Food and Drug Administration
Center for Biologics Evaluation and Research

SUMMARY MINUTES
172nd VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE

April 6, 2022

Committee Members
Hana El Sahly, M.D., Chair +
Arnold Monto, M.D. (Acting Chair)
Adam Berger, Ph.D.
Henry Bernstein, D.O. MHCM, FAAP
Archana Chatterjee, M.D., Ph.D. +
CAPT. Amanda Cohn, M.D.
Hayley Altman-Gans, M.D.
Holly Janes, Ph.D. +
David Kim, M.D. M.S. M.H.A.
Paul Offit, M.D.
Eric Rubin, M.D. Ph.D.
Steven Pergam, M.D., M.P.H.+
Andrea Shane, M.D., M.P.H., M.Sc. +
Geeta K. Swamy, M.D. +
Jay Portnoy, M.D. (CR) +

Industry Representatives
Paula Annunziato, M.D.
Gregg Sylvester, M.D., M.P.H. <+

Consumer Representative
Randy Hawkins, M.D. * (Temp. Acting)

Designated Federal Officers (DFO)
Prabhakara Atreya, Ph.D.
Christina Vert, M.S.

Committee Management Specialist(s)
Lisa Wheeler
Joanne Lipkind

* Consumer Representative
+ Not in attendance
< Alternate Industry representative

Temporary Voting Members
A. Oveta Fuller, Ph.D.
James Hildreth, Sr., Ph.D., M.D.
Jeannette Lee, Ph.D.
Ofer Levy, M.D., Ph.D.
Wayne Marasco, M.D. Ph.D.
H. Cody Meissner, M.D.
Michael Nelson, M.D., Ph.D.
Stanley Perlman, M.D., Ph.D.
Mark Sawyer, M.D., F.A.A.P.
Melinda Wharton, M.D., M.P.H.

Speakers and Guest Speakers
CAPT. Ruth Link-Gelles, Ph.D. - CDC
CDR. Heather Scobie, Ph.D. M.P.H. – CDC
John Beigel, M.D. – NIH
Robert Johnson, Ph.D. - BARDA
Subbarao, Kanta, M.D. – WHO Collaborating CTR. Australia
Trevor Bedford, Ph.D. – Howard Hughes Medical Institute
Christopher Murray, M.D. D.Phil. University of Washington
Ron Milo, Ph.D. Weizmann Institute, Israel
Sharon Alroy-Preis, M.D. M.PH.MBA, Ministry of Health, Israel

FDA Participants
Doran Fink, M.D. (Speaker)
Jerry Weir, Ph.D. (Speaker)
Peter W. Marks, M.D., Ph.D.

These summary minutes for the April 6 2022 meeting of the Vaccines and Related Biological Products Advisory Committee were approved on May 6, 2022.

I certify that I participated in the April 6 2022 meeting of the Vaccines and Related Biological Products Advisory Committee and that these minutes accurately reflect what transpired.

S

Prabhakara Atreya, Ph.D.
Designated Federal Officer

S

Arnold Monto, M.D.
Acting Chair

On April 6 2022, at 8:30 a.m. Eastern Standard Time (EST), the 172nd meeting of the Vaccines and Related Biological Products Advisory Committee (VRBPAC) took place in open session to discuss considerations for COVID-19 vaccine booster doses and the process for COVID-19 vaccine strain selection to address current and emerging variants.

Dr. Arnold Monto, the Acting Chair, called the meeting to order. The DFO made administrative remarks, conducted roll call and invited the committee members to introduce themselves, and read the Conflict of Interest (COI) statement into the public record. It was stated that one conflict of interest waiver was issued to a consultant and a temporary voting member, Dr. James Hildreth, under 18 U.S. Code 208 in connection with the meeting and the waiver was posted on the FDA website for public disclosure.

Dr. Peter Marks, Director for the Center for Biologics Evaluation and Research (CBER), FDA made welcoming remarks and Dr. Doran Fink, Deputy Director – Clinical, of the Division of Vaccines and Related Product Applications (DVRPA), Office of Vaccines Research and Review (OVRR), FDA introduced the topic of the meeting with a presentation titled "COVID-19 vaccines: Framework for Future Decisions on Strain Composition and Use of Additional Booster Doses." Then CDR. Heather Scobie of Centers for Disease Control and Prevention (CDC) made a presentation titled "Update on the Epidemiology of SARS-CoV-2 Strains." This was followed by a presentation by LCDR. Ruth Link-Gelles also with CDC titled

"COVID-19 Vaccine Effectiveness in Children and Adults." The committee then heard a combined presentation by Dr. Sharon Alroy-Preis from the Ministry of Health, Jerusalem and Dr. Ron Milo, from the Weizmann Institute, Rehovot, Israel on the "Israeli Experience with Fourth Booster Dose in Older Adults". Following their presentations, the Committee was released for a 10-minute break. After the break, Dr. John Beigel, with NIAID, NIH made a presentation titled, "SARS-CoV-2 Antigenic Space" followed by another presentation by Dr. Trevor Bedford from the Howard Hughes Medical Inst. On the topic of "Continuing SARS-CoV-2 evolution under population immune pressure".

