April 1, 2022

Jennifer Mero

Secretary to the Board of Trustees

H. Carl McCall SUNY Building,

ST-6, Albany, New York 12246

Dear Ms. Mero,

I am a published epidemiologist (citation below) and graduate of the State University of New York, Albany, School of Public Health ('97). I would like to speak at the Trustee meeting on April 19, 2022.

My statement concerns the COVID-19 vaccine mandates. These mandates disproportionately burden low-risk students vs higher-risk faculty (who are generally not required to be vaccinated or boosted) with a medical intervention that is not supported by safety and effectiveness data in this population, does not accommodate a safe interval after infection to receive vaccination, does not prevent community transmission nor demonstrate any additional protection against severe disease compared to two doses, and finally does not accommodate immunity afforded by prior infection. In short, there is no data to substantiate the need for, nor the safety of, this mandated medical intervention in a healthy young adult population. COVID-19 vaccines should be aligned with routine vaccine requirements which allow documentation of immunity via prior infection.

> Allison Krug, Josh Stevenson, Tracy Beth Høeg. BNT162b2 Vaccine-Associated Myo/Pericarditis in Adolescents: A Stratified Risk-Benefit Analysis. *European Journal of Clinical Investigation*. First published: 14 February 2022 https://doi.org/10.1111/eci.13759

Very sincerely,

Allison Krug, MPH

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# COVID-19 booster mandates for American university students: Are they ethical and science-based?

*Statement by Allison Krug, MPH to SUNY Board of Trustees April 19, 2022*

Thank you for this opportunity to speak today. I don't have a child in the SUNY system but I was trained as an epidemiologist at SUNY Albany and hold the educational system in high regard. I am speaking today because parents with children at SUNY schools really cannot. They don't want to disrupt or complicate their son or daughter's transition to the wonderful world of higher ed and adulthood. During the past year, I have collaborated with scientists and physicians on vaccine safety in adolescents and young men. As a mother of two young men, this began as a very personal question related to the emerging signal of myocarditis, or—heart inflammation. In this testimony, I provide the risk-benefit analysis that CDC should be offering as guidance. I encourage the SUNY system to align its covid policies with existing vaccine requirements, such as MMR and meningitis, which allow for documentation of immunity OR a waiver acknowledging risks.

A risk-benefit analysis is critical when considering vaccines in young people who have a very low risk for bad outcomes due to either COVID or vaccination. To do a risk benefit analysis, we need some data points. First, the number of people we need to vaccinate to prevent one hospitalization for covid. The CDC has twice estimated that this number is between 9,000 to 12,000 18-29-year-olds. This hasn't been updated to account for the

decreased severity of Omicron, which would at least double this number to 20-to-30,000 boosted to prevent one COVID-19 hospitalization. Second, we need to know how many serious adverse events are expected when we boost that many young adults.

The rate of post-booster myocarditis in college-age males was estimated in two recent studies to be at least one in 7,000. If we boost a campus the size of SUNY Buffalo (approximately 30,000 students) to prevent one covid hospitalization, we risk causing at least 2 myocarditis cases. Those who have had covid before have 2 times the risk of an adverse event, and 4 times the risk of myocarditis, making this trade-off even worse in the post-Omicron era when nearly all have been infected.

Although most media reports dismiss vaccination-associated myocarditis as "mild" and followed by rapid recovery, 90% of cases are hospitalized and 69% of adolescents have LGE (or scarring) on the heart 3-8 months later. The long-term implications of this scar tissue on heart conduction and the risk of sudden death remains unknown.

Bioethicists consider vaccine mandates for young people to be problematic for many reasons. Coercion erodes trust, and these are the parents of tomorrow. How will we convince them that vaccination is the right thing to do when nearly 5% are adamant about not receiving a booster? Doctors struggle for a decade to gain a 5% increase in pediatric vaccination, and we've lost ground with COVID already. Vaccination is the cornerstone of public health. My first position out of grad school was preventive health program management, and I also

worked for Merck Vaccine Division here in the Northeast. During this time, I focused on barrier reduction and targeted outreach to improve preventive health program engagement. I encourage you to think similarly about student health. Roll back coercive policies and pivot to investing in student and faculty *wellness*. This will promote confidence in your ability to truly care for your highest risk students and faculty.

