Andrea Garcia, JD, MPH, discusses FDA's full approval of Pfizer vaccine

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Featured topic and speakers

In today's COVID-19 Update, a discussion with AMA's Director of Science, Medicine & Public Health, Andrea Garcia, JD, MPH, to review COVID-19 vaccine numbers and trending topics related to the pandemic over the past week. Also covering the FDA's full approval of the Pfizer COVID-19 vaccine, booster shots and vaccine mandates.

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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. Today we have our weekly look at the numbers, trends and latest news about COVID-19 with 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. Well, Andrea, let's cut right to the big news for the week, which is the FDA's full approval of the Pfizer vaccine. Can you tell us what that means?

Garcia: Yeah. Thanks for having me, Todd. The FDA had initially set an unofficial deadline of Labor Day for the full approval of the Pfizer vaccine but we know with the highly contagious Delta variant circulating the sharp rise in cases across the country, the agency's really been working to accelerate that timeline with an all hands-on deck approach to reviewing the necessary data without cutting any corners. So on Monday, we did see the FDA grant full approval of Pfizer's COVID-19 vaccine for people aged 16 and older. This makes it the first vaccine to move beyond emergency use in the United States. Although, full approval means the company's now free to market the drug under the name "Comirnaty," the company has said that only the federal government will distribute doses in the United States.

Unger: What about the other two vaccines, the Moderna and the J&J? Do we expect full approval for those to follow shortly?

Garcia: We do. I mean, we know that they were authorized later than the Pfizer vaccine, so regulators are still reviewing Moderna's application for full approval of its COVID-19 vaccine and a decision could come on that in several weeks. Johnson & Johnson is expected to apply soon for full approval as well.

Unger: One of the things you mentioned was that the Pfizer's full approval is for those who are 16 and older. What about the 12- to 15-year-olds that are covered under the EUA right now?

Garcia: The Pfizer vaccine will be continued to be authorized for emergency use for children ages 12 to 15 while the company collects and submits the necessary data required for full approval for that population. I think the question on everyone's mind, including parents such as myself, is with the kids heading back to school, when will the vaccine be authorized for children younger than 12. And we expect that decision is still several months away. I think it's important to know, and AAP released a statement on this yesterday, really discouraging the administration of the Pfizer vaccine off-label for children under age 11 and younger, saying that we really need to see the data from those studies before we give this vaccine to children who are younger.

Unger: Well, the full approval has been cited as one of those obstacles and a thing that people who are hesitant to take the vaccine were waiting for. Now that that's here, do we expect to see in terms of impact of the full approval, particularly in realm of mandates, can you tell us what's happening there?

Garcia: Yeah. This decision is expected to kick off a series of vaccine requirements by public and private organizations who were really waiting on that final regulatory action before putting mandates into effect. We're seeing that start to happen. United Airlines announced that its employees will be required to show proof of vaccination within five weeks of regulatory approval. Oregon has adopted a similar requirement for state workers. And we've also seen a host of universities and states from Louisiana to Minnesota enact similar requirements. We had previously talked about the Pentagon and they made good on their promise to mandate the vaccine for the country's 1.4 million active duty troops once the Pfizer approval came through. And President Biden, in a speech on Monday

afternoon, told corporate state and local leaders and no uncertain terms, "Do what I did last month, require your employees to get vaccinated or face strict requirements, such as frequent testing."

Unger: Well, on the subject of mandates, there is a statement that came out from the AMA today regarding support for mandates. Can you give just a brief overview of what that look like?

Garcia: Yeah. The statement that came out today is encouraging the public and private sectors to move forward with vaccine mandates for COVID-19. The statement notes that vaccine mandates have been used successfully for other vaccine-preventable diseases. And we think now is the time to move forward with COVID-19 vaccine mandates as well.

Unger: We are going to be talking with AMA president, Dr. Gerald Harmon, on tomorrow's episode and we'll get into more detail on that. Back to the topic of full approval and vaccine hesitancy, we're hoping that that will inspire confidence in folks that have been on the fence or in the moveable middle. Do we think that that's going to make a difference and push some people over to the get the vaccine column, given especially what we're seeing with the Delta variant right now?

