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UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA

PIERRE KORY, M.D., LE TRINH HOANG, D.O., BRIAN TYSON, M.D., PHYSICIANS FOR INFORMED CONSENT, a not-for-profit corporation, and CHILDREN'S HEALTH DEFENSE, a not-for-profit corporation,

Plaintiffs,

v.

ROB BONTA, in his official capacity as Attorney General of California, REJI VARGHESE, in his official capacity as Executive Director of the Medical Board of California, ERIKA CALDERON, in her official capacity as Executive Officer of the Osteopathic Medical Board of California,

Defendants.

Case No: 2:24-cv-00001-WBS-AC

SANJAY VERMA, M.D. DECLARATION

Date: April 1, 2024
Time: 1:30 PM
Courtroom: 5, 14th Floor

Action Filed: January 2, 2024

I, SANJAY VERMA, MD declare as follows:

1. I have personal knowledge of the facts set forth herein. I submit this declaration in support of Plaintiffs' Motion for a Preliminary Injunction to stop the medical and osteopathic medical boards from disciplining physicians for the information and recommendations they share with patients about COVID-19 infection, prognosis, treatments, and vaccines.

2. I am a California licensed, board-certified internist with a subspecialty in cardiovascular disease. My C.V. is attached as Exhibit A. I treat COVID-19 patients who present with cardiac symptoms. I also treat patients who appear to present with severe adverse cardiac side effects from the COVID-19 vaccines. I am frequently asked by patients about various aspects of COVID-19 including the risks of cardiac complications, the efficacy of the COVID-19 vaccines and boosters, the risks of COVID-19 vaccines, the extent to which the new vaccines are tested, and post market surveillance for severe adverse effects (especially cardiac issues) after COVID-19.

3. I also engage in research projects for Plaintiff Physicians for Informed Consent ("PIC"). I interact with PIC's physician and lay members about my research and the reports I write for the group. Consequently, I understand what concerns patients and front-line physicians experience and what these physicians would want to tell patients. I have a good working understanding on current scientific research on these topics. I understand what information and scientific studies physicians might want to share with patients who want more than a cursory overview or merely a perfunctory reiteration of public health recommendations to take each successive booster.

4. I would bring to attention of the Court that in California as in most places around the country, people who want to take the COVID-19 vaccine or booster can do so at a pharmacy or clinic. At these facilities people do not have to pay for a medical visit to receive the COVID-19 vaccines and boosters. My experience and common sense suggest that in COVID-19 times, patients go to their doctors because they have questions or concerns about the safety and efficacy of the COVID-19 vaccines despite the public health media campaign

extolling the benefits of the vaccines and their "exceedingly rare" side effects. In my experience treating COVID-19 vaccine associated cardiac complications (especially myocarditis), virtually all my patients had not previously heard of the risk of cardiac complications before taking their primary series or boosters. Patients also have questions about the off-label treatments for COVID-19. Patients go to physicians for information and advice about COVID-19 vaccines and treatments and want to hear from an honest medical professional who will be willing to transparently share information and perspectives that might be at odds with what they hear from the public health authorities, the mainstream medical associations and the large media outlets. The fact the most of my patients with cardiac complications after COVID-19 vaccination had not previously been educated on these risks underscores the material and sometimes fatal consequence of silencing physicians who engage in an ethically transparent and comprehensive risk-benefit discussion.

5. However, sharing information contrary to the mainstream COVID-19 narrative could subject California physicians to the same type of covid misinformation prosecutions under Bus. & Prof. Code 2234, just as they could have been subjected to discipline under Section 2270. I believe the boards' use of its statutory standard of care authority will certainly dangerously censor speech of some California physicians the same way Section 2270 did. Patients deserve to engage in comprehensive and transparent risk-benefit discussions with physicians to fulfill the ethical edicts of informed consent.

6. Regarding the two different statutes being used to sanction and chill the information and recommendations which have been used by the medical board, operatively, from the physician's point of view there is little, if any, practical difference. First, the two statutes have a common standard, being the "standard of care." However, for the same reasons that it there is no actual contemporary scientific consensus regarding COVID-19, there is also no actual standard of care. The standard of care is or is supposed to be based on the contemporary scientific consensus, and the evidence of the problems with the latter is equally applicable to evaluating the standard of care. Many physicians are simply regurgitating the latest public health pronouncements to their patients concerned with key issues like the need

for continued boosters and the use off-label medications, despite the lack of evidence of efficacy of the former and the emerging body of evidence for the later.

7. The "standard of care" has evolved so frequently during the past four years of the COVID-19 era, that the public has lost all confidence in public health recommendations. According to CDC, as of Dec 23, 2023 only 7.9% of children and 18.9% of adults nationally have elected to be up to date with the current COVID-19 vaccine. Even in California, the rates are 7.0% for children and 20.7% for adults. Even the highest risk group (65-74 year-old) only have 37.5% rate of being up to date with current boosters. Clearly the public does not accept public health experts' recommendations as "standard of care". The return of mask mandates this winter is more aligned with political affiliation than with any agreed upon "standard of care".

i. https://www.cdc.gov/vaccines/imz-managers/coverage/covidvaxview/interactive/vaccination-dashboard.html

8. In addition to the information presented in my declaration in support of the Preliminary Injunction Motion in the related case, *Hoang v Bonta* which challenged notions of contemporary scientific consensus, herewith I present studies which have been published after my previous declaration which further demonstrate that there is no such thing as a contemporary scientific consensus, and/or studies which suggest that some of what is asserted as scientific and part of the contemporary scientific consensus are actually invalid (i.e., have proven to be incorrect or stultified). Rather, they are public health edicts which are not consistent with the recent scientific literature. Or, they represent public health decisions made by the U.S. government about vaccines, in contradistinction to other countries or public health authorities who have made different decision and recommendations.

9. From the practicing physicians' point of view, in a time of rapidly evolving public health situations, without the benefit of long-term studies and long-term epidemiological data, public health expert recommendations are often erroneous and ephemeral (changing before the recommendations can even be fully understood and adopted by practicing physicians and general public). Public health authorities' edicts have repeatedly (and

tragically) lagged many months behind valid scientific concerns raised by scientists and practicing physicians. This has led to a *de facto* rejection of any notion of *standard of* care on almost all aspects of the COVID-19 both by the general public and by practicing physicians who have undertaken a deep, comprehensive analysis of the epidemiological data. In all other aspects of clinical medicine, *standard of care* is developed *and sustained* for years; it withstands the scrutiny of repeated published scientific studies over time. For scientists, practicing physicians and the general population, whimsical and ephemeral scientific consensus of public health experts and standard of care regarding COVID-19 issues cannot be materially distinguished.

10. I will focus on five specific issues:

(1) Differing public health approaches to vaccines in other countries which supports the view that there is no contemporary scientific consensus, but rather different countries make quite different risk/benefit decisions about Covid vaccines.

(2) the increased risk of myocarditis from the vaccines,

(3) Changing views on the efficacy of the vaccines,

(4) The benefits of masking as a public health measure, and

(5) Use of off-label drugs

Any of the information covered in this (and my other) declaration could be included in conversations between physicians and patients. This type of information is necessary for patients to make educated decisions and give ethically mandated informed consent. However, relating such information could lead to the California medical boards to charge a physician with disseminating false or misleading information under Section 2270.