As you think about Fall 2022, consider that half the country never had vaccine or booster mandates. Other countries, including the UK and most of Europe, never mandated Covid-19 vaccines for university students. In my opinion, a better use of resources would be to focus on outreach to the students who are medically vulnerable, ensure they are linked to student health services, have ready access to testing and a ride to the clinic if needed, and case management when ill to catch worsening conditions promptly. You could also embed trained counselors in dorms to address the mental health crisis. Going forward, pushing boosters on a population with two doses of vaccine *and* natural immunity makes less sense than ever due to the compounding of risks. Focus, instead, on a future which respects students as adults, promotes personal agency and risk assessment, and engages the entire university community in physical and emotional wellbeing.

Thank you for your consideration.

# EVIDENCE AGAINST SARS-COV-2 BOOSTER MANDATE

At least 1000 schools are requiring all students to receive a COVID-19 vaccine and over 300 are requiring a booster within 21 days of their date of eligibility.[1] Failure to comply may result in fines, dropped classes and expulsion. This mandate disproportionately burdens low-risk students vs higher-risk faculty (who are generally not required to be vaccinated or boosted) with a medical intervention that was not supported by safety and effectiveness data in this population, does not accommodate a safe interval after infection to receive vaccination, does not prevent community transmission nor demonstrate any additional protection against severe disease compared to two doses, and finally does not accommodate immunity afforded by prior infection. In short, there is no data to substantiate the need for, nor the safety of, this mandated medical intervention in a healthy young adult population. COVID-19 vaccines should be aligned with routine vaccine requirements which allow documentation of immunity via prior infection.

With respect to demonstrating need, the FDA's advisory committee (VRBAC) voted 16-2 against a booster recommendation for healthy adults in September 2021, and six months of real-world data has still not demonstrated any additional benefit of protection against severe disease conferred by boosting healthy adults. In the Pfizer trial, 5 out of 6 outcomes (safety, transmission, hospitalization, death) had no data or very low certainty of evidence.[2] The interval between immune activations from either disease or vaccination is important, yet this is not considered in the mandate language. For instance, Israel requires a minimum 3-month interval before vaccination of those who were previously infected[3] yet the colleges are mandating boosters immediately upon eligibility, regardless of the interval since last positive COVID test.

With respect to safety, males younger than age 40 face an increased risk of myo/pericarditis following both the second dose of vaccination and the booster which exceeds their risk of myocarditis due to COVID-19 infection.[4] A recent study of Israel Defense Forces[5] members age 18-24 found the rate of booster-associated myocarditis was 1 in 7000 to 1 in 9000, equivalent to the number of vaccines CDC estimates must be administered to prevent one COVID-19 hospitalization thus nullifying the risk-benefit equation for young men.

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[1] https://www.bestcolleges.com/news/2021/12/14/what-colleges-require-covid-vaccine-booster-omicron/

[2] https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-11-19/06-COVID-Oliver-508.pdf slides 29, 36

[3] Gazit, et al. Annals of Internal Medicine 2022. https://www.acpjournals.org/doi/10.7326/M21-4130

[4] Patone, et al. 2021 [preprint] https://www.medrxiv.org/content/10.1101/2021.12.23.21268276v1.full.pdf

[5] Friedensohn L. *JAMA* https://jamanetwork.com/journals/jama/fullarticle/2790421?resultClick=1

With respect to broader goals like reducing community transmission, there is little evidence that vaccination appreciably reduces secondary attack rates compared to the unvaccinated.[6] Booster effectiveness against Omicron infection appears to wane faster than against Delta[7] reflecting immune evasion vs intrinsic viral infectivity.

