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Testimony Before the Food and Drug Administration's
Vaccines and Related Biological Products Advisory Committee Meeting
Regarding the Supplemental Biologics License Application Seeking Approval for a Booster Dose of the Pfizer-BioNTech mRNA COVID-19 Vaccine (COMIRNATY)

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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 emergency use authorization and subsequent approval of the Pfizer-BioNTech COVID-19 vaccine because clinical trial data demonstrated the vaccine was highly effective and safe.

However, Pfizer and BioNTech have failed to provide sufficient data to assess the risk-benefit profile of a booster (third) dose of their COVID-19 vaccine in individuals aged 16 or older in the general population. In particular, there is a lack of data on the effectiveness (and its duration) of booster vaccination in preventing important COVID-19-related outcomes (i.e., serious illness resulting in hospitalization or death) in individuals aged 16 and older in the general population, and safety data for booster vaccinations are very limited.

Importantly, observational studies indicate that the primary series of the Pfizer-BioNTech vaccine still affords robust protection against severe COVID-19 disease and death in the U.S.

We agree with the following assessment and conclusions offered by Drs. Marion Gruber and Phillip Krause — the Director and Deputy Director, respectively, of the Food and Drug Administration's Office of Vaccines Research and Review — and other experts in their Viewpoint article published in the *Lancet* this week:

> "Current evidence does not...appear to show a need for boosting in the general population, in which efficacy against severe disease remains high...
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> "The limited supply of [COVID-19] vaccines will save the most lives if made available to people who are at appreciable risk of serious disease and have not yet received any vaccine. Even if some gain can ultimately be obtained from boosting, it will not outweigh the benefits of providing initial protection to the unvaccinated. If vaccines are deployed where they would do the most good, they could hasten the end of the pandemic by inhibiting further evolution of variants."[1]

[1] Krause PR, Fleming TR, Peto R, et al. Considerations in boosting COVID-19 vaccine immune responses. *Lancet*. DOI:https://doi.org/10.1016/S0140-6736(21)02046-8. Published online September 13, 2021.

Finally, any move to widespread distribution of COVID-19 vaccine boosters in the U.S. would make it even more ethically imperative that the U.S. government move to ramp up global vaccine manufacturing so that every person on the planet can be vaccinated. The world currently is suffering an artificial scarcity of high-quality COVID-19 vaccines because governments are permitting drug corporations to maintain monopolies. While the U.S. has been planning its booster vaccination campaign, the vast majority of people in low- and middle-income countries had no access to any COVID-19 vaccine, let alone the highly effective mRNA vaccines.

If the U.S. is to proceed with COVID-19 vaccine boosters, we take on a special, greater obligation to do everything in our power to get as many vaccine doses as possible, as quickly as possible, to people in low- and middle-income countries — and especially to invest immediately in expanded manufacturing to create an adequate supply to vaccinate the entire world.