September 3, 2022

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

At its meeting on September 1, 2022 the Western States Scientific Safety Review Workgroup reviewed the evidence concerning booster doses of the Moderna and Pfizer-BioNTech COVID-19 bivalent BA.4/BA.5 variant vaccines presented at the meeting of the federal Advisory Committee on Immunization Practices (ACIP) on September 1, 2022.

To sustain protection against COVID-19, the Workgroup concurs with ACIP recommendations for a single booster dose of an updated bivalent BA.4/BA.5 COVID-19 vaccine among people 12 years and older who have completed a primary COVID vaccine series.

The bivalent Covid-19 vaccines include spike protein mRNA from the currently prevalent BA.4/BA.5 strains of SARS-CoV-2 in a process analogous to the annual updating of influenza vaccines. The Pfizer-BioNTech bivalent BA.4/BA.5 variant vaccine is authorized for use in people 12 years and older and the Moderna bivalent BA.4/BA.5 variant vaccine is authorized for use in people 18 years and older, including individuals who are moderately or severely immunocompromised. People 12 years and older who are eligible for their first or subsequent booster dose of COVID-19 vaccine should receive a bivalent vaccine, as monovalent mRNA COVID-19 vaccines for this age group are no longer authorized for booster doses.

COVID-19 bivalent BA.4/BA.5 variant vaccines should be administered as a booster no sooner than two months after a prior dose of COVID-19 vaccine has been used to complete the primary series or as a booster. <u>Guidance</u> for spacing of a bivalent booster vaccine following SARS-CoV-2 infection is the same as with prior booster recommendations.

Evidence available to date supports the safety of authorized and licensed COVID-19 vaccines, with over 610 million doses administered in the U.S. However, the Workgroup remains concerned about the potential for errors in the administration of the various COVID-19 vaccines, given that formulations for different age groups look alike. To minimize the frequency of such errors, which should be reported to VAERS, it is imperative that clear COVID-19 vaccination guidelines be disseminated to all vaccine providers. The Workgroup reiterates the importance of reporting to VAERS any suspected adverse events following receipt of a COVID-19 vaccine, whether as part of an initial series or as a booster dose and continued national safety surveillance efforts.

Given the anticipated burden of COVID-19 infections this fall/winter season with variants of concern, the Workgroup believes that the benefits of bivalent booster doses that more closely match currently circulating SARS-CoV-2 variants will improve protection against COVID-19-related hospitalizations and deaths and substantially outweigh any potential risks. Provision of bivalent booster doses should not impede vaccinating those who have not yet received an initial series of a COVID-19 vaccine, as unvaccinated persons remain at much higher risk of COVID-19 infection than those who have received COVID-19 vaccines. To control the pandemic, the Workgroup urges vaccination against COVID-19 for everyone who is eligible.

A bivalent COVID-19 booster dose can be co-administered with other vaccines, including influenza vaccines.

The Workgroup remains concerned that the limited supply and distribution of COVID- 19 BA.4/BA.5 bivalent vaccines will create challenges to the equitable administration of these vaccines and calls for strong efforts to ensure equal access and for careful monitoring of vaccine utilization across all populations.

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 Corporation (not present at the September 1, 2022 Western States Workgroup meeting)
- Eric Goosby, MD, UCSF School of Medicine (not present at the September 1, 2022 Western States Workgroup meeting
- Rodney Hood, MD, UC San Diego Alumnus and National Medical Association (not present at the September 1, 2022 Western States Workgroup meeting)
- 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 (not present at the September 1, 2022 Western States Workgroup meeting)
- Mark H. Sawyer, MD, UC San Diego School of Medicine and Rady Children's Hospitals (not present at the September 1, 2022 Western States Workgroup meeting)
- Robert Schechter, MD, California Department of Public Health (not present at the September 1, 2022 Western States Workgroup meeting)
- Peter G. Szilagyi, MD, MPH, UCLA Health and David Geffen School of Medicine (not present at the September 1, 2022 Western States Workgroup meeting)
- Matt Zahn, MD, Orange County Health Care Agency

Nevada Members:

- Ihsan Azzam, MD, Ph.D., Chief Medical Officer, State of Nevada
- Kyle Devine, Bureau of Child, Family and Community Wellness
- Kristy Zigenis, COVID-19 Vaccine Manager (not present at the September 1, 2022 Western States Workgroup meeting)

Oregon Members:

- Laura Byerly, MD, Virginia Garcia Memorial Health Center
- Louis J. Picker, MD, OHSU Vaccine and Gene Therapy Institute

Washington Members:

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