

Congress of the United States
House of Representatives

SELECT SUBCOMMITTEE ON THE CORONAVIRUS CRISIS
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WASHINGTON, DC 20515-6143
Phone (202) 225-4400
<https://coronavirus.house.gov>

April 25, 2022

Dr. Robert M. Califf
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Califf:

The Food and Drug Administration's (FDA) authorization and approval of safe and highly effective vaccines for the majority of Americans have been critical to saving millions of lives and allowing the country to safely emerge from the crisis phase of the coronavirus pandemic. However, millions of young children still remain unprotected because no vaccine has yet been authorized for children under five. Although the virus poses less risk to children than to older Americans, the American Academy of Pediatrics estimates that up to 1.5 percent of all child coronavirus cases result in hospitalization.¹ During the surge of the Omicron variant, children younger than five were hospitalized at approximately five times the rate of the previous peak during the height of the Delta variant.² I therefore write today to request a staff briefing on the status of coronavirus vaccine candidates for young children.

Recent reports indicate that FDA is considering postponing its decision on whether to authorize Moderna's vaccine for young children until early summer, so that it can be evaluated—and potentially authorized—at the same time as Pfizer's vaccine. Moderna reportedly plans to apply to FDA for emergency use authorization of its two-dose vaccine candidate for children ages six and younger by the end of this month, while Pfizer is likely to request authorization of its three-dose vaccine candidate for children under five in June.³ White House Chief Science Adviser Dr. Anthony Fauci recently indicated that FDA is weighing whether to consider authorization of both the Moderna and Pfizer vaccine candidates at the same time—rather than considering them separately—so as not to “confuse people” with a staggered rollout of two vaccines with different dosing regimens, potentially with varying degrees of efficacy. Such a

¹ *More Children Were Hospitalized for COVID During Omicron, CDC Study Finds. Most Were Unvaccinated*, USA Today (Apr. 23, 2022) (online at www.usatoday.com/story/news/health/2022/04/23/cdc-study-more-kids-5-11-hospitalized-covid-most-unvaccinated/7384841001/).

² Kristin J. Marks, et al., *Hospitalization of Infants and Children Aged 0–4 Years with Laboratory-Confirmed COVID-19 — COVID-NET, 14 States, March 2020–February 2022*, Morbidity and Mortality Weekly Report (Mar. 18, 2022) (online at www.cdc.gov/mmwr/volumes/71/wr/mm7111e2.htm).

³ See, e.g., *Waiting for a Covid Vaccine for Your Under-5 Kid? It May Take a Bit Longer*, Politico (Apr. 21, 2022) (online at www.politico.com/news/2022/04/21/biden-kids-vaccine-covid-00026798).

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decision could delay the potential authorization and administration of the Moderna vaccine by several weeks.⁴

The staff briefing, which is requested by May 9, 2022, should provide information on whether these recent reports are accurate and, if so, the scientific basis and any other rationale for such a delay.

This request is consistent with the House of Representatives' authorization of the Select Subcommittee on the Coronavirus Crisis "to conduct a full and complete investigation" of "issues related to the coronavirus crisis," including "the development of vaccines and treatments" and "executive branch policies, deliberations, decisions, activities, and internal and external communications related to the coronavirus crisis."⁵

Thank you for your attention to this matter. If you have any questions regarding this request, please contact Select Subcommittee staff at (202) 225-4400.

Sincerely,



James E. Clyburn
Chairman

cc: The Honorable Steve Scalise, Ranking Member

⁴ *When Will the US Have a Covid-19 Vaccine for the Youngest Children?*, CNN (Apr. 22, 2022) (online at www.cnn.com/2022/04/22/health/vaccine-timeline-under-5-wellness/index.html).

⁵ H.Res. 8, sec. 4(f); H.Res. 935, 116th Cong. (2020).