What would a more sensible COVID-19 policy look like? First, a harmonizing understanding of vaccine-induced and infection-induced immunity would recognize the protection conferred by infection, either before or after vaccination. Infection following vaccination elicits broadly neutralizing antibodies against variants of concern[8] and the longer the interval following vaccination before breakthrough infection, the better the boost with respect to antibody affinity and potency.[9]

1. **COVID-19 vaccine recommendations should recognize immunity from prior infection as well as vaccination.**
2. **Additional doses should be recommended by a physician based on an individual's unique medical circumstances and only after informed consent regarding risks and benefits.**
3. **CDC Director Walensky explained that infection is equivalent to a "natural booster."**

In summary, the science is not settled, vaccine mandates are coercive, and the result will be inequitable access to education given the disparities in vaccine coverage by socioeconomic status. The following addendum provides the clinical trial, real world and laboratory data referenced to form this opinion.

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[6] Singanayagam A. *Lancet*. https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(21)00648-4/fulltext

[7] Twitter @BarakRaveh https://twitter.com/BarakRaveh/status/1473749810868019214/photo/1

[8] Zhou R. Vaccine-breakthrough infection by the SARS-CoV-2 Omicron variant elicits broadly cross-reactive immune responses https://www.biorxiv.org/content/10.1101/2021.12.27.474218v1

[9] Miyamoto S. Vaccination-infection interval determines cross-neutralization potency to SARS-CoV-2 Omicron after breakthrough infection by other variants https://www.medrxiv.org/content/10.1101/2021.12.28.21268481v1

**September 17, 2021: FDA's Vaccines and Related Biologics Advisory Committee (VRBAC) voted 16-2 against a booster recommendation for healthy adults younger than 65 years.**

Summary of the evidence and vote presented to VRBAC on September 21, 2021 (page 31):[10]

> The VRBPAC was asked to vote on the following question: Do the safety and effectiveness data from clinical trial C4591001 support approval of a COMIRNATY booster dose administered at least 6 months after completion of the primary series for use in individuals 16 years of age and older? **Please vote Yes or No.**
>
> The results of the vote were as follows: Yes=2, No=16.
>
> Thus, the committee voted against approval of a booster dose for individuals 16 years of age and older. Committee members expressed concern regarding uncertainties about the benefit afforded by a booster dose relative to the benefit provided by previous vaccination with the primary series in persons 16 years of age and older. Concerns were expressed about post-authorization data demonstrating increased risks of myocarditis and pericarditis, particularly within 7 days following the second dose of COMIRNATY with the highest risk in males 16 to 17 years of age. There is currently only limited data whether this risk may be further increased after a booster dose of COMIRNATY. Some committee members also noted the absence of robust data regarding the effectiveness of a booster dose against the currently circulating Delta variant of SARS-CoV-2.

**September 24, 2021: CDC's Advisory Committee on Immunization Practice (ACIP) supports the FDA position**

Statement from Director Walensky via press release on September 24, 2021 states that those aged 18-64 *may* receive a booster shot based on individual benefits and risks:[11]

> CDC recommends:
>
> - people 65 years and older and residents in long-term care settings **should** receive a booster shot of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after their Pfizer-BioNTech primary series,
> - people aged 50–64 years with underlying medical conditions **should** receive a booster shot of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after their Pfizer-BioNTech primary series,
> - people aged 18–49 years with underlying medical conditions **may** receive a booster shot of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after their Pfizer-BioNTech primary series, based on their individual benefits and risks, and
> - people aged 18-64 years who are at increased risk for COVID-19 exposure and transmission because of occupational or institutional setting **may** receive a booster shot of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after their Pfizer-BioNTech primary series, based on their individual benefits and risks.

[10] https://www.fda.gov/media/152432/download page 31
[11] https://www.cdc.gov/media/releases/2021/p0924-booster-recommendations-.html

