Chicago Scientific Vaccine Work Group Report
December 21, 2020

Based on concerns about potential political pressure on the Food and Drug Administration (FDA) to approve COVID-19 vaccines without proper scientific review, the Chicago Department of Public Health assembled the Chicago Vaccine Scientific Work Group, to assess the integrity of the FDA process for granting an Emergency Use Authorization (EUA) for the Pfizer-BioNTech and Moderna COVID-19 vaccines. Members of this Work Group have expertise in vaccinology, clinical trials, health disparities, bioethics, data analysis, infectious diseases, pediatrics, reproductive health, regulatory affairs, and public health. The goal of this Work Group was not to perform an independent analysis of safety and efficacy data, or to usurp the FDA's role, but to evaluate the quality of the FDA's decision-making process.

Background

On December 14, 2020, the Work Group issued a report expressing confidence in the integrity of the FDA process resulting in granting EUA for the Pfizer-BioNTech Covid-19 vaccine for use in individuals 16 years of age and older. This report also contained background information on the EUA process and FDA standards for COVID-19 vaccine EUA approval. COVID-19 vaccine EUA approval criteria are described in additional detail in FDA guidance documents issued in June and October 2020.[1,2]

Moderna submitted an EUA application to the FDA for the use of its COVID-19 vaccine as a two-dose series in individuals 18 years of age and older, on November 30, 2020. Information submitted with Moderna's EUA request included safety and efficacy data from a phase 3 clinical trial involving over 30,000 participants, with an average of seven weeks of follow up after the second vaccine dose. A subsequent submission to the FDA on December 7, 2020 included a median followup of nine weeks.

FDA review of the EUA application included verification of clinical data and of Moderna's analyses. In addition, the FDA independently analyzed raw data from the submission. During the review process, Moderna responded to multiple information requests from the FDA, to address questions and clarifications.

On December 17, 2020, the FDA held a public meeting with its Vaccines and Related Biological Products Advisory Committee (VRBPAC) to seek input from independent experts on Moderna's EUA request. VRBPAC is a scientific advisory committee of scientists with a wide range of expertise in vaccine development, virology, clinical trials, statistics, and public health, as well as consumer representation. Screening for conflicts

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[1] FDA.Development and Licensure of Vaccines to Prevent COVID-19. **Guidance for Industry, June** 2020.
[2] FDA. Emergency Use Authorization for Vaccines to Prevent COVID-19 Guidance for Industry October 2020. https://www.fda.gov/media/142749/download.

of interest (COIs) occurs prior to each meeting, and members cannot participate if they have a COI.

Moderna submitted updated data to FDA after its initial submission, which was included in FDA's final analysis. In the FDA's final analysis, vaccine efficacy (VE) was 94.1%. (VE measured the reduction of incidence of COVID-19 occurring at least 14 days after the second vaccine dose, with a median follow-up of >2 months post-dose two.) Subgroup analyses showed similar efficacy across genders, racial and ethnic groups, and participants with medical comorbidities associated with high risk of severe COVID-19. A lower VE point estimate was observed in participants ≥65 years of age compared to that in younger adults 18 to <65 years of age, although confidence intervals for these different age groups overlapped. Safety data supported a favorable safety profile, with no specific safety concerns identified that would preclude issuance of an EUA.

At the conclusion of the December 17, 2020, VRBPAC meeting, members voted in support of the FDA granting an EUA for the Moderna vaccine. For the voting question ("Based on the totality of scientific evidence available, do the benefits of the Moderna COVID-19 vaccine outweigh its risks for use in individuals 18 years of age and older?"), the tally was 20-0 with one abstention. The VRBPAC member who abstained indicated he believed the authorization should have been targeted to high-risk groups and that, instead of an EUA, the vaccine should be made available under an expanded access protocol.[3] The difference in the vote tally for the Pfizer and Moderna vaccines was a reflection of the nuances of the voting questions and did not reflect a preference of VRBPAC for one vaccine over the other.

On December 18, 2020, the FDA issued an EUA for the Moderna COVID-19 vaccine as a two dose vaccine series for individuals 18 years of age and older.

