FDA official explains decision on 'simplified' booster shots

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The U.S. government's booster campaign got a lot simpler Friday after Food and Drug Administration officials authorized extra shots of Pfizer and Moderna COVID-19 vaccines for all adults.

It replaces a complicated system in which eligibility was based on age, health conditions and other factors.

"It's simplified things, I think significantly over the situation that we had in place previously," FDA's vaccine chief Dr. Peter Marks told The Associated Press.

The FDA action comes after months of debate among experts over whether everyone 18 and older should get an extra shot for protection.

Just two months ago, the FDA's own advisers soundly rejected the idea, based on the vaccines' continued strong performance. But the White House continued pressing for broader use to head off another potential surge. And in the last week, nearly a dozen states jumped ahead of FDA to make booster shots available to millions of Americans.

"I think we are at a point in this pandemic that everyone, including state governors, are getting a little bit desperate," said Marks.

The FDA ultimately ruled that the extra booster protection outweighed risks of rare vaccine side effects, including cases of heart inflammation, called myocarditis, that mostly occur in young men. That's a different approach than several European countries, which limited use of Moderna's vaccine due to signs it carries a slightly higher heart risk than other shots.

Marks spoke with the AP Friday about how the agency made the decision on boosters. The conversation has been edited for clarity and length.

Q: The FDA reviewed data submitted by the companies but also trends in how the virus is spreading across the U.S. How did that factor into this decision?

A: If you look at the numbers for COVID-19, the seven-day rolling average just this week is up roughly 15% to 20%—depending on whose numbers you use. So the direction is not a good one. People are going inside more and "oops," next week happens to be the largest travel week of the year, so it probably makes sense to do whatever we can here to try to turn the tide.

Q: Some experts, including Dr. Anthony Fauci of the National Institutes of Health, have suggested boosters should have been authorized for all adults months ago. Why didn't the FDA move faster?

A: We move as rapidly as we can. But we have to do the right analyses to make sure that when we take an action, we can stand behind it. Our goal is to make sure that the person who is on the fence, or perhaps doubting whether to take the vaccine, feels confident enough in our decisions that they are willing to come along and take the vaccine or take the booster. We wanted to make sure that we had a good justification. And so I think we acted reasonably nimbly to get this done.

Q: Some European countries have decided against the use of Moderna's vaccine in young people because of rare cases of myocarditis. Why did the FDA reach a different conclusion?

A: Some countries have said, 'OK, we won't use this vaccine in that age range or it's not a preferred vaccine.' We have done our own analysis and for transparency put this in the fact sheet (for vaccine providers and recipients) that some—but not all—studies have shown this side effect. So it's there for health providers to note and they can make an informed decision on the rates, which are not incredibly high. And we're continuing to work to better understand what the actual rates are.

Q: So what is the risk of having this side effect when getting a Moderna booster?

A: The rate of myocarditis for men in the age range of 18 to 24 is probably somewhere between 1 in 5,000 and 1 in 10,000 with Moderna. The exact number, I can't tell you, because it depends on what study you're using.

Myocarditis sounds like a scary word. It is. But myocarditis has a range from mild—which is basically almost a laboratory abnormality—to something that's really bad and you're in the intensive care unit. These cases, 98% of these, were the really mild form where the most common thing given to people were pain medicines like acetaminophen. We don't dismiss this. We still take it as a serious thing. But I'm just trying to say that in terms of the spectrum of side effects, thankfully, it's a mild finding.

Q: So what would you say to a young person who is weighing whether or not to get a booster?

A: If you're a younger person, you're probably at reasonably low risk of getting severe COVID-19 and ending up in a hospital. You probably want to prevent yourself from getting any COVID-19, however, because even if you're vaccinated and get infected, you still have a risk of long COVID.

So that's for yourself, but there's also those around you. We do believe that being vaccinated reduces the risk of spreading COVID-19, and so that's a good thing as well. So I would encourage people to help protect themselves against getting breakthrough COVID, which could be associated with long COVID and to protect others around them, particularly as we go into the holiday season.