



Date

Sent via certified mail and email Salutation First Name Last Name Title College Name Street Address City, State Zip

Dear Salutation Last Name,

My name is Spiro P. Pantazatos, PhD. I am an Assistant Professor of Clinical Neurobiology with training and experience in biomedical data science, applied statistics and clinical informatics at Columbia University Irving Medical Center. I, along with several colleagues, write to you today on behalf of No College Mandates and Liberty Now to share a letter we sent to leadership at Columbia University in New York. We hope you will consider the data presented herein when deciding vaccine policies for your students.

As background, in December 2021, I contacted the Columbia University COVID response Director to share vaccine safety research and global policy updates, including Moderna vaccine restrictions for young adult males in Nordic countries due to safety concerns [1,2], and to notify the university of my presentation at the Columbia COVID Symposium on age-stratified risk-benefit analysis using data-driven vaccine mortality risk estimates from publicly available US CDC data¹ [3]. To date, however, Columbia University still has not updated its COVID vaccine policies and guidelines. Hence, I prepared and recently sent my institution this letter which includes over 100 references and footnotes on why their policies and guidelines should be revised ASAP.

We request that your university update its vaccine policies and recommendations to reflect the most recent global data on the COVID vaccine and booster's (limited) effectiveness, especially in relation to their increasingly apparent and concerning safety signals such as unacceptably high rates of myocarditis in young adult males [4–6].

This letter serves to notify your university of potential liability for proceeding with the current COVID-19 vaccination policy, which is based on the unfounded assumption that vaccines and boosters are sufficiently safe, necessary and effective in implementing its COVID-19 vaccine policies, especially for students who are mostly 24 years old or younger, which could potentially put your university's endowment at risk.

Please see the references in this letter so the university can verify whether or not the university should rely on recommendations from public health agencies.

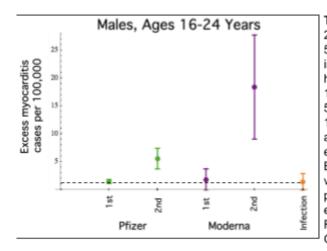
Please be advised that your university's COVID vaccine policy makers should not blindly trust the FDA and CDC claims regarding the risk-benefit of COVID-19 vaccines when making decisions on University-wide vaccine policy. Despite promising full transparency regarding the COVID-19 vaccines², the FDA had to be sued by NYC-based law firm Siri & Glimstad in September, 2021 just to release the Pfizer safety data they relied

¹See also this interview <u>https://www.bitchute.com/video/J0Q2VPVyckxF/</u> by Perspectives on the Pandemic whose first interviewee was John Ioannides at Stanford University. It was censored by Youtube and is available only on other sites. ²<u>https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-announces-advisory-committee</u> <u>-meeting-discuss-second-covid-19-vaccine</u>

upon to issue the EUA and approval of the Pfizer vaccine (documents which should have been in the public domain to begin with)³. Moreover, the FDA requested the federal judge give them 75 years to release them⁴.

Fortunately, the judge denied the FDA's request and ordered them to promptly release the documents. The first set of documents, released in March, 2022, show that 42,086 adverse events (AEs), including 1,223 deaths, 932 hematological, 1,403 cardiovascular, and 1050 autoimmune events were reported in the first 3 months of the Pfizer vaccine rollout⁵. These events occurred within a median of 1 day or <24 hours, evidencing a causal link to the vaccine that cannot be explained by propensity to report over time [7]. However, the Pfizer vaccine (marketed as Comirnaty) fact sheets for healthcare providers and patients do not mention any of these severe AEs other than myocarditis⁶. Moreover, neither the fact sheets nor the CDC links cited in the fact sheets⁷ mention incidence rates for myopericarditis, and simply claim vaccine benefits outweigh the risks *without providing any supporting data*.

As of June 29th, 2022, the CDC indicates that 15,312 US deaths following COVID-19 vaccination have been reported to the Vaccine Adverse Events Reporting System (VAERS). While the fraction of deaths having an established causal association with vaccination has not yet been published, the CDC has used VAERS to report a crude mortality rate 0.0026%⁸. This risk is *higher* than the risk of death following infection with omicron in young adults⁹. In response to recent FOIA requests, the CDC has admitted they did not follow their own standard procedures for monitoring 'early warning safety signals'¹⁰, and apparently did not even begin looking at those signals until April 2021, 4 months after the vaccination program began¹¹. In January, 2022 the CDC director admitted vaccines cannot prevent transmission of currently circulating variants.¹² There is therefore no justification to mandate or recommend vaccines or boosters to University undergraduate and graduate students, or any University staff or faculty member who does not wish to take them.



The cure may be worse than the disease. Among 23,122,522 Nordic residents (81% vaccinated by study end; 50.2% female), 1,077 incident myocarditis events and 1,149 incident pericarditis events were identified (Karlstad et al, https://doi.org/10.1001/jamacardio.2022.0583). Among males 16 to 24 years of age, adjusted incident rate ratios (IRRs) were 5.31 (95% CI, 3.68-7.68) for a second dose of BNT162b2 and 13.83 (95% CI, 8.08-23.68) for a second dose of mRNA-1273, and numbers of excess events were 5.55 (95% Cl, 3.70-7.39) events per 100,000 vaccinees after the second dose of BNT162b2 and 18.39 (9.05-27.72) events per 100,000 vaccinees after the second dose of mRNA-1273. Estimates for pericarditis were similar. For reference, dashed line indicates estimated excess cases of myocarditis following infection. Figure credit: Paul Bourdon, Professor of Mathematics, General Faculty at the University of Virginia (Retired).

³See <u>https://aaronsiri.substack.com/p/fda-asks-federal-judge-to-grant-it?s=r</u> and

https://phmpt.org/wp-content/uploads/2021/10/001-Complaint-101021.pdf

⁴<u>https://www.reuters.com/legal/government/wait-what-fda-wants-55-years-process-foia-request-over-vaccine-data-2021-11</u> -18/

⁵<u>https://phmpt.org/wp-content/uploads/2022/04/reissue_5.3.6-postmarketing-experience.pdf</u> (see Table 2 and 7).

