

To: Commissioner Deidre Gifford, M.D., MPH
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Co-Chairs, Governor's COVID-19 Vaccine Advisory Group

From: Jason L. Schwartz, Ph.D.
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Date: December 19, 2020

Subject: Emergency Use Authorization of Moderna COVID-19 Vaccine

On behalf of the Science Subcommittee of the Governor's COVID-19 Vaccine Advisory Group, we strongly recommend that COVID-19 vaccination in Connecticut expand to include the Moderna COVID-19 vaccine, for which an Emergency Use Authorization (EUA) was issued by the U.S. Food and Drug Administration (FDA) on December 18. Vaccination should be administered in a manner consistent with the recommendations of the Advisory Committee on Immunization Practices to the U.S. Centers for Disease Control and Prevention.

The subcommittee has closely monitored the development of the Moderna vaccine, using the same process we undertook for our review of the recently authorized Pfizer-BioNTech vaccine. We reviewed and discussed materials including, but not limited to:

- FDA regulatory guidance documents related to COVID-19 vaccine development and potential EUAs,
- The Phase 3 clinical trial protocol developed by Moderna,
- Peer-reviewed scientific publications about the vaccine and its clinical testing,
- The extensive briefing documents about the vaccine prepared by FDA scientists and Moderna as part of the meeting of FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) held on December 17,
- The presentations and deliberations at the meeting of VRPBAC in which it recommended FDA authorization by a vote of 20-0 (with one abstention),
- The FDA letter of authorization released on December 18, and
- The EUA Fact Sheet for Healthcare Providers and EUA Fact Sheet for Recipients and Caregivers released by the FDA on December 18.

We found that the process of developing, reviewing, and authorizing the Moderna vaccine was rigorous, transparent, and scientifically sound, mirroring our principal finding for the Pfizer-BioNTech vaccine. The subcommittee once again has full confidence in the integrity of the FDA review and authorization process for this vaccine and the quality of the work performed by FDA scientists, reviewers, and advisory committee members.

In clinical testing, the Moderna vaccine has shown high levels of efficacy against symptomatic COVID-19 and a very favorable safety profile. In the coming months, additional evidence will be collected and analyzed regarding the vaccine's performance in specific subgroups, its duration of protection, the extent to which it may prevent asymptomatic infection, alternative dosing strategies, and its adverse events, among other topics. We will continue to carefully monitor this research—for the Moderna vaccine, the Pfizer-BioNTech vaccine, and other vaccines in development—and consider its implications for state vaccination activities going forward.

The authorization of a second COVID-19 vaccine adds a significant asset in support of the planned expansion of vaccination efforts in Connecticut in the weeks and months ahead. Our subcommittee is grateful to you for your leadership of the Advisory Group, and we look forward to continuing to contribute to our shared efforts to facilitate the rapid, safe, and equitable delivery of COVID-19 vaccines throughout our state.