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Testimony Before the Food and Drug Administration's
Vaccines and Related Biological Products Advisory Committee Meeting
Regarding the Emergency Use Authorization for a Booster Dose of the Moderna mRNA COVID-19 Vaccine

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I am Dr. Michael Carome, Director of Public Citizen's Health Research Group. I have no financial conflicts of interest.

Public Citizen supported the initial emergency use authorization (EUA) of the primary two-dose series of the Moderna COVID-19 vaccine because clinical trial data demonstrated that the vaccine was highly effective and safe.

Importantly, data from observational studies summarized by the Centers for Disease Control and Prevention at the September 17, 2021, meeting of the Vaccines and Related Biological Products Advisory Committee indicated that the primary series of the Moderna COVID-19 vaccine continued to afford robust protection against severe COVID-19 disease and death in the U.S.[1]

Although there may be a role for a booster (third) dose of the Moderna vaccine in certain populations, such as individuals 65 years of age or older who are at least six months post-completion of the primary series, we want to highlight three limitations regarding the clinical trial data submitted in support of Moderna's request for an EUA for such booster doses.

First, the efficacy of booster doses of the vaccine against symptomatic or severe COVID-19 disease was not evaluated in the phase 2 clinical trial, study P201 Part B.[2]

Second, the subject population enrolled in the phase 2 clinical trial was not representative of the racial and ethnic diversity of the U.S. population. Specifically, with regards to race, the subject population was 95.3% White, 2.3% Black or African American, 0.9% Asian, 0.6% American Indian or Alaska Native, and 0.3% Native Hawaiian or Other Pacific Islander and with regards to ethnicity was 93.8% not Hispanic or Latino and 7.6% Hispanic or Latino.[3] In contrast, the U.S. population, according to the 2020 U.S. census, is 61.6% White, 12.4% Black or African American, 6.0% Asian, 1.1% American Indian or Alaska Native, and 0.2% Native Hawaiian or

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[1] Centers for Disease Control and Prevention. Presentation by Sara Oliver, M.D., M.S.P.H., September 17, 2021, VRBPAC meeting: Updates to COVID-19 epidemiology and COVID-19 vaccines. https://www.fda.gov/media/152243/download. Accessed October 13, 2021.
[2] Food and Drug Administration. Vaccines and Related Biological Products Advisory Committee meeting, October 14, 2021; FDA briefing document: EUA amendment request for a booster dose of the Moderna COVID-19 vaccine. https://www.fda.gov/media/152991/download. Accessed October 13, 2021. Page 6.
[3] *Ibid*. Page 23.

Other Pacific Islander, and 81.3% not Hispanic or Latino and 18.7% Hispanic or Latino.[4] The significant overrepresentation of White and not Hispanic or Latino populations and underrepresentation of Black or African American, Asian, American Indian or Alaska Native, and Hispanic or Latino populations raises concerns about the generalizability of the clinical trial findings to a large proportion of the U.S. population. Moreover, the lack of diversity in the enrolled subject population indicates a failure of Moderna and the trial investigators to ensure that selection of subjects was equitable and satisfied the basic ethical principle of justice articulated in the 1979 Belmont report.[5]

Third, although no serious safety signals were identified during the clinical trial of the proposed 50-microgram (μg) booster dose of the Moderna vaccine, the safety dataset for this booster dose is very small, including only 171 subjects who received a 50-μg booster dose administered at least six months after completion of a primary series of two 100-μg vaccine doses — the dose authorized under the initial EUA granted by the FDA — and 173 subjects who received a 50-μg booster dose administered at least six months after completion of a primary series of two 50-μg vaccine doses — a dose not authorized under the EUA.[6] For the former subject group, median followup was just 5.7 months, with a range of 3.1-6.4 months.[7]

Finally, while the U.S. already is implementing widespread distribution of COVID-19 vaccine boosters, the vast majority of people in low- and middle-income countries have had no access to any COVID-19 vaccine, let alone the highly effective mRNA vaccines. The world continues to suffer from an artificial scarcity of high-quality COVID-19 vaccines because governments are permitting drug corporations to maintain monopolies. It is ethically imperative that the U.S. government move to rapidly ramp up global vaccine manufacturing so that every person on the planet can be vaccinated.

[4] U.S. Census Bureau. Race and Ethnicity in the United States: 2010 Census and 2020 Census. https://www.census.gov/library/visualizations/interactive/race-and-ethnicity-in-the-united-state-2010-and-2020-census.html. Accessed October 13, 2021. Data reported is for White alone, Black or African American alone, Asian alone, American Indian or Alaska Native alone, and Native Hawaiian or Other Pacific Islander alone.
[5] National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. Ethical principles and guidelines for the protection of human subjects of research. April 18, 1979. https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html. Accessed October 12, 2021.
[6] Food and Drug Administration. Vaccines and Related Biological Products Advisory Committee meeting, October 14, 2021; FDA briefing document: EUA amendment request for a booster dose of the Moderna COVID-19 vaccine. https://www.fda.gov/media/152991/download. Accessed October 13, 2021. Page 6.
[7] *Ibid*. Page 7.