⁶See PostMarketing Experience under Warnings in <u>https://labeling.pfizer.com/ShowLabeling.aspx?id=15623&format=pdf</u> ⁷<u>https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html</u>

⁸See <u>https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html</u>

⁹The wild type/delta infection fatality rate for ages 25 yrs is 0.01%. Omicron is 1/10th as deadly (see Lewnard et al. in refs) ¹⁰<u>https://www.ronjohnson.senate.gov/services/files/9914278B-A73B-4434-8349-91091138E18B</u>

¹¹ https://jackanapes.substack.com/p/new-foia-release-shows-cdc-lied-about

¹²https://www.msn.com/en-us/health/medical/cdc-director-covid-vaccines-cant-prevent-transmission-anymore/ar-AASDndg

The Hippocratic Oath says "First, do no harm". On the basis of the above facts alone, the University-wide COVID-19 vaccine mandates should be lifted immediately and guidelines and recommendations adjusted accordingly in order to provide fully informed consent regarding vaccine and booster risks.

The rest of this letter elaborates and provides supporting data on the following four points (the references below mention Columbia University (CU) but are generally applicable):

- A. Vaccine risks outweigh the benefits in most age groups, and particularly in adolescents and young adults where the infection mortality risk is extremely low (i.e. 0.003% and 0.006% in ages 15-19 and 20-24 respectively [8] who are the majority age group facing the mandates), and the vaccine risks appear to increase with each dose or booster.
- B. Vaccines do not measurably reduce transmission and community spread. The originally stated purpose of most University vaccine mandate policies (i.e. to prevent COVID transmission and community spread) is not (and never was) backed by empirical evidence.
- C. Vaccination is both unnecessary, and more risky, in individuals with previous coronavirus infection. Most university policies ignore the substantial body of evidence documenting robust and durable natural immunity and increased risks of vaccine adverse reactions in those with previous infection. As of February 2022, about 75% and 67% of adolescents 12-17 and adults ages 18-49 respectively had infection-derived immunity and these proportions are likely higher today [9].
- D. Publications and sources that claim or imply sufficient vaccine safety and favorable risk-benefits profiles are untrustworthy and unreliable because their raw data are inaccessible or their claims are not backed by supporting data or contradict existing evidence, especially for the student age population.

In light of the evidence presented herein, we urge the following actions and remediations be taken ASAP following receipt of this letter:

- The vaccine and booster mandates should be lifted immediately, and any official University guidance and recommendations should be updated to provide true informed consent about vaccine safety risks. This includes removing vaccine requirements regarding access to campus and updating the University website which may contain misinformation about the safety, effectiveness and risk-benefit of the COVID vaccines, as necessary. It causes more harm to mandate primary series vaccinations against variants that are no longer in circulation [10] and boosters that carry much higher risks relative to low-lethality omicron variants.
- 2. Replace any policy making bodies which mandated COVID vaccines (such as the Task Force at Columbia)¹³ with a more robust and inclusive method for deciding future University-wide health policy decisions. Columbia University's leadership and COVID task force failed to conduct reasonable due diligence to ensure the safety and health of the Columbia community. Perhaps your University had a similar policy making body. University-wide mandates impact the lives and well-being of not only Columbia members but other universities who take cues from the Ivy League, and they should not be made by a few specialists with little interdisciplinary expertise, viewpoint diversity and capacity to think critically and independently from bureaucracies with extensive financial conflicts of interest, and without soliciting input and debate with the wider University community.
- 3. Any University employee who was "suspended without pay" for refusing COVID vaccination, or whose medical or religious exemption request was denied, should be fully compensated for their lost wages. These coercive tactics are not ethical [11–14], and especially for an experimental therapeutic whose effectiveness and safety risks are being obfuscated or whitewashed by those profiting from the product (see Section D below).
- 4. Any University member who took the vaccine because of the mandate, and who was injured or suffered systemic and long-lasting side effects from the vaccine that negatively affected their ability to work and function, should be offered a fair and generous opportunity to apply for compensation. A well-publicized

¹³The decision was based on "strong recommendation...(from CUIMC) public health colleagues", see <u>https://web.archive.org/web/20220605232227/https://covid19.columbia.edu/content/covid-19-vaccine-mandate</u>). The decision was apparently made over the course of a single Zoom call with support from only a handful of specialists with little viewpoint diversity and formal procedure for debating pros and cons (<u>https://news.columbia.edu/news/how-and-why-columbias-vaccine-mandate-worked</u>).

strategy and procedure for identifying and assisting such individuals should be implemented. Commit resources to promote research and development of interventions for vaccine injury.

5. Provide any and all documents related to how and why the University COVID policy making body decided to mandate COVID (as well as influenza) vaccination including key decisionmaker's full financial disclosures and any ties with industry or other funding sources that could be perceived as a financial conflict of interest regarding the mandate.

It is critically important that university leadership give full and fair consideration and attention to all available evidence regarding vaccine risks and benefits because the current policies may be exposing University members to unnecessary medical risks and without true informed consent based on reliable global data [13]. In my view, university mandates clearly violate international human rights and informed consent standards as set forth by the Universal Declaration on Bioethics and Human Rights adopted unanimously by 193 countries including the US in 2005.¹⁴

Mounting evidence suggests that mRNA vaccines, particularly the PEG and spike glycoprotein components of all currently available COVID vaccines, are linked to increased risk for innate immune suppression and autoimmune, thrombotic, and cardiovascular side effects [5,10,12,84]. This letter serves to notify the university of potential liability for proceeding on the unfounded assumption that vaccines and boosters are sufficiently safe and effective in implementing its COVID-19 vaccine policies, especially for University students who are mostly 24 years old or younger. These misguided policies could potentially put the University's endowment at risk.

At Columbia University, I have emailed and offered to meet with University leadership and decision makers several times since late summer 2021, and most recently in early June 2022, to present the current state of knowledge on vaccine safety research. I received one response in December 2021 from the University COVID response director.

Please see the references in this letter so the University can verify whether or not the University should blindly rely on recommendations from conflicted public health agencies. This letter also serves to notify the university that it may not be enough to rely on public health authorities to protect the university when global data clearly contradict the recommendations upon which the University's policy relies. We hope this letter will ultimately help to restore sanity and trust in the University's public health policies and responses.

