# Vaccines and Related Biological Products Advisory Committee October 14-15, 2021 Meeting Presentation Meeting

Individuals using assistive technology may not be able to fully access the information contained in this file. For assistance, please send an e-mail to: <a href="mailto:ocod@fda.hhs.gov">ocod@fda.hhs.gov</a> and include 508 Accommodation and the title of the document in the subject line of your e-mail.



## Welcome Remarks

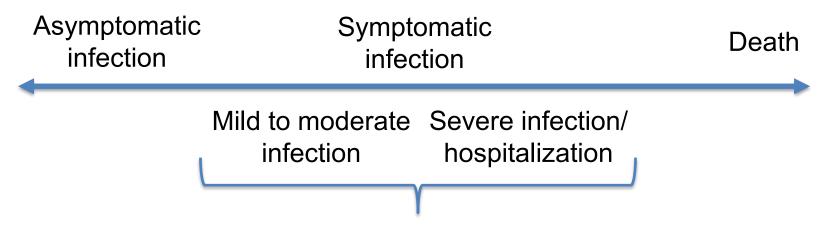
Peter Marks, MD, PhD

169<sup>th</sup> Meeting of the Vaccines and Related Biologic Products Advisory Committee

October 14, 2021



# The Spectrum of SARS-CoV-2 Infection



Potentially associated with Long COVID-19: Cardiac, pulmonary, neurologic and other symptoms

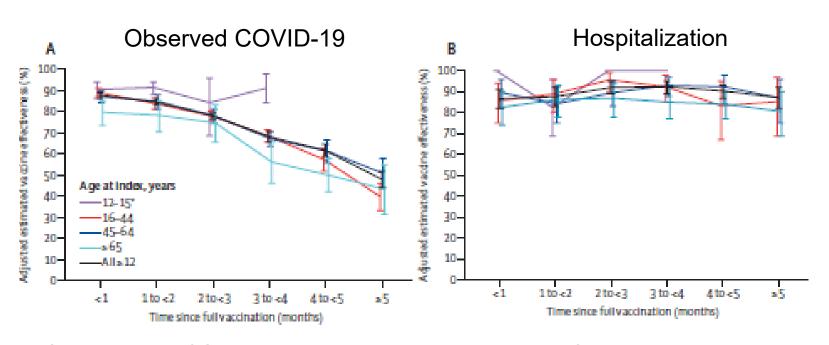


#### Vaccine Effectiveness Over Time

- Pfizer-BioNTech, Moderna, and Janssen have all submitted data suggesting some waning of effectiveness over time
- Most evidence is based on neutralizing antibody titers or realworld evidence (RWE) on symptomatic infection
- Separating waning effectiveness from reduced effectiveness against variants, such as Delta, can be challenging
- Vaccines are still very effective against serious outcomes



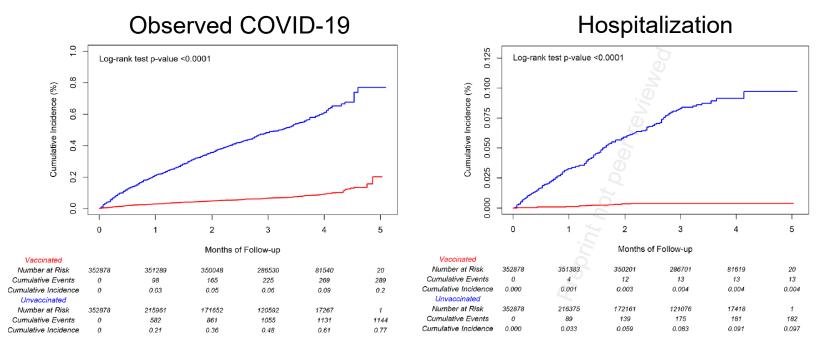
#### RWE on Effectiveness of Pfizer-BioNTech



Source: Tartof SY et al., Lancet, published online October 4, 2021



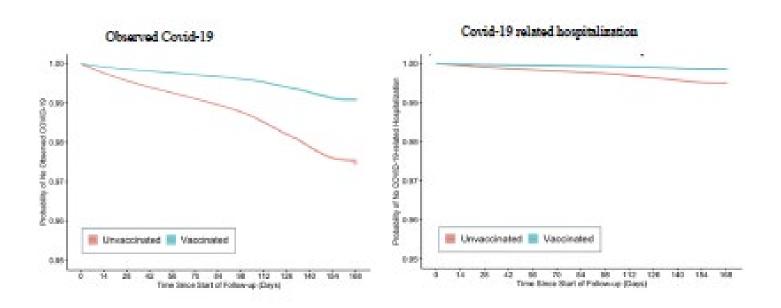
### RWE on Effectiveness of Moderna



Source: Bruxvoort KJ et al., Lancet, preprint posted Sept 4, 2021



#### RWE on Effectiveness of Janssen



Source: Janssen Briefing Document



#### Vaccine Effectiveness Over Time

- Vaccines still provide strong protection against serious outcomes, especially for younger age groups
- Vaccine effectiveness against mild and moderate disease appears to wane over time for the different vaccines
- Mild to moderate COVID-19 can be associated with adverse outcomes such as blood clots and long COVID-19
- Facilitating higher primary coverage of the entire vaccineeligible population should still be a key priority

