

December 12, 2020

To: Governors of California, Nevada, Oregon, and Washington State

- Governor Gavin Newsom, California
- Governor Steve Sisolak, Nevada
- Governor Kate Brown, Oregon
- Governor Jay Inslee, Washington

From: Arthur Reingold, MD, Chair

Western States Scientific Safety Review Workgroup

Summary of Findings:

The Western States Scientific Safety Review Workgroup, after its thorough review,

- *Recommends unanimously that the Pfizer BioNTech COVID-19 vaccine be used in our states, as we conclude that the vaccine is safe and efficacious;*
- *Endorses the transparency and objectivity of the FDA Vaccines and Related Biological Products Advisory Committee (VRBPAC) and the CDC Advisory Committee on Immunization Practices (ACIP) review processes and the rigor, validity and reliability of their analyses;*
- *Concludes that equity has been considered appropriately in the clinical trials and urges that equity continue to be a guiding principle in immunization implementation, monitoring and communication; and*
- *Recommends that our states avoid any undue delay in providing access to the Pfizer BioNTech COVID-19 vaccine.*

The Western States Scientific Safety Review Workgroup was named by the Governors of California, Nevada, Oregon and Washington, to independently review and assess data made available by manufacturers of candidate COVID-19 vaccines, as well as review the processes of federal advisory committees and agencies considering approval of these vaccines prior to their introduction in the United States.

The Workgroup includes members with diverse relevant expertise in medicine, pediatrics, infectious disease, immunology, vaccinology and vaccine safety, epidemiology, public health, equity and biostatistics. Three members of the workgroup are current members of the FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) and the CDC's Advisory Committee on Immunization Practices (ACIP) and nine members have participated in multiple prior ACIP and VRBPAC vaccine reviews over many decades, including as members of these independent advisory committees. Members of the Workgroup have held multiple virtual meetings to review the available evidence concerning the safety, immunogenicity, and efficacy of the Pfizer BioNTech COVID-19 vaccine recently approved by FDA under the Emergency Use Authorization (EUA).

The Workgroup's deliberations are guided by four considerations:

- assuring the safety and efficacy of COVID-19 vaccines that might be used in our states;
- assessing the transparency and objectivity of the FDA VRBPAC and CDC ACIP review processes and the rigor, validity and reliability of their data analyses;

- ascertaining whether equity has been considered appropriately in the design, implementation and analysis of the clinical trials; and
- avoiding any undue delay in making available to our states' residents COVID-19 vaccines deemed by the FDA and CDC to be safe and efficacious.

We have focused our efforts on a careful and thorough review and discussion of the data presented to VRBPAC and ACIP and the processes and deliberations of those committees. The members of VRBPAC and ACIP include highly respected, independent experts who have been fully vetted for conflicts of interest and operate under strict rules requiring meetings that are open to the public. Both of these committees receive and carefully scrutinize data submitted by vaccine manufacturers concerning the safety, immunogenicity, and efficacy of any new vaccines for which approval is being sought for use in the U.S.

Data from the Phase 1 and Phase 2 studies concerning safety and immunogenicity of the Pfizer BioNTech COVID-19 vaccine had been previously presented and reviewed by our Workgroup at its meetings on November 12, 2020 and December 3, 2020. Phase 3 trial data concerning the safety, immunogenicity, and efficacy of the Pfizer BioNTech COVID-19 vaccine were presented in open meetings to VRBPAC on December 10, 2020 and to the ACIP on December 11 and 12, 2020. Multiple members of our Workgroup either directly participated in or observed the VRBPAC meeting on December 10, 2020 and the ACIP meetings on December 11 and 12, 2020, and the various presentations and discussions from those meetings were reviewed and discussed at length by our Workgroup in our meetings on December 10, 2020 and December 12, 2020.

Data presented to VRBPAC and ACIP and reviewed by the Workgroup demonstrated that the Pfizer BioNTech COVID-19 vaccine had an efficacy of 95% (95% credible interval: 90.3% to 97.6%) against COVID-19 disease of any severity. The data presented did not reveal any differences in efficacy in various subgroups of the population.