Please do not hesitate to let us know if we can be of service in guiding your University's COVID vaccination policies in the future. Given the imminent deadlines for students to submit their exemption requests for Fall 2022, please respond to this letter via email (CC kevin@mermigislaw.com) within one week of receiving the letter. We provide a preliminary list of co-signers below and links to the online version of the Columbia University letter which will be updated to include additional references as well as additional signatures which may be collected in August and this fall.

Sincerely,

Spiro P. Pantazatos, PhD Assistant Professor of Clinical Neurobiology at Columbia University Irving Medical Center Email: spp2101@columbia.edu

http://portal.unesco.org/en/ev.php-URL_ID=31058&URL_DO=DO_TOPIC&URL_SECTION=201.html)

¹⁴ Article 3 on Human dignity and human rights states: 1. Human dignity, human rights and fundamental freedoms are to be fully respected. and 2. The interests and welfare of the individual should have priority over the sole interest of science or society. Article 6 on Consent states: 1. Any preventive, diagnostic and therapeutic medical intervention is only to be carried out with the prior, free and informed consent of the person concerned, based on adequate information. The consent should, where appropriate, be express and may be withdrawn by the person concerned at any time and for any reason without disadvantage or prejudice. (see

CU co-signers

Brian E. Scully, MD Professor of Medicine at Columbia University Irving Medical Center (CUIMC) (Division of Infectious Diseases) and co-chair of Joint Infection Control Committee and Joint Antimicrobial Subcommittee of the Pharmacy Committee

Eric Urban, PhD Professor of Mathematics and Director of Graduate Studies Department of Mathematics at Columbia University

Claire-Marie Vacher, PhD Assistant Professor at CUIMC (Department of Pediatrics) NewYork-Presbyterian Morgan Stanley Children's Hospital

Non-CU co-signers

Kevin M. Barry, Esq. Mermigis Law Group 85 Cold Spring Rd. Syosset, NY 11791 kevin@mermigislaw.com Libertynow.world, Co-Founder

Ioannis Papazoglou, PhD

Shaun R. Barcavage, FNP-BC Research Nurse Practitioner at Weill Cornell Medicine Research Director at React19 (<u>https://react19.org</u>)

Living document

This letter is adapted from the letter that was sent to leadership at Columbia University (CU) that has garnered ~850 CU and other university affiliate signatures as of September 29th, 2022. The CU letter is a living document and contains the most up-to-date version of this letter. To view the CU letter please see https://tinyurl.com/27djpkrf or the below QR code.



<u>A. The CU-wide vaccine mandate violates medical ethics and the principles of personalized medicine.</u> <u>Quantitative risk-benefit assessments using published and publicly available data show that vaccine risks</u> <u>outweigh the benefits, especially in age groups that comprise the majority of CU</u>

- 1. A stated purpose of mandating the primary series (mandated April 19th, 2021) and 3rd booster dose (mandated in December, 2021) was "ensuring the health of Columbia students and the broader University and surrounding community".¹⁵ The decision considered only the (temporary) vaccine benefits on COVID outcomes and ignored the costs including potential life-altering injury or death resulting from other causes such as autoimmune disorders, myocarditis, heart attack, or stroke.
- 2. For a medical treatment to be ethical, the benefits of the treatment need to outweigh the risks of no treatment, or the risks of an alternative treatment. A treatment's risk-benefit ratio can vary widely depending on the population or individual and the disease in question. This is especially true for COVID-19, where the risks of hospitalization and death resulting from an infection decrease substantially as a function of age. For example, a 25-year-old has >100 fold less risk of death if infected (wild type/delta) with no prehospital treatment (<0.01%) than a 75 year old (>1%) [8,15].
- 3. A possible risk of myocarditis caused by the Pfizer vaccine in young adult males was first reported by the Israeli Health Ministry in April, 2021.¹⁶ A 25x fold increased risk of myocarditis following Pfizer 2nd dose (between 1 in 3000 to 6000 2nd doses, or 0.02-0.03%) in men ages 16-24 yrs was then reported by the same agency in June, 2021¹⁷.
- 4. In June, 2021 the US FDA added a warning to Fact Sheets for Healthcare Providers Administering Vaccines, noting that "reports of adverse events suggest increased risks of myocarditis and pericarditis, particularly following the second dose and with onset of symptoms within a few days after vaccination [16]." However, to this day, neither the fact sheets¹⁸ nor the CDC links cited in the fact sheets¹⁹ mention myopericarditis incidence rates following vaccination, and simply claim vaccine benefits outweigh the risks *without providing any supporting data*. Comparing incidence rates of myopericarditis and other severe adverse events (AEs) of vaccination vs. natural infection are critical for risk-benefit analyses by age, sex and other COVID risk factors. Prior to 2022, studies of myocarditis studies through August, 2021 identified 54 case reports and 5 cohorts (only 215 patients total) [17]), further underscoring the fact that the FDA, CDC and Pfizer had no basis to claim that benefits of vaccinating young adult males outweighed the risks in their warnings about myocarditis in June, 2021.
- 5. Myocarditis incidence rates following mRNA vaccination similar to or higher than those initially reported by Israel have since been replicated and confirmed by a number of peer reviewed studies using passive surveillance [4], hospital EMR [5,6], and national health registries [12,18]. By early fall, 2021 the risk of myocarditis was deemed high enough that Nordic governments suspended the Moderna vaccine in males <30 years old [1,2]. A few recent articles claim myocarditis risk following infection is higher than vaccination but appear to be motivated only to provide a "post hoc" justification for COVID vaccination in young males in response to the above reports. For example, Rafaniello et al. claimed myocarditis risk following infection is 1k-4k cases per 100k without citing any source and used VAERS to report rates of myocarditis following vaccination in males ages <24 yrs old that are 15 to 30 times lower than conservatives estimates by Oster et al. which also used VAERS [19]. Singer et al. reported myocarditis risk following infection based on only 6 cases identified in an EHR is that not publicly accessible [20].</p>
- 6. CU vaccine guidelines ignore the substantial body of evidence showing unacceptably high risk of myocarditis following vaccination, especially in young males. As of July 18th, 2022 the CU FAQ²⁰ on vaccine safety (see D.Q5 "How safe are the vaccines?)" only mentions risks associated with the J&J vaccine (i.e. blood clotting and low blood platelets), while there is ZERO mention of the myocarditis risk

