

November 3, 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

The Western States Scientific Safety Review Workgroup thoroughly reviewed the evidence from the clinical trial in children ages 5 – 11 years of the 10 µg Pfizer-BioNTech COVID-19 vaccine presented to the U.S. Federal Drug Administration's Vaccine Related Biological Products Advisory Committee (VRBPAC) on October 26, 2021 and the U.S. Centers for Disease Control and Prevention's Advisory Committee on Immunizations Practices (ACIP) on November 2, 2021 and considered the committees' discussions.

The Workgroup carefully assessed the safety data for the vaccine, including the absence of any severe adverse events among vaccine recipients in the clinical trial. Reactions were mild, self-limited, similar to those seen in adolescents and adults and with other vaccines routinely recommended for children and were less common in those ages 5-11 years than in those 16-25 years. Based on the substantial experience in older children and adolescents, the Workgroup concluded that the risk of myocarditis following receipt of the lower dose vaccine in children 5-11 years of age is likely to be low.

The Workgroup noted the vaccine's efficacy of more than 90% against symptomatic COVID-19 disease in this age group. Expanding COVID-19 vaccination in this age group will protect children 5-11 years of age who are vaccinated and allow them to more safely engage in educational and other activities important to their health and development; give parents a means of further protecting their children; and contribute to control of the COVID-19 pandemic in our states. The Workgroup strongly urges that states make every effort to reduce or eliminate disparities in the availability and uptake of COVID-19 vaccines in children 5-11 years of age, as well as in older children, adolescents, and adults.

Based on this review, the Workgroup concluded the vaccine is safe and effective in this age group. Because substantial numbers of children of this age remain at risk of COVID-19 illness and its complications, including hospitalization and death, the Workgroup is confident that the benefits of this vaccine for children ages 5-11 years substantially outweigh any known or likely risks. Therefore, the Workgroup supports its use under Emergency Use Authorization (EUA) as a two-dose series of 10 µg per dose given three weeks apart.

The Workgroup will continue to monitor the rigorous ongoing national safety surveillance of COVID-19 vaccines. The Workgroup strongly advises parents and caregivers to register their children in the V-safe system and urges that all suspected adverse events following receipt of the vaccine be reported to the Vaccine Adverse Event Reporting System (VAERS).

Respectfully submitted:

Members of the Western States Scientific Safety Review Workgroup:
Arthur Reingold, MD, Chair, UC Berkeley School of Public Health

California Members:

- Tomás J. Aragón, MD, DrPH, California Department of Public Health and State Health Officer
- Oliver Brooks, MD, Watts Healthcare
- Eric Goosby, MD, UCSF School of Medicine
- Rodney Hood, MD, UC San Diego Alumnus and National Medical Association
- Nicola Klein, MD, Ph.D., Kaiser Permanente Northern California
- Grace M. Lee, MD, MPH, Stanford Children's Health and Stanford University School of Medicine
- Bonnie Maldonado, MD, Stanford University School of Medicine and Stanford Children's Health
- Mark H. Sawyer, MD, UC San Diego School of Medicine and Rady Children's Hospital
- Robert Schechter, MD, California Department of Public Health
- Peter G. Szilagyi, MD, MPH, UCLA Health and David Geffen School of Medicine
- Matt Zahn, MD, Orange County Health Care Agency

Nevada Members:

- Ihsan Azzam, MD, Ph.D., Chief Medical Officer, State of Nevada
- Karissa Loper, MPH, Health Bureau Chief, Nevada Department of Health and Human Services

Oregon Members:

- Laura Byerly, MD, Virginia Garcia Memorial Health Center
- Louis J. Picker, MD, OHSU Vaccine and Gene Therapy Institute (*not in attendance at Western States meeting on November 2, 2021*)

Washington Members:

- John Dunn, MD, MPH, Kaiser Permanente Washington
- Edgar K. Marcuse, MD, MPH, University of Washington School of Medicine