**October 9, 2021: Opinion on boosters published in *Lancet* by team of international authors**

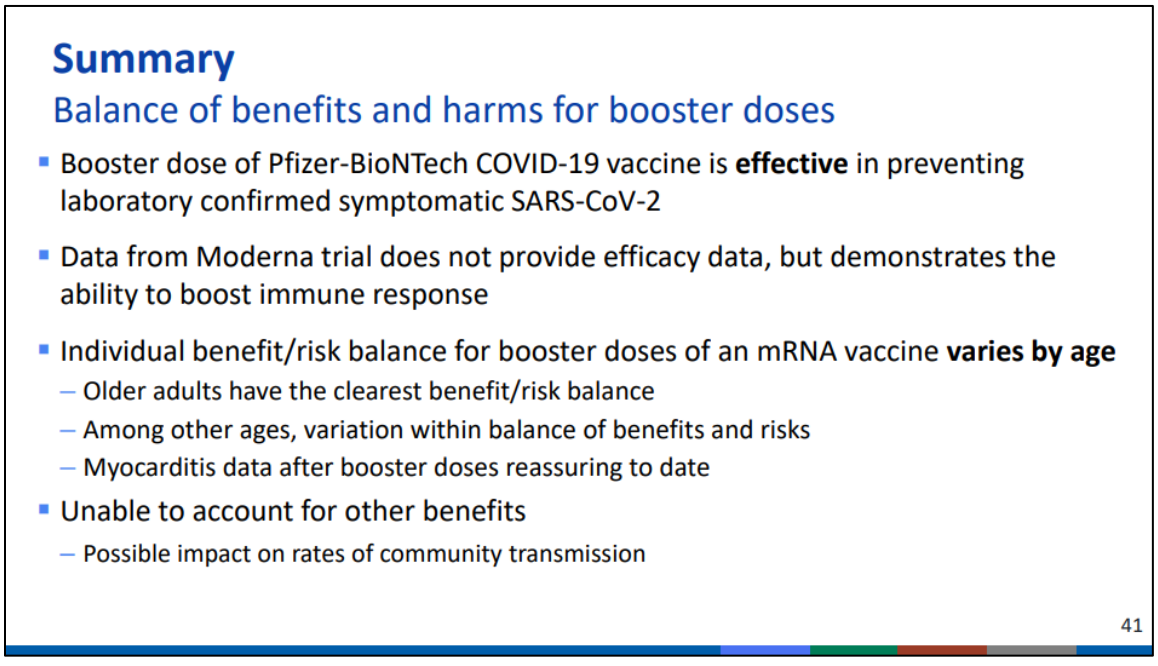
Drs. Krause and Gruber, FDA officials working on vaccine research, publish an opinion on the weak evidence for a universal booster recommendation with an international team of scientists in *The Lancet* entitled: *Considerations in boosting COVID-19 vaccine immune responses*:[12]

> "Current evidence does not, therefore, appear to show a need for boosting in the general population, in which efficacy against severe disease remains high. Even if humoral immunity appears to wane, reductions in neutralising antibody titre do not necessarily predict reductions in vaccine efficacy over time, and reductions in vaccine efficacy against mild disease do not necessarily predict reductions in the (typically higher) efficacy against severe disease. This effect could be because protection against severe disease is mediated not only by antibody responses, which might be relatively short lived for some vaccines, but also by memory responses and cell-mediated immunity, which are generally longer lived."

**November 19, 2021: CDC's ACIP expands booster recommendation, overturning VRBAC**

Booster shot recommendation expanded to all adults on November 19, 2021.[13]

ACIP Summary of benefits and harms states that individual benefit/risk balance varies by age and a "possible impact on rates of community transmission".[14]




[12] Krause, et al. *Lancet*. https://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736(21)02046-8.pdf
[13] https://www.cdc.gov/media/releases/2021/s1119-booster-shots.html
[14] https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-11-19/06-COVID-Oliver-508.pdf slide 41

**Evidence from booster trials insufficient to support a mandate.**

The following policy question presented during the November 19, 2021 ACIP meeting was whether booster access should be opened to all persons aged 18 years or older given increased transmission during delta[15]: *Do the balance of benefits and risks and facilitation of implementation warrant an update to COVID-19 vaccine policy?*

The Pfizer booster trial was not designed to assess safety or efficacy in people younger than 39:

