Food and Drug Administration
Center for Biologics Evaluation and Research

SUMMARY MINUTES
175th VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE

June 28, 2022

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

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

Consumer Representative
Jay Portnoy, M.D.*+
Randy Hawkins *> (Acting)

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

Committee Management Specialist(s)
Joanne Lipkind
Karen Thomas
Lisa Wheeler

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

Speakers and Guest Speakers
Heather Scobie, Ph.D., M.PH. – CDC
Ruth Link-Gelles, Ph.D. -CDC
Matthew Biggerstaff, Ph.D. - CDC
Gregory Glenn, M.D. – Novavax
Stephen Hoge, M.D. Moderna
Kena Swanson, Ph.D. - Pfizer
Justin Lesser, M.D. – Univ. North Carolina
Kanta Subbarao, M.D., M.PH. - WHO

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

+Not Attending
*Consumer Representative
*>Acting Consumer Rep
***Industry Representative
< Alternate Industry Representative

These summary minutes for the June 28, 2022, meeting of the Vaccines and

Related Biological Products Advisory Committee were approved on July 15, 2022.

I certify that I participated in the June 28, 2022, meeting of the Vaccines and Related Biological Products Advisory Committee and that these minutes accurately reflect what transpired.

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Prabhakara Atreya, Ph.D. Acting Designated Federal Officer	Arnold Monto, M.D. Acting Chair

On June 28, 2022, at 8:30 a.m. Eastern Time (ET), the 175th meeting of the Vaccines and Related Biological Products Advisory Committee (VRBPAC) took place in open session to discuss whether and how the SARS-CoV-2 strain composition of COVID-19 vaccines should be modified.

Dr. Arnold Monto, the Acting Chair, called the meeting to order. The DFO, Dr. Prabhakara Atreya made administrative remarks, conducted roll call and invited the committee members to introduce themselves. The alternative DFO, Dr. Sussan Paydar read the Conflict of Interest (COI) statement into the public record.

Dr. Peter Marks, Director for the Center for Biologics Evaluation and Research (CBER), FDA made a 15-minute FDA Introduction titled "Considerations for whether and How the COVID-19 Vaccine Strain Composition Should be Modified".

There were two 20-minute presentations from Centers for Disease Control and Prevention (CDC), each followed by 10-minute Q&A. The first CDC presentation was titled "update on Current Epidemiology of the COVID-19 Pandemic and SARS-CoV-2 Variants" made by Dr. Heather Scobie, Deputy Team Lead, Surveillance and Analytics, COVID-19 Emergency Response at CDC. The second presentation titled "Update on the effective of COVID-19 Vaccines was made by Dr. Ruth Link-Gelles, COVID-19 Vaccine Effectiveness Program Lead at CDC. Dr. Justin Lessler, professor from University of North Carolina then made a presentation on the topic of "Modeling Future Epidemiology of the COVID-19

Pandemic". Following a 10-minute Q&A, the Committee was released for 15-minute break.

After the break, there were three 15-minute Sponsor Presentations on "Clinical Data Regarding Variant Vaccines by Dr. Stephen Hoge, President, ModernaTX, Dr. Kena Swanson, Pfizer, Inc., and Dr. Greggory Glenn from Novavax, Inc. Each presentation was followed by a 5-minute Q&A.

Afterwards, Dr. Kanta Subbarao from WHO made a 20-minute presentation on "Considerations for Vaccine Strain Composition from the WHO TAG-Co-VAC". After a 5-minute Q&A, a 25-minute FDA Presentation was made by Dr. Jerry Weir on "FDA Assessment of Available Data for Modified COVID-19 Vaccine Candidates and Consideration of Potential Changes to COVID-19 Vaccine Strain Composition". The committee was given 10 minutes for Q&A before being released for a 30-minute lunch.

After lunch, an Open Public Hearing (OPH) session was held in which 17 pre-registered public speakers made either presentations or oral comments only. 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 was given a 10-minute break before starting the 100-minute "Committee Discussion and Questions".

Discussion Summary: The committee was presented with several discussion questions and asked to provide input and discuss whether additional data are needed to facilitate a recommendation to update the strain composition for COVID-19 vaccines in the U.S.

The first discussion question asked whether a change to the current COVID-19 vaccine strain composition is necessary at this time. There was general agreement among the committee members that a change in composition is needed, based on the available virus epidemiological data, the emerging picture of waning immunity provided by current vaccines, and the early immunogenicity data from ModernaTX and Pfizer, Inc with their candidate vaccines containing an Omicron component. Committee members noted the complexities involved, including implementation issues and the limited amount of data available, issues that were further elaborated on during discussion of the second topic presented to the committee.

In the second discussion topic, the Committee was asked to discuss the evidence

supporting 1) the selection of a particular Omicron sub-lineage in the vaccine, 2) the choice of a monovalent versus a bivalent vaccine formulation, and 3) the extrapolation of the available clinical data for modified vaccines to different age ranges. This was a complex set of issues and most committee members chose to try to address most of the three points at the same time during their remarks. The discussion elicited a wide range of opinions, but of the committee members who expressed a firm preference, a bivalent booster vaccine containing an Omicron BA.4/BA.5 seemed to be the preferred option. Several committee members expressed a concern about the limited amount of pediatric data available for modified vaccines and the need to obtain additional safety data in these populations, and some committee members noted the need for additional data related to the clinical meaningfulness of the improved antibody responses and the need for more information on correlates of protection. The extensive deliberations elicited by this 3-part second topic precluded discussion of the planned third discussion question related to the possible updating of the COVID-19 primary series vaccine.

After Committee Discussion, there was a 40-minute session held for Voting and Vote Explanation. The following question was presented to the Committee of **21 voting members**:

Voting Question:
Does the committee recommend inclusion of a SARS-CoV-2 Omicron component for COVID-19 booster vaccines in the United States?

The voting results were as follows: **19 Yes, 2 No, 0 Abstain**

Following the vote, committee members were invited to make further comments about their voting decision. Several members stressed the need to continue to accumulate additional data on this difficult and complex issue.

Following the voting discussion, the meeting was adjourned on June 28, 2022, at 5:00 PM ET.

Additional information and details may be obtained from the transcript and the recording of the webcast of the meeting that may be viewed at:

Vaccines and Related Biological Products Advisory Committee – 6/28/2022 - YouTube