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Dear President Bollinger,

In December, 2021, I contacted the CU COVID response director (Dr. Lynne) to share vaccine safety research and global policy updates including Moderna vaccine restrictions for young adult males in Nordic countries [1,2] and to notify her of my presentation at the CU COVID Symposium on age-stratified risk-benefit analysis using data-driven vaccine mortality risk estimates from publicly available US CDC data[1] [3]. She kindly forwarded my email and manuscript [3] to other public health colleagues whose input she relies upon when making decisions regarding CU COVID policies. To my surprise, as of July, 2022, CU has still not updated its vaccine policies and recommendations to reflect the most recent data on the COVID vaccine and boosters' (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 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 CU students who are mostly 24 years old or younger, which could potentially put CU's endowment at risk. Please see the references in this letter so CU can verify whether or not CU should rely on recommendations from public health agencies. The CU COVID task force should not blindly trust the FDA and CDC claims regarding the risk-benefit of COVID-19 vaccines when making decisions on CU-wide vaccine policy. Despite promising full transparency regarding the COVID-19 vaccines[2], 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 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 55 years to release them[4].

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 rollout[5]. These events occurred within a median of 1 day or <24 hours, evidencing a causal link to the vaccine. However, the Pfizer vaccine (marketed as Comirnaty) fact sheets for healthcare providers and patients do not mention any of these severe AEs other than myocarditis[6]. Moreover, neither the fact sheets nor the CDC links cited in the fact sheets[7] mention incidence rates for myopericarditis, and simply claim vaccine benefits outweigh the risks *without providing any supporting data.*

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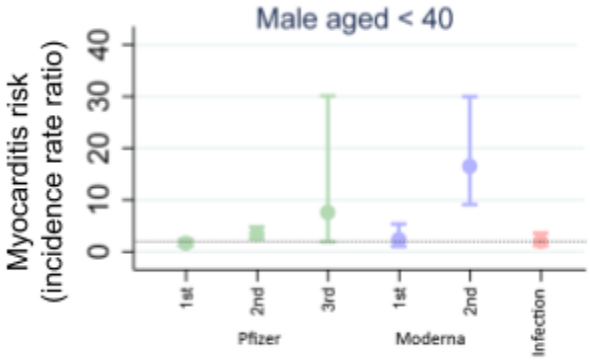
[1]See also this interview https://www.bitchute.com/video/J0Q2VPVyckxF/ by Perspectives on the Pandemic whose first interviewee was John Ioannides at Stanford University. It was censored by Youtube and is available only on other sites.
[2]https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-announces-advisory-committee-meeting-discuss-second-covid-19-vaccine
[3]See https://aaronsiri.substack.com/p/fda-asks-federal-judge-to-grant-it?s=r and https://phmpt.org/wp-content/uploads/2021/10/001-Complaint-101021.pdf
[4]https://www.reuters.com/legal/government/wait-what-fda-wants-55-years-process-foia-request-over-vaccine-data-2021-11-18/
[5]https://phmpt.org/wp-content/uploads/2022/04/reissue_5.3.6-postmarketing-experience.pdf (see Table 2 and 7).
[6]See PostMarketing Experience under Warnings in https://labeling.pfizer.com/ShowLabeling.aspx?id=15623&format=pdf
[7]https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html

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) and reports an estimated vaccine mortality risk of 0.0026%[8]. This risk is *higher* than the risk of death following infection with omicron in young adults[9]. 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 begin looking at those signals until April 2021, 4 months after the vaccination program began[11]. In January, 2022 the CDC director admitted vaccines can not prevent transmission of currently circulating variants.[12] Thus there is no justification to mandate or recommend vaccines or boosters to CU students, or any CU member who does not wish to take them.



The cure may be worse than the disease. In males <40 years old, myocarditis risk following Pfizer 2nd and 3rd (booster) and Moderna 2nd dose is higher than myocarditis risk following SARS-CoV-2 infection, and the risk increases with each dose. Figure adapted from Patone et al. Risk of myocarditis following sequential COVID-19 vaccinations by age https://doi.org/10.1101/2021.12.23.21268276 which analyzed >40M health records from the English National Immunisation (NIMS) Database of COVID-19 vaccination. Graph plots myocarditis incident rate ratios relative to background rates. Dotted line shows risk following infection for visualization purposes.