1. The trial included 10,125 participants age 16 years or older: 4975 males, only 90[16] of whom were ages 16-17, only 46 participants were in the vaccine arm, of these only half would have been male.
2. 5530 were ages 18-55, with a mean age 51.7. In short, the age range of most SUNY students was not sufficiently represented in the trial.
3. The booster was given 10-12 months after second dose; only 6 participants given the booster less than 6 months after second dose[17]
4. Reactogenicity (local and systemic reactions to the vaccine, such as fever, headache, muscle aches, nausea, diarrhea, etc.) data were not collected in this booster study (trial C4591031).[17]
5. Pfizer notes that booster that although reactogenicity data was not collected in the booster trial, it was collected in trial C4591001.[18] The safety data in trial C4591001 included 306 subjects age 16-55.
6. One case of myocarditis was found in the 16-17 yr old strata of C4591031, reported by CBER on December 8, 2021.[19]
7. Evidence of protection against symptomatic infection: 94.9% within 2 months, 93.3% 2-4 months; no longer-term follow-up. I.e. the trial does not show what protection the booster does or does not confer after 4 months.
8. No evidence for critical endpoints of hospitalization, death, or transmission of SARS-CoV-2.[20]
9. Trial not powered to identify the most common serious adverse event in this population (myo/pericarditis).[21]

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[15] https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-11-19/06-COVID-Oliver-508.pdf slide 7
[16] https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-11-19/02-COVID-Perez-508.pdf slide 4
[17] https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-11-19/06-COVID-Oliver-508.pdf slide 22
[18] https://www.fda.gov/media/152161/download page 40
[19] https://www.fda.gov/media/154869/download page 6
[20] https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-11-19/06-COVID-Oliver-508.pdf slide 25
[21] https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-11-19/06-COVID-Oliver-508.pdf slide 27

10. Data from Israel show booster myocarditis rates of 5.2 and 3.6 per 100k (ages 16-19 and 20-24, respectively). These rates are 1.7-2.5x higher than the background rate of 2.1 within 21 days.[22]
11. Summary of evidence regarding benefits shows high certainty for protection against infection (2-4 months), very low for hospitalization, and no data for death due to COVID-19 or transmission of SARS-CoV-2 infection.
12. Summary of evidence regarding harms shows low evidence certainty regarding serious adverse events and very low evidence certainty for reactogenicity (not measured in this trial).
13. Overall for Pfizer there were no data, very low, or low evidence certainty on 5 of 6 important or critical endpoints.[23]
14. Pfizer's own risk-benefit scenario finds 29-69 hospitalizations avoided but 23-69 myocarditis cases caused among males following a booster.[24]

Similarly, the Moderna booster trial was not designed to demonstrate safety or efficacy in young males:

1. Severe reactogenicity occurred among 10.8% of participants receiving a booster dose.[25]
2. Of the 6 important or critical endpoints, three had "no data" or "very low" evidence.[26]
3. No phase 3 efficacy data available for Moderna.[26]
4. Immunogenicity data suggests antibodies are boosted. [26]
5. Effectiveness after the primary series waned less for Moderna than Pfizer. [26]
6. Myocarditis risk following Moderna is unknown, but multiple sources suggest a higher risk for Moderna than Pfizer. [26]

**Public health rationale insufficient to mandate a booster.**

The number needed to vaccinate (NNV) for Pfizer and Moderna to prevent one hospitalization over 6 months is 11,994 and 8,738, respectively.[27] To illustrate the utility of this metric, the largest State University of New York (SUNY) campus is University at Buffalo with approximately 30,000 students; SUNY Oneonta enrolls 6,000 students. Given that the omicron variant is approximately half as severe than the delta variant[28] as measured by the need for emergency care or hospitalization, and a third as

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[22] Li, et a. https://www.bmj.com/content/373/bmj.n1435

[23] https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-11-19/06-COVID-Oliver-508.pdf slide 29

[24] Pfizer review memorandum. (Dec. 8, 2021) https://www.fda.gov/media/154869/download page 7

[25] https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-11-19/06-COVID-Oliver-508.pdf slide 34

[26] https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-11-19/06-COVID-Oliver-508.pdf slide 35

[27] https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-11-19/06-COVID-Oliver-508.pdf slides 36, 37

[28] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1045619/Technical-Briefing-31-Dec-2021-Omicron_severity_update.pdf pg 9

severe when considering hospitalization, the NNV is likely to be closer to 36,000 for Pfizer and 26,100 for Moderna. While the Omicron variant is less severe, vaccine effectiveness against symptomatic disease and hospitalization is also reduced due to immune evasion (63%[29] compared to 94% during Delta) thus the relative trade-off between benefits and harms is greatly reduced.