A. DIFFERING PUBLIC HEALTH APPROACHES TO VACCINES IN OTHER COUNTRIES

11. The World Health Organization (WHO) no longer recommends COVID-19 vaccination in low-risk populations (e.g., pediatric population) depending upon the country's specific disease burden. At this point in the (post) pandemic, "The update is based on the

scenario that assumes that the virus will continue to evolve but cause less severe disease" and also considers the overall decline in disease severity, including post-COVID conditions." Furthermore, the "update considers the steep increase in the seroprevalence of SARS CoV2 antibodies globally in all age groups, indicating high levels of immunity due to infection-induced, vaccine-induced, or hybrid immunity." The recent FDA update acknowledges this also, stating "Evidence is now available that most of the U.S. population 5 years of age and older has antibodies to SARS-CoV-2, the virus that causes COVID-19, either from vaccination or infection." In fact, 96% of the pediatric population in the United States has antibodies to SARS-CoV2 (from vaccination or infection). Acknowledging the overall very low risk of COVID-19 to children and accounting for the widespread seroprevalence (i.e., evidence of immunity by infection or vaccination), the UK announced in January 2023 that it "will stop widely providing the vaccine to those under 50 next month,"[i] (except to those at high risk for severe illness).

i. https://www.who.int/news/item/28-03-2023-sage-updates-covid-19-vaccination-guidance
ii. https://cdn.who.int/media/docs/default-source/immunization/sage/2023/march-2023/sage_march_2023_meeting_highlights.pdf?sfvrsn=a8e5be9_4 https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-changes-simplify-use-bivalent-mrna-covid-19-vaccines
iii. https://covid.cdc.gov/covid-data-tracker/#pediatric-seroprevalence
iv. https://apnews.com/article/fact-check-covid-pandemic-vaccine-uk-britain-324766934158

12. In England, COVID-19 vaccines are no longer offered to young healthy people.
    i. "Now, the vaccine will only be offered to those aged 65 and over along with health and care workers and people living with certain health conditions."
    ii. "Health officials are following advice on the UK booster programmes from the Joint Committee on Vaccination and Immunisation (JCVI)."

iii. https://www.itv.com/news/2023-08-08/who-is-eligible-for-a-covid-booster-jab-under-new-guidelines

13. In Sweden COVID-19 vaccines are recommended to those 65 years and older, as well as those 18- 64 years old who have high risk chronic medical conditions. COVID-19 vaccines are not recommended for children or healthy adults under 65 years old.

i. https://www.folkhalsomyndigheten.se/the-public-health-agency-of-sweden/communicable-disease-control/vaccinations/vaccination-against-flu-and-covid-19/

14. Denmark only recommends that those "who are at risk of becoming severely ill should be vaccinated" against COVID-19.

i. https://www.sst.dk/en/english/Vaccination-against-influenza-and-covid-19

15. The common thread in all these examples is that many developed countries have made different vaccine recommendations, most notably concerning low risk demographic groups like children and healthy young adults, based on a risk-benefit analysis different from that made by the public health authorities and the U.S. infectious disease establishment. Some of the specific reason for these differing vaccine and other COVID-19 recommendations are set forth below.

B. COVID-19 VACCINES' RISK OF CARDIOVASCULAR COMPLICATIONS

16. As noted in my other Declaration, reports of vaccine associated myocarditis initially surfaced in April 2021 from Israel. CDC's initial response was quite dismissive. Although CDC later acknowledged myocarditis as a risk after COVID-19 vaccination, it continues to insist most cases are "generally mild" and "self-limiting". However, studies continue to be published that contradict CDC's dismissive and scientifically inaccurate assessment.

17. A study of 4928 high school students from Taipei City found that 1% had abnormal EKG and the incidence of myocarditis was 0.02% (1 in 5,000 or 200 per million). This corroborates previously published international studies on myocarditis after COVID-19

vaccination and is much higher than the rates calculated from Vaccine Adverse Event Reporting System (VAERS), which CDC uses for part of its risk-benefit calculation.

i. https://link.springer.com/article/10.1007/s00431-022-04786-0

18. Heterologous dosing (mixing manufacturers for dose 1 and dose 2) has been shown by two other studies to have an even higher risk of myocarditis after vaccination. Despite this, CDC continues to state that heterologous dosing is acceptable. A case report from Australia describes myocarditis in two individuals who had completely recovered from initial myocarditis after dose 1, but subsequently developed myocarditis again after dose 2 (heterologous dosing whereby second dose was different manufacturer than first dose).

i. https://aacijournal.biomedcentral.com/articles/10.1186/s13223-022-00750-7

ii. https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html

19. CDC continues to describe myocarditis after vaccination to be "generally mild" and report that "most recovered". Adding to previous cardiac MRI (CMR) studies, another recent study found that 100% of adolescents with myocarditis had persistent late gadolinium enhancement (LGE) on follow-up CMR 3-6 months later. Persistent LGE on follow-up CMR indicates myocardial scar tissue and consequent increased risk of fatal cardiac arrhythmias. A condition that increases the risk of fatal cardiac arrhythmias can hardly be characterized as "generally mild". This is not merely a hypothetical concern. "Cardiac autopsy findings consistent with (epi-)myocarditis were found in five cases of the remaining 25 bodies found unexpectedly dead at home within 20 days following SARS-CoV-2 vaccination" as reported in a recent study. A study that performed 6-month follow-up cardiac MRI in myocarditis patients found that myocardial fibrosis is associated with a significantly worse survival (Appendix D).

i. https://www.tandfonline.com/doi/abs/10.1080/23744235.2022.2157478

ii. https://link.springer.com/article/10.1007/s00392-022-02129-5

iii. https://www.jacc.org/doi/abs/10.1016/j.jacc.2019.08.1061

20. A very large Nordic preprint study[ii] of 8.9 million residents found the risk of myocarditis after BNT1262b2 (Pfizer) COVID-19 vaccine to be *359% higher* after dose 2 for

12-15-year-old males compared to unvaccinated controls. The rate was *1256% higher* after mRNA-1273 (Moderna) COVID-19 vaccine dose 2 in 12-39-year-old males.

i. https://www.medrxiv.org/content/10.1101/2022.12.16.22283603v1

21. One study in American Heart Association's flagship journal, *Circulation*, found a possible explanation for adolescents being at such higher risk of myocarditis after COVID-19 vaccination. The study "discovered distinct differences in how adolescents respond to mRNA vaccination compared with adults, which warrant further investigation." Unlike adults, the study found that adolescents have much higher rate of unbound (i.e., not bound by antibodies) circulating spike protein after vaccination. The differential immune response to COVID-19 vaccination between adults and adolescent children certainty warrants greater caution in categorical recommendations across all age groups.

i. https://www.ahajournals.org/doi/10.1161/CIRCULATIONAHA.122.061025

22. Persistence of spike protein and risk of myocarditis: One study found that *50% of patients had circulating spike protein has been detected 6 months (up to 187 days) after injection*. This is in stark contrast to CDC's claims that circulating spike protein from the COVID-19 vaccine is gone within a few days or weeks (as noted in my original Declaration). This would explain why a study found molecular damage in the heart (myocardial injury by altered gene expression) *up to 6 months after injection.* Circulating spike protein (up to 6 months after injection) and myocardial injury (up to 6 months after injection) may explain why two adolescent males were reported to have *(potentially unprovoked) relapsing* myocarditis 6 months after the initial episode of vaccine associate myocarditis.

