

April 24, 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

***Summary of Findings:***

*The Western States Scientific Safety Review Workgroup, after a thorough review of the evidence concerning the safety of the Janssen Biotech, Inc. (Johnson & Johnson) COVID-19 vaccine,*

- *Concludes that the Janssen Biotech, Inc. 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.*
- *Applauds the thorough and transparent assessment of the safety and effectiveness of the Janssen Biotech, Inc. COVID-19 vaccine by the U.S. Food and Drug Administration (FDA) and by the U.S. Centers for Disease Control and Prevention (CDC)'s Advisory Committee on Immunization Practices (ACIP), including its assessment of the risk of thrombosis – thrombocytopenia syndrome (TTS).*

- *Recognizes the importance of the multiple systems in place in the U.S. to monitor the safety of COVID-19 (and other) vaccines and strongly urges vaccine providers and vaccine recipients in our states to report all suspected adverse events following receipt of any COVID-19 vaccine.*

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

Dr. Arthur Reingold welcomed the members of the 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, after which Dr. Grace Lee, who is a current member of the ACIP, reprised the findings and discussions presented at its meeting earlier today regarding the risks and benefits of resuming the use of the 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. A number of other Western States Scientific Safety Review Workgroup members participated in or watched the ACIP meetings on April 14 and April 23.

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 Biotech, Inc. COVID-19 vaccine administered in the U.S. All of the 15 cases had been 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 <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. Information was also provided concerning similar blood clotting disorders among recipients of the Astra Zeneca COVID-19 vaccine in Europe; this vaccine has not yet been approved for use in the U.S. but shares the same virus vector technology as the Janssen Biotech, Inc. COVID-19 vaccine.

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 Biotech, Inc. COVID-19 vaccine on morbidity and mortality in the U.S. related to COVID-19 illnesses and Janssen Biotech, Inc. TTS following vaccination with Janssen Biotech, Inc. 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 Biotech, Inc. 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  $\geq 18$  years of age. Furthermore, individuals should be informed about the risk for TTS, particularly in women <50 years of age. The press release also made note of the importance of those administering the Janssen Biotech, Inc. 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.

The Workgroup discussed in depth the deliberations and recommendations of the ACIP, including perspectives from state and county health department officials in multiple states, and diverse other members of the Workgroup. Members of the Workgroup were unanimous in their support of the ACIP recommendation to resume use of the Janssen Biotech, Inc. COVID-19 vaccine in the U.S. and in our states. However, 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 our states. 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 Biotech, Inc. 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 in our states 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.

Respectfully submitted:

Arthur Reingold, MD, Chair, UC Berkeley School of Public Health

### **Members of the Western States Scientific Safety Review Workgroup:**

California Members:

- Tomás J. Aragón, MD, DrPH, California Department of Public Health and State Health Officer
- 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

Washington Members:

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