**Based on clinical trial and observational data, boosting 36,000 students with the intent of preventing one hospitalization could cause approximately 3,600 cases of severe reactogenicity[17] and 1.3 to 1.9 hospitalizations due to myopericarditis would be expected for every 36,000 males vaccinated.** For comparison, the NNV for influenza among 18-49 year-olds during a severe flu season (2017-18) was 5,758.[30] Promoting annual influenza vaccination offers a much better benefit-risk profile with respect to public health promotion, hospitalizations prevented and reduction in transmission. Indeed, the reason influenza vaccination is promoted among the general population ages 6 months to over 65 years is the impact on community immunity.

Effectiveness against symptoms requiring emergency medical care – Omicron dominant period[31]:

1. 2 doses of any mRNA vaccine at least 5 months after last dose: 37%
2. 3 doses of any mRNA vaccine at least 5 months after last dose: 31%
3. 2 vs 3 doses at 2-3 months following last dose: 50% vs 81%, respectively
4. Effectiveness of prior infection against symptomatic disease: 56%[31]

Effectiveness against hospitalization – Omicron dominant period[31]:

1. 2 doses of any mRNA vaccine at least 5 months after last dose: 54%
2. 3 doses of any mRNA vaccine at least 4 months after last dose 78%
3. 2 vs 3 doses at 2-3 months following last dose: 65% vs 88%, respectively
4. Effectiveness of prior infection against hospitalization: 87.8%[31]

Cases of myocarditis following booster among recipients 18-24 years of age[32]:

1. Pfizer – males 4.1 per million, females <1 per million
2. Moderna – males 8.7 per million, females 1.1 per million

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[29] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1045619/Technical-Briefing-31-Dec-2021-Omicron_severity_update.pdf pg 12

[30] Rolfes, et a. *Clinical Infectious Diseases* 2019. https://academic.oup.com/cid/article/69/11/1845/5305915

[31] CDC MMWR https://www.cdc.gov/mmwr/volumes/71/wr/mm7107e2.htm?s_cid=mm7107e2_w

[32] CDC MMWR https://www.cdc.gov/mmwr/volumes/71/wr/mm7107e1.htm?s_cid=mm7107e1_w#F1_down

**Number of doses and timing after infection suggest only 1 dose and at least 6 months post infection.**
In a Cleveland Clinic study of 39,700 personnel with immunity from prior infection ("natural immunity") vs vaccine-induced immunity who received a booster, no additional benefit was conferred by administering more than one dose to those who had recovered from SARS-CoV-2 infection[33]:

1. Previous infection within 6 months provides substantial protection against reinfection even without vaccination.
2. Those who received 1 dose of vaccine after prior infection had a lower risk of reinfection, but those who received 2 doses had a higher risk of reinfection.
3. These findings held true in multivariable analysis: for those previously infected or vaccinated, boosting at least 6 months or more after infection or vaccination provided significant protection against reinfection. For those with natural immunity, there was no advantage to more than 1 dose of vaccine after recovery.

**Superior protection of hybrid immunity negates the benefit of a booster mandate.**
Setting aside for a moment the question of boosting a person with immunity (either from vaccine or prior infection), it is important to consider the relative benefit of the primary series for a person who natural immunity from a prior SARS-CoV-2 infection. A systematic review and pooled analysis of the literature evaluated the equivalency of immunity among recovered persons compared to vaccinated persons.[34] The authors conclude that vaccination of COVID-recovered persons provides a modest incremental benefit but the absolute difference in infection rates is small. The number needed to vaccinate to prevent one infection annually in this review was 218 vs 6.5 in the COVID-recovered vs COVID-naïve, respectively, a 33.5-fold difference in benefit between the two populations.