i. https://onlinelibrary.wiley.com/doi/10.1002/prca.202300048

ii. https://www.sciencedirect.com/science/article/pii/S2452302X22003278?via%3Dihub

iii. https://pubmed.ncbi.nlm.nih.gov/37303596/

23. COVID-19 infection can also cause myocarditis. Contrary to CDC's assertion, the risk of myocarditis after infection is not greater than risk of myocarditis after vaccination. A large study from Israel found that *COVID-19 was not associated with an increased risk of*

myocarditis (compared to background rate in general population). Another recent large study from Italy confirmed that *COVID-19 was not associated with an increased risk of myocarditis*. Therefore, continued assertions that COVID-19 infection poses a greater risk of causing myocarditis than COVID-19 vaccines (especially in children and young adults) are inaccurate and not supported by the prevailing scientific research. A study from Canada compared the incidence of myocarditis after mRNA COVID-19 vaccination with expected rates based on historical background rates in British Columbia. The study found that young males receiving mRNA-1273 (Moderna) COVID-19 vaccination were *148 times more likely* to suffer from myocarditis (compared to historical background rate). Most studies on myocarditis limit their analysis to within 21 or 28 days after COVID-19 vaccination. However, an autopsy report has demonstrated death from myocarditis even *four months after vaccination*. As noted above, circulating spike protein (and consequent molecular myocardial injury) persist for at least 6 months. Therefore, continued assertions that COVID-19 infection poses a greater risk of causing myocarditis than COVID-19 vaccines (especially in children and young adults) are inaccurate and not supported by the prevailing scientific research.

i. https://pubmed.ncbi.nlm.nih.gov/35456309/
ii. https://journals.lww.com/jcardiovascularmedicine/Fulltext/2022/07000/Incidence_of_acute_myocarditis_and_pericarditis.5.aspx
iii. https://www.cmaj.ca/content/194/45/E1529
iv. https://www.preprints.org/manuscript/202209.0051/v1

24. Despite CDC's repeated assertions, myocarditis cases after COVID-19 vaccination are not "temporary and mild". In a study of CDC's 90-day follow-up data published in *Lancet*: *47% were lost to follow-up and about a third still had activity restrictions at median follow-up of 98 days. 25% were treated in an intensive care unit.* (Appendix E) A cardiac MRI study (in addition to prior cardiac MRI studies) indicated 100% of adolescents had evidence of scar on follow-up MRI 3-6 months later. Evidence of scar 3-6 months later indicates increased risk of fatal cardiac arrhythmias (as confirmed in autopsy study). While CDC continues to insist most of the myocarditis cases after COVID-19 are "generally mild" a

study on autopsy findings of fatal fulminant myocarditis and persistent cardiac MRI abnormalities are noted in 100% of patients with myocarditis in this follow-up study. Persistent abnormalities on cardiac MRI at 6-month follow-up after myocarditis has been proven to be associated with significantly increased mortality (Appendix F).

i. https://www.thelancet.com/journals/lanchi/article/PIIS2352-4642(22)00244-9/fulltext
ii. https://www.tandfonline.com/doi/abs/10.1080/23744235.2022.2157478
iii. https://www.jpeds.com/article/S0022-3476(22)00282-7/fulltext
iv. https://www.tandfonline.com/doi/abs/10.1080/23744235.2022.2157478
v. https://www.sciencedirect.com/science/article/pii/S0735109719377368?via%3Dihub

25. A one-year follow-up study of adolescents with myocarditis after COVID-19 vaccination found over 20% had persistent abnormalities on echocardiogram and over 50% had persistent abnormalities on cardiac MRI.

i. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10373639/

26. A nationwide Korean study of vaccine related myocarditis (VRM) found severe VRM in 19.8% of cases. Sudden Cardiac Death (SCD) attributable VRM was found in 1.7% (8) of the 480 cases of VRM in the study. This comprehensive nationwide study starkly contrasts with CDC's repeated assertions that these myocarditis cases are "generally mild" and self-limiting.

i. https://pubmed.ncbi.nlm.nih.gov/37264895/

27. While CDC continues to insist that most cases of vaccine associated myocarditis are self-limiting (most recover with supportive treatment) a recent study reported two cases of relapsing myocarditis 8-9 months after the initial episode. Both cases were 16- year-old males and had ostensibly fully recovered (with return to play at 6-month follow-up). This raises the concern that even those who apparently fully recovered may continue to be at significantly elevated risk of cardiovascular complications.

i. https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/myocarditis.html

ii. https://pubmed.ncbi.nlm.nih.gov/37303596/

28. Most of the follow-up data on myocarditis cases after vaccination is based upon symptoms (as seen in CDC's follow-up data published in Lancet) and some even report data on follow-up cardiac MRI. As noted above, evidence of fibrosis (scar) on follow-up cardiac MRI portends an ominous prognosis (much lower survival in the long term). A study performing serial heart biopsies on myocarditis patients found *persistent molecular changes (adversely altered gene expression of key myocardial proteins) up to 182 days after mRNA COVID-19 vaccination!* This could explain the underlying mechanism of the relapsing myocarditis cases reported above. It also underscores the importance of continued vigilance in surveillance even after the initial acute myocarditis seems to have resolved.

i. https://pubmed.ncbi.nlm.nih.gov/36281440/

29. Myocarditis after COVID-19 vaccination occurs at a greater rate than CDC estimates (which are exclusively based upon data from VAERS). Repeated studies have affirmed that risk of myocarditis after vaccination (for children and young adults) is greater than risk of myocarditis after COVID-19 infection. The cases are not "generally mild" as CDC asserts. The long-term sequelae are just now being better elucidated. It is therefore of paramount and critical importance that physicians be able to engage in a candid and comprehensive informed consent dialogue with patients (especially younger ones) about the safety of COVID-19 vaccines. In my own cardiology practice, virtually all my patients with vaccine associated myocarditis or cardiomyopathy were unaware of the actual extent of the risk prior to being vaccinated against COVID-19.

30. Risk-benefit analysis (and additional side effects of COVID-19 vaccination)

a. CDC has often misrepresented the risk of COVID-19 to children and young adults. During the early months of the COVID-19 pandemic in 2020, it was emphatically stated that "everyone is equally susceptible". Even when CDC later conceded that children were at low risk compared to older adults, CDC continues to promote COVID-19 vaccination for everyone starting at the age of 6. The risk benefit analysis conducted by CDC has frequently neglected

seroprevalence data (i.e., underestimated the denominator for infections) and relied almost exclusively on data from VAERS (i.e., underestimated the numerator for severe adverse events after vaccination). CDC's risk-benefit analysis has been deeply and tragically flawed. AB 2098 would sanction physicians for challenging CDC's flawed data analysis on safety of COVID-19 vaccines (especially for children and young adults).

