Andrea Garcia, JD, MPH, on when the youngest kids can get vaccinated [Podcast]
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, thanks so much for joining us this week. The big news is that the FDA's vaccine advisory committee is meeting as we speak to talk about EUAs for Moderna and Pfizer's vaccines for the youngest age group. What's the latest there?

Garcia: Well, thank you for having me back Todd and that's right—VRBPAC, FDA's advisory committee, has been meeting today. The FDA had provided the clinical trial data from both Pfizer and Moderna to the committee. That data showed that the vaccines met the criteria for safety and effectiveness in the age groups that was 230 pages of documents for those outside advisors to review.
And as of the time of this filming, the advisory committee had just unanimously voted that the benefits of both the Moderna and the Pfizer vaccines in the respective populations outweighed the risks.

And so the FDA could grant those easy EUAs for Pfizer and Moderna and those youngest kids as early as Friday. Then, of course, we know that the next step is the Advisory Committee on Immunization Practices, CDC's advisory committee, will be meeting on Friday and Saturday. They'll be issuing their own clinical recommendations. And that would mean that children could start getting vaccinated, assuming the CDC director signs off as early as next week.

**Unger:** Well, Andrea, that's certainly great news for parents who've been waiting for quite a while. But even with those potential authorizations, some questions still remain. Why don't you take us through what those might be?

**Garcia:** Yeah. Well essentially, we're trying to predict the future because neither of those vaccines have been tested against the subvariant that are now common across the U.S. Those clinical trials were largely conducted when the Omicron variant was prevalent. And that was before the emergence of the subvariant we're seeing now. We know that BA.4 and BA.5 could be dominant here in the U.S. within a month. And given the waning protection that we have seen in adults, and of course the rapid evolution of the virus, regulators have said that pediatric recipients of both Pfizer and Moderna vaccines will most likely require a booster. And since Pfizer's vaccine is already three doses, Moderna's is two, that would mean a potential four-dose course for Pfizer and three doses for Moderna.

**Unger:** Well, speaking of predicting the future, Moderna's also been working on a booster dose that would specifically target variants. Where does that stand right now?

**Garcia:** Last Wednesday, Moderna released preliminary results on an updated COVID booster that targets the Omicron variant. They're calling it their leading candidate to serve as a U.S. booster dose in the fall. Their research tested a booster dose that combined the original vaccine with one that specifically targets Omicron. They found that among those with no evidence of prior infection, that the combination produced a 1.75 time level of neutralizing antibodies against Omicron, as their existing vaccine did alone. That's pretty significant but while the results are encouraging many worry that as we just talked about, the virus is evolving so quickly that it's going to outpace our ability to modify our vaccines. Moderna did not release any data on how the updated vaccine works against the BA.4 or BA.5 subvariants. The company has said that researchers are still trying to gather data on those in other subvariants.

**Unger:** When do you think we'll have more news about boosters for the fall?

**Garcia:** FDA's vaccine advisory committee is going to meet to discuss that on June 28. They're going to be looking at the formulation that would work best for a fall booster. The timing is tight. Vaccine
manufacturers have said that they need to get started on production soon, in order to have the number of boosters we'll need ready in time for the fall. Given this, we know that FDA may need to make its final decision based largely on lab results and animal data, as opposed to large human clinical trials. Even in the face of these obstacles, Moderna’s leadership is touting its latest formulation as a fundamental turning point in our fight against the virus and proof that we can adapt to a variant.

**Unger:** Well, in addition to the news about the younger age group, Moderna also got some good news from the FDA's vaccine advisory committee about its vaccine for older children. What's happening there?

**Garcia:** Yeah. Earlier this week, that same committee voted unanimously to recommend Moderna's COVID vaccine for use and children ages 6 to 17. It's extremely likely that FDA will follow that panel's advice and grant the EUA in the upcoming days. We know up until now, Moderna's vaccine was limited to authorization for adults. With that being said, this authorization is likely not going to have an immediate impact because we know this age group already has access to the Pfizer vaccine. They've had access to the vaccine since last year and because of this FDA and CDC are expected to prioritize decisions on vaccines for those younger children in the under five age group. We know they still do not have an option available to them. So that's where we're likely to see those decisions first.