After these presentations concluded, Dr. Christopher Murray of the University of Washington, Seattle, provided a follow-up presentation titled "Modeling of Future U.S. COVID-19 Outbreaks." Dr. Kanta Subbarao from the WHO collaborating Center for Reference and Research on Influenza located in Melbourne, Australia presented "WHO Perspective on variants for COVID-19 vaccine composition from discussions of the WHO Technical Advisory Group on COVID-19 vaccine composition (TAG-CO-VAC). This is followed by a presentation by Dr. John Beigel from the Biomedical Advanced Research and Development Authority (BARDA) on the topic of "COVID-19 Vaccine Strain Selection - Points to Consider for Manufacturing Timelines".

The Committee was then released to a 30-minute lunch break. Once the Committee returned from lunch, a 60-minute Open Public Hearing (OPH) session was held in which 21 pre-registered public speakers made presentations and oral comments. The names of OPH speakers and their oral remarks may be obtained from the transcript posted on the website. Following the OPH session, the Committee heard the presentation made by Dr. Jerry Weir, from the Office of Vaccines Research and Review (OVRR), CBER, on Agency's Proposed Framework for Addressing Future COVID-19 Vaccine Strain Composition". After this last presentation, the committee proceeded with the discussion portion of the meeting.

The VRBPAC committee was then asked to discuss the following questions. The following topics were presented for committee discussion.

• What considerations should inform strain composition decisions to ensure that available COVID-19 vaccines continue to meet public health needs, e.g.:

- Role of VRBPAC and FDA in coordinating strain composition decisions
- Timelines needed to implement strain composition updates
- Harmonization of strain composition across available vaccines

• How often should the adequacy of strain composition for available vaccines be assessed?

• What conditions would indicate a need for updated COVID-19 vaccine strain composition, and what data would be needed to support a decision on a strain composition update?

• What considerations should guide the timing and populations for use of additional COVID-19 vaccine booster doses?

Discussion Summary:
There was general agreement among committee members that given the complexities of changing COVID-19 vaccine strain composition, decisions on this should be undertaken as a coordinated process led by FDA, with input from VRBPAC, and also considering any recommendations that WHO might provide. Several committee members opined that strain change decisions should be data-driven and based on compelling evidence that current vaccine strain composition is not adequately effective against severe disease cause by circulating variants but also compelling evidence that a specific modified vaccine composition will improve upon vaccine effectiveness. While a modified vaccine would ideally be assessed in efficacy studies, or based on an immune correlate of protection, given the current imperfect understanding of COVID vaccine immunology and time constraints involved, evaluation of modified vaccines will need to rely mainly on neutralizing antibody data. Committee members expressed that ideally, a single recommendation for strain composition apply to all available vaccines, and ideally vaccines based on a modified strain composition could be used as both primary series and booster doses. The committee found it challenging to make more specific recommendations without a concrete proposal and data from studies; FDA acknowledges this challenge and conveyed the intent to further discuss data from studies of modified vaccines and a more concrete proposal for strain composition recommendation at an upcoming VRBPAC meeting once such data are available.

Committee members expressed that recommendations on the use of additional doses as part of a fall vaccination campaign should be aligned with the goals of public health vaccination programs, which at this time and considering characteristics of currently available vaccines is prevention of severe disease, hospitalization, and death. Committee members agreed that frequent use of booster doses is neither practical or sustainable, especially considering the incremental benefit against severe disease and transient benefit against infection and more mild

disease suggested by available data for second booster doses of mRNA vaccines. Some committee members opined that annual vaccination campaigns similar to the seasonal influenza vaccine model might be considered, but other committee members felt that additional time and experience with COVID vaccines was needed to determine whether this would be a practical, sustainable, or necessary approach. There was consensus among committee members that continued monitoring of vaccine effectiveness will be critical for making decisions about the need for additional doses.

Following the discussion, the meeting was then adjourned on April 6 2022 at 5:00 PM EST.

Additional information and details may be obtained from the transcript and the recording of the webcast of the meeting that may be viewed at: https://www.youtube.com/watch?v=x8rq247E80I