 ¹⁵https://web.archive.org/web/20220605232227/https://covid19.columbia.edu/content/covid-19-vaccine-mandate
 ¹⁶https://ottawacitizen.com/news/world/israel-finds-heart-inflammation-in-people-who-received-pfizer-covid-19-shot
 ¹⁷https://ottawacitizen.com/news/local-news/increased-risk-of-heart-muscle-inflammation-linked-with-mrna-vaccines-seen-in-ottawa

¹⁸See PostMarketing Experience under Warnings in <u>https://labeling.pfizer.com/ShowLabeling.aspx?id=15623&format=pdf</u> ¹⁹<u>https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html</u>

in young males following Pfizer or Moderna vaccination, despite the fact that conservative estimates of the risk (100 cases per million based on Oster et al. [4]) is over 10x higher than risk of blood clots quoted in the CU FAQ (7 cases per million). This leads to reasonable conjecture that key decision makers involved in CU's mandate may have financial ties with Pfizer and/or Moderna.

- 7. CU vaccine guidelines simply echo CDC recommendations and ignore increased risks when mixing vaccine brands. For example, regarding mixing and matching vaccine types, CU advises that "Some people...may prefer to get a different booster. CDC's recommendations now allow for this type of mix and match dosing for booster shots."²¹ A large study of Nordic health registries (>23M persons) found the risk of myo/pericarditis resulting in hospitalization in males ages 16-24 post Pfizer-Moderna combination was 380/1M (1/2600), which is 28x higher than the 13.7/million rate they found post-covid infection [21]. A similar study using the Ontario health registry (>14M persons) found an even higher rate up to 777/1M (1/1287) in males 18-24 yrs old post Pfizer-Moderna combination [22].
- 8. Even with a homologous vaccine schedule, risk of myocarditis following vaccination is higher than following natural coronavirus infection. A study of ~38M people in the English National Immunisation (NIMS) Database estimated about 10 cases of myocarditis per million exposed within 4 weeks following natural infection in ages <40 yrs (see Figure 2 in [18]). In males ages 12-24 yrs, Oster et al. reported 70-100 cases of myocarditis per million mRNA vaccine doses in the first week post-injection based on passive surveillance (VAERS) [4], while Sharff et al. used a subset of Vaccine Safety Datalink (VSD) in 65K patients to estimate ~370 to 530 myocarditis cases per million 2nd doses using a longer risk window [5,6]. In other words, young males are 5-10x more likely to develop myocarditis following the 1st dose, and up to 50x more likely following a second dose, than following infection.</p>
- 9. Oster et al. compared risk of myocarditis within a one-week risk interval following 1st and 2nd dose of mRNA vaccines to expected background rates. In males 12-15 yrs old, 70 cases per million 2nd doses was 133x higher than the expected background rate, while in males 16-17 yrs old 106 cases per million 2nd doses was 79x higher than the expected background rate (see Table 2 in Oster et al. [4]). The actual risk of myocarditis is likely higher [5,6,23] since VAERS is a passive reporting system and because Oster et al. only examined a one week risk window and other studies suggest the risk of myocarditis remains similar or is higher in the 2nd week post-injection [18,24].
- 10. Incidence rates for other severe AEs are difficult to discern from the medical literature, owing to the facts that a) such critical information is obfuscated or outright whitewashed in many articles due in large part to well-known financial conflicts of interest between medical journals, institutions and pharma companies [25,26]; b) most academics and clinicians do not have the time or the expertise to critically examine published studies and instead must rely on their headlines for key takeaways, and c) research that challenges vaccine safety is systematically suppressed. For example, MedRXiv reserves the right to refuse any preprints that "challenge or could compromise accepted public health measures and advice regarding infectious disease transmission, immunization, and therapy" (see MedRXiv FAQ).
- 11. The CDC website claims the COVID vaccine benefits "far outweigh the risks" but remarkably does not cite any formal quantitative risk-benefit ratio analysis to back up the claim²². Influential studies that claim sufficient vaccine safety based on the Vaccine Safety Datalink (VSD) [27,28] may have under- or misreported risk for severe AEs including acute myocardial infarction, pulmonary embolism and death [3]. The raw data used for the VSD are not publicly accessible, and one or more authors report funding from Pfizer, indicating a lack of transparency and suggesting FCOI may have influenced conclusions.
- 12. The FDA's recommendation to administer a single homologous Pfizer booster dose to individuals 16 to 17 years of age was based on a risk-benefit assessment (conducted by Pfizer) and also discussed data from Pfizer's placebo-controlled booster clinical trial which include 78 individuals ages 16-17 yrs old (out of 10,125 total in in the trial)²³. Even with only ~39 participants in the booster arm, *1 case of myopericarditis was observed*, while 2 cases of symptomatic COVID-19 (neither resulting in hospitalization) occurred in the placebo arm in this age group. In their risk-benefit analysis, Pfizer

²¹Eligibility section in <u>https://covid19.columbia.edu/content/faqs-regarding-covid-19-vaccination</u>
²²<u>https://www.cdc.gov/coronavirus/2019-ncov/vaccines/vaccine-benefits.html</u> and
<u>https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html</u>
²³<u>https://www.fda.gov/media/154869/download</u>

predicted that boosters would prevent 29-69 COVID-associated hospitalizations per 1M booster doses (see [29] for sources of model misspecification that that can bias such estimates) which would come at a cost of 11-54 and 23-69 myopericarditis cases per 1M booster doses in 16-17 and 16-19 yr age groups, respectively (see Table 1 on pg 7 of the memorandum). First, 'COVID-associated hospitalizations' is not a good comparison with myocarditis cases because 'COVID-associated hospitalizations' need not be *due* to COVID²⁴. Second, Pfizer's own analysis suggested boosters would prevent as many 'COVID-associated hospitalizations' as myocarditis events following boosters. Third, Pfizer's myocarditis incidence rates used for their risk-benefit assessments are for the 2nd dose (not booster), and the risk is underreported since it is based on passive surveillance (VAERS). Marks goes on to note that Pfizer's estimates of myocarditis risk post 2nd-dose in 16-17 year old males is about 6-7x lower than the risk estimated by the FDA's own analysis of the Optum healthcare claims database (200 cases 1M). In other words, the letter presents data suggesting boosters will cause 6-7x more cases of myocarditis (most of which result in hospitalizations) than a 'best case scenario' estimate of hospitalizations prevented in males 16-17 yrs old (assuming Pfizer's assumptions about effectiveness against hospitalizations were accurate), and yet still recommended the booster for this group.

