FDA Will Follow The Science On COVID-19 Vaccines For Young Children

As schools reopen, parents have questions about when COVID-19 vaccines will be available for children under 12.

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This statement from Acting FDA Commissioner Janet Woodcock MD, and Peter Marks, MD, PhD, director of the FDA's Center for Biologics Research and Evaluation, was released by the Food and Drug Administration on September 10, 2021.

As schools around the country are re-opening for in-person learning and families are returning to their busy school year schedules, we know many parents are anxious about the pandemic and protecting their children. Many parents have questions about COVID-19 and when vaccines will be available for children younger than 12 years of age.

Many of our team at the FDA are parents and grandparents themselves, and our team shares the same concerns as many in our country about protecting our loved ones from COVID-19. We are therefore also eager to see COVID-19 vaccines available for young children. We also know that we all share the interest in making sure this process is done with safety at top of mind. As regulators, we recognize we have an important task ahead of us that will require us to act expeditiously while undertaking an extremely meticulous and thoughtful review once we receive requests to authorize a COVID-19 vaccine for emergency use or submissions for approval of a COVID-19 vaccine for this population.

We know there have been questions and public commentary on the process surrounding vaccines for young children, so we think it's important to share information about the process and the necessary considerations involved to provide greater clarity to the public about this effort.

It's important that the public recognize that, because young children are still growing and developing, it's critical that thorough and robust clinical trials of adequate size are completed to evaluate the safety and the immune response to a COVID-19 vaccine in this population. Children are not small adults – and issues that may be addressed in pediatric vaccine trials can include whether there is a need for different doses or different strength formulations of vaccines already used for adults.

Steps the FDA will take to ensure the safety and efficacy of these products for children:

- First, vaccine manufacturers have reported that the necessary clinical trials involving children as participants are currently underway. Some have stated that they are still enrolling, and some are still administering doses or following participants. This process is expected to include a follow-up period of at least about two months, to allow for proper safety monitoring following the administration of vaccine doses for at least half of the clinical trial vaccine recipients.
- Once the manufacturers complete the relevant portion of their clinical trials, they have to complete the analysis of the data from the studies to understand how safe the vaccine is and how well it works in the clinical trial participants. The FDA will work closely with each manufacturer to ensure this data analysis is robust and meets regulatory standards. After manufacturers analyze their clinical trial data, they will compile the information and may request an emergency use authorization (EUA) or submit for approval a biologics license application (BLA), as appropriate, for this young population to the FDA.
- When a completed request for EUA or approval has been received by the FDA, the agency will carefully, thoroughly and independently examine the data to evaluate benefits and risks and be prepared to complete its review as quickly as possible, likely in a matter of weeks rather than months. However, the agency's ability to review these submissions rapidly will depend in part on the quality and timeliness of the submissions by manufacturers.

Just like every vaccine decision we've made during this pandemic, our evaluation of data on the use of COVID-19 vaccines in children will not cut any corners. Conducting clinical trials to determine an appropriate vaccine dose in children requires additional work over that done in the adult studies, including ensuring that the vaccine dosage and formulation strength used is the appropriate one from the perspective of safety and generating an immune response. Our multi-disciplinary teams of doctors, scientists, statisticians and other experts will thoroughly assess this complex data in making any determination about COVID-19 vaccines in young children. We may also consult with our Vaccines and Related Biological Products Advisory Committee on any questions that warrant a public discussion by external experts. Importantly, once a decision to authorize or approve a vaccine for a younger population has been made, the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices will meet to discuss further clinical recommendations.

Parents may be wondering if they can ask their health care providers to go ahead and vaccinate their kids using one of the currently available vaccines outside of the FDA-authorized or approved uses. Parents need to remember that the vaccine doses that are currently being studied in

younger children are not necessarily the same vaccine doses that were authorized for individuals 12 years and older or approved for individuals 16 years of age and older—there are different dosing regimens being investigated. It is important for the clinical trials to be completed before vaccinating young kids, so the FDA's team can conduct a thorough evaluation and ensure the data show that the vaccine under consideration is likely to work to prevent COVID-19 in young children and doesn't cause unexpected safety issues separate from those that have already been observed in adolescents and adults.

Just like you, we are eager to see our children and grandchildren vaccinated against COVID-19 as soon as possible. We have to let the science and data guide us. The FDA is working around the clock to support the process for making COVID-19 vaccines available for children. As outlined above, this process is complex and relies on robust manufacturer trials and data, and while we cannot offer a specific date or timeline for when it may be completed for the various manufacturers' vaccine candidates, we can assure the public we are working as expeditiously as possible to meet this critical public health need and we very much hope to have pediatric COVID-19 vaccines available in the coming months.

Until we authorize or approve a vaccine for this younger population, it's especially important that parents and others who interact closely with children under 12 years of age get vaccinated, wear masks, and follow other recommended precautions so that we can protect those who cannot yet protect themselves through vaccination.