31. A concrete and comprehensive analysis of risks and benefits of COVID-19 booster vaccine amongst college aged students found that booster "may result in a net harm to healthy young adults". The authors emphasize that CDC's risk-benefit analysis is "not based on an updated (Omicron era) stratified risk-benefit assessment for this age group." With each subsequent variant, the virulence (i.e., risk of hospitalization and death) continues to decrease.

i. https://jme.bmj.com/content/early/2022/12/05/jme-2022-108449

32. CDC's risk-benefit analysis does not adjust for seroprevalence. Seroprevalence is the assessment of disease prevalence based upon antibodies in sera samples and accounts for those who may never have tested for COVID-19 but nevertheless have evidence of prior infection. CDC's own seroprevalence estimates now indicate that 96% of all children have already been infected with COVID-19. A robust analysis of 31 national seroprevalence studies found the infection fatality rate (IFR) in 0-19-year-olds to be 0.0003%. CDC continues to use only PCR confirmed cases for their denominator to calculate COVID-19 morbidity and mortality (grossly overestimating the risk of hospitalization and death). When adjusting for seroprevalence, the actual IFR calculated is far lower, thereby supporting conclusions that the COVID-19 vaccines may result in net harm for children and young adults.

i. https://covid.cdc.gov/covid-data-tracker/#pediatric-seroprevalence

ii. https://www.sciencedirect.com/science/article/pii/S001393512201982X?via%3Dihub

33. COVID-19 infection can also cause myocarditis. Contrary to CDC's assertion, the risk of myocarditis after infection *is not greate*r than risk of myocarditis after vaccination. A large study from Israel found that COVID-19 as not associated with an increased risk of

myocarditis (compared to background rate in general population). Another recent large study from Italy confirmed that COVID-19 was not associated with an increased risk of myocarditis. Therefore, continued assertions that COVID-19 infection poses a greater risk of causing myocarditis than COVID-19 vaccines (especially in children and young adults) are inaccurate and not supported by the prevailing scientific research. A study from Canada compared the incidence of myocarditis after mRNA COVID-19 vaccination with expected rates based on historical background rates in British Columbia. The study found that young males receiving mRNA-1273 (Moderna) COVID-19 vaccination were *148 times more likely* to suffer from myocarditis (compared to historical background rate). Most studies on myocarditis limit their analysis to within 21 or 28 days after COVID-19 vaccination. However, autopsy report has demonstrated death from myocarditis even *four months after vaccination*. Therefore, continued assertions that COVID-19 infection poses a greater risk of causing myocarditis than COVID-19 vaccines (especially in children and young adults) are inaccurate and not supported by the prevailing scientific research.

i. https://pubmed.ncbi.nlm.nih.gov/35456309/

ii. https://journals.lww.com/jcardiovascularmedicine/Fulltext/2022/07000/Incidence_of_acute_myocarditis_and_pericarditis.5.aspx

34. One reason for this common misconception is the assessment of myocarditis after vaccination based upon aggregate population analysis (i.e., not performing stratified analysis by age, sex, etc.). A systematic review of myocarditis studies found that only 28% of studies were comprehensively stratified. When appropriately stratified, the risk of myocarditis (in younger population) is far greater than pooled analysis suggests (when combining all ages). This study demonstrates the risk is much higher in in adolescent males for both Pfizer (390 / million) and Moderna.

i. https://onlinelibrary.wiley.com/doi/10.1111/eci.13947

35. Numerous studies have demonstrated an increased risk of myocarditis after mRNA COVID-19 vaccination (especially for adolescent males after mRNA-1273 Dose 2). As noted, a common (mistaken) refrain by CDC and other public health experts is that the risk of

myocarditis after COVID-19 infection is greater than after mRNA vaccination. Yet another recently published study contradicts CDC's claims that the risk of myocarditis is greater after COVID-19 infection. This study of almost 300,000 persons[iii] found that the risk of myocarditis after mRNA COVID-19 vaccination was about 150% greater than after COVID-19 infection. Furthermore, previous reports suggested the increased risk of myocarditis in adolescent males occurred mostly with mRNA-1273. However, the FDA recently published a very large study analyzing about three million children ages 5-17 years old who received the BNT162b2 mRNA COVID-19 vaccination. This study by the FDA found the BNT1262b2 mRNA COVID-19 vaccination to have almost *twenty-two times* increased risk of myocarditis within 7 days of vaccination for 12-15-year-olds and almost *thirty times* for 16-17-year-olds. (Table 2) The study analysis combined males and females. Since previous studies have all demonstrated that adolescent males have higher risk than female for myocarditis after COVID-19 vaccination, it is scientifically reasonable to conclude with certainty that if the FDA authors had ethically performed subgroup analysis (by males and females), the reported risk would be even higher for adolescent males (i.e., combining males and females dilutes the true risk to males alone).

i. https://www.nature.com/articles/s44161-022-00177-8

ii. https://pubmed.ncbi.nlm.nih.gov/34432976/

iii. https://www.sciencedirect.com/science/article/pii/S1878540922001128

C. CHANGING VIEWS ON THE EFFICACY OF THE COVID-19 VACCINES

(1) STUDIES CORRECTING THE MISREPRESENTATION THAT THE VACCINE PREVENT INFECTION

36. In the early stages of implementing mass COVID-19 vaccine administration, the claim that COVID-19 vaccines prevent transmission was repeated by numerous public health officials (including CDC Director Dr. Rochelle Walensky). In fact, this was the entire basis of the OSHA employer COVID-19 vaccine mandate (as well as for schools and colleges). Supreme Court Justice Kagan (during oral arguments on the OSHA mandate) stated, "the best way" to prevent the spread of COVID-19 is "for people to get vaccinated". However, the

COVID-19 vaccines were never tested for preventing secondary transmission (as Pfizer CEO Peter Bourla subsequently admitted).

i. https://www.washingtonexaminer.com/opinion/liberal-supreme-court-justices-spread-covid-19-misinformation

ii. https://www.news.com.au/technology/science/human-body/pfizer-did-not-know-whether-covid-vaccine-stopped-transmission-before-rollout-executive-admits/news-story/f307f28f794e173ac017a62784fec414

iii. https://www.michigancapitolconfidential.com/news/pfizer-admits-covid-vaccine-was-never-meant-to-stop-transmission

37. Emails recently obtained through a Freedom of Information Act request show that CDC Director Rochelle Walensky and former NIH Director Francis Collins were aware of, and discussed, "breakthrough cases" of COVID in January 2021 — right when the vaccines became widely available. In her email, Walensky says that "clearly," it is an "important area of study," links to a study raising the issue, and assures the person she is sending it to that Dr. Anthony Fauci is looped into these conversations. However, in public, Walensky's rhetoric was quite different. Two months after discussing this data, she said vaccinated people "don't carry the virus" and "don't get sick." In congressional testimony, after it became evident vaccinated people were able to get infected with COVID-19, she defended her original statements by claiming it was true at the time she said it — namely, for the strands we were dealing with in early 2021.

i. https://www.washingtonexaminer.com/opinion/new-emails-show-covid-vaccine-mandates-were-based-on-a-lie

ii. https://twitter.com/michaelpsenger/status/1668669558054600708

iii. https://www.businessinsider.com/cdc-director-data-vaccinated-people-do-not-carry-covid-19-2021-3?r=US&IR=T

38. The unproven and false claim that COVID-19 vaccines prevent secondary transmission (i.e., prevent infecting others) was the entire bases of the Occupational Safety and Health Administration (OSHA) mandate as well as school and university COVID-19 vaccine

mandates. Early on many physicians had been challenging this claim. Food and Drug Administration (FDA) briefing documents for (Emergency Use Authorization (EUA) application for both Pfizer and Moderna *did not contain any data analysis on secondary prevention* to warrant such claims. In my own practice, I have several young adults who chose to be vaccinated against COVID-19 "to protect the elderly" (older more vulnerable family members) who subsequently developed vaccine associated myocarditis and cardiomyopathy. If the general populace were permitted to have a more genuine and comprehensive risk-benefit analysis (i.e., engage in informed consent) many of these cases of myocarditis might have been prevented. Children, who are otherwise at very low risk for hospitalization and death from COVID-19 should never have been subjected to COVID-19 vaccine mandates "to protect the vulnerable" elderly and teachers (since they do not prevent transmission to others). As noted below, CDPH elected not to add COVID-19 vaccine to the children's school schedule of mandated vaccines. CDC's misrepresentation of the COVID-19 vaccine's ability prevent transmission was not only scientifically unjustified, their recommendations may have actually caused harm to low-risk individuals who mistakenly took the COVID-19 vaccine "to protect the elderly".

