

December 20, 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 Moderna 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 use the Moderna COVID-19 vaccine, in addition to the Pfizer BioNTech COVID-19 vaccine, to expand our states' ability to respond to the COVID-19 pandemic, including in underserved communities.*

The Western States Scientific Safety Review Workgroup was established by the Governors of California, Nevada, Oregon and Washington, to independently review and assess data on U.S. candidate COVID-19 vaccines and 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, many of whom have participated in multiple prior VRBPAC and ACIP vaccine reviews. The Workgroup held two virtual meetings on December 17, 2020 and December 19, 2020 to review the available evidence concerning the safety, immunogenicity, and efficacy of the Moderna COVID-19 vaccine.

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 review on the data presented to VRBPAC and ACIP and the processes and deliberations of those committees.

Phase 3 trial data concerning the safety, immunogenicity, and efficacy of the Moderna COVID-19 vaccine were presented in open meetings to VRBPAC on December 17, 2020 and to the ACIP on December 19, 2020. Multiple members of our Workgroup either directly participated or observed the VRBPAC meeting on December 17, 2020 and the ACIP meeting on December 19, 2020. These presentations and discussions were reviewed and discussed by our Workgroup on December 17, 2020 and December 19, 2020.

Data reviewed by the Workgroup demonstrated that the Moderna COVID-19 vaccine had an efficacy of 94.1% (95% confidence interval: 89.3% - 96.8%) 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 Moderna COVID-19 vaccine were reviewed by FDA and CDC staff, VRBPAC and ACIP. Given the escalating rate of COVID-19 hospitalizations and deaths throughout the U.S., the Workgroup agreed that the two-month review supports distribution and use according to ACIP recommendations of the Moderna COVID-19 vaccine under an FDA EUA.

Confirming the safety of COVID-19 vaccines by continued close monitoring and surveillance of vaccine recipients for adverse health events is of paramount

importance to gain and sustain the public acceptance of COVID-19 vaccination. The CDC and FDA have implemented multiple systems to rapidly obtain and investigate reports of adverse health events following receipt of COVID-19 vaccines. The Workgroup endorses these efforts and encourages our states to support active and regular reporting to these systems, which are already yielding valuable results.

At the December 19, 2020 ACIP meeting, CDC noted that it is investigating reports of anaphylactic reactions in six recipients of the Pfizer BioNTech vaccine. 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 Pfizer BioNTech COVID-19 vaccine. Moderna reported to ACIP on December 19, 2020 that one participant in the Phase 3 clinical trial had an episode of anaphylaxis 63 days after immunization. The Scientific Safety Review Workgroup wants to underscore the importance – as with any vaccine – of providing COVID-19 vaccines in locations that are prepared to treat anaphylactic reactions or any other unexpected reactions, as noted in standard guidance from CDC. CDC has produced enhanced guidance to ensure that appropriate equipment is available in all locations where COVID-19 vaccines are being administered and that vaccine recipients be monitored for 15 - 30 minutes after vaccination.

The Workgroup noted that several important attributes of the Moderna COVID-19 vaccine remain to be defined, including the duration of vaccine-induced

protection; the efficacy of vaccination in preventing asymptomatic infection; and the efficacy and safety of the vaccine in pregnant women and children.

Efficacy and safety of the Moderna COVID-19 vaccine were observed to be consistent across age, gender, race and ethnicity subgroups in the Phase 3 clinical trial. Ongoing monitoring of the efficacy and safety of the Moderna 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 acceptability of the vaccine by a majority of residents in our states.

At its meeting on December 19, 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 Moderna meets or exceeds FDA standards for safety, immunogenicity, and efficacy. Its widespread use in our respective states at this time under an EUA is justified. 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 Moderna COVID-19 vaccine at this time.

The Western States Scientific Safety Review Workgroup recommends that our states make available to our states' residents the Moderna COVID-19 vaccine deemed by the FDA and CDC to be safe and efficacious. We believe that this vaccine will expand our states' ability to respond as quickly as possible to the

COVID-19 pandemic and will – along with the Pfizer BioNTech COVID-19 vaccine – expand access in underserved communities.

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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