

**Food and Drug Administration
Center for Biologics Evaluation and Research**

**SUMMARY MINUTES
173rd VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY
COMMITTEE**

June 7, 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.
Geeta K. Swamy, M.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, M.D. + (Temp. 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,
A. Oveta Fuller, Ph.D.
Bruce Gellin, M.D., M.PH.
Jeannette Lee, Ph.D.
H. Cody Meissner, 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.
Pamela McInnes, DDS, MSc.
Stanley Perlman, M.D., Ph.D.
Wayne Marasco, M.D. Ph.D.

Speakers and Guest Speakers

CDR. Heather Scobie, Ph.D. M.P.H. – CDC
CAPT. Tom Shimabukuro, M.D. M.PH, M.B.A.- CDC
Goutam Sen, Ph.D. – FDA
Lucia Lee, M.D. FDA
Filip Dubovsky, M.D., MPH, FAAP - NOVAVAX
Raburn Mallory, M.D., - NOVAVAX
Denny Kim, M.D., - NOVAVAX
Gregory A. Poland, M.D., NOVAVAX

FDA Participants

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

* Consumer Representative
+ Not in attendance
< Alternate Industry representative

These summary minutes for the June 7, 2022, meeting of the Vaccines and Related Biological Products Advisory Committee were approved on July 11, 2022.

I certify that I participated in the June 7, 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 7, 2022, at 8:30 a.m. Eastern Standard Time (EST), the 173rd meeting of the Vaccines and Related Biological Products Advisory Committee (VRBPAC) took place in open session to discuss Emergency Use Authorization (EUA) request by Novavax for a vaccine to prevent COVID-19 in individuals 18 years of age and older.

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.

Dr. Peter Marks, Director for the Center for Biologics Evaluation and Research (CBER), FDA made welcoming remarks and Dr. Goutam Sen, Review Committee Chair, Division of Vaccines and Related Product Applications (DVRPA), Office of Vaccines Research and Review (OVRR), FDA introduced the topic, “Emergency Use Authorization (EUA) request by Novavax for a vaccine to prevent COVID-19 in individuals 18 years of age and older.”

Then CDR. Heather Scobie, Deputy Team Lead, Surveillance and Analytics, Epidemiology Task Force of Centers for Disease Control and Prevention (CDC) made a presentation titled, “Current Epidemiology of COVID-19 and COVID-19 Vaccination Rates in the United States.” This was followed by the presentation titled, “Overview of COVID-19 Vaccine Associated Myocarditis” made by CAPT. Tom Shimabukuro, Director, Immunization Safety Office of CDC.

The committee then heard combined presentations made by the Sponsor speakers on the topic of “Emergency Use Authorization (EUA) request by Novavax for a vaccine to prevent COVID-19 in individuals 18 years of age and older.” First, Dr. Filip Dubovsky, Executive Vice President & Chief Medical Officer, Novavax, Inc. presented the “Emergency Use Authorization (EUA) Application for NVX-CoV2373.” His talk was followed by Dr. Raburn Mallory’s presentation on “Immunogenicity and Efficacy.” Dr. Denny Kim then spoke on “Safety,” followed by Dr. Gregory Poland on “Clinical Perspective.” Dr. Filip Dubovsky wrapped up this section with “Conclusion” remarks. The Committee was then released for a 15-minute break. After the break, Dr. Lucia Lee, Lead Medical Officer, Clinical Review Branch 1, DVRPA/OVRR/CBER, made a presentation titled, “FDA Review of Effectiveness and Safety of Novavax COVID-19 Vaccine in individuals 18 years of age and older.”

The Committee was then released for a 45-minute lunch break. Once the Committee returned from lunch, a 60-minute Open Public Hearing (OPH) session was held in which 8 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 released for a 10-minute break before continuing with a 50-minute session of “Additional Q&A Regarding Sponsor and FDA presentations.” The Committee then continued with 120-minutes of Committee Discussion and Voting session.

Discussion Summary:

In their discussions, committee members generally agreed that available clinical efficacy data supported the benefit of the Novavax COVID-19 Vaccine, Adjuvanted but noted the limitations of clinical endpoint efficacy data assessed prior to emergence of the Omicron variant. Committee members also commented on lower efficacy estimates in the Hispanic/Latino population and individuals 65 years of age and older compared to the overall study population. Committee members stressed the importance of post-authorization assessments of vaccine effectiveness in these subgroups as well as in the setting of continually evolving epidemiology of the COVID-19 pandemic. The likely need for booster doses following a primary series of Novavax COVID-19 Vaccine, Adjuvanted, was also discussed extensively.

Committee members also generally agreed that available safety data was favorable

to support EUA but stressed the importance of continued post-authorization safety surveillance, in particular for myocarditis/pericarditis, and endorsed that reported events consistent with myocarditis/pericarditis in clinical trials of Novavax COVID-19 Vaccine, Adjuvanted provided reasonable evidence of a causal association, thereby supporting inclusion of a Warning statement in EUA Fact Sheets if the vaccine were to be authorized for use under EUA.

After committee discussion, the following voting question was presented to the Committee of **22 voting members**:

Question: Based on the totality of scientific evidence available, do the benefits of the Novavax COVID-19 Vaccine when administered as a 2-dose series outweigh its risks for use in individuals 18 years of age and older?

The Committee voting results were as follows: 21 Yes, 0 No, 1 Abstain

Following the voting, the meeting was adjourned on June 7, 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 – 6/7/2022 - YouTube](#)