The Hippocratic Oath says "First, do no harm". **On the basis of the above facts alone, the CU-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:

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 [7] 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 the CU vaccine mandate (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. The CU policy ignores 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 [8].
D. Publications and sources (including the CU vaccine policy FAQ[13]) 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.

In light of the evidence presented herein, we urge the following actions and remediations be taken ASAP following receipt of this letter, and preferably before any future CU-wide COVID policy announcements

1. The vaccine and booster mandates should be lifted immediately, and official CU guidance and recommendations should be updated to provide informed consent about vaccine safety risks. This includes removing vaccine requirements to enter CU premises and updating the CU FAQ which is replete with misinformation about the safety, effectiveness and risk-benefit of the COVID vaccines. It causes more harm to mandate primary series vaccinations against variants that are no longer in circulation [9] and boosters that carry much higher risks relative to low-lethality omicron variants.

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[8]See https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html
[9]The 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]https://www.ronjohnson.senate.gov/services/files/9914278B-A73B-4434-8349-91091138E18B
[11]https://jackanapes.substack.com/p/new-foia-release-shows-cdc-lied-about
[12]https://www.msn.com/en-us/health/medical/cdc-director-covid-vaccines-cant-prevent-transmission-anymore/ar-AASDndg
[13]https://covid19.columbia.edu/content/faqs-regarding-covid-19-vaccination

2. Replace the CU COVID task force with a more robust and inclusive method for deciding future CU-wide health policy decisions[14]. The CU leadership and COVID task force failed to conduct reasonable due diligence to ensure the safety and health of the CU community. CU-wide mandates impact the lives and well-being of not only CU 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 FCOI, and without soliciting input and debate with the wider CU community.
3. Any CU employee who was "suspended without pay" for refusing vaccination or whose medical or religious exemption request was denied should be fully compensated for their lost wages. These coercive tactics are not ethical [10], and especially for an experimental therapeutic whose effectiveness and safety risks are being obfuscated or whitewashed by those profiting from the product.
4. Any CU 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 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 CU COVID task force 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 FCOI wrt the mandate.

It is critically important that CU leadership give full and fair consideration and attention to all available evidence regarding vaccine risks and benefits because the current CU policies may be exposing CU members to unnecessary medical risks and without informed consent. I have emailed and offered to meet with CU 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 Dr. Lynne. In my view the mandates 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.[15]

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 [5,9,11–14]. As previously mentioned, this letter 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 CU's policy relies. We hope this letter will ultimately help to restore sanity and trust in CU's public health policies and response. Please do not hesitate to let us know if we can be of service in guiding CU policies in the near 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) by **Friday, August 5th.** We provide a preliminary list of CU and non-CU co-signers below and links to the online version of this document 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

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[14]The decision was based on "strong recommendation…(from CUIMC) public health colleagues", see https://covid19.columbia.edu/content/covid-19-vaccine-mandate). 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 (https://news.columbia.edu/news/how-and-why-columbias-vaccine-mandate-worked).

[15] **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.**

CU co-signers

Brian E. Scully, MD
Professor of Medicine at 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
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Claire-Marie Vacher, PhD
Assistant Professor at CUIMC (Department of Pediatrics)
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Online document

This letter is a living document. Please see https://tinyurl.com/27djpkrf and below QR code to see the most up-to-date version as well as any additional signatures. If the links do not work for some reason please email us (spp2101@columbia.edu) for working URLs.