Garcia: We hope so. I mean, I think health officials are really hoping that this decision will shift public sentiment and increase vaccination rates among those who were concerned that the vaccine was authorized for emergency use. We know that the Kaiser Family Foundation has really been tracking public attitudes during the pandemic. And they found that three of every 10 unvaccinated people said that they would be more likely to get vaccinated once the vaccine was fully approved. Others think this number is high and we may only see an increase in just 5% of those who are unvaccinated going to get shots now that it's fully approved. But even so, I think that's a good number of people. At a minimum, I think full approval should help shake that false assertion that vaccines are experimental.

Unger: Absolutely. And to paraphrase Harmon's statement from yesterday, if you've been waiting for full approval, that time is now, it's time to get the vaccine. We'll cover, again, more in detail on tomorrow's episode. Well, turning to a slightly different topic, I want to talk more about another thing that's been in the news, which are booster shots. Last week, the president gave a press briefing where he suggested that most people will need a booster shot. Andrea, can you tell us more about this and where we stand on a third dose for a wider spread of the population?

Garcia: Yeah. We think this is the next major decision for the FDA and the CDC and it's whether or not to authorize and recommend booster shots. We know the CDC's Advisory Committee on Immunization Practices is going to be meeting August 30 and 31, and we expect that this will be a topic of discussion at their meeting. You mentioned the Biden administration said last week, that pending agency clearance, it will offer third shots to adults who got the Pfizer and Moderna vaccines eight months after their second injections, starting on September 20. As we talked about last week, third doses are already authorized and recommended for some people with immune deficiencies but that risk benefit calculus is different for the general population.

Unger: Talk more about that. What does that mean about the calculation and how it informs the decision about a booster shot?

Garcia: Federal health officials are saying that the Pfizer and Moderna vaccines, which rely on similar technology, wane in potency over time. That trend is converging with the rise of the Delta variant, making those who completed their vaccination at the start of the year, increasingly vulnerable to infection. Other health experts are really challenging that decision to recommend booster shots right now. They're saying it's premature, that the data is showing that these vaccines are holding up well against severe disease in hospitalizations, including against the Delta variant. So, many in this camp feel that boosters would only be warranted if the vaccines were failing to prevent hospitalizations for COVID-19. I think this is why that ACIP review of the evidence is going to be really critical to informing this decision.

Unger: Well, in the meantime, we are seeing a continuing and not positive trends in the world of cases, deaths and hospitalizations. Can you take us through some of the numbers this week?

Garcia: Yeah. We really can't help but remember that we began summer with COVID seeming to fade into the background and that's really been upended now that the Delta variant continues to drive up case totals across the U.S. Less than two months ago, we appeared to curb the spread of the virus and we're now averaging 150,000 new cases a day. Hospitals are once again stressed with more than 90,000 COVID patients in hospitals nationwide. That's more than any previous surge, except for last winter's. And the death rate is now averaging about 1,000 new deaths a day. That number has been climbing. It's still lower than it was last winter and we think that's because the vast majority of elderly people who are particularly vulnerable are vaccinated. Much of the south is continuing to contend with the most serious outbreak of the pandemic, including Florida, Louisiana and Mississippi. And some Western states with relatively high vaccination rates are also struggling with the Delta variant.

Unger: Well, I realize it's very recent about the full authorization but given what we've seen with the Delta variant out there, are we seeing movement in the vaccine numbers this week?

Garcia: Vaccine rates have been rising in recent weeks likely because of fears about the virus. Providers were administering about 837,000 vaccines per day. In his press briefing on Monday, the president said the most recent seven-day total was the highest since early July. He said, "More people in Alabama, Arkansas, Louisiana and Mississippi got their first shots in the past month than in the previous two months combined." That's good news and we're hoping with this full approval, we see those numbers continue to increase. Currently, about 201.7 million people or 60.8% of the population have received one dose, and 171 million people or slightly more than half of the population are fully vaccinated.

Unger: That's a big milestone, crossing that 200 million mark. So that is good news and hope that trend continues. Just in closing, Andrea, any other messages the AMA wants us to hear this week?

Garcia: Yeah. Yesterday, the AMA together with the American Hospital Association and the American Nurses Association released a statement applauding the full FDA approval of the Pfizer vaccine, encouraging all Americans to get vaccinated. I know you'll be talking more about that with Dr. Harmon tomorrow.

Unger: Indeed, we will. Andrea, thanks again for this week's update. That wraps up today's COVID-19 segment. We'll be back with another one shortly. In the meantime, for resources on COVID-19, visit ama-assn.org/COVID-19. Thanks for joining us. Please take care.
