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

From: Jason L. Schwartz, Ph.D.
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Co-Chairs, Science Subcommittee, Governor's COVID-19 Vaccine Advisory Group

Date: December 12, 2020

Subject: Emergency Use Authorization of Pfizer-BioNTech COVID-19 Vaccine

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On behalf of the Science Subcommittee of the Governor's COVID-19 Vaccine Advisory Group, we strongly recommend that COVID-19 vaccination in Connecticut begin at the earliest opportunity, using the Pfizer-BioNTech COVID-19 vaccine for which an Emergency Use Authorization (EUA) was issued by the U.S. Food and Drug Administration (FDA) on December 11. Vaccination should be administered in a manner consistent with the recommendations of the Advisory Committee on Immunization Practices (ACIP) to the U.S. Centers for Disease Control and Prevention (CDC).

The subcommittee has closely monitored the development of the 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 2/3 clinical trial protocol developed by Pfizer-BioNTech,
- Peer-reviewed scientific publications about the vaccine and its clinical testing,
- The extensive briefing documents about the vaccine prepared by FDA scientists and Pfizer-BioNTech as part of the meeting of FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) held on December 10,
- The presentations and deliberations that occurred at that meeting of VRPBAC in which that committee recommended FDA authorization, and
- The FDA letter of authorization released on December 11.

We found that the process of developing, reviewing, and authorizing the Pfizer-BioNTech vaccine was rigorous, transparent, and scientifically sound. The subcommittee 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 vaccine has been shown to have extremely high levels of efficacy in preventing COVID-19 and a very favorable safety profile. The scientific, medical, and public health communities will continue to learn more about the vaccine in the coming months, as additional data become available regarding its duration of protection, its performance in specific subgroups, and its adverse events. We support the robust planning and the multiple systems in place by federal partners to monitor post-authorization vaccine safety and to rapidly investigate potential safety signals. Our subcommittee is prepared to evaluate the implementation of these systems and to assist the Vaccine Advisory Group and Connecticut Department of Public Health should any expansion of these systems be deemed necessary.

The authorization of the first vaccine against COVID-19 is a milestone in our response to the pandemic. Our subcommittee will continue to closely monitor the Pfizer-BioNTech vaccine, as well as the others in development, including the specific recommendations for their use from the ACIP. We stand ready to provide additional guidance and recommendations upon the request of the Vaccine Advisory Group, and we look forward to continuing to support COVID-19 vaccination efforts in Connecticut during the critical months ahead.