(II) COVID-19 VACCINES' WANING EFFICACY AND RISK OF REPEATED VACCINATION

39. CDC continues to recommend everyone (regardless of prior infection or individual risk stratification) be "up to date" on COVID-19 vaccines by receiving at least one Pfizer-BioNTech or Moderna updated (bivalent) COVID-19 vaccine (November 8, 2023): However, this recommendation is not based on a contemporary scientific consensus because the published scientific research does not support the recommendations.

i. https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html

40. Repeated studies have demonstrated rapidly waning vaccine efficacy (VE) with both the original (monovalent) and updated (bivalent) COVID-19 vaccines. Furthermore, some studies also suggest that repeated vaccination may *increase* the risk of infection and hospitalization and cause harm to the immune system.

41. For example, a meta-analysis of 40 studies found VE of primary (monovalent) COVID-19 vaccination series against Omicron to be *less than 20%* at six months. Nine months after booster administration, VE against Omicron was *lower than 30%*. Previous recommendations by public health experts indicated repeated boosters were needed because of this well-established waning VE. However, research now suggests that repeated vaccination may have numerous deleterious effects. Authors of one study caution that repeated vaccination "could promote unopposed SARS-CoV2 infection and replication by suppressing natural antiviral responses." Additionally, the authors caution that repeated vaccination "may also cause autoimmune diseases, and promote cancer growth and autoimmune myocarditis in susceptible individuals." This risk of worsening infection risk with repeated vaccination is not merely speculative. In a study from Cleveland Clinic, the authors found "The higher the number of vaccines previously received, the higher the risk of contracting COVID-19" (Appendix E). However, up until very recently, CDC continued to recommend repeated boosters and repeated its refrain that they were "safe and effective".

i. https://pubmed.ncbi.nlm.nih.gov/37133863/
ii. https://pubmed.ncbi.nlm.nih.gov/37243095/
iii. https://pubmed.ncbi.nlm.nih.gov/37243095/
iv. https://www.nature.com/articles/s41598-023-40103-x
v. ttps://academic.oup.com/ofid/article/10/6/ofad209/7131292
vi. https://www.cdc.gov/media/releases/2022/s0901-covid-19-booster.html

42. The original (monovalent) vaccines have not been found to be effective against the predominant variants in circulation end of 2022 thru mid-2023. A study evaluating effectiveness of antibodies against current variants found that "BQ and XBB subvariants … render inactive all authorized antibodies, and may have gained dominance in the population because of their advantage in evading antibodies."[iv] The bivalent booster did not perform better as the authors note that "[s]erum neutralization was markedly reduced, including with the bivalent booster."

i. https://www.cell.com/cell/pdf/S0092-8674(22)01531-8.pdf

43. CDC's own presentation June 15, 2023 of COVID-19 vaccine efficacy reported abysmally low VE for the monovalent and bivalent COVID-19 vaccines. VE against hospitalizations and critical illness for monovalent vaccines was 21% and 31%, respectively. The bivalent vaccines did not perform much better, with VE of 24% and 52% against hospitalizations and critical illness, respectively. In fact, analysis of their IVY network found that the monovalent and bivalent vaccines *may increase* the risk of hospitalization with XBB variant. (See Appendix C)

i. https://s3.documentcloud.org/documents/23852341/cdc-presentation-on-vaccine-effectiveness.pdf?fbclid=IwAR3HLG-eUHA4JSW-qr25-242Aph4tXg8B9GOlmRDaZ3nJemRI2RPFK9e39I

44. A study from Cleveland Clinic found rapid precipitous drop on VE for the bivalent COVID-19 boosters and an *increased risk of COVID-19 with each additional booster*.

i. "The estimated vaccine effectiveness was 29% (95% confidence interval, 21%–37%), 20% (6%–31%), and 4% (−12% to 18%), during the BA.4/5-, BQ-, and XBB-dominant phases, respectively. The risk of COVID-19 also increased with time since the most recent prior COVID-19 episode and with the number of vaccine doses previously received. "

ii. https://academic.oup.com/ofid/article/10/6/ofad209/7131292

45. Vaccinated people have increased risk of immune escape compared to unvaccinated.

i. "Overall, the relatively higher intra-host diversity among vaccinated individuals and the detection of immune-escape mutations, despite being rare, suggest a potential vaccine-induced immune pressure in vaccinated individuals."

ii. https://www.cell.com/iscience/fulltext/S2589-0042(22)01710-2

46. In addition to the well-established risk of myocarditis after COVID-19 vaccination, new research has now demonstrated other severe adverse reactions not previously recognized by CDC. A meta-analysis found increased risk of autoimmune skin disorders. Another study found increased risk of retinal vascular occlusion (and consequent blindness)

that persisted for *two years* after COVD-19 vaccination. This corroborates my own professional experience in which I have seen an increasing number of patients with retinal vascular occlusion. Other visual complications include macular neuroretinopathy and paracentral acute middle maculopathy. A link between COVID-19 vaccines and Long Covid-like illness is also now being recognized, as are new onset multiple sclerosis and inflammatory rheumatic disease. COVID-19 vaccination has also been associated with postural orthostatic tachycardia syndrome (POTS).

i. https://onlinelibrary.wiley.com/doi/full/10.1111/ddg.15114
ii. https://www.nature.com/articles/s41541_023_00661_7
iii. https://www.mdpi.com/2076-393X/11/2/474
iv. https://www.science.org/content/article/rare-link-between-coronavirus-vaccines-and-long-covid-illness-starts-gain-acceptance
v. https://pubmed.ncbi.nlm.nih.gov/37077605/
vi. https://rmdopen.bmj.com/content/rmdopen/9/2/e003022.full.pdf
vii. https://pubmed.ncbi.nlm.nih.gov/37303827/

47. COVID-19 infection may be *no worse* than influenza and sepsis for long term medical and mental complications

i. https://pubmed.ncbi.nlm.nih.gov/37338892/

48. To have a meaningful discussion with patients with genuine and comprehensive informed consent, physicians need to be able to share accurate risks of COVID-19 (individualized risk stratification). It is undeniably untrue that "everyone is equally susceptible". For children and young-adults the risk of hospitalization and death from COVID-19 is very, very low. This should be factored into all the risk-benefit analyses before making blanket recommendations. The risks after COVID-19 vaccination need to be discussed with accurate representation of the incidence and severity of each of the side effects. All the known side effects ought to be discussed freely and without restrictions. The putative standard of care (which is indistinguishable from contemporary scientific consensus) would sanction physicians for contradicting CDC's risk-benefit analysis. Many of the disabling and fatal side effects of

COVID-19 vaccination in children and young adults may have been prevented had there been more objective and transparent discussion of stratified risks and benefits earlier.

