California Health and Human Services Agency (CHHS)

California Department of Public Health (CDPH)

WESTERN STATES SCIENTIFIC SAFETY REVIEW WORKGROUP

March 1, 2021 - 6:30pm – 8:30pm

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; **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

Rodney Hood, MD, Trustee, Alliance Healthcare Foundation

California State Representatives Attending

Tomas Aragon, Director California Department of Public Health and State Health Officer; **Erica Pan, MD**, 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

Candice McDaniel, Health Bureau Chief, Bureau of Child, Family, and Community Wellness

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

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

Welcome and Review Today's Agenda
Arthur Reingold, MD, Chair
Erica Pan, MD, California State Epidemiologist

Dr. Reingold welcomed the Western States Scientific Safety Review Workgroup and reviewed the agenda. The primary issue for discussion is the safety and efficacy review of the Janssen Biotech, Inc. (Johnson & Johnson) COVID-19 vaccine approved February 27, 2021 by the FDA.

Dr. Pan thanked members for joining and commented that California is requesting input and potential guidance from the Workgroup on additional topics, in addition to the safety and efficacy review of the Janssen Biotech, Inc. COVID-19 vaccine. Specifically, the issues are: 1) input on individuals who might benefit most from a single dose vaccine as suggested by the Drafting Guidelines Workgroup (attached to the agenda); 2) guidance to States on whether one dose of mRNA vaccine is recommended in someone with evidence of previous COVID-19 infection; and 3) input on whether fetal tissue was used in the Janssen Biotech, Inc. COVID-19 vaccine.

Dr. Pan reported that the first week's allocation of the Janssen Biotech, Inc. COVID-19 vaccine to California is projected to be 320,000 doses. There is no information about future allocations; however, California generally receives approximately 12% of the total vaccine doses available nationally.

Discussion of EUA for Janssen Biotech, Inc. COVID-19 vaccine and Statement Schedule from Western States Scientific Safety Review Workgroup
Mark Sawyer, MD, VRBPAC Member
Grace Lee, MD, ACIP Member
Art Reingold, MD, Chair

Dr. Sawyer reviewed the information and conclusions of the FDA Vaccine Related and Biological Products Advisory Committee (VRBPAC) meeting for the Janssen Biotech, Inc. COVID-19 vaccine. The safety profile is comparable to those of the mRNA COVID-19 vaccines previously approved. There were reports of local and systemic adverse events, but no indication of any safety concerns in the clinical trial. The efficacy data were well-received by VRBPAC members. There were questions related to a suggestion of lower efficacy in those over age 60 with co-morbid conditions; however, VRBPAC members were comfortable that this was likely a function

of the smaller sample size of individuals over age 60 in the study and resulting wide confidence intervals.

Other Workgroup members who attended the VRBPAC meeting added their view that the efficacy data are strong and, in particular, that the efficacy against COVID-19 caused by the South African variant of SARS-COV-2 was high. Members commented that there was 75% efficacy against sero-conversion (asymptomatic infection), which was higher than that of previously approved COVID-19 vaccines. Also important was the 93% reduction in COVID-19 related hospitalizations and the absence of deaths in the vaccination group. Members agreed that messages to counter media stories suggesting the Janssen Biotech, Inc. COVID-19 vaccine is inferior should emphasize that it is comparable to the existing vaccines in its prevention of serious illness and death.

Dr. Lee reported on the CDC Advisory Committee on Immunization Practice (ACIP) meeting February 28, 2021. Two cases of possible anaphylaxis in vaccine recipients were identified after submission of the data to the FDA and were discussed at ACIP. These cases are still being evaluated and it is not known if they meet the Brighton Collaboration Criteria for anaphylaxis. Dr. Lee summarized the results concerning the Janssen Biotech, Inc. COVID-19 vaccine presented to ACIP as follows:

- 72-75% efficacy against symptomatic COVID-19 disease and 66 - 75% efficacy against asymptomatic SARS-COV-2 infection.
- 93-100% efficacy against hospitalization at day 14 and at day 28 following receipt of the vaccine.
- 100% efficacy against death at day 14 and at day 28.
- equivalent efficacy against SARS-COV-2 variants.
- 75% reduction in all-cause deaths.

The safety data reviewed were reassuring. There was no greater reactogenicity from the Janssen Biotech, Inc. COVID-19 vaccine than that seen after the first dose of the mRNA COVID-19 vaccines, including among people who had a prior COVID-19 infection. There was an increase in reports of tinnitus in the vaccine group compared to the placebo group that will be tracked as the vaccine is rolled out. No cases of Bell's palsy were reported.

In terms of messages, there are important positive features of the Janssen Biotech, Inc. COVID-19 vaccine in that it is a single dose and can be stored at refrigerator temperatures. It has functionally equivalent efficacy against COVID-19 related hospitalization and death as other available COVID-19 vaccines, and there is evidence of protection against COVID-19 caused by certain SARS-COV-2 variants.

Additional Issues for Consideration

Art *Reingold, MD, Chair*

Dr. Reingold introduced the additional issues for consideration and asked members to comment.