- 13. A CDC presentation to the Advisory Committee on Immunization Practices (ACIP) on September 23, 2021 included a risk-benefit analysis on boosters stratified by age²⁵. According to the author, 8,738 booster doses are needed to prevent one hospitalization (Slide 45) and 24 cases of myocarditis per 1M doses are expected in 18-29 year-old males (Slide 46). The author concludes the (booster) risk-benefit is "most favorable for adults ≥65 years of age using current estimates of vaccine effectiveness" while there is "uncertainty around the balance of benefits and risks" for younger populations and acknowledges that the risks of myocarditis after a 3rd dose is unknown (see Slide 47). The authors' myocarditis risk estimate (24 cases/1M 2nd doses) underestimates the risk in young males 18-24 yrs old by 2-20x (Oster et al. used passive surveillance to estimate 50 cases/1M 2nd doses in the first week post-injection [4] and Sharff et al. used VSD to estimate over 500 cases/1M 2nd doses in this age group [5].)
- 14. In a study of the Israeli Defense Forces, Friedensohn et al. report rates of 64.3 and 112.5 cases of myocarditis in per 1M Pfizer booster (3rd) doses in males 18-24 yrs old in the first week and 2nd week, respectively [24]. The actual estimates within the accepted risk window of 6 weeks post-injection [30] is at least 20% higher (>200 cases per 1M) since the authors excluded 2 of 9 myocarditis cases because one was preceded by COVID-19 infection and another occurred >2 weeks post-injection. The 64.3 cases per 1M boosters is higher than the 50.7 cases per 1M 2nd doses in the first week post-injection reported by Oster et al. [4], though methods and cohorts differ between the two studies.
- 15. A simple, back-of-the-envelope comparison of previously published age-stratified infection fatality rates (IFR) [15,31] with CDC-reported vaccine mortality risk shows the risk of vaccination or boosting against omicron outweigh the benefits in undergraduate and graduate students. The omicron IFR for age 25 is roughly 0.001% (0.01% for wild type/delta variants [15] times 1/10 lethality of omicron [32]), which is *lower* than the CDC-reported vaccine mortality risk of 0.0026%²⁶.
- 16. The CDC-reported mortality risk is based on the Vaccine Adverse Events Reporting System (VAERS). However, VAERS is a passive reporting system and may only capture ~1% of all vaccine-related side effects [33]. Fewer than 1% of VAERS death reports are unconfirmed. An analysis of VAERS reports from December 14th, 2020 through June 14th, 2021 published in Lancet Infectious Disease reports that "Of 4496 deaths, [only] 25 were excluded as they could not be confirmed or were duplicate reports upon review" [34].
- 17. Rose and Crawford derived data-driven estimates of the under-reporting factor (URF) for anaphylaxis, a potentially life-threatening severe allergic reaction to vaccine components, in order to infer the VAERS URF for vaccine-induced death [7]. They compared the incidence rate of anaphylaxis following mRNA COVID vaccination reported by Blumenthal et al. (~2.5 per 10,000) based on active surveillance of 60K

²⁴ https://gis.cdc.gov/grasp/COVIDNet/Documents/320393-A_COVID-NET_cumulative-qeo2.pdf

²⁵ https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-9-23/03-COVID-Oliver.pdf

²⁶Calculated by dividing the number of VAERS death reports divided by the number of doses administered (see <u>https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html</u>). The actual risk is higher since the calculation does not account for the VAERS under-ascertainment bias.

healthcare workers [35], to the incidence rates calculated using VAERS to estimate a 41-fold URF for anaphylaxis. In reporting the safety of mRNA vaccines with respect to anaphylaxis incidence, the CDC cites estimates which are based on VAERS²⁷ but does not cite the Blumenthal et al. study, thus the CDC underreports the risk of anaphylaxis following mRNA vaccination by a factor of 41x.

- 18. The primary author of this document applied ecological regression to publicly available US CDC vaccination and all-cause (and non-COVID) mortality data [3]. Results show that vaccination rates *positively predict mortality* differences across states within one month post-injection while controlling for prior year deaths. Results from fitted slopes suggest the COVID vaccine mortality risk may be 20x higher then the CDC-reported risk (i.e. an URF of 20x for death). These estimates are strikingly similar to estimates by Rose and Crawford and others based on data-driven estimates of the VAERS URF and conservative estimates of VAERS reports confirmed to be caused by the vaccines [7], providing independent validation of these results which use distinct datasets and methods. Despite amassing >500K views and receiving desk rejections from numerous medical and public health journal editors and two rounds of peer-review, the preprint has yet to receive substantive critiques that refute or contradict the main findings and conclusions²⁸ (see the Comments section of the preprint [3] which has functioned as an open pre publication peer review). The raw data and user-friendly tables and code are publicly available²⁹ allowing anyone to easily access, inspect, reanalyze and/or refute the results in contrast to most, if not all, studies that claim or conclude favorable vaccine risk-benefit profiles.
- 19. Associations between vaccination and mortality within the accepted vaccine risk window post-injection (6-weeks) meets all 10 Bradford Hill Criteria for causality in epidemiology (the World Health Organization requires that only 5 are met to demonstrate causality)³⁰. The Pfizer post-marketing safety data which FDA relied on to approve Comirnaty show that life-threatening adverse events (i.e. 932 hematological and 1,403 cardiovascular events) occurred within *a median* of 1 day or <24 hours post-injection, further evidencing a causal link between vaccination and AEs.³¹
- 20. Young women are also at increased risk of myocarditis relative to background rates following vaccination [4]. In addition, survey data suggest that both premenopausal and postmenopausal women experience disrupted menstruation patterns or heavy bleeding at high rates (between 13% to 66% of survey respondents) following COVID vaccination, which could be indicative of more serious side effects that warrant further investigation³².
- 21. The cardiovascular events safety signal was strong enough to be detected in Emergency Medical Services (EMS) call data. Using Israeli national EMS data, Sun et al. found a 25% increase in cardiac emergency calls among ages <40 yrs that were caused by vaccine rollout but not COVID waves [36].
- 22. Since November, 2021, the UK Office of National Statistics (ONS) has consistently reported higher age-standardized mortality rates (ASMR) for vaccinated vs. unvaccinated for deaths due to all causes, and since April, 2022 ONS has reported higher ASMR in vaccinated vs. unvaccinated for deaths involving COVID-19³³. The latter is consistent with previous predictions and observations of enhanced respiratory disease via antibody dependent enhancement based on preclinical studies [10,37–39].

