

## FDA to review COVID vaccine for kids under 5 with Andrea Garcia, JD, MPH

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Watch the AMA's COVID-19 Update, with insights from AMA leaders and experts about the pandemic.

### Featured topic and speakers

In today's COVID-19 Update, AMA Chief Experience Officer Todd Unger reviews the latest timeline on Moderna and Pfizer vaccine authorizations for young children with AMA Director of Science, Medicine and Public Health Andrea Garcia, JD, MPH. Also covering the rise in COVID cases, FDA's proposed timing to review data on Novavax and variant-specific vaccines, as well as how to spot fake COVID-19 at-home tests.

On May 9, AMA's immediate past president, Susan Bailey, MD, will host the live webinar: "Fourth dose boosters and pediatric vaccine update with Dr. Peter Marks"

Register for AMA's webinar with FDA's Peter Marks, MD.

Learn more at the AMA COVID-19 resource center.

### Speaker

- Andrea Garcia, JD, MPH, director of science, medicine & public health, American Medical Association

### Transcript

**Unger:** Hello, this is the American Medical Association's COVID-19 Update video and podcast. Today we have our weekly look at the numbers, trends and latest news about COVID-19 with the AMA's Director of Science, Medicine and Public Health Andrea Garcia in Chicago. I'm Todd Unger, AMA's chief experience officer, also in Chicago. Andrea, thank you so much for joining us this week. The big news is about vaccines for very young kids. Are we getting any closer to an authorization at this point?

**Garcia:** Well, thanks for having me back, Todd, and it looks like we are getting closer. I mean, this has certainly been an area of concern and frustration for parents over the delays we've seen in having a vaccine for this population. We were initially expecting that in the spring and here we are heading into summer. There are roughly, we know 18 million children who are younger than five in the U.S. and that remains the only population not yet eligible for a COVID vaccine. The good news came on Thursday when Moderna announced that it had asked the FDA to authorize its COVID vaccine for children under six, they're the first manufacturer to do so and a top official at Moderna said it would finish submitting the data to regulators by May 9.

**Unger:** It's kind of interesting, because Moderna, the vaccine is only authorized so far for adults and not for other age groups younger than that. What's the situation with that?

**Garcia:** Yeah, so that's right and it's the Pfizer vaccine that has been the one authorized to vaccinate kids in that five to 17 age group. We know the FDA generally authorizes the COVID vaccine according to that age group and they like to calculate the risk and benefit, beginning with that oldest population first. We know Moderna has already requested authorization for its COVID vaccine in those six- to 11-year-olds, and in the 12- to 17-year-old population. They will be continuing to submit data supporting and updating those requests in a couple of weeks. So, at the moment, it seems like FDA could be leaning towards considering all three of the company's applications to vaccinate children simultaneously.

**Unger:** So, is there any sense of a timeline at this point?

**Garcia:** So, the FDA announced that they will be convening their outside advisory panel of experts, VRBPAC, and they're going to review the data before the agency authorizes any vaccine for the youngest children. FDA has outlined a tentative timetable. They've announced June 8 as the earliest date that they'll present the data, those advisors for a recommendation. Certainly, FDA understands the urgency of protecting these young children, especially as we roll back other mitigation measures, and they said they're going to act quickly if the data supports a clear path forward following their evaluation. So, the dates are tentative and that's only because the companies have not yet completed their applications for the EUA. They're still submitting that data.

**Unger:** You said that Moderna expects to complete its application by next week. What's the timeline for Pfizer's application and are they going to try to sync up on that, if the FDA, to review them together or not?

**Garcia:** So, right now, Pfizer is not expected to complete their application until June. Top FDA officials, so Dr. Peter Marks, Dr. Robert Califf have said that the FDA is not going to delay an authorization for the Moderna vaccine in order to just wait for the Pfizer application and data. I think we need to keep in mind that the vaccines, while both mRNA platforms are different in key ways. We know Moderna is proposing a two-dose regimen for children under six and they're using a one-fourth

strength dose, one-fourth of the adult dose. Pfizer, we know, has moved to a three-dose regimen at one-10th strength of their adult dose.

**Unger:** Our immediate past president, Dr. Susan Bailey will also be talking to Dr. Marks in a live webinar on May 9. We can put that information in the registration link in the description of this episode. I'll be talking to a friend of the show, Dr. Paul Offit, about kids in vaccines next week. So, we'll have a lot more coverage on this topic as it unfolds, so check both those things out. Andrea, any other vaccine news this week?

