Food and Drug Administration
Center for Biologics Evaluation and Research

SUMMARY MINUTES
159th VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE

March 4, 2020

Committee Members
Hana El Sahly, M.D., Chair
Tammy Beckham, D.V.M., Ph.D.
Archana Chatterjee, M.D., Ph.D.
CAPT Amanda Cohn, M.D. +
Hayley Gans, M.D.
Holly Janes, Ph.D. *
Michael Kurilla, M.D., Ph.D.
Myron Levine, M.D., D.T.P.H., F.A.A.P.
H. Cody Meissner, M.D.
Paul Offit, M.D.
Steven Pergam, M.D., M.P.H. +
Andrea Shane, M.D., M.P.H., M.Sc.
Paul Spearman, M.D.
Geeta K. Swamy, M.D.

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

Consumer Representative
Sheldon Toubman, J.D. *

Designated Federal Officer (DFO)
Kathleen Hayes, M.P.H.

Committee Management Specialist(s)
Monique Hill, M.H.A.
Joanne Lipkind, M.S.

+ Not in attendance
* By phone
< Alternate Industry representative

Temporary Voting Members
Jack Bennink, Ph.D. (Topic I)
COL Andrew Wiesen, M.D., M.P.H. (Topic I)
Melinda Wharton, M.D., M.P.H. (Topic II)

Temporary Non-Voting Members
David Wentworth, Ph.D. (Topic I)

Guest Speakers
CAPT Lisa Grohskopf, M.D., M.P.H. *
CDR Mark Scheckelhoff, Ph.D., M.P.H.

Industry Speakers
Penny Post, Ph.D., Sanofi

FDA Speakers
Topic I
Anissa Cheung, M.Sc.
Manju Joshi, Ph.D.
Topic II
Carolyn Wilson, Ph.D.
Jay Slater, M.D.
Michael Schmitt, Ph.D.

FDA Participants
Topic I
Marion Gruber, Ph.D.
Philip Krause, M.D.
Konstantin Chumakov, Ph.D.
Jerry Weir, Ph.D.
CDR Valerie Marshall, M.P.H., P.M.P.
Zhiping Ye, M.D., Ph.D.
Topic II
Drusilla Burns, Ph.D.

These summary minutes for the March 4, 2020 Meeting of the Vaccines and Related Biological Products Advisory Committee were approved on _____, 2020.

I certify that I participated in the March 4, 2020 Meeting of the Vaccines and Related Biological Products Advisory Committee and that these minutes accurately reflect what transpired.

_____	_____
Kathleen Hayes, M.P.H.	Hana El Sahly, M.D.
Designated Federal Officer	Chair

On March 4, 2020 at 8:45 a.m. Eastern Standard Time (EST), the 159th Meeting of the Vaccines and Related Biological Products Advisory Committee (VRBPAC) met in open session to discuss and make recommendations on the selection of strains to be included in the influenza virus vaccines for the 2020-2021 influenza season. Also, on March 4, 2020, under Topic II, the committee met in partially closed session to hear an overview of the research programs in the Laboratory of Respiratory and Special Pathogens (LRSP), Division of Bacterial, Parasitic, and Allergenic Products, Office of Vaccines Research and Review, CBER.

Dr. Hana El Sahly, the Chair, called the meeting to order and invited the committee members to introduce themselves. The DFO made administrative remarks and read the Conflict of Interest (COI) statement into the public record. It was stated that no waivers were issued for conflicts of interest for this meeting.

Dr. Anissa Cheung of FDA introduced Topic I and provided an introductory presentation titled "Influenza Virus Vaccine Strain Selection 2020-2021 Northern Hemisphere." This was followed by a presentation by CAPT Lisa Grohskopf from the CDC entitled, "U.S. Influenza Surveillance and Interim Vaccine Effectiveness Estimates, 2019-20 Season." Then Dr. David Wentworth, also from the CDC provided a presentation entitled, "Information for the Vaccine and Related Biological Products Advisory Committee, CBER, FDA: Global Influenza Virus Surveillance and Characterization."