For those with immunity established through vaccination, infection boosts the quality and quantity of antibody response in laboratory and international, real-world studies:

1. *Nature* paper reviewed antibody (humoral) response following infection, vaccination, hybrid immunity (infection *then* vaccination) and breakthrough (vaccination *then* infection).[35]
2. Study found no difference in antibody response following one vs. two doses of vaccine among those with prior infection, thus these two groups were studied in aggregate. [35]
3. Infection either before or after vaccination improves breadth, quantity and quality of immune response.[35]

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[33] Shrestha, et al. [preprint] https://www.medrxiv.org/content/10.1101/2022.02.10.22270744v1.full.pdf
[34] Shenai, et al. *Cureus* 2021. https://www.ncbi.nlm.nih.gov/labs/pmc/articles/PMC8627252/
[35] Bates, et al. *Nature* 2022. https://www.science.org/doi/10.1126/sciimmunol.abn8014

4. *NEJM* study in Israel found no difference in protection against subsequent infection with one vs two doses of vaccine among those with immunity from prior infection (natural immunity).[36]
5. Single dose of vaccine (Pfizer) provided 82% protection against reinfection among those aged 16-64. No significant difference in vaccine effectiveness was found for one dose as compared with two doses.[36]
6. Rates of infection during delta in California and New York were consistently higher among those who were vaccinated but had no history of infection compared to those with natural immunity (2-3x higher) or hybrid immunity (3-4x higher).[37]
7. Study in Qatar among a young adult population found prior infection conferred 56% protection against infection and 87.8% protection against hospitalization during the Omicron wave—comparable to the transient protection conferred by boosting.[38]

**Mucosal immunity stimulated by prior infection, not vaccination.**

The route of exposure is important to the subsequent immune response:

1. Vaccination delivers strong systemic protection against severe disease through serum (blood) IgG antibody production but stimulates very weak mucosal immunity (IgA).[39] Salivary IgA was detected following vaccination only in those who had first recovered from SARS-CoV-2.
2. A study of 26 Pfizer-vaccinated healthcare workers found a 5x boost in IgA antibodies following breakthrough infection.[40] The breakthrough infections provided broad cross-variant protection.
3. The longer the interval, the higher the potency and the higher the quality of antibodies.[41]

**Protections for the immunocompromised and medically vulnerable.**

Medically vulnerable populations are twice at risk: less likely to mount an immune response after the primary series and more likely to develop serious illness requiring hospitalization. A rapid review[42] evaluated the efficacy of an additional vaccine dose following any WHO-recognized vaccine platform 1-3 months after the last vaccine dose.

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[36] Hammerman, et al. *NEJM* 2022. https://www.nejm.org/doi/full/10.1056/NEJMoa2119497
[37] León, et al. CDC *MMWR* 2022. https://www.cdc.gov/mmwr/volumes/71/wr/mm7104e1.htm#T2_down
[38] Altarawneh H., et al. *NEJM* 2022. https://www.nejm.org/doi/full/10.1056/NEJMc2200133
[39] Azzi, et al. eBiomedicine (*Lancet*) 2022. https://www.thelancet.com/journals/ebiom/article/PIIS2352-3964(21)00582-X/fulltext
[40] Bates, et al. *JAMA* 2021. https://jamanetwork.com/journals/jama/fullarticle/2787447
[41] Miyamoto, et al. 2022. [preprint] https://www.medrxiv.org/content/10.1101/2021.12.28.21268481v1.full
[42] Parker, et al. *Lancet* 2022. https://www.thelancet.com/journals/langlo/article/PIIS2214-109X(21)00593-3/fulltext

1. Seroconversion (development of detectable antibody response) increased from 41% to 67%.
2. Reactogenicity (where reported) generally the same as the primary series; no safety concerns.
3. Prophylactic monoclonal antibodies offering 6 months of pre-exposure protection have been approved via EUA by the FDA for Evusheld (AztraZeneca)[43] for patients age 12 years and older. FDA notes the prophylaxis is not a substitute for vaccination.

**Summary**

Dr. Paul Offit, a member of the FDA vaccine advisory panel and Director of the Vaccine Education Center and an attending physician in the Division of Infectious Diseases at Children's Hospital of Philadelphia, is a widely recognized expert on and advocate for vaccines who maintains that the initial vaccination course is sufficient to protect against severe disease in most cases. Offit advised his own son, who is in his 20's, not to get a booster, stating, "[G]iven that two doses of an mRNA-containing vaccine are very likely to protect against severe illness, I'm even more convinced that we should hold off on pushing boosters when such an unusual variant is circulating . . . . [T]here may be benefits to waiting for a booster that's more tailored to a variant that is completely resistant to protection against serious illness afforded by the vaccine."[44]

