How the FDA’s approaching COVID-19 vaccines for kids under 5

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With the U.S. passing the once unthinkable figure of 1 million COVID 19 deaths, people who are unvaccinated remain at the greatest risk for acquiring SARS-CoV-2 and are dramatically more likely to suffer from severe illness and death.

While about two thirds of eligible Americans are fully vaccinated and nearly 80% have received at least one dose, only about 30% of those eligible to receive a booster dose have done so. On top of that, there continues to be a need for a safe and effective COVID-19 vaccine for children under 5 years old.

All that “means we have some work to do here to educate the public on the importance of staying up to date on COVID-19 vaccinations,” said Susan R. Bailey, MD, immediate past president of the AMA, said during an AMA “COVID-19: What Physicians Need to Know” webinar on second booster doses and a pediatric vaccine update.

“To make sure that patients have their questions answered, we need to first make sure that we as physicians have a deep understanding of the vaccine and the booster-development process, the scientific rigor involved and how their effectiveness helps combat COVID-19,” said Dr. Bailey, moderator of this webinar.

During the webinar, Peter Marks, MD, PhD, director of the Center for Biologics Evaluation and Research at the Food and Drug Administration (FDA), discussed pediatric COVID-19 vaccines, the latest on COVID-19 vaccine boosters and a change in Johnson & Johnson vaccine use.

Learn why Dr. Marks was among seven honored by the AMA for their work during the COVID-19 pandemic.
Pediatric vaccines may be near

“There are completed trials from two sponsors in the process of submission and review, and we are moving as fast as we can to review these. I fully expect that we’ll have the data by June ready for review,” he added. “But we’re not going to hold anything back here because we hear very much from parents how desperate they are to have these vaccines.”

“We have to do it right, because we need parents to feel confident to get their kids vaccinated,” said Dr. Marks.

Learn more from this “AMA COVID-19 Update” on a COVID-19 vaccine for young children.

Boosters may prevent long COVID

“An additional vaccine dose can provide better immunity, preventing hospitalization and death, emergency department and urgent care visits, and potentially serious complications such as long COVID-19,” said Dr. Marks. “As additional data come out on the neurologic complications of COVID-19 and the potential impact on the brain, preventing long COVID-19 may be one of the important things that vaccination helps do.

“We do know that people who are vaccinated, even if they do get COVID-19, tend to have a lower subsequent rate of long COVID,” he added.

Find out what doctors wish patients knew about long COVID.

J&J vaccine use narrowed

The FDA recently revised the Johnson & Johnson COVID-19 vaccine “emergency use authorization based on the continued occurrence of thrombosis with thrombocytopenia syndrome,” said Dr. Marks. “We found it occurring about three and a quarter per million doses of vaccine given, which is pretty rare.

“Unfortunately, it’s associated with about one death per 2 million doses and those are pretty clearly attributable to the vaccination,” he added. “This is in the setting of the United States where we have the mRNA vaccines, of which now hundreds of millions of doses have been given where we cannot identify any similar risk.”
That’s why “we felt it was appropriate to narrow this to a vaccine for individuals who could not take one of the mRNA vaccines because it was clinically not appropriate—because of either allergic reactions or myocarditis—or because they were unwilling to take an mRNA vaccine,” Dr. Marks said.

Stay informed by visiting the AMA COVID-19 resource center for physicians, which features frequently updated information on clinical questions, advocacy, medical ethics and more.