# California Health and Human Services Agency (CHHS)

# California Department of Public Health (CDPH)

# WESTERN STATES SCIENTIFIC SAFETY REVIEW WORKGROUP

# MEETING #21 – Thursday, October 21, 2021 – 5:30pm – 7:00pm

# MEETING SUMMARY

**Workgroup Members Attending**

STATE OF CALIFORNIA

**Tomas Aragon, MD, Dr.PH,** Director California Department of Public Health and State Health Officer; **Oliver Brooks, MD,** CMO, Watts Health Care; **Nicola Klein, MD**, Director, Kaiser Permanente Vaccine Study Center; **Grace Lee, MD**, Professor of Pediatrics and Associate Chief Medical Officer for Practice Innovation, Stanford Children's Health; **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; **Matt Zahn, MD,** Medical Director, Communicable Disease Control Division, Orange County Health Care Agency.

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:

**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;

STATE OF OREGON

**Laura Byerly, MD**, Chief Medical Officer, Virginia Garcia Health Center

**Louis Picker, MD,** Associate Director of Oregon Health & Science University's Vaccine and Gene Therapy Institute

**Workgroup Members Not Attending**

**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.

**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 Dr. Oliver Brooks has joined the Workgroup as a new member. Today's discussion will focus on review of data concerning booster doses of the Moderna and Janssen (Johnson & Johnson) COVID-19 vaccines discussed at meetings of the federal Vaccines and Related Biological Products Advisory Committee (VRBPAC) on October 14-15, 2021 and Advisory Committee on Immunization Practices (ACIP) on October 21, 2021. The Workgroup previously reviewed the evidence and recommendations pertaining to booster doses of the Pfizer BioNTech COVID-19 vaccine.

Dr. Aragon thanked Workgroup members for their continuing service and underscored the value of recommendations from the group to the Governors of the four Western States participating.

**Update from ACIP Meeting on October 21, 2021**
Discussion and Recommendations on FDA Approval of Moderna and Johnson & Johnson booster vaccinations for select individuals

*Arthur Reingold, MD, Chair*
*Grace Lee, MD, Stanford Children's Health*

Dr. Lee and other Workgroup members offered a summary of the data and discussion at the ACIP meeting. Data were presented on both Moderna and Janssen (Johnson & Johnson) booster vaccinations, including safety data from the Vaccine Adverse Event Reporting System (VAERS) and V-safe. Safety data indicated no unexpected patterns of adverse events and found that ≥92% of VAERS reports following dose 3 of Moderna and dose 2 of Janssen COVID-19 vaccine were nonserious. Members of the Western States Scientific Safety Review Workgroup reviewed and discussed the ACIP recommendation outlined below:

- ACIP voted 15-0 to recommend the Moderna 50 μg (half dose) booster dose for adults 18+ at least 6 months after the second dose of the primary series in the same risk groups as recommended for the Pfizer booster: "A single COVID-19 vaccine booster dose is recommended greater than or equal to 6 months after completion of an mRNA primary series, in the same risk groups for whom CDC recommended a booster of Pfizer-BioNTech, under FDA's Emergency Use Authorization"

Among recipients of the Moderna COVID-19 vaccine, those who should receive a booster dose of COVID-19 vaccine include those at increased risk for hospitalization and severe disease, including those:
• Age 65 years and older
• Age 18 years and older residing in a long-term care facility, or
• Age 50 through 64 years with underlying medical conditions or at increased risk of social inequities.

Among recipients of the Moderna COVID-19 vaccine, those who may receive a booster dose of COVID-19 vaccine include persons:
• Age 18 through 49 years with underlying medical conditions or at increased risk of social inequities, or
• Age 18 through 64 years who are risk for SARS-CoV-2 exposure and transmission because of occupational or institutional setting.

- ACIP voted 15-0 to recommend the Johnson & Johnson booster dose for all adults 18 and older who received the J&J primary series at least 2 months after the initial dose: "A single COVID-19 vaccine booster dose is recommended for persons aged 18 years and older, greater than or equal to 2 months after receipt of the initial Janssen dose, under the FDA's Emergency Use Authorization."

**COVID-19 Vaccines for Children under 12**
*Arthur Reingold, MD, Chair*
*Grace Lee, MD, Stanford Children's Health*

The group did not discuss this topic as data are not available for review.

**Mix and Match mRNA Vaccines**
*Arthur Reingold, MD, Chair*

Workgroup members discussed information from the ACIP discussion of Heterologous Booster Doses summarized below:

*Heterologous booster doses elicited similar or higher serologic responses as compared to their respective homologous booster responses and no safety concerns were identified with "mixing" vaccine doses. The committee felt strongly that allowing for permissive and flexible language on heterologous booster doses will likely increase vaccine access, improve the booster dose campaign, reduce safety concerns, and increase equity.*

Workgroup members discussed information to include in a statement to the Western State Governors. In particular, members suggested that the statement should:

1. Highlight the fact that the recommendation for boosters underwent rigorous review of data. Data on adverse reactions following booster doses were within expected levels

based on data from clinical trials. “After reviewing the recommendations, all authorized vaccines continue to demonstrate safety and efficacy, however there is waning immunity observed which highlights a need for boosters.”

2. Include a statement to the effect that, “The Western States Scientific Safety Review Workgroup reviewed FDA and CDC data and agrees with the ACIP statement that COVID-19 vaccines are safe and effective. There is a robust safety monitoring system in place to capture adverse events and practitioners are encouraged to continue to report adverse events.
3. Support that individuals eligible for a booster may receive either the same or a different COVID-19 vaccine as a booster dose, depending on advice from a health care provider, individual preference, availability or convenience. Take care not to indicate that every person should consult with a clinical provider before receiving a booster vaccine.
4. Include information similar to the previous statement that underscores underlying conditions is inclusive of systemic social and health inequities. Consider retaining language on the link between social inequities and global supply.
5. Reiterate that the Workgroup remains concerned about the limited global supply of COVID-19 vaccines.
6. Continue to emphasize the need for anyone not yet vaccinated to become fully vaccinated.

**Timing of Statement and Next Steps**
*Arthur Reingold, MD, Chair*

A statement will be distributed to the Workgroup for review and comment by 10 AM tomorrow, October 22, 2021, to finalize the statement for distribution by end of day. All Western State representatives weighed in with a preference that a statement be issued as soon as possible on Friday, October 22, 2021.