Food and Drug Administration
Center for Biologics Evaluation and Research

SUMMARY MINUTES
174th VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE

June 14, 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.
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.
Pamela McInnes, DDS, MSc.
Stanley Perlman, M.D., Ph.D.
Wayne Marasco, M.D. Ph.D.

Speakers and Guest Speakers
Katherine Fleming-Dutra, M.D. - CDC
Ruth Link-Gelles, Ph.D. M.PH. – CDC
Tom Shimabukuro, M.D. M.PH, M.B.A.- CDC
Sudhakar Agnihothram, B. Pharm, Ph.D. – FDA
Hui-Lee Wong, Ph.D. – FDA
Rachel Zhang, M.D. - FDA
Carla Vinals, Ph.D.- Moderna
Evan Anderson, M.D., FAAP - Moderna
Jacqueline Miller, M.D., FAAP - Moderna
Rituparna Das, M.D., Ph.D. - Moderna

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 14, 2022, meeting of the Vaccines and Related Biological Products Advisory Committee were approved on July 8, 2022.

I certify that I participated in the June 14, 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.	Arnold Monto, M.D.
Acting Designated Federal Officer	Acting Chair

On June 14, 2022, at 8:30 a.m. Eastern Standard Time (EST), the 174th meeting of the Vaccines and Related Biological Products Advisory Committee (VRBPAC) took place in open session to discuss amending the emergency use authorization (EUA) of the Moderna COVID-19 Vaccine to include the prevention of COVID-19 in children and adolescents 6 years through 17 years of age.

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 welcoming remarks and Dr. Sudhakar Agnihothram, Primary Reviewer, Division of Vaccines and Related Product Applications (DVRPA), Office of Vaccines Research and Review (OVRR), FDA made a presentation titled, “Introduction to Topic 1: Moderna COVID-19 Vaccine: Request for Emergency Use Authorization (EUA) Amendment, Use of a 2-Dose Primary Series in Children and Adolescents 6 years through 17 years of age.”

There were three 15-minute presentations followed by 10 minutes Q&A from 3 speakers from the Centers for Disease Control and Prevention (CDC). The first was titled “COVID-19 Epidemiology and Disease Burden in Infants, Children and Adolescents,” made by Dr. Katherine E. Fleming-Dutra, Medical Officer, COVID-

19 Vaccine Policy Unit at CDC. The second presentation was titled, "Update on mRNA COVID-10 Vaccine Effectiveness," made by Dr. Ruth Link-Gelles, COVID-19 Vaccine Effectiveness Program Lead at CDC. The third and final presentation was by Dr. Tom Shimabukuro from CDC on the topic of "Update on mRNA COVID-19 Vaccine Post Authorization Safety Assessment in Pediatric Age Groups."

Following the three CDC presentations and Q&A, Dr. Hui-Lee Wong from CBER, FDA made a presentation titled, "Safety Surveillance of COVID-19 Vaccines in Children and Adolescents." The Committee was then released for a 10-minute break.

The committee then heard a combined presentation for 50 minutes made by four speakers from the Sponsor, Moderna, on the topic of "mRNA-1273 (Moderna COVID-19 Vaccine) – Request for Emergency Use Authorization in Individuals 6 - 17 Years of Age." The session was started by Dr. Carla Vinals, Vice President, ModernaTX, and then followed by Dr. Evan Anderson, Associate Professor, Pediatrics and Medicine, Emory University School of Medicine, and by Dr. Jacqueline Miller, Senior Vice President, Therapeutic Area Head, Infectious Diseases, and finally Dr. Rituparna Das, Vice President, Clinical Development, COVID-19 Vaccines, ModernaTX. Following these presentations, the committee held a 10-minute Q&A session.

Afterwards, Dr. Rachel Zhang of the Clinical Review Staff, Immediate Office of Director, DVRPA, OVRR, CBER, FDA, made a presentation titled, "FDA Review of Effectiveness and Safety of Moderna COVID-19 Vaccine in Children and Adolescents 6 through 17 Years of Age."

The Committee was then released for 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 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 then held a 60-minutes of "Additional Question and Answer session for CDC, FDA and Sponsor Presenters." The Committee was given a 10-minute break after which a 110-minute session weas held for Committee Discussion and Voting.

Discussion Summary: Committee members noted the limitations of clinical endpoint efficacy data for the age groups of 6-17 years in that efficacy was

assessed prior to the emergence of the Omicron variant but generally agreed that the immunobridging data for each of these age groups, along with available supportive efficacy data and post-authorization effectiveness data in adults, supported the benefits of the vaccine. Committee members stressed the importance of data to support authorization of a third (booster) dose of Moderna COVID-19 Vaccine for pediatric age groups in the near future, based on available data overwhelmingly indicating the need for three doses of available mRNA vaccines to achieve more optimal protection against COVID-19 and serious outcomes caused by the Omicron variant. Committee members also stressed the importance of post-authorization assessments of vaccine effectiveness in the setting of continually evolving epidemiology of the COVID-19 pandemic.

Committee members also generally agreed that available safety data was clearly favorable to support EUA in these age groups but stressed the importance of continued post-authorization safety surveillance, in particular for myocarditis/pericarditis. Some committee members encouraged Moderna to continue pediatric development of the vaccine with assessment of alternative dose levels or dosing intervals that could improve upon effectiveness or decrease the risk of myocarditis.

After committee discussion, the following 2 voting questions were presented to the Committee of **22 voting members**:

Question 1:
Based on the totality of scientific evidence available, do the benefits of the Moderna COVID-19 Vaccine when administered as a 2-dose series (100 μg each dose) outweigh its risks for use in adolescents 12 through 17 years of age?

The voting results for Question 1were as follows: 22 Yes, 0 No, 0 Abstain

Question 2. Based on the totality of scientific evidence available, do the benefits of the Moderna COVID-19 Vaccine when administered as a 2-dose series (50 μg each dose) outweigh its risks for use in children 6 through 11 years of age?

The voting results for Question 2 were as follows: 22 Yes, 0 No, 0 Abstain

After the voting and closing remarks were completed, the meeting was adjourned on June 14, 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 – 6/14/2022 - YouTube