

# Four reasons to reject covid-19 vaccine mandates

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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 is an editor at **The BMJ**.

The views and opinions expressed here are those of the author/presenter and do not necessarily reflect official policy or position of the University of Maryland.

## 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

## Four reasons

1. **Wrong product.** Mandates assume performance characteristics these vaccines do not have
2. **Wrong target.** Mandates must—but cannot—exempt all for whom risks outweigh benefits
3. **Wrong context.** Mandates are socially unacceptable
4. **No data.** Mandates should only be contemplated when the raw data from vaccine trials is available

## Wrong product. What if this were a drug?

### vaccine noun

2006 to Jan 18, 2021



vac·cine | \ vak-'sēn , 'vak-,sēn \

#### Definition of vaccine

: a preparation of killed microorganisms, living attenuated organisms, or living fully virulent organisms that is administered to produce or artificially increase immunity to a particular disease

### vaccine noun

Jan 26, 2021



vac·cine | \ vak-'sēn , 'vak-,sēn \

#### Definition of vaccine

: a preparation that is administered (as by injection) to stimulate the body's immune response against a specific infectious disease:

- a : an antigenic preparation of a typically inactivated or attenuated (see ATTENUATED sense 2) pathogenic agent (such as a bacterium or virus) or one of its components or products (such as a protein or toxin)
- b : a preparation of genetic material (such as a strand of synthesized messenger RNA) that is used by the cells of the body to produce an antigenic substance (such as a fragment of virus spike protein)

#### Definition of vaccine

Oct 23, 2021

- 1 : a preparation that is administered (as by injection) to stimulate the body's immune response against a specific infectious agent or disease: such as
  - a : an antigenic preparation of a typically inactivated or attenuated (see ATTENUATED sense 2) pathogenic agent (such as a bacterium or virus) or one of its components or products (such as a protein or toxin)
  - b : a preparation of genetic material (such as a strand of synthesized messenger RNA) that is used by the cells of the body to produce an antigenic substance (such as a fragment of virus spike protein)
- 2 : a preparation or immunotherapy that is used to stimulate the body's immune response against noninfectious substances, agents, or diseases

- Doesn't stop infection
- Doesn't stop transmission

Sources: Merriam-Webster dictionary. Oct 17, 2006 to Jan 18, 2021 (<https://bit.ly/3Cw9UAI> and <https://bit.ly/3pQh2UL>); Jan 26, 2021 (<https://bit.ly/2ZHVYFe>); Oct 23, 2021. (<https://bit.ly/3GAiDEj>)

**Wrong target.** Mandates must—but cannot—exempt all for whom risks outweigh benefits

- **A mandate must exclude those populations for whom risks outweigh benefits**
- **Risks outweigh benefits in those with past SARS-CoV-2 infections**
- Many Americans have past infections
  - Pre-Delta, CDC estimated that **by May 2021, 32-43% of Americans (120 million people) were infected** with SARS-CoV-2.
  - As of May 30, as per CDC, there were 33 million cases
- But we lack the practical means to identify many of these people, and therefore we have no means of excluding them from the mandate

**Sources:** Menni et al. Vaccine side-effects and SARS-CoV-2 infection after vaccination in users of the COVID Symptom Study app in the UK: a prospective observational study. Lancet Infect Dis 2021;21:939-49. [https://doi.org/10.1016/S1473-3099\(21\)00224-3](https://doi.org/10.1016/S1473-3099(21)00224-3)  
Mathioudakis et al. Self-reported real-world safety and reactogenicity of covid-19 vaccines: a vaccine recipient survey. Life (Basel) 2021;11:249. <https://doi.org/10.3390/life11030249>

# Wrong context. Mandates are socially unacceptable

- Mandates have many consequences beyond vaccine and covid-19 related metrics
- Unintentional consequences also matter, and can potentially outweigh the intended consequences
- Mandates will have profoundly negative social consequences
  - Segregation of people into vaccinated / unvaccinated
  - Anger, resentment, loss of trust
- We should not pursue socially divisive policies

**For more, see:** Doshi P, Bhargava A. Vaccine mandates: a new form of 'institutional segregation', Baltimore Sun. Aug 31, 2021.

<https://www.baltimoresun.com/opinion/op-ed/bs-ed-op-0901-no-vaccine-mandates-20210831-3f7ljoolbvg4bob76yqlnabqv4-story.html>

**“Data transparency is not a “nice to have.” Claims made without access to the data—whether appearing in peer reviewed publications or in preprints without peer review—are not scientific claims. Products can be marketed without access to the data, but doctors and professional societies should publicly state that, without complete data transparency, they will refuse to endorse covid-19 products as being based on science.”**

Doshi and Healy. BMJ. 2020 Aug 24;370:m3260.  
<https://doi.org/10.1136/bmj.m3260>

Phase 3 trial data	When might it become available	Why
Pfizer (NCT04368728)	May 2025	“24 months after study completion”; estimated study completion date 5/2/23
Moderna (NCT04470427)	Oct 2022	Data “may be available ... with publication of the final study results in [est. October] 2022.”
J&J (NCT04505722)	July 2022	Current reason trial not available: “trial ongoing/completed <18 months ago”

**Pfizer:** Thomas et al. N Engl J Med. 2021 Sep 15;NEJMoa2110345. doi: 10.1056/NEJMoa2110345

**Moderna:** El Sahly et al. N Engl J Med. 2021 Sep 22;NEJMoa2113017. doi: 10.1056/NEJMoa2113017

**J&J:** <https://yoda.yale.edu/details-trials-have-been-determined-be-unavailable>