

The 'Fix Was In' on Reformulating COVID Booster Doses, FDA Advisor Says



In a rare break from the consensus, a member of the U.S. Food and Drug Administration's (FDA) vaccine advisory panel explained why he voted against [adding an Omicron component](#) to fall COVID-19 booster shots raising serious questions over a lack of critical data and the Biden administration's role in politicizing the process.

In a July 6 [interview with ZDoggMD](#), Dr. Paul Offit, director of the Vaccine Education Center and professor of pediatrics in the Division of Infectious Diseases at Children's Hospital of Philadelphia, described the Vaccines and Related Biological Products Advisory Committee's (VRBPAC) [recent meeting](#) as "unusual."

"I've seen nothing like this," Offit said. "I guess the thing that's most upsetting to me is normally when you get something from the FDA when we have these meetings, you usually get it a few days before you meet. You usually get a couple of hundred

pages.”

Offit continued:

“Here on the other hand, normally you get the EUA [Emergency Use Authorization] submission from the company, which is 85 to 100 pages long, and then you get the FDA’s review of all those data. It’s a very thorough review. Not here though. Here, it was 22 pages from the FDA, which included a half-page on Pfizer’s data and a half-page on Moderna’s data.”

“You could get that from the [press release](#),” Offit said. “In fact, it was no more detail than the press release provided.”

The question vaccine advisors are always asked to consider in the end is whether the benefits outweigh the risks – even if the risks are generally small and sometimes unknown, Offit said. “I didn’t see the benefits.”

Offit said he was surprised that out of 21 voting members, 19 voted “yes” because he “just didn’t see the evidence for that.”

“I think this was something that was desired by the Biden administration,” he said.

“I could be wrong but the other thing that was odd about this meeting was that we’re an advisory committee, we’re being asked for our advice,” he added. “So normally what happens is that they just present the data. Here’s the data. What’s your advice? And people can ignore our advice.”

However, during the [June 28 meeting](#), someone from the World Health Organization presented their opinion and their opinion was that this was a good idea, Offit said. “Then you had someone from the FDA presenting where they also had an opinion.”

“That’s unusual,” Offit said. “Then the next day you read a

press release from HHS that says the government has decided to purchase at least 105 million doses from Pfizer with up to 300 million doses.”

The press release mentioned VRBPAC had just made its decision the day before, “so you just kind of felt like the fix was in a little bit,” Offit said. “Maybe that’s not the right phrase but it was something they wanted and I felt like we were being led here and with a critical lack of information.”

Offit said all COVID-19 vaccines are based on the ancestral Wuhan strain before it “mutated and left China,” and now that BA.4 and BA.5 Omicron subvariants represent a little more than half of the circulating strains in this country.

It’s reasonable the FDA would consider trying to broaden immunity by including Omicron or Omicron subvariants in a bivalent vaccine, he said. But “both Moderna and Pfizer presented data during the June 28 meeting and it was not compelling.”

Offit explained:

“They did the studies the right way. So, they took people who had already received three doses of the ancestral strain and then gotten a fourth dose with the ancestral strain and compared that to three doses of the ancestral strain, plus the fourth dose of the bivalent strain which contains the omicron mRNA vaccine [BA.1] as well as the ancestral vaccine. That’s the right way to do the study.

“Then ... they looked at virus-specific neutralizing antibodies against omicron and ... found ... when you got the omicron boost you had a 1.75-fold increase in neutralizing antibodies against omicron.

“Well, the question is, what does that mean? What does that number mean, and the answer is I think while statistically

significant, I don't think that's a clinically significant difference.

"The reason I say that is because if you look at the original vaccines when they were authorized back in mid-December 2020, there was a two-fold difference between Moderna and Pfizer regarding neutralizing antibodies. Moderna had a two-fold increase in neutralizing antibodies, but it did not translate into a clinically significant difference in terms of protection against severe disease, which is the goal of this vaccine."

In other words, having a two-fold increase in neutralizing antibodies does not necessarily [correlate to efficacy](#).

Offit said his second concern was whether COVID-19 vaccines protect against BA.4 and BA.5 subvariants once Omicron is gone.

"Now both companies interestingly presented data after a fourth dose that showed you what the neutralizing antibody titer was to BA.4/BA.5, but they didn't show you what the neutralizing antibody titer to BA.4/BA.5 was if your fourth dose was the ancestral strain," Offit said. "They never showed those data."

"That's the obvious thing to do because that's why you have control groups for your experiment, and I just found it odd that neither presented," he added. "That bothered me."

Offit also pointed out there were no animal models or "neutralizing antibody data that supports this."

FDA signed off on boosters with 'uncomfortably scant evidence'

"There are potentially billions of dollars at stake to transform a vaccine from the ancestral strain to a new

bivalent strain including these Omicron-specific boosters, without clear and compelling evidence that it's actually going to improve the outcome we care about most which is protection against severe disease," [ZDoggMD told Offit](#). "And yet it seems like the burden of proof for FDA seems to be going down and down and down instead of being at a level that you're comfortable with."

Offit said a reformulated booster is a new product and it surprised him so many were willing to go forward with such "uncomfortably scant evidence of benefit."

"No one would have predicted myocarditis associated with mRNA vaccines. I don't think anybody would have predicted this clotting problem so-called thrombosis with thrombocytopenia syndrome," Offit said. "So humble yourself. ... If you clearly have evidence of benefit, great, but if you clearly don't have evidence of benefit then say no."

HHS on June 29 announced it had made an [advance purchase](#) of 105 million doses of Pfizer-BioNTech's vaccine for \$3.2 billion, with options to buy up to 300 million doses.

The Biden administration used repurposed money to buy the additional vaccines, "betting on a next generation of boosters without knowing who might need one or how they will perform."

The [contract](#) includes a combination of adult and pediatric doses and supplies of re-formulated booster doses that will [contain the original Wuhan variant](#) and BA.4 and BA.5 Omicron subvariants.

The announcement was made one day after the FDA's VRBPAC voted 19 to 2 to recommend future COVID-19 booster doses be reformulated to include an Omicron component, and before the FDA's announced it had made recommendations to vaccine makers that their boosters should target Omicron subvariants leading many to question the nature of the White House' relationship with Pfizer.

Watch ZDoggMD's full interview with Dr. Paul Offit here: