August 31, 2021

Dear Colleague,

The New York City (NYC) Department of Health and Mental Hygiene is pleased to report that **on August 30, 2021, the Advisory Committee on Immunization Practices (ACIP) recommended use of the Pfizer COVID-19 vaccine for people 16 years of age and older under the U.S.** Food and Drug Administration (FDA) Biologics License Application (BLA) <u>approval</u>. This updated recommendation follows an updated review of post-authorization <u>vaccine safety monitoring data</u> from passive and active surveillance systems in the U.S. and globally. Additionally, the Pfizer COVID-19 vaccine continues to be available under Emergency Use Authorization (EUA) for individuals 12 through 15 years of age and for the administration of a third dose in certain immunocompromised individuals.

ACIP's recommendation is supported by a robust <u>body of evidence</u> from randomized controlled trials and observational studies of the Pfizer vaccine. Specifically, trials involving more than 40,000 people have demonstrated vaccine efficacy against symptomatic COVID-19 disease and hospitalization through six months of follow-up, and multiple observational studies involving more than 680,000 people have demonstrated continued vaccine effectiveness against COVID-19 hospitalization and deaths in real world settings. Severe adverse events (i.e., myocarditis and anaphylaxis) are very rare, and ACIP concluded that <u>the desirable consequences of vaccination clearly outweigh undesirable consequences</u> across all age and sex groups evaluated.

Please continue to refer to the <u>FDA fact sheets</u> and the Centers for Disease Control and Prevention's (CDC's) <u>clinical considerations</u> for detailed information about the Pfizer vaccine. As a reminder, COVID-19 vaccination providers continue to be responsible for adhering to all requirements outlined in the CDC <u>COVID-19 Vaccination Program Provider Agreement</u>. This applies to both EUA and FDA approved COVID-19 vaccines. Use of these products outside of those that have been approved and authorized by FDA (often referred to as "off-label use") is not recommended.

Finally, we urge you to leverage the updated Pfizer recommendation to talk to your patients about COVID-19 vaccination and to offer vaccination at every opportunity. Providers can play an important role in ensuring that all New Yorkers, especially Black, Indigenous, people of color (BIPOC) and other marginalized communities who are most vulnerable to COVID-19 get vaccinated. For the latest information on COVID-19 vaccines in NYC, visit our <u>provider webpage</u>. Thank you for your continued efforts in protecting New Yorkers from COVID-19.

Sincerely,

Jane R. Zucker, MD, MSc Assistant Commissioner

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Bureau of Immunization