After a 10-minute break, Dr. Mark Scheckelhoff from the Armed Forces Health Surveillance Branch and representing the Department of Defense CONUS and OCONUS lab-based influenza surveillance activities provided a presentation titled, "DoD Influenza Surveillance and Mid-Season Vaccine Effectiveness." Following this, Dr. Manju Joshi from the FDA made a presentation entitled, "Candidate Vaccine Strains and Potency Reagents: 2020-21 Northern Hemisphere Influenza Season." This was followed by comments made by the manufacturers' representative, Dr. Penny Post from Sanofi Pasteur in a presentation titled "Influenza Vaccine Manufacturing, Industry Perspective for 2020-21 Northern Hemisphere Influenza Vaccine Supply."

After a 45-minute lunch break, the Open Public Hearing session was announced. However, there

were no public speakers pre-registered or presented themselves for this portion of the meeting.

Therefore, the Committee immediately proceeded with discussions followed by voting for Topic 1. There were four voting questions presented to the Committee for Topic 1:

1) For the influenza A (H1N1) component of the 2020-2021 influenza virus vaccines in the U.S., does the committee recommend:

- An A/Guangdong-Maonan/SWL1536/2019 (H1N1)pdm09-like virus for egg-based vaccines
- An A/Hawaii/70/2019 (H1N1)pdm09-like virus for cell- or recombinant-based vaccines

For question 1, the Committee voting results are as follows: 15 Yes, 0 No, 0 Abstain

2) For the influenza A (H3N2) component of the 2020-2021 influenza virus vaccine in the U.S., does the committee recommend:

- An A/Hong Kong/2671/2019 (H3N2)-like virus for egg-based vaccines
- An A/Hong Kong/45/2019 (H3N2)-like virus for cell- or recombinant-based vaccines

For question 2, the Committee voting results are as follows: 15 Yes, 0 No, 0 Abstain

3) For the influenza B component of the 2020-2021 trivalent influenza virus vaccine in the U.S., does the committee recommend inclusion of a B/Washington/02/2019-like virus (B/Victoria lineage)

For question 3, the Committee voting results are as follows: 15 Yes, 0 No, 0 Abstain

4) For quadrivalent 2020-2021 influenza vaccines in the U.S., does the committee recommend inclusion of a B/Phuket/3073/2013-like virus (B/Yamagata lineage) as the 2nd influenza B strain in the vaccine

For question 4, the Committee voting results are follows: 15 Yes, 0 No, 0 Abstain

Following the Committee vote for Topic I, the meeting proceeded to Topic II, Presentations of the Laboratory of Respiratory and Special Pathogens (LRSP), Division of Bacterial, Parasitic, and Allergenic Products (DBPAP) of the Office of Vaccines Research and Review (OVRR), Center for Biologics Evaluation and Research (CBER) of the Food and Drug Administration (FDA).

After the COI statement was read by the DFO, the presentations began with Dr. Carolyn Wilson who provided an overview of the Research/Site Visit Process in CBER. Following this presentation, Dr. Jay Slater provided an overview of OVRR and an overview of DBPAP. Dr. Michael Schmitt, the Chief of the LRSP then gave an overview presentation of the research programs in LRSP. The Committee then proceeded with the Topic II Open Public Hearing

(OPH) session, however, there were no public speakers pre-registered or whom presented themselves for this portion of the meeting. Following the OPH session, the Committee held 10-minute break. Following the break, the Committee met in closed session to proceed with Site Visit report discussions followed by a vote.

The meeting was then adjourned on March 4, 2020 at 2:34 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://collaboration.fda.gov/pxuir8ckg7le/

https://collaboration.fda.gov/pkn7gkfzppfn/

https://collaboration.fda.gov/pbksfxcknfpq/