**Unger:** But the vaccination for this age group does continue to be important, correct?

**Garcia:** Absolutely. As of last month, CDC data showed that 189 children in that 5 to 11 age group and 433 adolescents and teenagers had died of COVID. We know the Omicron surge we saw over last winter led to the highest number of pediatric COVID cases, emergency department visits and hospitalization rates of the pandemic. And roughly, two-thirds of children in that 6 to 17 age group who were hospitalized with COVID had underlying conditions. So vaccination is especially important for those children.

**Unger:** Well, in more vaccine news, shortly after we wrapped filming last week, news also broke about a potentially new vaccine option for adults. Where do we stand with that?

**Garcia:** Yeah. So, when we were talking last week, advisors to the FDA were meeting to discuss the safety and efficacy of a COVID vaccine developed by Novavax, and that's a more traditional protein-based technology. The end result was that the committee overwhelmingly recommended that it receive emergency use authorization for people ages 18 and over. Those 21 members voted in favor and there was one abstention. So far, we have not seen the FDA issue that EUA and while they're not obligated to follow their committee’s recommendation, they normally do.

**Unger:** Any insight as to what the hold that might be?
**Garcia:** Well, last Wednesday a spokesperson for the FDA said the agency needs to review changes in Novavax's manufacturing process before they can authorize the vaccine in the U.S. We don't have a lot of detail on that, other than Novavax has disclosed in early June, that it had made changes to their manufacturing process. We know that outside of the U.S., Novavax has already received emergency use authorization in more than 40 countries. And it's listed for emergency use by the WHO.

**Unger:** All right. Well, we'll continue to follow that because as we talked about last week, it could be a good alternative for people who are concerned about for whatever reason, about allergic reactions to mRNA platform vaccines or other reasons. How are we looking on cases this week?

**Garcia:** Well, the good news is that we're starting to see some leveling off. And if you look at the New York Times database for just about 105,000 new reported COVID cases a day on average. That rate has more or less held steady over the last month. There are also signs of steadying in hospitalization. That number is growing but it's growing slowly. And the average number is hovering around 29,000. Deaths are also, they're increasing, they've increased about 8% over the last two weeks but that number is staying below 400 per day. And with those key indicators, as you know, we're in a surge but they're far below the Omicron winter peak. So we are starting to see some of those long-standing public health orders being lifted.

**Unger:** Well, speaking of which one of the most significant that we saw last week was the order regarding international travel and testing, besides complete pandemonium apparently, in all European airports from surge on-demand. What does that mean exactly?

**Garcia:** As of last Sunday, passengers no longer need to provide that negative test to enter the U.S., and CDC announced it was lifting that requirement. And the reason is that widespread adoption of vaccines and treatment for COVID no longer make it necessary. In a press release, Dr. Rochelle Walensky, the CDC director, cited booster doses and the milder Omicron variant, which she said has generally caused less severe disease among those who are infected. And that's the driving factor for that change.

**Unger:** Well, we know the mask mandate for travel had already been lifted some time ago but that was done through the courts and went against a mandate the CDC had in place at the time. The AMA has subsequently and recently weighed in on this. Give us the background on this and where we stand on this issue?

**Garcia:** Last week, we issued a press release, defending the CDC's authority to enact reasonable evidence-based public health measures like masking, that curb the spread of illness and protect those at highest risk from serious harm. An AMA amicus brief was filed in the Health Freedom Defense Fund versus Biden. That brief urged the U.S. Court of Appeals for the 11th circuit to reverse a district court's order striking down the CDC's public transportation mass mandate, on a nationwide basis.
That press release explained that the CDC's core mission of protecting the public from serious illness, injury and death requires public health officials to have the ability to exercise reasonable judgment in the face of evolving conditions. And the authority to enact evidence-based measures when necessary. So the AMA is urging the court to acknowledge that the CDC's authority and to enact measures to protect the public's health. And we also went on to recognize that health authorities have the expertise to make these determinations to promote public health in rapidly involving circumstances.

Unger: And preserving that authority will continue to be so important as we navigate new variants and even outbreaks of other diseases down the road. Andrea, thanks again for being here today. That wraps up today's episode. We'll be back soon with another COVID-19 Update video and podcast. In the meantime, you can find all our videos and podcasts at ama-assn.org/podcasts. Thanks for joining us. Please take care.

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