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

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".[16] 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%) [7,15].
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.[17] A 25x fold increase 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, 2021[18].
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 sheets[19] nor the CDC links cited in the fact sheets[20] 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 risk following infection were sparse (i.e. a comprehensive review of COVID-19 and 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 [14,18]. 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].
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 FAQ[21] 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 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

[16] https://covid19.columbia.edu/content/covid-19-vaccine-mandate
[17] https://ottawacitizen.com/news/world/israel-finds-heart-inflammation-in-people-who-received-pfizer-covid-19-shot
[18] https://ottawacitizen.com/news/local-news/increased-risk-of-heart-muscle-inflammation-linked-with-mrna-vaccines-seen-in-ottawa
[19] See PostMarketing Experience under Warnings in https://labeling.pfizer.com/ShowLabeling.aspx?id=15623&format=pdf
[20] https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html
[21]

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."[22] 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.
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 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 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 claim[23]. 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)[24]. 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 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

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

hospitalizations' need not be *due* to COVID[25]. 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 or all 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 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 age[26]. 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 estimates 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 [6].)
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%[27].
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 [35]. 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 healthcare workers [36], 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 VAER[28] but does not cite the Klein 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

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[25] https://gis.cdc.gov/grasp/COVIDNet/Documents/320393-A_COVID-NET_cumulative-geo2.pdf

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

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

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

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 [35], 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 conclusions[29] (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 available[30] 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)[31]. 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.[32]
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 investigation[33].
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 [37].
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-19[34]. The latter is consistent with previous predictions and observations of enhanced respiratory disease via antibody dependent enhancement based on preclinical studies [9,38–40].

B. 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.

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.”[35] 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 [41–43]. The Moderna [41] and J&J [43] 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.

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[29] https://justthenews.com/politics-policy/coronavirus/monivy-league-researcher-hits-brick-wall-medical-journals-covid-vaccine

[30] https://github.com/spiropan/CoVFR

[31] https://jessicar.substack.com/p/the-bradford-hill-criteria?s=w. 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.

[32] https://phmpt.org/wp-content/uploads/2022/04/reissue_5.3.6-postmarketing-experience.pdf (see Table 2 and 7).

[33] https://www.science.org/content/article/thousands-report-unusual-menstruation-patterns-after-covid-19-vaccination

[34] https://www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/deaths/datasets/deathsbyvaccinationstatusengland (see Table 1 in Excel Spreadsheet downloads)

[35] See Question D.9 in https://covid19.columbia.edu/content/faqs-regarding-covid-19-vaccination

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% [44].
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 [45]. 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 immunity[36] [46–56].
4. In January, 2022 the CDC director Dr. Walenksy stated that the vaccines "can't prevent transmission anymore".[37] 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". [38]
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-injection[39]. A reanalysis [57] 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 [58]).

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

1. 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 efficacious[40]."
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 infection[41]. 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% [59]. A recent real world study of >2.5M medical records [60] 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 coronavirus[42].
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 infection[43] [61–67].
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.[44]

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[36] https://brownstone.org/articles/16-studies-on-vaccine-efficacy/
[37] https://www.msn.com/en-us/health/medical/cdc-director-covid-vaccines-cant-prevent-transmission-anymore/ar-AASDndg
[38] https://twitter.com/SKMorefield/status/1550586541239635969
[39] https://www.hartgroup.org/it-gets-worse-before-it-gets-better/
[40] Question 19 in https://covid19.columbia.edu/content/faqs-regarding-covid-19-vaccination
[41] https://brownstone.org/articles/79-research-studies-affirm-naturally-acquired-immunity-to-covid-19-documented-linked-and-quoted/
[42] https://www.swfinstitute.org/news/89518/foia-cdc-admits-no-record-of-unvaccinated-person-spreading-covid-after-recovering-from-covid
[43] https://covid.joinzoe.com/post/covid-vaccine-pfizer-effects
[44] https://nclalegal.org/2021/08/george-mason-univ-caves-to-nclas-lawsuit-over-vaccine-mandate-grants-prof-medical-exemption/

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

1. Official CDC and FDA guidance regarding COVID-19 vaccines are untrustworthy due to well-known and extensive financial conflicts of interest and the well-documented "revolving door" [26,68].
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"* [41]. 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 [41]). 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." [69]
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 [70–72].
5. Pro-vaccine modeling studies [73] 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].

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.

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