Safety and efficacy of a 3rd dose

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https://faculty.rx.umaryland.edu/pdoshi/#publications (slides here)
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FINANCIAL DISCLOSURES

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Summary

• Salary from University of Maryland & The BMJ
• Public, foundation, and non-profit funding of academic research
• Reimbursement (e.g. lodging, travel) from non-profits
• No industry funding

My views and opinions do not necessarily reflect official policies or positions of the University of Maryland.
Fauci: “This is still an outbreak, a pandemic of the unvaccinated.”¹

Biden: “Earlier today, our medical experts announced a plan for booster shots to every fully vaccinated American — adult American.”²

How to reconcile the disconnect?

Sources:
2. NPR. The Optimal Regimen To Fight COVID Will Be A 3rd Shot For A Boost, Fauci Says. (Sep 7, 2021) https://n.pr/3kd96di
Has vaccine efficacy dropped below 50%?

- June 2020: FDA set the bar at 50% efficacy against symptomatic covid-19.¹

- Aug 2021: FDA approved Pfizer’s vaccine reporting 91.1% vaccine efficacy.²

- If 2 doses deliver >50% efficacy, why should FDA contemplate approving a booster for the same population (16 and older)?

Sources:
AEs: trial unlikely to answer most important questions

• Jay Butler, CDC deputy director for infectious diseases
  • “We’re keenly interested in knowing whether or not a third dose may be associated with any higher risk of adverse reactions, particularly some of those more severe - although very rare - side effects”¹

• But Pfizer’s “booster dose” RCT is only enrolling 10,000 “healthy participants” volunteers from its phase 3 trial (C4591001)²
  • Unlikely to detect uncommon side effects
  • Unlikely to determine safety profile among individuals with history of reactions to dose 1 or 2 but who will be mandated to receive a booster
  • Current estimated study completion date: next year (Sep 29, 2022)

Sources:
   https://reut.rs/2YZDxeH
2. Inclusion criteria section of “Study to Evaluate the Safety and Efficacy of a Booster Dose of BNT162b2 Against COVID-19 in Participants ≥16 Years of Age” (NCT04955626). https://clinicaltrials.gov/ct2/show/NCT04955626
American Board of Family Medicine
American Board of Internal Medicine
American Board of Pediatrics

"Dear Dr. X, ... providing misinformation about the COVID-19 vaccine contradicts physicians' ethical and professional responsibilities, and therefore may subject a physician to disciplinary actions."

“We also want all physicians certified by our boards to know that such unethical or unprofessional conduct may prompt their respective board to take action that could put their certification at risk.”

American Academy of Pediatrics President Lee Savio Beers: “We also know all too well the dangers of misinformation and disinformation to child health. We are grateful to the American Board of Pediatrics for taking this important step.”

Sources: