FDA official hopeful younger kids can get shots this year

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In this Tuesday, May 11, 2021 file photo, Dr. Peter Marks, director of the Center for Biologics Evaluation and Research in the Food and Drug Administration, testifies during a Senate health, education, labor, and pensions hearing to examine an update from federal officials on efforts to combat COVID-19 on Capitol Hill in Washington. On Friday, Sept. 10, 2021, Marks urged parents to be patient, saying the agency will rapidly evaluate vaccines for 5- to 11-year-olds as soon as it gets the needed data. Credit: Jim Lo Scalzo/Pool via AP

The Food and Drug Administration's vaccine chief said Friday the agency will rapidly evaluate COVID-19 vaccinations for younger children as soon as it gets the needed data—and won't cut corners.

Dr. Peter Marks told The Associated Press he is "very, very hopeful" that vaccinations for 5- to 11-year-olds will be underway by year's end. Maybe sooner: One company, Pfizer, is expected to turn over its study results by the end of September, and Marks say the agency hopefully could analyze them "in a matter of weeks."

In the U.S., anyone 12 and older is eligible for COVID-19 vaccines. But with schools reopening and the delta variant causing more infections among kids, many parents are anxiously wondering when younger children can get the shots.

Pfizer's German partner BioNTech told weekly Der Spiegel Friday that it was on track "in the coming weeks" to seek approval of the companies' COVID-19 vaccine for 5- to 11-year-olds. Moderna, which makes a second U.S. vaccine, told investors this week to expect its data on that age group by year's end. Both companies also are testing their vaccines down to age 6 months, but those results will come later.

FDA's Marks spoke with the AP Friday about the steps involved in clearing pediatric vaccines. The conversation has been edited for clarity and length.

Q: Many parents had hoped for vaccines for children under 12 by the time schools reopened. Why is it taking so long?

A: Before you can actually approve something in an age range, you actually have to study in that age range. ... Children under the age of 12,

they're not little adults, they're not. And so one does actually have to study this and even change perhaps the dose that's being given—and in fact, that's had to happen, change the dose.

We have to then be able to look at the data at FDA when it gets submitted to us. We'll look at it very rapidly and feel confident that when we that we've looked through the data that these are going to be safe and effective and that we can reassure parents that the benefits of their child getting one of these vaccines certainly outweighs any risks.

Q: The American Academy of Pediatrics cited delta's growing threat to children in urging a faster decision, after FDA requested expanded child studies. Why does FDA want that extra data?

A: I'm not sure that there's much disagreement. We clearly want to see children in the age range 5 to 11 vaccinated as soon as possible. But the difference between the smaller dataset and the larger dataset is not very much in terms of time, because there were enough willing participants here—parents who were very interested in having their 5- to 11-year-olds vaccinated—that it didn't take that much longer.

We'll be able to give people I think a much better sense that these vaccines are indeed safe and effective for their children.

Q: Could 5- to 11-year-olds be vaccinated by the end of the year?

A: I am very hopeful in that regard. Very, very hopeful in that regard.

Q: How fast can FDA act once the companies submit their data?

A: Pfizer made a public statement that they intended to give us their data by the end of September. ... We're going to do a thorough job on that as quickly as we can so that at the end of the day, hopefully within a matter

of weeks rather than a matter of months, we'll be able to come to some conclusion—again, barring some finding that we're not expecting.

Q: How will the trials show effectiveness for kids?

A: In the 12- to 15-year-olds, we saw an immune response that was actually as good or better—in this case, it was for the Pfizer vaccine—it was actually better than in 16 and up. And so we'd want to see something similar to that.

Q: Will the trials give information about very rare side effects like the heart inflammation sometimes seen in teens and young adults?

A: We'll know at least that it's not ... happening at some much higher rate in younger children. That we can rule out. And we'll also make sure that there aren't any other side effects that we haven't seen in the older age range.

Q: Two of FDA's top vaccine reviewers recently announced they're leaving. The agency also is evaluating booster shots for adults. Is that making a child vaccination decision more difficult?

A: I'm not worried that we're going to suffer any delays because of that. ... We will be parallel processing.

Q: There are reports that some parents are seeking adult vaccines for their kids. What's your advice?

A: My strongest advice is please don't do that. Please let us do the evaluation that we need to do to ensure that when you do vaccinate your child, you vaccinate the child with the right dose and in a manner that's safe.

If you want to do something now for your child, make sure that you're vaccinated, that your household is vaccinated, that all the people that come in contact with your children are vaccinated and that your child knows how to wear a mask.