

# Safety and efficacy of a 3rd dose

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## FINANCIAL DISCLOSURES

I have received travel funds from the **European Respiratory Society** (2012) and **Uppsala Monitoring Center** (2018); grants from the **FDA (through University of Maryland M-CERSI; 2020)**, **Laura and John Arnold Foundation** (2017-22), **American Association of Colleges of Pharmacy** (2015), **Patient-Centered Outcomes Research Institute** (2014-16), **Cochrane** Methods Innovations Fund (2016-18), and **UK National Institute for Health Research** (2011-14); was an unpaid IMEDS steering committee member at the **Reagan-Udall Foundation for the FDA** (2016-20), and am an editor at **The BMJ**.

## 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.”<sup>1</sup>**

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

## How to reconcile the disconnect?

### Sources:

1. Remarks by President Biden on Fighting the COVID-19 Pandemic. (Aug 18, 2021) <https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/08/18/remarks-by-president-biden-on-fighting-the-covid-19-pandemic-2/>
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.<sup>1</sup>**
- **Aug 2021: FDA approved Pfizer's vaccine reporting 91.1% vaccine efficacy.<sup>2</sup>**
- **If 2 doses deliver >50% efficacy, why should FDA contemplate approving a booster for the same population (16 and older)?**

## Sources:

1. FDA. Development and Licensure of Vaccines to Prevent COVID-19. (June 2020)  
<https://www.fda.gov/media/139638/download#page=17>
2. FDA. Summary Basis for Regulatory Action (Comirnaty). (August 23, 2021).  
<https://www.fda.gov/media/151733/download#page=18>

# 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”<sup>1</sup>
- But Pfizer’s “booster dose” RCT is only enrolling 10,000 “healthy participants” *volunteers* from its phase 3 trial (C4591001)<sup>2</sup>
  - 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:

1. Reuters. U.S. health official says COVID-19 boosters could risk more serious side effects (July 13, 2021). <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>

## Important: Joint Statement from ABFM, ABIM & ABP on Dissemination of Misinformation

Dear Dr. \_\_\_\_\_,

The Federation of State Medical Boards (FSMB), which supports its member state medical licensing boards, has recently [issued a statement](#) saying that providing misinformation about the COVID-19 vaccine contradicts physicians' ethical and professional responsibilities, and therefore may subject a physician to disciplinary actions, including suspension or revocation of their medical license. We at the American Board of Family Medicine (ABFM), the American Board of Internal Medicine (ABIM), and the American Board of Pediatrics (ABP) support FSMB's position. 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.

Expertise matters, and board certified physicians have demonstrated that they have stayed current in their field. Spreading misinformation or falsehoods to the public during a time of a public health emergency goes against everything our boards and our community of board certified physicians stand for. The evidence that we have safe, effective and widely available vaccines against COVID-19 is overwhelming. We are particularly concerned about physicians who use their authority to denigrate vaccination at a time when vaccines continue to demonstrate excellent effectiveness against severe illness, hospitalization and death.

We all look to board certified physicians to provide outstanding care and guidance; providing misinformation about a lethal disease is unethical, unprofessional and dangerous. In times of medical emergency, the community of expert physicians committed to science and evidence collectively shares a responsibility for giving the public the most accurate and timely health information available, so they can make decisions that work best for themselves and their families.

Warren Newton, MD, MPH  
President and CEO  
American Board of Family Medicine

Richard J. Baron, MD  
President and CEO  
American Board of Internal Medicine

David G. Nichols, MD, MBA  
President and CEO  
American Board of Pediatrics

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.”<sup>2</sup>**

### Sources:

1. Joint Statement from the American Board of Family Medicine, American Board of Internal Medicine, and American Board of Pediatrics on Dissemination of Misinformation by Board-Certified Physicians About COVID-19. (Sept 9, 2021) <https://www.abp.org/news/statement-about-dissemination-covid-19-misinformation>
2. AAP News. Board-certified physicians who spread COVID vaccine misinformation risk certification. (Sep 10, 2021) <https://www.aappublications.org/news/2021/09/10/covidmisinformation091021>