

**California Health and Human Services Agency (CHHS)**

**California Department of Public Health (CDPH)**

**WESTERN STATES SCIENTIFIC SAFETY REVIEW WORKGROUP**

**MEETING #20 – Thursday, September 23, 2021 – 4:00pm – 5:30pm and  
Addendum Meeting - Friday, September 24, 2021 – 8:00am – 8:30am**

**MEETING SUMMARY COMBINED**

**Workgroup Members Attending either September 23 and/or September 24, 2021**

**STATE OF CALIFORNIA**

**Tomas Aragon, MD, Dr.PH**, Director California Department of Public Health and State Health Officer; **Eric Goosby, MD**, Distinguished Professor of Medicine and Director of the Center for Global Health Delivery, University of California, San Francisco; **Rodney Hood, MD**, Trustee, Alliance Healthcare Foundation; **Nicola Klein, MD**, Director, Kaiser Permanente Vaccine Study Center; **Bonnie Maldonado, MD**, Professor and Chief of the Division of Infectious Diseases, Department of Pediatrics, Stanford Medicine; **Arthur Reingold, MD**, School of Public Health Division Head of Epidemiology and Biostatistics, University of California, Berkeley; **Mark Sawyer, MD**, Infectious Disease Specialist, Rady Children's Hospital; **Rob Schechter, MD**, Chief, California Department of Public Health, Immunization Branch; **Peter Szilagyi, MD**, Professor and Vice Chair for Clinical Research, Department of Pediatrics and Mattel Children's Hospital.

**STATE OF WASHINGTON:**

**John Dunn, MD**, Medical Director for Preventive Care and Head of Immunization Program, Kaiser Permanente Washington  
**Edgar Marcuse, MD**, MPH, FPIDS, Emeritus Professor, Pediatrics, University of Washington

**STATE OF NEVADA:**

Unable to attend

**STATE OF OREGON**

**Louis Picker, MD**, Associate Director of Oregon Health & Science University's Vaccine and Gene Therapy Institute  
**Laura Byerly, MD**, Chief Medical Officer, Virginia Garcia Health Center.

**Workgroup Members Not Attending**

**Grace Lee, MD**, Professor of Pediatrics and Associate Chief Medical Officer for Practice Innovation, Stanford Children's Health; **Ihsan Azzam, MD**, Chief Medical Officer, Division of Public and Behavioral Health; **Karissa Loper**, MPH, Health Bureau Chief, Nevada Department of

Health and Human Services; **Matt Zahn, MD**, Medical Director, Communicable Disease Control Division, Orange County Health Care Agency.

### **Consultant**

**Bobbie Wunsch**, Founder and Partner, Pacific Health Consulting Group

### **Welcome and Review of Today's Agenda Topics**

*Arthur Reingold, MD, Chair*

Dr. Reingold welcomed Workgroup members and noted that today's discussion would focus on recommendations and a possible statement from the Workgroup related to Pfizer COVID-19 booster vaccine doses. This topic was discussed at meetings of the federal Vaccines and Related Biological Products Advisory Committee on September 17, 2021, and Advisory Committee on Immunization Practices (ACIP) on September 22 and 23, 2021. Dr. Reingold invited state representatives to offer framing comments.

Dr. Aragon thanked Workgroup members for their participation and underscored the value of the group offering its recommendations. Dr. Pan thanked the group for its ongoing expert input. She noted that California has met with pharmacies, providers, and other stakeholders to assess their capacity to implement boosters.

Oregon and Washington state representatives emphasized that it remains a top priority to increase overall vaccination rates. Washington state representatives added that it would be helpful for the Workgroup to discuss the implications of differing recommendations at the federal level between the FDA and the CDC.

### **Pfizer COVID-19 Vaccine Booster**

*Arthur Reingold, MD, Chair*

*Rob Schechter, MD*

Dr. Schechter provided an update from the September 22-23, 2021, ACIP meeting and circulated a summary of the votes taken by ACIP members.

1. ACIP voted 15-0 to recommend: A single Pfizer-BioNTech COVID-19 vaccine booster dose is recommended for persons **age 65+ and long-term care facility residents**, at least 6 months after a primary series under FDA Emergency Use Authorization.
2. ACIP voted 13-2 to recommend: A single Pfizer-BioNTech COVID-19 vaccine booster dose is recommended for **persons aged 50-64 years with underlying medical conditions**, at least 6 months after primary series under FDA Emergency Use Authorization.
3. ACIP voted 9-6 to recommend: A single Pfizer-BioNTech COVID-19 vaccine booster dose is recommended for persons based on **individual benefit and risk** who are **aged 18-49**

**years with underlying medical conditions**, at least 6 months after primary series under FDA Emergency Use Authorization.