**Garcia:** I think the other major, the news is also coming from FDA. We know that when they convene their advisory committee in June, they'll also be considering how to best update our existing vaccines, including any aversions that might better target new variants. We know from the previous VRBPAC meeting, that they'll need to come up with a recommended revised version by June, in order to give manufacturers the opportunity to create those doses by fall. That's of course, in anticipation of a possible surge as we go into the fall and winter months. Then the Novavax application, we know they've submitted that in January and so, FDA could be considering that application. It's a protein-based vaccine. We know protein-based vaccines have been used for decades. Generally, have a strong track record of safety, mild side effects. So, if authorized, Novavax may be an option for those people who have been hesitant to take the mRNA vaccines. I think the other option people are considering is if this protein-based vaccine might work well as a booster for those who got a mRNA vaccine as their primary series.

**Unger:** Now you mentioned a possible resurgence in the fall. Seems like, based on my friend group, a lot of people are getting it right now. What's the situation with cases?

**Garcia:** Well, cases are certainly continuing to rise. They were nearly flat at the beginning of April and as we've moved into May, they're increasing in all but three states. Hospitalizations are also on the rise, nationwide. They're up about 16% over the past two weeks and that's after dropping an early April to their lowest points since March 2020. We know that more than 30 states and territories have seen their hospitalization rates increase over the past two weeks. But, that being said, I think looking at the big picture, the number of new cases announced each day in the U.S. is, a mere seven-day average, is around 60,000 cases. So, that remains at its lowest level since last summer and despite the increase in hospitalizations overall, those remain low comparatively as well. Some are saying that reflects, could be reflective of greater immunity in the population, either from our vaccinations or from previous illness.

**Unger:** On that topic, the CDC released a report last week that suggested a pretty large percentage of people in the U.S., including children have already had COVID, likely. What are the figures on that?

**Garcia:** The CDC's report last Tuesday said that about 60% of the US population, including 75% of children had already been infected with COVID-19 as of February. They also said in that report that

the highly-contagious Omicron variant was responsible for most of those numbers. In doing this research, they looked at blood samples collected between September 2021 and February 2022, and looked at those samples for antibodies to the virus. They parsed the data by age, by sex, by geographical location. I think it's important to note they're specifically looking for the type of antibody produced after infection, not after vaccination. So, between September and December 2021, the prevalence of antibodies in the samples increased by one or two percentage points about every four weeks. But it jumped really sharply after December, increasing by nearly 25 percentage points as of February 2022.

**Unger:** Wow. That's a big jump and I'm sure the numbers were probably surprising a lot of people, although I hear a kind of refrain in my social media. I see this where people are saying, basically they made it two years but finally found me, and I said, "Well, these are pretty good two years to miss, now that you're vaccinated." What does this mean for our ability to move on from the pandemic at this point?

**Garcia:** I mean, I think overall it could help protect the population against future waves. It might also help explain why we haven't seen that level of surge that's hitting other countries, when we look at China or countries in Europe and some public health officials have said that these numbers could mean that even with more infections, we may see fewer cases of life-threatening illness or death, which we know would certainly be good news. At a briefing last week, Dr. Ashish Jha, a White House COVID coordinator, said that stopping infections was not even a policy goal, that the goal of our policy should be to minimize infection whenever possible but to really make sure that people don't get seriously ill.

**Unger:** But just to clarify on that topic, even if people have had COVID previously, they should still get vaccinated, correct?

**Garcia:** Yeah. I mean, absolutely. At that same press briefing, we know Dr. Jha and other officials warned against complacency, urging the U.S. population to stay up to date with their COVID vaccinations, including booster doses, saying that antibodies from prior infection don't guarantee protection from the virus. I think widespread infection also raises that potential for an increase in cases of long COVID, which we still have a lot of questions about, we still don't fully understand. So, I think the other thing is there are tens of millions of people in the U.S. who don't have immunity to the virus and they remain vulnerable to the short and long-term consequences of infection.

**Unger:** Absolutely. Just a word of warning, finally, about fake COVID tests. What is that about?

**Garcia:** Yeah. So, there have been multiple reports of fake at-home tests circulating in the market and I think we've seen similar things throughout the pandemic. If we think back to counterfeit PPE, when there was a shortage, that's when we see those counterfeits popping up. So, the FDA warning asks people to watch out for counterfeit rapid tests, including impostors mimicking the Flowflex and the

iHealth Test Kits. The fake test kits look very similar to those that have been authorized by the FDA, so they're urging consumers to look out for things like suspicious labeling, the spelling or grammar errors or poor quality images and packaging that lacks a lot number or a QR code. FDA did say that they're not aware of counterfeit tests being shipped through the federal government's distribution program. But I think it's good information for physicians to pass on to their patients, that these counterfeit tests are out there.

**Unger:** So, keep your eye up eyes peeled for that. Andrea, thanks so much for being here today with us. That's it for today's COVID-19 episode. We'll be back with another segment soon. In the meantime, for more resources on COVID-19, visit [ama-assn.org/COVID-19](https://ama-assn.org/COVID-19). Thanks for joining us. Please take care.

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