<u>B.</u> Contrary to the stated reasons for the CU vaccine mandate, there is little to no evidence that vaccines reduce transmission, infection or community spread. Evidence instead suggests they increase infectivity in the first week post-injection.

²⁷https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html

³¹https://phmpt.org/wp-content/uploads/2022/04/reissue_5.3.6-postmarketing-experience.pdf (see Table 2 and 7).
 ³²https://www.science.org/content/article/thousands-report-unusual-menstruation-patterns-after-covid-19-vaccination
 ³³https://www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/deaths/datasets/deathsbyvaccination
 statusengland (see Table 1 in Excel Spreadsheet downloads)

²⁸https://justthenews.com/politics-policy/coronavirus/monivy-league-researcher-hits-brick-wall-medical-journals-covid-vaccing

²⁹https://github.com/spiropan/CoVFR

³⁰<u>https://jessicar.substack.com/p/the-bradford-hill-criteria?s=w</u>. Note there is an error in Slide #3 which plots vaccine doses vs. disabilities as it does not adjust for population size which is a confound. See Reference 3 for similar plots of vaccine doses vs. all-cause mortality that do adjust for population size.

- 1. The CU vaccine mandate was announced with the expressed purpose to reduce transmission and community spread of COVID-19 on campus. The CU FAQ claims that "All three of the vaccines currently in use in the US have been shown to substantially reduce spread of the virus."³⁴ However, there is no empirical evidence showing that COVID vaccines reduced transmission and spread of Sars-CoV-2. None of the three vaccine clinical trials required regular COVID testing in the participants, and were thus not designed to test efficacy against pauci- or asymptomatic infection [40–42]. The Moderna [40] and J&J [42] trials confirmed COVID-19 with laboratory testing only in subjects that reported moderate to severe COVID symptoms. None of the three clinical trials claimed the vaccines reduced infection or transmission.
- 2. To date, there is little to no evidence that the vaccines reduce transmission or spread. One report claiming vaccination reduced infection and seroprevalence was based on a relatively small total sample size (~8.5K individuals) and a difference of only 22 cases between vaccinated and unvaccinated groups with an infection absolute risk reduction of 0.6% from 0.8% to 0.2% [43].
- 3. A July, 2021 CDC study was among the first to report a higher rate of infection and viral loads in vaccinated ("breakthrough infections") vs. unvaccinated [44]. Since then, a number of studies have reported similar or higher infection rates and/or viral loads in vaccinated vs. unvaccinated or those with infection-derived immunity³⁵ [45–55].
- infection-derived immunity³⁵ [45–55].
 In January, 2022 the CDC director Dr. Walenksy stated that the vaccines "can't prevent transmission anymore".³⁶ Dr. Deborah Birx, White House Coronavirus Response Coordinator from 2020-2021 admitted that she knew "these vaccines were not going to protect against infection and …we overplayed the vaccines".³⁷
- 5. Anecdotal and empirical evidence from both clinical trial and real-world data suggest the vaccines *increase* transmission and infectivity within the first week post-injection³⁸. A reanalysis [56] of a large Israeli real-world study (>1M persons) shows infections increased almost 3-fold in the first week post-injection (see Figure 1 in [29] which plots values from Table S7 Discrete Time Hazard per 100,000 in Vaccinated column in Dagan et al. 2021 [57]).

<u>C. CU's vaccine policy and guidelines contradict basic principles of immunology and data on increased vaccine</u> <u>AE risk with previous infection</u>

- CU advises that "vaccination should be offered to persons regardless of history of prior symptomatic or asymptomatic coronavirus infection, including a positive antibody test. For...COVID-19 long-haulers vaccination is similarly considered safe and likely efficacious³⁹."
- 2. This advice contradicts basic immunology and virology, which has taught us over a century that natural immunity confers protection against a respiratory virus's outer coat proteins, and not just one, e.g. the SARS-CoV-2 spike glycoprotein. Over 150 research studies support robust and durable natural immunity against COVID-19 resulting from coronavirus infection⁴⁰. A Cochrane methodology review of 11 large cohort studies (>600,000 with laboratory-confirmed COVID-19) estimated that the risk of reinfection over a 10 month period is between 0 and 1.1% [58]. A recent real world study of >2.5M medical records [59] concluded "Effectiveness of primary infection against severe, critical, or fatal COVID-19 reinfection was 97.3% (95% CI: 94.9- 98.6%), irrespective of the variant of primary infection or reinfection, and with no evidence for waning".
- 3. According to a FOIA request to the CDC, there is no documented case of an unvaccinated individual who transmitted the virus to another person after being reinfected with coronavirus⁴¹.

³⁴See Question D.9 in <u>https://covid19.columbia.edu/content/faqs-regarding-covid-19-vaccination</u> ³⁵<u>https://brownstone.org/articles/16-studies-on-vaccine-efficacy/</u>

³⁶<u>https://www.msn.com/en-us/health/medical/cdc-director-covid-vaccines-cant-prevent-transmission-anymore/ar-AASDndg</u>
³⁷ <u>https://twitter.com/SKMorefield/status/1550586541239635969</u>

³⁸ https://www.hartgroup.org/it-gets-worse-before-it-gets-better/

³⁹Question 19 in <u>https://covid19.columbia.edu/content/faqs-regarding-covid-19-vaccination</u>

⁴⁰<u>https://brownstone.org/articles/79-research-studies-affirm-naturally-acquired-immunity-to-covid-19-documented-linked-and-quoted/</u>

⁴¹https://www.swfinstitute.org/news/89518/foia-cdc-admits-no-record-of-unvaccinated-person-spreading-covid-after-recove ring-from-covid

