

Food and Drug Administration
Center for Biologics Evaluation and Research

SUMMARY MINUTES
156th VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY
COMMITTEE

March 22, 2019

Committee Members

Hana El Sahly, M.D., Acting Chair
David Greenberg, M.D. + (IR)
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.
Arnold Monto, M.D. +
Paul Offit, M.D. +
Andrea Shane, M.D., M.P.H., M.Sc.
Paul Spearman, M.D. +
Geeta K. Swamy, M.D. +
Sheldon Toubman, J.D. (CR)
Melinda Wharton, M.D., M.P.H.

Industry Representative

Leonard Friedland, M.D. (ALT IR)

Consumer Representative

Sheldon Toubman, J.D.

Designated Federal Officer (DFO)

CAPT Serina A. Hunter-Thomas, M.S.A., R.N.

Committee Management Specialist(s)

Monique Hill, M.H.A.
Joanne Lipkind, M.S.

Temporary Voting Members

Tammy Beckham, D.V.M., Ph.D.
Jack Bennink, Ph.D.
COL Andrew Wiesen, M.D., M.P.H.

Temporary Non-Voting Members

Jacqueline Katz, Ph.D.

Speakers/Guest Speakers

Jacqueline Katz, Ph.D.

FDA Speakers

Jerry Weir, Ph.D.

FDA Participants

Philip Krause, M.D.
Zhiping Ye, M.D., Ph.D.

+ Not in attendance

These summary minutes for the March 22, 2019 Meeting of the Vaccines and Related Biological Products Advisory Committee were approved on April 3, 2019.

I certify that I participated in the March 22, 2019 Meeting of the Vaccines and Related Biological Products Advisory Committee and that these minutes accurately reflect what transpired.

/s/

Serina A. Hunter-Thomas
Designated Federal Officer

/s/

Hana El Sahly, M.D.
Acting Chair

On March 22, 2019 at 8:35 a.m. Eastern Standard Time (EST), Dr. Hana El Sahly, Acting VRBPAC Chair, called to order the 156th Meeting of the Vaccines and Related Biological Products Advisory Committee (VRBPAC) to discuss Topic I: “H3N2 Strain Selection for the Influenza Virus Vaccines for the 2019 – 2020 Influenza Season.” The Acting Chair invited committee members on the phone to introduce themselves, followed by introductions of those in the room which was then followed the DFO’s administrative remarks and reading of the Conflict of Interest (COI) statement into the public record. There were no waivers issued for conflicts of interest for this meeting. The meeting proceeded with Dr. Jerry Weir who gave the FDA introductory presentation titled “Influenza Virus Vaccine 2019-2020 Strain Selection – H3N2,” followed by Dr. Jacqueline Katz’s presentation titled “Global Surveillance and Virus Characterization Influenza A (H3N2) Update.” Following Dr. Katz’s presentation, the meeting proceeded with the Open Public Hearing portion. Ms. Beverly Taylor from Seqirus read a statement that represented the industry perspective. Ms. Taylor is the Chair of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA). Afterward, the committee proceeded with discussion followed by a vote for Topic I. There was one voting question presented to the committee for the topic:

1. For the composition of the 2019-2020 influenza virus vaccine in the U.S., does the committee recommend:
 - A. Inclusion of an A/Kansas/14/2017 (H3N2)-like virus

For question 1 the committee voted as follows: 10 Yes, 0 No, 0 Abstain

The meeting was then adjourned at 10:30am EST on March 22, 2019.

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

- Part 1: <https://collaboration.fda.gov/pn5plz28vo7p/>
Part 2: <https://collaboration.fda.gov/plozo9w4bmw5/>
Part 3: <https://collaboration.fda.gov/p8ky2d0s0kt7/>