

NEW YORK CITY DEPARTMENT OF HEALTH AND MENTAL HYGIENE Dave A. Chokshi, MD, MSc Commissioner

October 29, 2021

Dear Colleague:

On October 26, 2021, **the Vaccines and Related Biological Products Advisory Committee** (VRBPAC), an independent advisory body to the U.S. Food and Drug Administration (FDA), **voted 17-0 to recommend that the Pfizer COVID-19 vaccine be authorized for children ages 5 to 11 years, administered as a two-dose series (10 µg per dose, 3 weeks apart).** The committee reviewed the totality of scientific evidence available and concluded that the benefits of the vaccine outweigh the risks for this age group.

Before VRBPAC's recommendations can be implemented, the FDA must issue an Emergency Use Authorization (EUA), the Advisory Committee on Immunization Practice (ACIP) must meet to advise the Centers for Disease Control and Prevention (CDC) (scheduled for November 2, 2021), and the CDC must provide its approval and recommendations. **Providers cannot vaccinate children ages 5 to 11 years until after CDC Director approval, which is expected next week.**

The VRPBAC recommendation was based on a review of the <u>epidemiology</u> of COVID-19 in this age group and findings from a clinical trial of the vaccine. Children ages 5 to 11 years have accounted for approximately <u>9% of reported COVID-19 cases</u> in the U.S. Hospitalizations and deaths are less frequent in children than in adults, but pediatric age groups nonetheless account for substantial morbidity and mortality. Multisystem inflammatory syndrome (MIS-C) is of particular concern in children who have COVID-19.

In a <u>clinical trial</u> of 2,268 children ages 5 to 11 years, the two-dose Pfizer COVID-19 vaccine series had a vaccine efficacy rate of 90.7% against symptomatic COVID-19 in participants who had no evidence of prior SARS-COV-2 infection. Children who were vaccinated in the clinical trial also had immune responses similar to those observed in people ages 16 to 25 years who were vaccinated against COVID-19 with the full-dose ($30 \mu g$) Pfizer series. Most reactions after vaccination were mild to moderate in severity and resolved within 1 to 2 days. All severe adverse events reported in the clinical trial were determined to be unrelated to vaccination and there were no cases of myocarditis or pericarditis, though the sample size for the study was not large enough to detect rare events.

In addition to considering individual benefits and risks of vaccination, the committee recognized that vaccinating children against COVID-19 has other <u>societal benefits</u>. For example, children play a role in disease transmission and vaccination may limit school outbreaks, helping to ensure in-person learning, which is critical for childhood development.



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Note that the Pfizer COVID-19 vaccine for children ages 5 to 11 years is a different vaccine product than the existing Pfizer COVID-19 vaccine product for people ages 12 years and older; **providers cannot use the existing Pfizer vaccine product for children ages 5 to 11 years.** Providers can find information about ordering COVID-19 vaccine <u>here</u>. We will share updated information after further review and recommendations from CDC, anticipated late next week.

Thank you for your work to protect New Yorkers from COVID-19.

Sincerely,

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Jane R. Zucker, MD, MSc Assistant Commissioner Bureau of Immunization