California Health and Human Services Agency (CHHS)

California Department of Public Health (CDPH)

COVID 19 VACCINE SCIENTIFIC SAFETY REVIEW WORKGROUP

December 3, 2020 - 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; **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

Workgroup Members Not Attending

Tomas Aragon, MD, Health Officer, City & County of San Francisco.

California State Representatives Attending

Tricia Blocher, Deputy Director, Office of Emergency Preparedness, California Department of Public Health **Ron Chapman**, MD, MPH, Former Director, California Department of Public Health; **Chuck Deyoe,** California Department of Public Health; **Nancy Barrera**, California Department of Public Health.

Western States Representatives Attending

STATE OF WASHINGTON:

John Dunn, MD, Medical Director for Preventive Care and Head of Immunization Program, Kaiser Permanente Washington

Ed 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
Laura Hogan, Senior Health Consultant, Pacific Health Consulting Group

Welcome, Review Agenda and Focus of Workgroup
Arthur Reingold, MD, Chair

Dr. Reingold welcomed a new member from Oregon, Dr. Louis Picker. Dr. Picker introduced himself and offered a short description of his background in HIV, tuberculosis, and malaria, and his work as Associate Director of Oregon Health & Science University's Vaccine and Gene Therapy Institute. Dr. Reingold reviewed the agenda.

Non-Disclosure Agreement and Disclosure of Interest Agreement
Tricia Blocher, Deputy Director, Office of Emergency Preparedness, CDPH
Chuck Deyoe and Nancy Barrera, CDPH Legal Counsel

Ms. Blocher introduced Nancy Barrera and Chuck Deyoe, CDPH legal counsel participating to provide background and answer questions related to the Non-Disclosure Agreement and Disclosure of Interest Agreement documents sent to the Workgroup with the agenda.

Ms. Barrera spoke to the need for this process. The state often receives Public Records Act requests. The Workgroup has high visibility and pertains to sensitive and proprietary information. The overall intent of the documents is to ensure transparency to the public while protecting internal deliberation and proprietary information. She presented the Disclosure of Interest Agreement and form to disclose possible interests that members may have during their service on the committee. Recusal from the committee will not be required. This is being done in the interest of transparency. CDPH counsel can review any possible conflicts of interest on a case by case basis if needed.

Dr. Reinhold emphasized that transparency is the goal. There are members of the Workgroup who provide research and work on studies funded through the pharmaceutical industry and this is important to disclose in the interest of public transparency. There is also a Nondisclosure Agreement (NDA) that was discussed at the last meeting and everyone should have completed.

Member Comments and Discussion

- There was a request to make a small change on the NDA form so that it references "federal and state" laws, rather than only federal and California law.

- Will the committee review confidential and proprietary information from Pfizer that is not public?
    - CDPH: It is unlikely that will happen but not certain.

- Are we creating meeting summary reports of the Workgroup?
    - Meeting summaries are developed. They include comments and questions without attribution to any individual.

Workgroup members discussed the process, format and scope of the Workgroup recommendations and work product. The charge for the Workgroup recommendation is to endorse or not endorse that the process to approve the Emergency Use Authorization (EUA) for vaccine(s) was thorough and complete and that safety and approval of EUA seems appropriate. It is expected that, following the Vaccine and Related Biological Products Advisory Committee (VRBPAC) and the subsequent Advisory Committee Immunization Practices (ACIP) recommendation, the Workgroup will discuss and form a consensus recommendation to the Governors of the Western States. Several members offered a construct of "trust but verify". This would convey that the Workgroup has reviewed the data and the process and concluded that the recommendation and Federal Drug Administration (FDA) approval is consistent with the data. This was summarized as a "thumbs up or down" on the recommendation and approval. There was also discussion of the tight timing for this deliberation process. The Workgroup will act quickly in order not to delay the implementation of vaccine(s) in the states.

There is no specific format pre-determined for the recommendation. This Workgroup is not a regulatory body. Several members reiterated that the bar should be high for the group not to accept the ACIP recommendation. The primary purpose for the Workgroup is to act as a disinterested observer to accept and verify the process as fair, transparent and equitable.

Dr. Reingold summarized the conversation as a consensus to create a recommendation that endorses, or does not endorse, the FDA approval and recommend that the vaccine should be distributed. The Governors of each state are the audience for our recommendation. Members can submit additional comment for further discussion.

Request from Pfizer to Present Data to Workgroup
Tricia Blocher, Deputy Director, Office of Emergency Preparedness, CDPH

Ms. Blocher reported that Pfizer has offered to make a presentation of the data during the week of December 14th, 2020. If we decide to have a presentation, we may need it sooner in order not to delay our timeline.

Dr. Reingold asked members to weigh in on where there is utility in having a presentation by Pfizer. He reminded the group that the VRBPAC and ACIP meetings are open to the Workgroup

and a Pfizer presentation will be part of those meetings. In addition, if the Workgroup has a presentation from Pfizer, there should be one from Moderna as well.

Several members weighed in that the industry presentation is only part of the data presented during VRBPAC and therefore would not represent the full story. If the Workgroup does not hear the FDA staff summary and review of the data, independent of the company, then it would not have the full information and, moreover, it would be a biased view. A Pfizer presentation would not add to the information available to the Workgroup and would not answer specific questions of the Workgroup. In addition, some weighed in that the expectation is that this group should act without any delay.