While the vaccines appear to be relatively safe at a population level, like all medical interventions, they carry the potential for individual adverse health consequences, including severe ones. Evidence has emerged regarding the real risk of vaccine-induced myocarditis (heart inflammation), particularly for men under 40, like the student petitioning here. Multiple independent data sets suggest that vaccine-induced myocarditis occurs at rates 400 to 500% greater than the CDC's estimates and may in fact exceed the rates of COVID-related cardiac complications in healthy men under 40 years.[3] In other words, the risk of cardiac complications from the vaccine may be greater than the risk posed by COVID itself. As cardiologist Anish Koka has explained[45] the notion that myocarditis can be dismissed as "minor"—as CDC, FDA, and various other public health authorities have tried to do—is absurd. Not only does one suffer chest pain and leak cardiac enzymes from damaged heart muscle, but a third of patients are found

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[43] https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-new-long-acting-monoclonal-antibodies-pre-exposure

[44] Dr. Paul Offit, "No, We don't need boosters for all—just for some," The Philadelphia Inquirer (Dec. 29, 2021), available at https://www.inquirer.com/opinion/commentary/booster-covid-mandate-vaccine-pro-con-20211229.html (last visited Jan. 26, 2022).

[45] Koka, A. Declaration. Available at: https://nclalegal.org/wp-content/uploads/2022/01/Demand-Letter_GMU_Fellner-Darling.pdf

to suffer fibrosis and scarring in the heart, leaving them with an uncertain long-term prognosis. Furthermore, following diagnosis, young men are put on activity restrictions for 3 to 6 months.

For young women, recent evidence confirms anecdotal reports of menstrual irregularities following vaccination. A recent editorial in the *British Medical Journal* (BMJ), for instance, noted that "there is still much to learn. Scientifically, it will be important to characterize the mechanism by which post-vaccination menstrual changes occur," and acknowledged that more studies are needed to determine if vaccination affects fertility.[46] Another study found a change in cycle length (<1 day) but not menses length.[47] Young people age 18-29 are the CDC's reference group against which all other age groups are compared with respect to COVID-19 risk. As such, they should be given every opportunity to make independent decisions in the best interest of their own personal health and wellbeing. The vaccines lose potency against infection, and as such cannot offer long-term protection against transmission but do retain some limited protection against severe disease and hospitalization. Hybrid immunity offers the best possible protection against infection, and thus transmission, within the campus community. Vaccine mandates do little to stop transmission on campus, and they coerce students to make decisions which they may not have made otherwise.

Finally, it is important to note that the SUNY system *recommends* meningitis vaccination for new students but families can decline vaccination upon documentation that they acknowledge the risks of disease using the vaccine portal.[48] Measles, mumps and rubella vaccination is also required but either evidence of medical history of disease *or* documentation of immunity (antibody titer) is sufficient. The CDC surveillance reports clearly show that infants and adolescents/young adults in college are at greatest risk of vaccine-preventable bacterial meningitis[49] which has a case fatality rate (CFR) of 6.1% for the most predominant vaccine-preventable strain (MenB).[50] For comparison, the CFR for COVID-19 in this age group is 1 per 100,000 (0.001%) among unvaccinated 18-49 year-olds, and 0 per 100,000 among fully vaccinated (not boosted) individuals aged 18-49.[51] The risk of meningitis is therefore 6,100x greater than COVID-19 for unvaccinated students.

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[46] Male V. "Menstruation and covid-19 vaccination," *BMJ* 2022. https://www.bmj.com/content/376/bmj.o142
[47] Edelmen A. *Obstetrics & Gynecology* 2022. https://pubmed.ncbi.nlm.nih.gov/34991109/
[48] https://suny.oneonta.edu/health-wellness-center/new-students
[49] https://www.cdc.gov/meningococcal/surveillance/index.html#trends
[50] https://www.cdc.gov/meningococcal/downloads/NCIRD-EMS-Report-2019.pdf
[51] CDC MMWR Jan. 28, 2022. https://www.cdc.gov/mmwr/volumes/71/wr/mm7104e2.htm