Safety data from a two-month follow-up of participants in the Phase 3 trial of the Pfizer BioNTech's COVID-19 vaccine were submitted to the FDA and reviewed by FDA and CDC staff, VRBPAC and ACIP. Review of the aggregate of post-licensing information on the many vaccines previously approved by FDA confirms that biologically plausible vaccine-associated adverse health events have been recognized within six weeks of vaccine administration. Given the very high and escalating rate of COVID-19 hospitalizations and deaths throughout the U.S., including in California, Nevada, Oregon and Washington State, the Workgroup agreed that the two-month review supports distribution and use according to ACIP recommendations for the Pfizer BioNTech COVID-19 vaccine under an FDA EUA. Full licensure of a new COVID-19 vaccine under the usual FDA Biologic License Application (BLA) process for new vaccines requires submission to the FDA of longer-term follow-up of vaccinees than is required under an EUA. The Workgroup noted that Pfizer BioNTech has already announced plans to pursue licensing under the BLA process in April 2021.

Confirming the safety of COVID-19 vaccine by close monitoring of vaccinees for adverse health events is of paramount importance to gain and sustain the public

acceptance of COVID-19 vaccination needed to achieve the immunization coverage to control this pandemic disease. Adverse health events following COVID-19 vaccination are expected given the coincidental frequency of such adverse health events over time even without vaccination. Thus, potentially causal relationships between receipt of COVID-19 vaccine and any such health events will need more investigation. The CDC and FDA announced extensive plans to rapidly obtain and investigate reports of adverse health events following receipt of COVID-19 vaccines utilizing the established and novel surveillance systems directed by FDA, CMS, CDC, the Department of Defense, the Veteran's Administration and Genesis Healthcare.

Three recipients of the Pfizer BioNTech vaccine in the United Kingdom are reported to have had anaphylactic reactions. Pfizer BioNTech reported at the FDA VRBPAC meeting on December 10, 2020 that such reactions had not occurred in any of the 18,000 Phase 3 clinical trial participants who received the COVID-19 vaccine. The Scientific Safety Review Workgroup wants to underscore the importance – as with any vaccine – of providing the vaccine in locations that are prepared to treat anaphylactic reactions or any other unexpected reactions, as noted in standard guidance from CDC.

The Workgroup noted that many important unknowns regarding the effects of Pfizer BioNTech COVID-19 vaccine remain, including the duration of vaccine-induced protection; the effect of vaccination on asymptomatic infection; the effect of vaccination on transmission of SARS-CoV-2; and the safety and efficacy

of the Pfizer BioNTech COVID-19 vaccine in pregnant women and children under 16 years of age.

The Workgroup notes that there are no known differences in either the efficacy or the safety of other vaccines in use in the U.S. by race, ethnicity, or gender.

Efficacy and safety of the Pfizer BioNTech COVID-19 vaccine were observed to be consistent across age, gender, race and ethnicity subgroups in the Phase 3 clinical trial. At the same time, we acknowledge that it will be critical for the manufacturer, the FDA, and the CDC to continue to carefully monitor and study the performance of the Pfizer BioNTech COVID-19 vaccine (i.e., its safety and efficacy) in various subgroups of the population over time. Ongoing monitoring of the efficacy and safety of the Pfizer BioNTech COVID-19 vaccine in diverse subgroups of the population, especially by race, ethnicity, age, and underlying disease status, will be crucial to ensuring confidence in and high uptake of the vaccine by a majority of residents in our states.

At its meeting on December 12, 2020, the Workgroup unanimously concluded that, based on our review of the data submitted to the FDA by the manufacturer and the VRBPAC and ACIP analyses of the data, the COVID-19 vaccine made by Pfizer BioNTech meets or exceeds FDA standards for safety, immunogenicity, and efficacy to justify its widespread use in our respective states at this time under an EUA. Furthermore, our conclusion is that VRBPAC and ACIP adherence to their usual standards of transparency and evidence-based decision making warrants full confidence in the recommendations made by these independent advisory committees for the use of the Pfizer BioNTech's COVID-19 vaccine at this time.

The Western States Scientific Safety Review Workgroup recommends that our states avoid any undue delay in making available to our states' residents the Pfizer BioNTech COVID-19 vaccine deemed by the FDA and CDC to be safe and efficacious.

We will perform similar assessments of additional COVID-19 vaccine candidates as they are presented for possible authorization or approval for use in the U.S.

Respectfully submitted:

Members of the Western States Scientific Safety Review Workgroup:

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California Members:

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Nevada Members:

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