E. EFFICACY OF MASKING

49. This is an issue which is becoming more important again as many institutions, corporations, and local governments are considering mask mandates for the new variants. The Court will recall that masks were heavily promoted with slogans "masks save lives" and mandated by numerous government agencies, often relying upon CDC's recommendations and published 'studies' for their justification. Any suggestion that masks are ineffective for an airborne virus (and *may* even be harmful) was deemed 'misinformation' for which physicians were censured and censored. However, the mounting scientific evidence indicates that community mask mandates may have had no meaningful contribution to curtailing the spread of this airborne virus. Some evidence even suggests mask mandates may have caused harm to specific subsets of the population.

50. *New York Times* now openly discusses the futility of mask mandates, where it previously strongly promoted masks to prevent COVID-19 spread:

i. https://www.nytimes.com/2023/02/21/opinion/do-mask-mandates-work.html

ii. https://www.nytimes.com/article/coronavirus-masks.html

iii. https://www.nytimes.com/2023/03/10/opinion/masks-work-cochrane-study.html

51. A study entitled "Correlation between mask compliance and COVID-19 outcomes in Europe" found that "countries with high levels of mask compliance did not perform better than those with low mask usage."

i. https://www.cureus.com/articles/93826-correlation-between-mask-compliance-and-covid-19-outcomes-in-europe?fbclid=IwAR1Gi9MaLy36UtUZX8VDqNj3EQl6IqopliaOVlrNLvcd4ZpTIHjdjjo6xBA#!/

52. Another study found "no additional effect was gained from mandating face masks" for children in schools:

i. https://pubmed.ncbi.nlm.nih.gov/37085807/

ii. https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-023-15624-9

53. Masks may even cause harm, as noted by this study:

i. "The findings contribute to existing literature by demonstrating that wearing the N95 mask for 14 hours significantly affected the physiological, biochemical, and perception parameters. The effect was primarily initiated by increased respiratory resistance and subsequent decreased blood oxygen and pH, which contributed to sympathoadrenal system activation and epinephrine as well as norepinephrine secretion elevation"

ii. https://pubmed.ncbi.nlm.nih.gov/37294572/

54. Masks may increase quantity of harmful volatile organic compounds

i. https://pubmed.ncbi.nlm.nih.gov/37079939/

55. Masks may increase toxic chronic carbon dioxide exposure, particularly in pregnant women, children, and adolescents

i. https://www.cell.com/heliyon/pdf/S2405-8440(23)01324-5.pdf?fbclid=IwAR34-NOACEQBNvdPwUDd0uehjfQz2w5QlrYKJ7Y1Vx6Z3MC8E9LdDBCDGpA_aem_AWWCmc1X2PqFlxT9QrBv1QatliNX47F14gOYP2B7sH9DAnC5zNNQt4wT9j1FlPdPTpY&mibextid=Zxz2cZ

56. A preprint study reviewing quality of evidence in CDC's Morbidity and Mortality Weekly Report (MMWR) mask studies found: "MMWR publications pertaining to masks drew positive conclusions about mask effectiveness over 75% of the time despite only 30% testing masks and <15% having statistically significant results. No studies were randomized, yet over half drew causal conclusions. The level of evidence generated was low and the conclusions drawn were most often unsupported by the data."

i. https://www.medrxiv.org/content/10.1101/2023.07.07.23292338v1

57. The study "Bacterial and fungal isolation from face masks under the COVID-19

pandemic" found pathogenic microbes on face masks and authors "propose that immunocompromised people should avoid repeated use of masks to prevent microbial infection." Perhaps this explains why CDC's own data show that more children died of bacterial pneumonia than COVID-19 infection throughout the COVID-19 pandemic.

i. https://www.nature.com/articles/s41598-022-15409-x

ii. https://data.cdc.gov/d/9bhg-hcku/visualization?fbclid=IwAR3YQqnTb3-2lyeCzw-LPp9U3IClHGOrF8mr5lG_Oii6-_wBKFRP9YTacv4

58. Despite virtually universal school mask mandates for primary schools, 92% of all children have evidence of COVID-19 antibodies from prior infection by CDC's own data (higher than any other age group). This strongly suggests that universal school mask mandates in schools were in fact futile.

i. https://covid.cdc.gov/covid-data-tracker/?fbclid=IwAR00sfsJCL8PLQj6DsWXM6ewC-x2ussgogfcwjcNw87r5TkJnGZJQH0dBfM#pediatric-seroprevalence

59. In a letter sent in November 2021 to the CDC, epidemiologist Michael Osterholm, informed the agency it was promoting flawed data and excluding data that did not reinforce their narrative on masks. "We believe the information and recommendations as provided *may actually put an individual at increased risk of becoming infected with SARS-CoV-2* and for them to experience a serious or even life-threatening infection," [emphasis mine] Mr. Osterholm wrote. He admonished the IDSA to remove the suggestion that masking prevents severe disease from its website and urged the CDC to reconsider its statements about the "efficacy of masks and face coverings for preventing transmission of SARS-CoV-2."

i. https://img.theepochtimes.com/assets/uploads/2023/08/21/id5477758-Letter-on-deadly-risks-on-CDC-IDSA-website-1.pdf?_gl=1*zgulv9*_gcl_au*MjA2NDcyNjY5Ny4xNjkzMDgwMTA3

60. Cochrane Database of Systemic Reviews is deemed to be one of the most robust and respectable sources of evidence-based medicine. In its very recent review ("Physical interventions to interrupt or reduce the spread of respiratory viruses") the authors conclude:

> "There is uncertainty about the effects of face masks. The low to moderate certainty of evidence means our confidence in the effect estimate is limited, and that the true effect may be different from the observed estimate of the effect. The pooled results of RCTs did not show a clear reduction in respiratory viral infection with the use of medical/surgical masks. There were no clear differences between the use of medical/surgical masks compared with N95/P2 respirators in healthcare workers when used in routine care to reduce respiratory viral infection. Hand hygiene is likely to modestly reduce the burden of respiratory illness, and although this effect was also present when ILI and laboratory-confirmed influenza were analysed separately, it was not found to be a significant difference for the latter two outcomes. Harms associated with physical interventions were under-investigated."

i. https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD006207.pub6/epdf/full?fbclid=IwAR0FAHQLl_UtEmdYKB8bI3E0J9wy3zrLDNhNShxyKdKXxl4ygbRfMm91BxY

61. The exorbitant resources that were spent in mandating masks "to prevent the spread of COVID-19" and censoring any contrarian views did not have any proven incremental benefit in containing the spread of this airborne virus. Furthermore, these futile efforts *may* have actually caused harm for some subsets of the population in susceptible individuals. Scientific integrity, informed consent, and medical ethics demand that physicians have the freedom to discuss the scientific risks and benefits of these interventions with their patients (especially for those whom prolonged wearing of masks throughout the day may have been unduly burdensome, impaired their cardiorespiratory status, or increased their risk of bacterial pneumonia). Patients deserve to have a candid informed scientifically balanced discussion of the risks and benefits (or lack thereof) of any intervention that putatively prevents disease.

