March 2, 2021

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,

- *Concludes that the Janssen Biotech, Inc. COVID-19 vaccine is safe and effective and that its use will lead to reduced severe and critical COVID-19 illnesses and hospitalizations and recommends unanimously that it be used in our states.*
- *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 Janssen Biotech, Inc. COVID-19 vaccine, which can be stored at normal refrigerator temperatures and requires only one dose to provide excellent clinical protection, to expand our response to the COVID-19 pandemic in all our states' 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 one virtual meeting on March 1, 2021 to review the available evidence concerning the safety, immunogenicity, and efficacy of the Janssen Biotech, Inc. 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 Janssen Biotech, Inc. COVID-19 vaccine were presented in open meetings to VRBPAC on February 26, 2021 and to the ACIP on February 28 and March 1, 2021. Multiple members of our Workgroup either directly participated or observed the VRBPAC meeting on February 26, 2021 and the ACIP meetings on February 28 and March 1, 2021. These presentations and discussions were reviewed and discussed by our Workgroup on March 1, 2021.

Data reviewed by the Workgroup demonstrated that the Janssen Biotech, Inc. COVID-19 vaccine had an efficacy of 66.9% (95% confidence interval: 59.0% - 73.4%) against symptomatic COVID-19 occurring at least 14 days after vaccination and 85.4% (95% confidence interval: 54.2% - 96.9%) against severe/critical COVID-19 occurring at least 28 days after vaccination. There were no COVID-19 related deaths among the vaccine group, yielding a point estimate of 100% (95% confidence interval: 93% - 100%) efficacy against COVID-19 related mortality. Furthermore, data from the Phase 3 clinical trial suggested that the Janssen Biotech, Inc. COVID-19 vaccine had efficacy against COVID-19 caused by variants of SARS-CoV-2 and that it reduced asymptomatic SARS-CoV-2 infection. The data presented did not reveal any significant 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 Janssen Biotech, Inc. COVID-19 vaccine were reviewed by FDA and CDC staff, VRBPAC and ACIP. Given the high rate of COVID-19 disease hospitalizations and deaths throughout the U.S., the Workgroup agreed that potential benefits of this vaccine greatly outweigh any known or likely risks and supports distribution of the Janssen Biotech, Inc. COVID-19 vaccine and its use according to ACIP recommendations.

Confirming the safety of COVID-19 vaccines by close monitoring of vaccine recipients for adverse health events remains of paramount importance to increase 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.

The Western States Scientific Safety Review Workgroup wants to underscore the importance – as with any vaccine – of providing COVID-19 vaccines by staff who 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 important attributes of the Janssen Biotech, Inc. COVID-19 vaccine remain to be defined, including the duration of vaccine-induced protection and the efficacy and safety of the vaccine in children.

Efficacy and safety of the Janssen Biotech, Inc. 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 Janssen Biotech, Inc. 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 March 1, 2021, 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 Janssen Biotech, Inc. 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 Janssen Biotech, Inc. COVID-19 vaccine at this time.

The Western States Scientific Safety Review Workgroup recommends that our states make available to our states' residents the Janssen Biotech, Inc. COVID-19

vaccine deemed by the FDA and CDC to be safe and efficacious. The Workgroup took note of the fact that the Janssen Biotech, Inc. COVID-19 vaccine can be stored at normal refrigerator temperatures and that a single dose of vaccine provides excellent protection against severe/critical COVID-19, preventing illnesses, hospitalizations, and deaths. We believe this vaccine should be used, along with the Pfizer BioNTech and Moderna COVID-19 vaccines, to curtail the COVID-19 pandemic by increasing access to COVID-19 vaccines for all of our states' 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:
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California Members:

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