

WND

# FDA panel deals blow to Biden vaccine booster plan

**Advisory committee rejects extra jab for most Americans**



By [Art Moore](#)

Published September 17, 2021 at 7:40pm



**Dr. Anthony Fauci, director of the National Institute of Allergy and Infectious Diseases, receives the Moderna COVID-19 vaccine at the COVID-19 Vaccine Kick-Off event at the National Institutes of Health on Dec. 22, 2020 (National Institutes of Health photo)**

With the Biden administration set to roll out its COVID-19 vaccination booster plan next week, a U.S. Food and Drug Administration advisory panel on Friday voted 16-2 to reject use of Pfizer's booster vaccine in people ages 16 and older.

The panel said there is insufficient data to judge the risks to younger groups, including the possible increased risk for heart inflammation, or myocarditis, particularly among males ages 16-17.

[A new study from the University of California at Davis](#) found that teenage boys are six times more likely to suffer from heart problems from the vaccine than be hospitalized from COVID-19.

Later, the panel, in a unanimous vote, endorsed emergency approval for the Pfizer-BioNTech COVID-19 vaccine booster shot for people ages 65 years and older and those at high risk of severe COVID-19.

The votes came one week after [the two top FDA officials responsible for vaccine research announced their resignations](#), strongly warning against vaccine boosters in a signed letter in the British medical journal The Lancet. The officials, Drs. Marion Gruber and Philip Krause, are leaving [amid criticism that the White House put political pressure on the FDA](#), essentially bypassing the agency to push ahead with its COVID-19 booster-shot plan. The development, [wrote Jeffrey A. Tucker of the Brownstone Institute](#), is about more than the boosters: "It's about the whole experience of taking away the control of health management from individuals and medical professionals and handing it over to modelers and government officials with coercive power."

The advisory votes now go before the FDA to issue final decisions, but the panel's recommendations usually are adopted.

The advisory committee was tasked with evaluating the safety and effectiveness data from Pfizer's clinical trial. FoxNews.com reported the meeting Friday included members of the FDA's Vaccines and Related Biological Products Advisory Committee and officials from the Centers for Disease Control and Prevention, Israel's Health Ministry, vaccine experts and Pfizer representatives.

### **'The unknown with kids'**

Dr. Marty Makary, a professor at Johns Hopkins University School of Medicine, said Friday in a live Fox News interview after the vote rejecting boosters for younger Americans that the committee clearly was "extremely frustrated with the insufficient data."

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"This is not the normal process," he explained. "Normally, they have people followed very closely in a trial."

Instead, Makary continued, they received data from a study from Israel and had leaders of that study present their findings.

"It's the insufficient data on younger people that really killed this vote," he said.

Markary noted that two members of the panel -- Dr. Meg Seymour of the National Center for Health Research and Dr. Jonathan Sterne, a professor of medical statistics and epidemiology in the U.K. -- warned about "the unknown with kids."

They argued that good data is necessary to consider a third shot, Makary said, because the incidents of myocarditis "have clustered around the second dose of the mRNA vaccine."

Sterne said his analysis of 76 studies on the vaccines' effectiveness around the world found that many factors can skew the results, including how many unvaccinated people in a study have natural immunity from having had COVID-19.

Fox News anchor Martha MacCallum pointed out that the CDC receives millions of dollars to do research, but it's not produced any studies on the benefit of natural immunity. Instead, the FDA is relying on an Israeli study.

"We have no studies that show the benefit of having had COVID, plus one shot, in young people," she said.

Markary agreed, pointing to a [recent Israeli study](#) showing natural immunity is superior to the protection provided by COVID-19 vaccines.

"If there was a wake-up call ever to the United States, it is how are we getting the biggest study worldwide on natural immunity, out of Israel, showing natural immunity is 27 times more effective than vaccinated immunity, and yet the CDC, with 21,000 employees, has not done any study comparable."

That's a "big miss," he said.

Makary said that public health officials "lose credibility" when amid the discussion about vaccines and the imposition of mandates they're "not talking about natural immunity."

Last week, [top White House coronavirus adviser Dr. Anthony Fauci demonstrated the disregard of natural immunity](#) when he was confronted in a CNN interview by the network's health correspondent, Dr. Sanjay Gupta.