F. THE USE OF OFF-LABEL DRUGS

62. Prior to 2020, SARS-CoV2 virus was not publicly known to the general medical community. Therefore, treatment options were not readily available as SARS-CoV2 began rapidly spreading in 2020, with many hospitals overwhelmed by critically ill patients. Despite the tremendous research efforts invested here in the US and internationally, physicians motivated to provide the best treatment options for their patients could not wait the customary

months or years required for development, research, and testing of new therapeutics. The impetus to try off-label medications was therefore scientifically and ethically justified. Off-label use of medications is more common in medical practice than many may realize. One of the most relevant here is the use of colchicine for pericarditis after COVID-19 infection or COVID-19 vaccination. Despite being off-label, colchicine is the standard of care for pericarditis.

63. Examples of off label medications routinely used:

a. Actiq (oral transmucosal fentanyl citrate) is approved solely for breakthrough cancer pain. However, it is used off-label to treat moderate to severe chronic, non-malignant pain.

i. https://www.drugs.com/actiq.html

ii. https://pubmed.ncbi.nlm.nih.gov/17305684/

b. Bevacizumab has been used off label against wet age-related macular degeneration, as well as macular edema.

i. https://www.theguardian.com/society/2006/jun/17/health.medicineandhealth

c. Buprenorphine has been shown experimentally to be effective against severe, refractory depression.

i. http://www.naabt.org/documents/The_Buprenorphine_effect_on_Depression.pdf

ii. https://journals.lww.com/psychopharmacology/abstract/1995/02000/buprenorphine_treatment_of_refractory_depression.8.aspx

d. Bupropion when sold under the brand name Wellbutrin is indicated for depression. It is also sold as a smoking cessation drug, under the name Zyban. A physician can write a prescription for Wellbutrin to assist with giving up the habit of smoking. Sometimes it is also prescribed as second-line treatment of ADHD, often in combination with the stimulant being used, but it was also shown to work on its own.

i. https://onlinelibrary.wiley.com/doi/10.1111/j.1440-1819.2011.02264.x

e. Carbamazepine, (Tegretol), has been used as a mood stabilizer and is accepted treatment for bipolar disorder.
   i. http://www.leeheymd.com/charts/dep4_1.html

f. Clonidine (Catapres) for ADHD: clonidine is approved and commonly used for the treatment of hypertension. Other off-label uses include cancer pain, hot sweats, certain psychiatric disorders, nicotine dependence, opioid withdrawal, migraine headaches, and restless leg syndrome.
   i. https://www.drugs.com/monograph/clonidine.html#uses

g. Colchicine for pericarditis: colchicine is indicated for the treatment and prevention of gout, though it is also generally considered first-line treatment (standard of care) for acute pericarditis (Appendix A, scientific recommendations from American College of Cardiology), as well as preventing recurrent episodes.
   i. https://pubmed.ncbi.nlm.nih.gov/31918837/

h. Dexamethasone and Betamethasone are used off label in premature labor, to enhance pulmonary maturation of the fetus.
   i. https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2017/08/antenatal-corticosteroid-therapy-for-fetal-maturation

i. Doxepin is a tricyclic antidepressant that has also been used to treat severe allergic reactions due to its strong antihistamine properties.
   i. https://pubmed.ncbi.nlm.nih.gov/3782654/

j. Gabapentin, approved for treatment of seizures and postherpetic neuralgia in adults, is used off-label for a variety of conditions including bipolar disorder, essential tremor, migraine prophylaxis, neuropathic pain syndromes, phantom limb syndrome, and restless leg syndrome.

i. https://universityhealthnews.com/daily/pain/gabapentins-off-label-uses-include-pain-relief/

k. Lithium is approved by the FDA for the treatment of bipolar disorder and is widely prescribed off-label as a treatment for major depressive disorder. often as an augmentation. Lithium is recommended for the treatment of schizophrenic disorders only after other antipsychotics have failed.

i. https://pubmed.ncbi.nlm.nih.gov/15982996/

ii. https://rxce.com/materials/Lithium-Antimanic-and-Off-label-Uses-Tech-Ceu.pdf

l. Magnesium sulfate is used in obstetrics for premature labor and preeclampsia.

i. https://pubmed.ncbi.nlm.nih.gov/19211496/

m. Memantine (Namenda) is approved for the treatment of Alzheimer's disease, but has also been used off-label for Obsessive Compulsive Disorder (OCD).

i. https://pubmed.ncbi.nlm.nih.gov/31846244/

n. Methotrexate (MTX), approved for the treatment of choriocarcinoma, is frequently used for the medical treatment of an unruptured ectopic pregnancy. There is no FDA-approved drug for this purpose and there is little incentive to sponsor an unpatented drug such as MTX for FDA-approval.

i. https://www.aafp.org/pubs/afp/issues/2020/0515/p599.html

o. Prazosin for nightmares: prazosin is approved for the use of hypertension. A meta-analysis and systematic review showed a small benefit for the treatment of PTSD-associated night terrors[v]. Other non-FDA-approved uses for prazosin include the treatment of Raynaud's disease and poisoning due to scorpion venom.

i. https://pubmed.ncbi.nlm.nih.gov/32362287/

p. Propranolol for performance anxiety: propranolol is a non-selective beta-blocker used for the treatment of hypertension and the prophylaxis of angina pectoris. Propranolol has been used off label for the treatment of anxiety

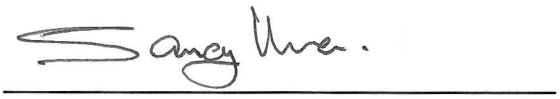
disorders. Other off-label uses for propranolol include the treatment of thyroid storm, portal hypertension, and neuroleptic-induced akathisia.

i. https://pubmed.ncbi.nlm.nih.gov/26487439/
ii. https://pubmed.ncbi.nlm.nih.gov/26487439/
iii. https://www.ebmconsult.com/articles/propranolol-preferred-thyroid-storm-thyrotoxicosis
iv. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5718179/
v. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1192441/

CONCLUSION

I wish to stress that the purpose of this declaration is to support the Plaintiffs' contention that it is not correct to say that there is a true standard of care about almost all the important scientific issues related to SARS-Covi 2 virus. Many of the edicts put out by the public health authorities have had to be changed or abandoned because of new data. As the new edicts change, so do the recommendations of many physicians, but I believe that it is a misuse of the term to call what most physicians are telling patients to be an actual standard of care. Of course, the standard of care can differ in different parts of the country and in different countries, but the divergence of views (as some of the key elements such as the need for continued boosters) shows that the so-called standard of care, at least in this country, is just opinion of public health authorities. Inconsistently, the opinions get promoted in various literature and media, which many physicians simply relate to their patients.

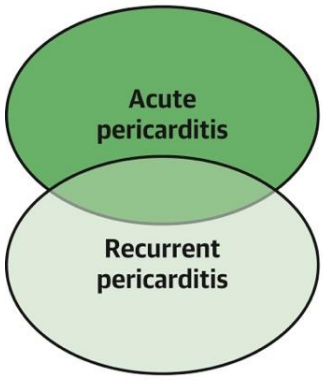
I submit this declaration under penalty of perjury under the laws of the State of California. Executed on February 9, 2024, at Palm Desert, California.