Dr. Reingold summarized the consensus to not have any presentations.

Additional Member Comments and Discussion

- It would be worth people attending VRBPAC because all the Pfizer data will be available on that date or just before. The United Kingdom has publicly published the Pfizer data submitted to their regulatory agency, available at this link: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/940565/Information_for_Healthcare_Professionals_on_Pfizer_BioNTech_COVID-19_vaccine.pdf

Update on ACIP and VRBAC Upcoming Meetings and Timeline for our Next Meetings
Workgroup Members on VRBAC and ACIP
Art Reingold, MD, Chair

Dr. Reingold requested information from members of VRBPAC and ACIP about the schedule and timing of the vaccine reviews. Members reported that the VRBPAC meeting is scheduled on December 10, 2020 at 6:00 a.m. PST. It is an open meeting via live stream media. Materials will be posted for the VRBPAC meeting and can be sent to the Workgroup. There are 2-4 days following the VRBPAC meeting for FDA internal review. The ACIP meeting will follow sometime in the window of December 11 – 14, 2020. This Workgroup is holding December 12, 2020 for a possible meeting and this may need to change.

Dr. Schechter reported that shipping is gearing up to go forward on December 14, 2020. Others confirmed that there are reports the vaccine will be available locally on December 15, 2020.

The VRBPAC meeting to review the Moderna vaccine candidate is set for December 17, 2020, 6:00 a.m. to 3:00 p.m. PST. The expectation is that ACIP will meet a few days after VRBPAC.

Dr. Reingold requested that Workgroup members receive the meeting link and any materials posted ahead of time.

https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-december-10-2020-meeting-announcement#event-information

Additional Member Comments and Discussion

- It would be useful to receive an outline of the expectations for how members should consider VRBPAC and ACIP information.
    - CDPH: Yes, we will send a set of guiding questions to consider as members participate in those meetings.

- The Governors want reassurance that the FDA VRBAC and CDC ACIP processes have not skipped any important steps while these federal agencies and advisory committees are coming to their decisions "at warp speed."

Safety Issues/Concerns Being Raised
Members, Scientific Safety Review Workgroup
Art Reingold, MD Chair

Dr. Reingold opened the discussion by commenting that members may be receiving questions or concerns from outside the Workgroup that would be useful to discuss. One issue raised was that the Workgroup cannot confirm safety if members do not go to the factory to review the process for producing the vaccine. Members noted this is outside the scope of the Workgroup. It should rely on FDA staff to conduct all inquiries relevant to the determination of safety.

A member requested guidance and updated talking points to respond to press inquiries. Others noted it might be helpful to codify the conversation today about the Workgroup scope of work to help with communication with media. In addition, Dr. Reingold mentioned CDPH staff are coordinating media responses and asked that contact information be sent out to members again. Do not hesitate to reach out to CDPH for support in responding to any media inquiry.

There is no restriction in speaking to the press. For example, Dr. Reingold summarized that his media responses include the following points: the Workgroup will judge that the process was reasonable and the vaccine is safe and effective; a Workgroup goal is to raise confidence among the citizens of our state; the Workgroup does not want to undermine the credibility and importance of ACIP and VRBPAC; and, that the Workgroup will not delay the vaccine being accessible to the people of our state. A member suggested that, given the consensus discussion about the scope of the Workgroup, another talking point might be that the purpose of our work is to verify the process; that it was fair, transparent, and equitable.

Members noted that it would be helpful to begin to draft the background to the Workgroup statement or recommendation document now, in anticipation of the impending decision. The document should be short, 1-2 pages, and directed to the Governors of each state participating in the Workgroup.

Additional Member Comments and Discussion

- Do we consider the vaccine distribution process out of the scope for our Workgroup?
    - CDPH: We agree that it is not in the scope of this Workgroup. California has a separate Workgroup, the Drafting Guideline Workgroup, discussing this topic.

- Our discussion concluded that we are verifying the process; that it was fair, transparent and equitable. It seems the next statement is therefore, it is safe to distribute.

- Should we be saying we endorse the recommendation of the people who conducted the process, given we just reviewed it?

- I reviewed the charge for the Workgroup and it says: to help California's diverse community understand the safety and efficacy of the emerging vaccines available for distribution, the work group will stay abreast of vaccine candidates, trials, evidence of safety and efficacy, and other evolving data to independently provide recommendations to California leadership and vaccine planning efforts, as well as inform public confidence in vaccine safety, efficacy and implementation efforts.

- If the process is to have this Workgroup make statements to render confidence within diverse communities, the Workgroup needs to consider statements beyond the FDA and ACIP process and comment on what that process means. Intuitively, my thought is we need to speak to the fact that we looked at the data and the process and feel safe taking it; feel safe recommending it to my family.

- I like the idea of asking; would I be willing to receive the vaccine? That keeps it simple and communicates the intent.

- It is also important as a committee for us to make some statement about it being equitable and including diverse populations. As an editorial comment, I think taking the bully pulpit is part of the charge.

Closing Comments and Adjourn
Arthur Reingold, MD, Chair

Dr. Reingold thanked the members for a good discussion. There will follow up materials sent to provide members information about VRBPAC and ACIP meetings as well as timing for the next Workgroup meeting.