California Health and Human Services Agency (CHHS)

California Department of Public Health (CDPH)

WESTERN STATES SCIENTIFIC SAFETY REVIEW WORKGROUP

April 23, 2021 – 5:00pm – 6:30pm

MEETING SUMMARY

Workgroup Members 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; **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; **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

Workgroup Members Not Attending

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

California State Representatives Attending

Tomas Aragon, MD, Dr.PH, Director California Department of Public Health and State Health Officer; **Erica Pan, MD**, **MPH,** Deputy Director for the Center for Infectious Disease and California State Epidemiologist; **Rob Schechter, MD**, Chief, California Department of Public Health, Immunization Branch

Western States Representatives Attending

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

Consultants:
Bobbie Wunsch, Founder and Partner, Pacific Health Consulting Group

Welcome and Review Today's Agenda
Arthur Reingold, MD, Chair

Dr. Arthur Reingold welcomed the members of the Western States Scientific Safety Workgroup and thanked them for convening on short notice. Dr. Erica Pan, California State Epidemiologist, and Dr. Tomas Aragon, California State Health Officer and Director, California Department of Public Health, made brief introductory comments.

Update from ACIP Meeting Discussion and Recommendations on Janssen Biotech, Inc. COVID-19 Vaccine Pause and Western States Guidance to Governors
Arthur Reingold, MD, Chair
Grace Lee, MD, Stanford Children's Health and ACIP Member

Dr. Grace Lee, a current member of the Advisory Committee on Immunization Practices (ACIP), reprised the findings and discussions presented at its meeting earlier today regarding the risks and benefits of resuming the use of the Janssen Biotech, Inc. (Janssen) COVID-19 vaccine in the U.S., which was paused on April 13, 2021 to allow collection and analysis of additional data concerning cases of thrombosis – thrombocytopenia syndrome (TTS) following receipt of the vaccine. Several other Western States Scientific Safety Review Workgroup members participated in or watched the ACIP meetings on April 14 and April 23. Presentation slides and materials from the ACIP meeting are posted here.

Included in the information presented at the ACIP meeting was the finding that as of April 23, 2021, 15 cases of TTS had been reported among recipients of the almost 8.0 million doses of the Janssen COVID-19 vaccine administered in the U.S. All of the 15 cases were reported to VAERS, including the six cases reported before the pause in the use of the vaccine. All of the reported cases were in women between the ages of 18 and 59 years, with a median age of 37 years. According to the reports, symptom onset was between 6- and 15-days following vaccination.

TTS is a serious, potentially life-threatening illness involving the formation of blood clots (i.e. thrombosis) in blood vessels in the brain (i.e. cerebral venous sinuses) or blood vessels at other body sites, in conjunction with low blood platelet levels (i.e. thrombocytopenia). Early diagnosis and appropriate treatment, which differs from the treatment often used to treat blood clots, is important to reduce the risk of severe complications and death. Among the 15 women who developed TTS, no common underlying risk factors have been identified, other than sex

and age. The risk of TTS was highest among women less than 50 years of age, although TTS is extremely rare even in this group. The risk of TTS in adult men of all ages appears to be exceedingly rare.

Also presented at the ACIP meeting were the results of several modelling studies examining the probable positive and negative impacts of various policies concerning the use of the Janssen COVID-19 vaccine on morbidity and mortality in the U.S. following vaccination with Janssen COVID-19. These models showed that ending the pause in the use of this vaccine for men and for women of all ages would yield a very large net public health benefit by preventing a large number of COVID-related severe illnesses and deaths, but with the occurrence of a small number of serious adverse events. The final vote on a motion to end the pause in the use of the Janssen COVID-19 vaccine for men and for women of all ages by ACIP members was 10 in favor, 4 opposed, and 1 recusal. Those opposed expressed concerns related to providing adequate information concerning the risks and benefits of the various COVID-19 vaccines available in the U.S. to those seeking vaccination to ensure informed decision-making by individuals.

In a press release following the conclusion of the ACIP meeting, CDC announced that use of the Janssen Biotech, Inc. COVID-19 vaccine should be resumed in the U.S., based on the assessment by FDA and CDC that available data show the vaccine's known and potential benefits outweigh its known and potential risks in individuals 18 years of age or older. Furthermore, individuals should be informed about the risk for TTS, particularly in women under 50 years of age. The press release also made note of the importance of those administering the Janssen COVID-19 vaccine and those receiving the vaccine to review the Fact Sheets for providers (Janssen COVID-19 Vaccine Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and for recipients and caregivers (Fact Sheet for Recipients and Caregivers), which have now been revised to include information about the risk of TTS.

Summary of Discussion and Findings Concerning the Possible Resumption of the Use of the Janssen Biotech, Inc. (Johnson & Johnson) COVID-19 Vaccine

Arthur Reingold, MD, Chair

The Workgroup discussed in depth the deliberations and recommendations of the ACIP, including perspectives from state and county health department officials, providers and other experts in multiple states. Members of the Workgroup were unanimous in their support of the ACIP recommendation to resume use of the Janssen COVID-19 vaccine in the states represented by the Workgroup.

Members offered comment and input for consideration as the Janssen COVID-19 vaccine use is resumed, such as strategies for public education preceding arrival at a vaccination site to the extent feasible. The Workgroup noted that updated vaccine information sheets for recipients and fact sheets for providers of COVID-19 vaccines may not yet be available at all sites administering COVID-19 vaccines in states represented. These information materials must be

culturally and linguistically appropriate, available in multiple languages at an accessible reading level, and provide information concerning the rare risk of TTS among recipients of the Janssen COVID-19 vaccine. Appropriately crafted materials can help inform discussions between healthcare providers and those seeking vaccination against COVID-19 with regard to the choice of a vaccine. Workgroup members were also unanimous in their view that development and dissemination of such materials is of paramount importance and needs to be completed as quickly as possible, so that knowledgeable providers can resume offering this vaccine to fully informed vaccine recipients in our states.

CDC Recommendations on Vaccinations Received Outside the United States
Rob Schechter, MD, Chief, Immunizations Branch, CDPH
Bonnie Maldonado, MD, Stanford University School of Medicine

Due to time constraints, this agenda item is deferred to a subsequent meeting

Next Steps and Next Meeting
Arthur Reingold, MD, Chair

Workgroup members discussed the elements of a statement to the Governors of each participating state and the process for reviewing a statement to be finalized within 24 hours. Key points to be included in a statement:

- Janssen COVID-19 vaccine is generally safe and effective and that the resumption of its use is warranted once culturally and linguistically appropriate patient and provider educational materials in plain language that support informed decision-making are available; resumption of its use will support COVID-19 vaccine uptake and help reduce severe COVID-19 illnesses and control the pandemic in our states.

- The FDA and CDC conducted a thorough and transparent assessment of the safety and effectiveness of the Janssen COVID-19 vaccine, including its assessment of the risk of thrombosis – thrombocytopenia syndrome (TTS).

- There are the multiple systems in place in the U.S. to monitor the safety of COVID-19 (and other) vaccines and report all suspected adverse events following receipt of any COVID-19 vaccine and vaccine providers and vaccine recipients should be encouraged to participate.