- 4. CU's claim that vaccinating individuals with previous infection is as safe as vaccinating individuals without previous infection is misleading and false. Many studies have documented 1.5 to 2-fold higher risk for side effects, including severe AEs leading to hospital care, in vaccinees with previous infection⁴² [60–66].
- 5. Last year, George Mason University (GMU) was sued by a professor who claimed their COVID-19 vaccine mandate violated his federal and constitution rights because vaccination was unnecessary due to his natural immunity and also put him at greater risk. After reviewing the evidence in his suit, GMU granted the professor a medical exemption to the vaccine.⁴³

<u>D. Studies or sources that claim sufficient vaccine safety and favorable risk-benefit profiles are not trustworthy</u> <u>or reliable</u>

- 1. Official CDC and FDA guidance regarding COVID-19 vaccines are untrustworthy⁴⁴ due to well-known and extensive financial conflicts of interest and the well-documented "revolving door" [26,67].
- 2. Safety analyses in the original clinical trials were only required (by the FDA) to have a median follow-up duration of 2 months after the 2nd dose. The Moderna trial reported "the participants had a median follow-up duration of 64 days (range, 0 to 97) after the second dose, with 61% of participants having more than 56 days of follow-up" [40]. By mathematical definition, 39% of the participants could have had a follow-up of 0 days.
- 3. The Moderna clinical trial abstract claims "serious adverse events were rare, and the incidence was similar in the two groups", but their safety data tables show unacceptably high rates of solicited grade 3 or 4 adverse reactions in the vaccine group (5% and 20% incidence rates after 1st dose and 2nd dose, respectively, see Supplementary Tables 3 and 4 in [40]). A grade 3 adverse reaction is defined as "Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self care" and grade 4 adverse reaction is defined as "Life-threatening consequences; urgent intervention indicated." [68]
- 4. In depth examinations of the UK Office for National Statistics (ONS) vaccine mortality surveillance reports show that claims of mortality benefits of vaccination are misleading and may result from systemic mis-categorisation of vaccine status, delayed or non-reporting of vaccinations, systemic underestimation of the proportion of unvaccinated; and/or incorrect population selection for Covid deaths [69–71].
- 5. Pro-vaccine modeling studies [72] report grossly inflated estimates of lives saved from mass vaccination and lack face validity due to model misspecification. This misspecification results from inaccurate assumptions about infection- and vaccine-derived immunity and ignoring additional contributors of pandemic-related excess deaths [29].
- 6. VAERS data has been misrepresented in a way to suggest it contains no meaningful safety signals with respect to the COVID vaccines because it can not account for "background" death rates. For example, Morris has argued that 50k deaths within one week of vaccination is expected by chance alone (a number arrived at roughly by dividing 3M US yearly deaths by number of weeks in a year and multiplied by the fraction of US population that is vaccinated) and that this "is the background rates of death for the vaccinated subpopulation of the USA".⁴⁵ Morris states:

"To interpret in relation to vaccination, if vaccines were given at a random time, we would expect ~7k people to die the day of vaccination by random chance alone, even if the vaccines were perfectly safe and causing no deaths, >49k to die the week of vaccination, and >210k to die within a month of vaccination. These are the background rates of death for the vaccinated subpopulation of the USA. It is important to take this into account when

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⁴²<u>https://covid.joinzoe.com/post/covid-vaccine-pfizer-effects</u>

⁴³https://nclalegal.org/2021/08/george-mason-univ-caves-to-nclas-lawsuit-over-vaccine-mandate-grants-prof-medical-exe mption/

⁴⁴ <u>https://jackanapes.substack.com/p/new-foia-release-shows-cdc-lied-about</u>

https://www.covid-datascience.com/post/interpreting-vaers-what-is-the-expected-background-death-rate-for-the -usa-vaccinated-population

interpreting VAERs counts, since many of these background deaths would be reported to VAERs as post-vaccination events. In fact, <u>according to law, healthcare workers would be required to report all of these events to VAERs whether they thought they might be related to vaccines or not</u>. Thus, in principle, *ALL* of these deaths should be reported to VAERs"

However, Morris's definition of "background deaths" reflects the total expected deaths in the vaccinated US population, but the definition of background deaths that we need is the proportion of these deaths that happen to be included in VAERS due to random chance. If many or all of Morris's "background deaths" are reported to VAERS, then we should expect to see roughly 10k to 50k deaths per week reported in VAERS every year, which we do not. As the below chart from Rose and Crawford shows, weekly VAERS death reports in 2021 (after the introduction of COVID vaccines) range in the hundreds, while weekly VAERS death reports in 2020 and 2019 number in the single digits (the authors further discuss why a sudden increase in propensity to report in 2021 does not account for these differences) [7].

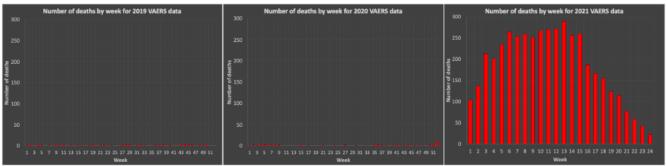


Figure 1: Bar plots showing the number of VAERS reported deaths per week for 2019, 2020 and 2021. Analysis: Dr. Jessica Rose

The authors apply various methods to calculate the appropriate background death rates <u>that are</u> <u>reported to VAERS</u>. In the first method, they sum yearly VAERS deaths for 2019 and 2020 to yield 500 (or 750 yearly background deaths when adjusting for the older age distribution of COVID vaccines) as their background deaths since the propensity to report did not increase in 2021. Note this estimate is much more plausible than the ~2.5M yearly background deaths that Morris suggests in his analysis because the estimate takes into account the fraction of deaths that are reported to VAERS (and does not assume that many or all deaths are reported to VAERS).

