they get older.”

Unsupported Claims About mRNA Vaccines

The COVID booster clampdown is supported by many adherents of the “Make America Healthy Again” movement, which casts suspicion on traditional medicine. Some opponents of COVID mRNA vaccines say without evidence that the shots cause “turbo” cancer, are genetic bioweapons, and cause more heart damage than the COVID virus.

There is no evidence the shots lead to rapid and aggressive cancers. Cancer rates decreased an average of 1.7% per year for men and 1.3% for women from 2018 to 2022, according to the National Institutes of Health. The COVID vaccines debuted in 2021.

Federal regulators say narrowing who can get the boosters will align the U.S. with policies of European nations. But other countries have vastly different economic structures for health care and approaches to preventive care. Many European countries, for example, don't recommend flu shots for the entire population. The U.S. does in part because of the financial drain attributed to lost productivity when people are sick.

They also want more information. "I think there's a void of data," Makary told CBS News on April 29. "And I think rather than allow that void to be filled with opinions, I'd like to see some good data."

A massive five-year study on COVID vaccine safety by the Global Vaccine Data Network, involving millions of people, was underway, with about a year left before completion. The Trump administration terminated funding for the project as part of cuts directed by the president's Department of Government Efficiency, and work on the study has stopped for now.

There are a multitude of studies, however, on the vaccines' effectiveness in preventing severe illness, hospitalization, and death.

Limiting boosters for healthy people can be risky, some doctors say, because people don't always know when they fall into higher-risk categories, such as individuals who are prediabetic or have high blood pressure. The COVID vaccine restrictions could deter them from getting boosted, and they might experience worse complications from the virus as a result. For example, about 40% of people with hepatitis C are unaware of their condition, according to a study published in 2023.

The number of people getting COVID vaccines has already dropped significantly since the height of the crisis. More than half of the more than 258 million adults in the U.S. had gotten a COVID vaccination as of May 2021, according to the CDC. In each of the past two seasons, less than 25% of Americans received boosters, CDC data shows.

While deaths from the virus have dropped, COVID remains a risk, especially when cases peak in December and January. Weekly covid deaths topped 2,580 as recently as January 2024, according to CDC data.

Some high-risk individuals are worried that the new restrictions are just the first salvo in halting all access to mRNA shots. "The HHS motivation really is hidden, and it's to dismiss all mRNA technology," said Michael Osterholm, an epidemiologist at the University of Minnesota.

Officials at the NIH have told scientists to remove references to mRNA in grant applications. HHS also announced plans in May to develop new vaccines without mRNA technology, which uses messenger RNA to instruct cells to make proteins that trigger an immune response.

Rose Keller, 23, is concerned about future access to COVID shots. She would be eligible under the current announcement — she has cystic fibrosis, a progressive genetic condition that makes the mucus in her lungs thick and sticky, so COVID could land her in the hospital. But she is concerned the Trump administration may go further and restrict access to the vaccines as part of a broader opposition to mRNA technology.

“I’ve had every booster that’s available to me,” said Keller, a government employee in Augusta, Maine. “It’s a real worry if I don’t have the protection of a COVID booster.”

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http://beta.docker.poz.com/article/trumps-team-cited-safety-limiting-covid-shots-patients-health-advocates-see-risk