Chicago COVID-19 Scientific Vaccine Work Group Review

Chicago Vaccine Advisory Work Group members reviewed Moderna briefing documents, the FDA's briefing document (an independent analysis of Moderna clinical trial data), FDA staff presentations at the December 17, 2020 VRBPAC meeting, as well as other VRBPAC meeting presentations and the Committee's deliberations. Appendix I contains a link to a recording of the VRBPAC meeting, as well as a list and links to all December 17, 2020 VRBAC meeting materials and presentations.

The information and analyses in the FDA's briefing book as well as the FDA's VRBPAC presentations are indicative of comprehensive, independent, and in-depth analysis of

[3] https://www.statnews.com/2020/12/17/moderna-vaccine-fda-panel/

Moderna's clinical trial data. In addition, the VRBPAC meeting adhered to high standards of transparency and evidence-based decision making by its members. The Chicago Scientific Vaccine Advisory Work Group has confidence in the process that led to the FDA granting an EUA for the Moderna COVID-19 vaccine at this time.

As noted by Work Group members, there are numerous unknowns regarding the vaccine including: the duration of vaccine induced protection; the effect of vaccination on asymptomatic infection; the effect of vaccination on transmission; and its safety and efficacy in pregnant women and individuals under 18 years of age. The Work Group underscores the importance of ongoing monitoring of the efficacy and safety of the Moderna COVID-19 vaccine among special populations (*e.g.,* by race, ethnicity, age, and underlying conditions) to ensure that these efforts are supported, particularly among communities disproportionately affected by the pandemic, and to promote confidence in and high uptake of COVID-19 vaccines, which will be challenging. For example, Work Group members expressed concerns that use of terms such as "tracking" and "monitoring", as well as efforts to collect the address and phone number of vaccine recipients, are easily misunderstood and can contribute to vaccine hesitancy and refusal. CDPH must engage with representatives from communities that distrust the government and the health care system to understand and address these concerns. Only by gaining the trust of these communities and leveraging their insights, skills, and expertise will the largest vaccination campaign in Chicago's history succeed.

Members of the Chicago Vaccine Advisory Work Group are available to offer recommendations to the Commissioner on additional science-related issues concerning COVID-19 vaccination that arise.

Vaccines and Related Biological Products Advisory Committee December 17, 2020 Meeting Materials and Presentations **Note: A recording of the proceedings is available at https://www.youtube.com/watch?v=l4psAfbUtC0&feature=youtu.be**
Vaccines and Related Biological Products Advisory Committee December 17, 2020 Discussion Item
Vaccines and Related Biological Products Advisory Committee December 17, 2020 Meeting Briefing Document - FDA
Vaccines and Related Biological Products Advisory Committee December 17, 2020 Meeting Briefing Document Addendum- Sponsor
Vaccines and Related Biological Products Advisory Committee December 17, 2020 Meeting Briefing Document- Sponsor
Vaccines and Related Biological Products Advisory Committee December 17, 2020 Meeting Draft Agenda

Vaccines and Related Biological Products Advisory Committee December 17, 2020 Meeting Draft Roster
Vaccines and Related Biological Products Advisory Committee December 17, 2020 Meeting Presentation - EUA Overview and Considerations for COVID-19 Vaccines
Vaccines and Related Biological Products Advisory Committee December 17, 2020 Meeting Presentation Considerations for placebo-controlled trial design if an unlicensed vaccine becomes available
Vaccines and Related Biological Products Advisory Committee December 17, 2020 Meeting Presentation- FDA Review of Efficacy and Safety of Moderna COVID- 19 Vaccine EUA
Vaccines and Related Biological Products Advisory Committee December 17, 2020 Meeting Waiver to Allow Dr. James Hildreth Participation in an FDA Advisory Committee
Vaccines and Related Biological Products Advisory Committee December 17, 2020 Presentation - Emergency Use Authorization (EUA) Application for mRNA-1273
Vaccines and Related Biological Products Advisory Committee December 17, 2020 Voting Question
Vaccines and Related Products Advisory Committee December 17, 2020 Meeting Acknowledgement of Financial Interests - Dr. James Hildreth

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