Issue 1: Persons who might benefit most from Single Dose Vaccinations

Drafting Guidelines Workgroup Discussion of the Issue

Persons who might benefit more from a one dose vaccine include those who are:

- Incarcerated or in detention, especially if in transit to other settings
- Experiencing homelessness
- Homebound
- Hard to reach in rural or isolated areas
- Fearful of public charge
- Difficult to schedule for vaccination, for example without internet connection and without anyone to assist them
- Distrustful of government and health agencies
- With little or no time to be vaccinated because they must work to make ends meet
- At specific worksites:
    - Agriculture and food production, including farmworkers, meat packing, poultry plants, etc.
    - Day laborers/migrant workers
    - High turnover jobs/transient workers
    - Construction
    - Truck drivers
    - Manufacturing
- Younger adults, with lower risk of severe COVID-19
- Residing in the community with mental illness or substance use disorders
- Sex workers/trafficked populations
- U.S. citizens or legal residents living in Mexico who travel back and forth across the border

The potential advantages of the Janssen Biotech, Inc. COVID-19 vaccine include:

1) A single-dose schedule that can more easily reach persons who are:
    a) Difficult to find and who might not return for a second dose
    b) Without a medical home; harder to follow-up or contact
    c) With limited transportation
    d) Homebound
    e) Afraid of adverse events and who might therefore not return for a second dose
2) Stable storage in a refrigerator for up to three months
    a) Easy storage and transport for a mobile clinic

3) Less expensive, if there are settings where the government does not subsidize costs.

Members discussed whether it would be useful or necessary to offer guidance to local health departments about how to deploy the various COVID-19 vaccines. The vaccines are all comparable in efficacy and safety. Singling out specific people or locations for a particular vaccine may create stigma. Additionally, there could be bias in deciding whether an individual fits into a described category. Members commented that the single dose has advantages for homeless, home-bound or other populations and the easy storage also has advantages for administration in locations where the storage requirements for the Pfizer and Moderna vaccines are a challenge. As one member noted, however, the single dose is more convenient for everyone.

The overriding goal of the COVID-19 vaccination effort is to vaccinate as many people as possible, rather than singling out specific populations for specific vaccines. Members suggested that the best message is a simple one: the Janssen Biotech, Inc. COVID-19 vaccine is one of three vaccines for reducing COVID-19 related hospitalizations and death and a single dose is convenient, safe and efficacious for both patients and providers. The approval of the Janssen Biotech, Inc. COVID-19 vaccine adds a third vaccine to be deployed. Members unanimously agreed with this message and support local health department decision-making, rather than centralized guidance.

Issue 2: Direction to States on Individuals who have had COVID-19 – is one dose of an mRNA vaccine recommended?

Dr. Reingold asked members for input about whether one dose of an mRNA vaccine is recommended for individuals who have had COVID-19. There was discussion of the difficulty in vaccination locations of establishing previous COVID-19 infection with certainty and it is not practical to do pre-vaccine serologic testing. There is no defined interval concerning administration of COVID-19 vaccine and a prior COVID-19 infection from the CDC. The Workgroup discussed data circulated to members indicating that a single dose of mRNA may provide protection for those with a previous COVID-19 infection. However, the consensus was that there are not sufficient data available at this time for the Workgroup to make a recommendation related to the question. The CDC will continue to review data related to this question and may issue recommendations in the future.

Dr. Reingold asked state partners to weigh in on the discussion. Representatives from all four states agreed that there had been robust discussion at ACIP and that ACIP members did not find there were sufficient data to make a recommendation concerning use of a single dose of COVID-19 vaccine among those with a history of prior COVID-19. One member noted that there is not an immediate need for a recommendation, although the question does come up and a review by the Workgroup would be valuable when data are available.

Issue 3: Input on statements related to fetal cells.

Dr. Reingold asked members if they have information about how and whether human fetal tissue was used in developing or testing the Janssen Biotech, Inc. COVID-19 vaccine. Members reported there were clones of cells derived many years ago from aborted human fetus cells used in developing the vaccine. The Vatican, however, has ruled that all COVID-19 vaccines can be used, even if they were made or tested using cells that may have originated from a human fetus. Members recommended the Workgroup statement not include any comment on this topic. A statement from the North Dakota health department that one member shared was shared with the group as a useful resource for responding to this question, linked here. **https://www.health.nd.gov/sites/www/files/documents/COVID%20Vaccine%20Page/COVID-19_Vaccine_Fetal_Cell_Handout.pdf**

Next Steps and Timing of Statement(s)and Adjourn

Arthur Reingold, MD, Chair

Dr. Pan suggested that it would be helpful if the statement from the Workgroup can address public concerns about the Janssen Biotech, Inc. COVID-19 vaccine being inferior that are arising from media stories comparing efficacy across vaccines. Members commented that a statement comparing vaccines is problematic for several reasons. First, the efficacy studies for the three COVID-19 vaccines did not compare them to each other. Each COVID-19 vaccine was compared to a placebo, with the studies taking place in different locations and at different points in time. Members recommended that the statement focus on the characteristics of the Janssen Biotech, Inc. COVID-19 vaccine and not on a comparison of COVID-19 vaccines. Members reiterated important points to be included in the statement discussed earlier in the meeting.

Dr. Reingold will draft a brief statement and distribute to members for review by tomorrow, March 2, 2021 at 10 AM. Comments from members should be returned the same day by 4 pm and the statement will be finalized by end of day.

Looking forward, the Astra-Zeneca vaccine is forecasted for review by the FDA and CDC in April 2021 and the Novavax vaccine is projected for review sometime in Spring 2021.

Dr. Aragon and Dr. Pan both thanked the group for their time and helpful discussion.