Another approach that helps put the COVID vaccines in perspective with respect to VAERS is to compare them to other vaccines. A comparison to the flu vaccine shows that the rate of VAERS death reports per COVID-19 vaccine doses administered published by the CDC (0.0026%)⁴⁶ is >100x higher than a similarly calculated rate for the 2019-2020 flu shot (0.000019%). The former is calculated by dividing 607 million doses of COVID-19 vaccines administered in the United States from December 14, 2020, through August 17, 2022 by 16,077 VAERS death reports among people who received a COVID-19 vaccine. The latter is estimated by dividing the total number of deaths reported after any flu vaccine to VAERS over age 18 (24) by the number of flu shots administered (~72,300,000) between Oct 1st 2019 and April 4th 2020.⁴⁷

7. A recent study in the Lancet Infectious Diseases that analyzed VAERS reports from December 14th, 2020 through June 1st., 2021 whitewashes or downplays the safety signals in VAERS. The authors state "In our review and analysis of death reports to VAERS following mRNA vaccination, we found no unusual patterns in cause of death among the death reports received. Under the COVID-19 vaccine EUA regulations, health-care providers are required to report deaths and life-threatening adverse health events after COVID-19 vaccinations to VAERS regardless of their potential association with

⁴⁶ https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html

⁴⁷ https://data.cdc.gov/Vaccinations/Weekly-Cumulative-Estimated-Number-of-Influenza-Va/83ng-twza

vaccination." However, close examination of their Supplementary Table 2⁴⁸ shows a pattern that evidences causal associations with the vaccine. First, of 3,663 deaths reported against both mRNA vaccines, the majority (54%) are listed as Unknown/unclear. The leading known cause, diseases of the heart (17%), is in line with the known myocarditis risk discussed above as well as case reports of myocardial infarction and other cardiac events following mRNA vaccination [73-77]. The second leading known cause (COVID-19) (8.7%) is consistent with evidence that COVID vaccination increases infectivity and transmission in the first week post-injection (Section C), previous observations of and concerns about enhanced respiratory disease based on preclinical and molecular modeling studies of SARS and MERS vaccines [10,38,78-81]. A recent review of preclinical and clinical evidence that COVID-19 vaccines could worsen disease upon exposure to challenge or circulating virus concluded that COVID-19 vaccines "may worsen COVID-19 disease via antibody-dependent enhancement (ADE)" and that the "risk is sufficiently obscured in clinical trial protocols and consent forms for ongoing COVID-19 vaccine trials that adequate patient comprehension of this risk is unlikely to occur, obviating truly informed consent by subjects in these trials." [13]. The third leading known cause is cerebrovascular disease (5.6%), consistent with a relatively high proportion (4,579) of VAERS reports for "thrombosis" or "thrombocytopenia" for mRNA vaccines as of Oct 22nd, 2021 and case reports of stroke following both viral vector and mRNA vaccines [82,83], while the fourth leading cause is listed as "Other" (3.8%). Other causes of deaths listed such as intentional self-harm are consistent with cases in which vaccine injury caused chronic pain and grief, leading to suicide (personal communications with https://react19.org, a vaccine injury support group), while accidents/unintentional injury may be the result of heart attack or stroke during operation of machinery or vehicles. Finally, other causes listed such as various cancers may arise in instances where vaccines cause sustained synthesis of the SARS-CoV-2 spike protein, which may impair DNA repair mechanisms and type I IFN signaling [84].

The authors also claim "the benefits of immunisation in preventing serious morbidity and mortality strongly favour vaccination." The three references they cite to support this claim [85–87] all apply the same type of risk-benefits analysis⁴⁹ that compares incidence rates of a specific severe AEs (costs) to benefits that are estimated using compartmental *modeling* (simulations) to estimate the number COVID-associated hospitalizations, ICU admissions and deaths averted over a certain time frame (i.e. 6 months). The models are calibrated using past COVID-19 incidence data and then used to estimate forward trajectories in terms of COVID-19 hospitalizations and deaths in the presence or (hypothetical absence) of the vaccines. It is important to note the benefit estimates are *not* validated, they are simply numbers that are spit out by the computer that heavily depend on the assumptions and input parameters of the model. If the input parameters and the assumed relationships between them are inaccurate, the outputs will also be inaccurate, and the outputs are not subjected to additional validation.

Critically, the models include beneficial indirect effects ('herd protection') that are based on the assumption that the vaccine can block transmission to unvaccinated persons and that *all* incident cases occur in unvaccinated persons, assumptions which we now know are grossly inaccurate [88]. Moreover, the approach negatively biases the costs because they only compare one type of severe event (i.e. TTS or myocarditis) whose incidence rates are underestimated because they are based on VAERS reports (passive surveillance) which underreports COVID vaccine AEs by factors of 20x up to 100x [3,7,33]. For example, Gargano et al. [86] estimate that 1M 2nd doses of mRNA vaccines will prevent 215 COVID-19 hospitalizations (a computer-generated number that is not validated and that is based on inaccurate model assumptions) in 12-17 yr old boys at a cost of 56–69 myocarditis cases (estimates that are at least 4x or more lower than the actual rates, see Section A).

For a more in-depth discussion of how model misspecification can grossly overestimate vaccine benefits and lead to invalid results, please see our commentary [29] on a recent study published in the Lancet Infectious Diseases [72] that used a similar modeling approach to claim that vaccines saved

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https://www.thelancet.com/cms/10.1016/S1473-3099(22)00054-8/attachment/26ad2884-3326-401c-a106-d2bd0c954984/ mmc1.pdf

⁴⁹ https://www.cdc.gov/vaccines/covid-19/info-by-product/janssen/risk-benefit-analysis.html

14-19 millions lives globally during the first year of the pandemic. A more straightforward, interpretable, and reliable risk-benefit analysis would be to compare *incidence rates for the same AEs following vaccination vs. infection.* We speculate the authors did not implement this simpler approach in order to make the vaccines appear more favorable. Note that all three studies were published in MMWR Morb Mortal Wkly Report and by the CDC, and that most articles appearing in the journal are not peer-reviewed⁵⁰.

In conclusion, a critical and comprehensive examination of all available evidence to date makes it clear that COVID-19 vaccines do not noticeably reduce transmission or community spread, and that the risks of COVID-19 vaccination outweigh the benefits in most, if not all, age groups, and particularly in young adults who comprise a majority subject to the CU-wide vaccine and booster mandates.

⁵⁰ <u>https://www.cdc.gov/mmwr/preview/mmwrhtml/su6004a2.htm</u> "Although most articles that appear in *MMWR* are not "peer-reviewed" in the way that submissions to medical journals are, to ensure that the content of *MMWR* comports with CDC policy, every submission to *MMWR* undergoes a rigorous multilevel clearance process before publication."

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