Gupta asked Fauci how he can make the case for taking the vaccine to the many Americans -- by some estimates 100 million -- who have natural immunity after recovering from COVID-19.

"You know, that's a really good point, Sanjay. I don't have a really firm answer to you on that," Fauci replied.

### **Vaccine complications for previously infected**

In the Fox News interview Friday, Makary referred to the concern, backed by studies, that the rate of complications from vaccination may be higher in those who had natural immunity through a previous infection.

MacCallum said "that's because they already have built-up immunity, then they get a shot on top of that, and now we're talking about potentially another shot on top of that, for them."

She said she wanted to make it clear that "all we're saying here is that we need to have the data."

"We need to know how these young people respond," MacCallum said, because once the FDA approves a third Pfizer shot, "the next time we're going to be talking about mandates for this, right?"

"That's right," Makary replied.

In a feature for the 180-year-old British medical journal *The BMJ* titled "Vaccinating people who have had COVID-19: why doesn't natural immunity count in the US?" journalist Jennifer Block cited health experts who are concerned about the risk of people with a previous COVID-19 infection experiencing adverse complications from vaccination.

She quoted Christine Stabell Benn, a vaccinologist and professor in global health at the University of Southern Denmark, who reasons that if "natural immunity is strongly protective, as the evidence to date suggests it is, then vaccinating people who have had COVID-19 would seem to offer nothing or very little to benefit, logically leaving only harms — both the harms we already know about as well as those still unknown."

The real risk in vaccinating people who have had COVID-19 "is of doing more harm than good," Benn said.

Block cited a large study in the U.K. and an international survey that found people with a history of SARS-CoV-2 infection experienced greater rates of side effects after vaccination.

Patrick Whelan, an associate clinical professor of pediatrics at UCLA, told Block that the "sky high" antibodies after vaccination in people who were previously infected may have contributed to the systemic side effects.

"Most people who were previously ill with COVID-19 have antibodies against the spike protein," he said.

"If they are subsequently vaccinated, those antibodies and the products of the vaccine can form what are called immune complexes," he explained, which may get deposited in joints, meninges and even kidneys, creating symptoms.

Three professors at the University of Arkansas medical school, Manish Joshi, Thaddeus Bartter and Anita Joshi, [wrote a letter to BMJ](#) in response

to Block's article, affirming natural immunity. They said the doubt about natural immunity cast by "most scientific journals, media outlets, self-proclaimed health experts and public policy messaging" has "real-world consequences, particularly for resource limited countries."

They argue "the data suggest that people confirmed to have been infected with SARS-CoV-2 may not need vaccination."

"We should not be debating the implications of prior infection; we should be debating how to confirm prior infection," they said.

Last month, President Biden announced booster shots would be made available beginning the week of Sept. 20 to most adults who had received a second Pfizer or Moderna vaccine at least eight months prior.

Fauci has backed the booster campaign, saying this month that Americans likely will need a third dose of the mRNA vaccines to be considered fully vaccinated against COVID-19.

### **Senator to Biden administration: Why ignore natural immunity?**

Meanwhile, Sen. Ron Johnson, R-Wis., [sent a letter Thursday to Fauci](#) along with Centers for Disease Control and Prevention Director Dr. Rochelle Walensky, and FDA commissioner Dr. Janet Woodcock, demanding the Biden administration justify its decision not to take into account natural immunity from a prior infection.

"This administration's decision to disregard the effectiveness of natural immunity and demand vaccination ignores current data and is an assault on all Americans' civil liberties," he wrote in the letter, [which was obtained by the Daily Caller](#).

Johnson emphasized the Biden administration and federal health agencies "owe the American people answers about why they have made the decision to disregard the effectiveness of natural immunity and ignore current data."

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Art Moore, co-author of the best selling book [See Something, Say Nothing](#), entered the media world as a PR assistant for the Seattle Mariners and a correspondent covering pro and college sports for Associated Press Radio. He reported for a Chicago-area daily newspaper and was senior news writer for Christianity Today magazine and an editor for Worldwide Newsroom before joining WND shortly after 9/11. He earned a master's degree in communications from Wheaton College.

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