4. ACIP voted 9-6 to **NOT recommend**: A single Pfizer-BioNTech COVID-19 vaccine booster dose is recommended for persons based on **individual benefit and risk** who are **aged 18-64 years who are in occupational or institutional setting** where the burden of COVID-19 and risk of transmission are high, at least 6 months after primary series under FDA Emergency Use Authorization. This interim recommendation as stated did NOT pass.

There was discussion to clarify that the ACIP recommendation for COVID-19 booster vaccinations applies only to individuals receiving the Pfizer COVID-19 vaccine as their primary series. Policy flexibility is constrained due to language in COVID-19 vaccine provider agreements with the CDC, and the fact that COVID-19 vaccines are government funded and distributed.

Members discussed several aspects of the ACIP recommendations with a focus on the equity implications. Members generally agreed that recommendations for a diverse population require consideration of data disaggregated by race/ethnicity in addition to age. California data on deaths due to COVID-19 by age and race/ethnicity were reviewed and discussed. The data indicated that deaths due to COVID-19 for all races and ethnicities are higher among individuals over 65 years of age. However, data also indicate that deaths from COVID-19 for individuals 50-64 years of age who are African-American, Latino, Hawaiian Native/Pacific Island and American Indian are much higher than COVID-19 deaths in the White population.

There was general agreement that there is higher risk of COVID-19 exposure and death associated with long-standing inequities and social determinants of health. Members discussed ACIP recommendations #2 and #3 for COVID-19 boosters among individuals with underlying medical conditions. The Workgroup noted that social determinants of health are an underlying medical condition, and noted by the CDC as well (<https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html>). There was consensus to include language in the Workgroup's recommendation that social determinants of vulnerability be included in the assessment of medical conditions that qualify individuals for booster doses.

The Workgroup discussed capacity and operational issues related to the ACIP recommendations. Currently, pharmacies are conducting approximately 70% of COVID-19 vaccinations. In rural locations, there are fewer pharmacies and therefore, greater reliance on providers to deliver COVID-19 vaccinations. Western state representatives weighed in that the capacity to deliver COVID-19 vaccination for individuals included in the ACIP recommendations does not appear to represent a constraint.

There is clear benefit to a booster dose of Pfizer BioNTech COVID-19 vaccine based on evidence of waning protection against COVID-19 deaths among older adults six months following a primary series. The Workgroup confirmed that available data indicate no basis for concern

related to the safety for Pfizer BioNTech COVID-19 booster vaccinations in those ages 50 years and older.

Dr. Reingold asked if there was a consensus for endorsing the ACIP recommendations with the additional language that social determinants be considered as an underlying medical condition that contributes to a higher risk of SARS-CoV-2 exposure and death due to COVID-19. Members noted that increasing vaccination rates among the unvaccinated remains a continuing priority and important to include in a statement. Members commented on the need to increase COVID-19 vaccination rates globally, acknowledged the donation to date of supplies of COVID-19 vaccine to nations in need, and called for an expansion of these efforts.

### **Timing of Statement and Next Steps**

*Arthur Reingold, MD, Chair*

A statement from the Workgroup for distribution is needed as quickly as possible. A draft will be circulated for comment and approval early on September 24, 2021. The statement will endorse the ACIP recommendations 1, 2 and 3 and will include language that longstanding systemic social and health inequities are an underlying medical condition. The statement will acknowledge the need for global equity of vaccine supply.

## **WESTERN STATES SCIENTIFIC SAFETY REVIEW WORKGROUP**

**MEETING #20 ADDENDUM – Friday, September 24, 2021 – 8:00am – 8:30am**

### **MEETING SUMMARY ADDENDUM**

Dr. Reingold welcomed Workgroup members to this additional discussion of Pfizer COVID-19 vaccine booster recommendations. Subsequent to the Workgroup discussion September 23, 2021, CDC Director Walensky announced that all four recommendations discussed at the ACIP meeting September 22, 2021, are approved. The CDC recommendation includes approval of recommendation #4 that did not pass by vote of ACIP members.

*Recommendation 4: A single Pfizer-BioNTech COVID-19 vaccine booster dose is recommended for persons based on **individual benefit and risk** who are **aged 18-64 years who are in occupational or institutional setting** where the burden of COVID-19 infection and risk of transmission are high, at least 6 months after primary series under FDA Emergency Use Authorization.*

Members discussed a revised statement from the Western States Science Workgroup based on Director Walensky's announcement. There was consensus among members that individuals at greatest risk who should receive a booster dose include:

- Age 65 years and older or residing in a long-term care facility, or
- Age 50 through 64 years with underlying medical conditions.

Members also discussed including language that those who may receive a booster dose include:

- Age 18 through 64 years
  - with underlying medical conditions, or
  - who are at increased risk for SARS-CoV-2 exposure and transmission because of occupational or institutional setting.

There was consensus that the statement include language, previously discussed, that social determinants of vulnerability be included in the assessment of medical conditions that qualify individuals for booster doses.

A draft statement will be circulated to the Workgroup for review and comment following this discussion for approval today.