Sanjay Verma, MD

APPENDIX A

- Figure 3: Treatment for Acute and Recurrent Pericarditis and Their Complications from "Management of Acute and Recurrent Pericarditis: *JACC* State-of-the-Art Review" (PMID: 31918837 DOI: 10.1016/j.jacc.2019.11.021)



DRUG	DOSE	DURATION
Aspirin	750-1,000 mg every 8 h	1-2 weeks
Ibuprofen	600-800 mg every 8 h	1-2 weeks
Colchicine	0.5-1.2 mg in one or divided doses	3 months
Aspirin	750-1,000 mg every 8 h	Weeks-months
Ibuprofen	600-800 mg every 8 h	Weeks-months
Indomethacin	25-50 mg every 8 h	Weeks-months
Colchicine	0.5-1.2 mg in one or divided doses	At least 6 months
Prednisone	0.2-0.5 mg/kg/daily	Months
Anakinra	1-2 mg/kg/daily up to 100 mg/daily	Months
Rilonacept	320 mg once, then 160 mg weekly	Months
Azathioprine	1 mg/kg/daily up to 2-3 mg/kg/daily	Months
Methotrexate	10-15 mg weekly	Months
MMF	2,000 mg daily	Months
IVIGs	400-500 mg/kg/day	5 days

Pericardiocentesis

Pericardial window

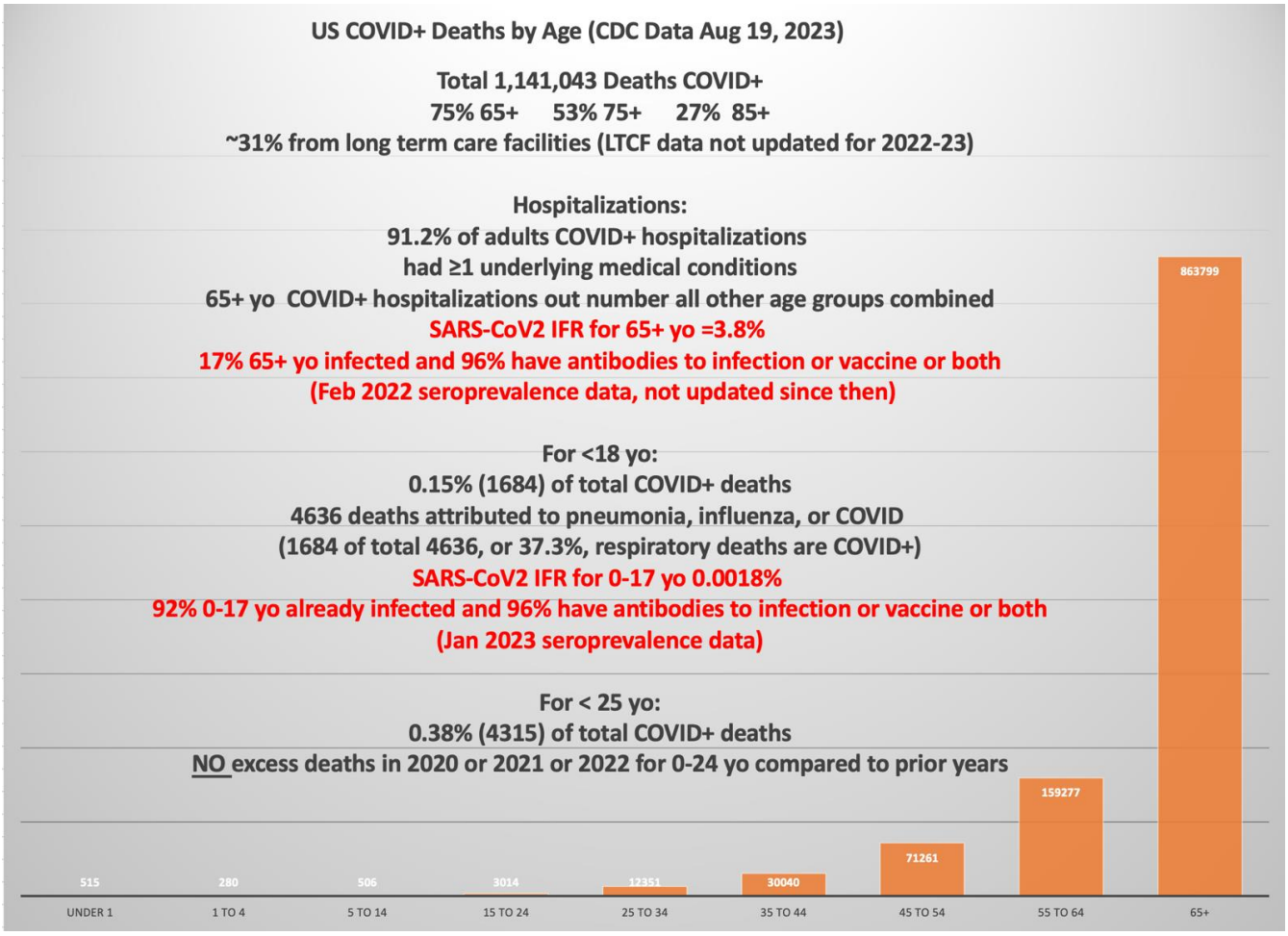
Active inflammation
- Yes → Anti-inflammatory therapy as first line, pericardiectomy for refractory cases
- No → Pericardiectomy

APPENDIX B

CDC data on COVID+ deaths by age and seroprevalence

https://data.cdc.gov/d/9bhg-hcku/visualization?fbclid=IwAR3YQqnTb3-2lyeCzw-LPp9U3IClHGOrF8mr5lG_Oii6-_wBKFRP9YTacv4

https://covid.cdc.gov/covid-data-tracker/#pediatric-seroprevalence



APPENDIX C

Centers for Disease Control and Prevention
National Center for Immunization and Respiratory Diseases

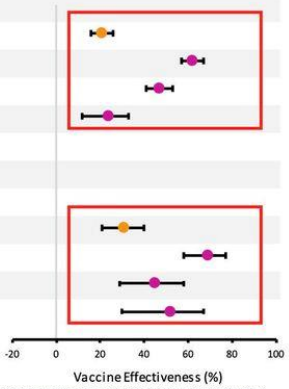
COVID-19 vaccine effectiveness updates

15 June 2023

Ruth Link-Gelles, PhD, MPH
LCDR, US Public Health Service
COVID-19 Vaccine Effectiveness Program Lead
Centers for Disease Control and Prevention

VISION: *Absolute* VE of *monovalent* and *bivalent* booster doses against *hospitalization* and *critical illness* among immuno*competent* adults aged ≥18 years – September 2022 – May 2023

mRNA Dosage Pattern	Total tests	SARS-CoV-2-test-positive, N (%)	Median interval since last dose, days (IQR)	Adjusted VE (95% CI)
Hospitalization				
Unvaccinated (ref)	16,219	1,835 (11)	--	Ref
Monovalent doses only	38,843	4,086 (11)	381 (275-513)	21 (16-26)
Bivalent booster, 7-59 days earlier	4,894	329 (7)	35 (21-47)	62 (57-67)
Bivalent booster, 60-119 days earlier	5,283	491 (9)	87 (73-103)	47 (41-53)
Bivalent booster, 120-179 days earlier	3,756	346 (9)	146 (132-161)	24 (12-33)
Critical illness				
Unvaccinated (ref)	14,762	378 (3)	--	Ref
Monovalent doses only	35,415	658 (2)	380 (275-514)	31 (21-40)
Bivalent booster, 7-59 days earlier	4,614	49 (1)	34 (21-47)	69 (58-77)
Bivalent booster, 60-119 days earlier	4,880	88 (2)	87 (73-103)	45 (29-58)
Bivalent booster, 120-179 days earlier	3,445	35 (1)	146 (132-161)	52 (30-67)

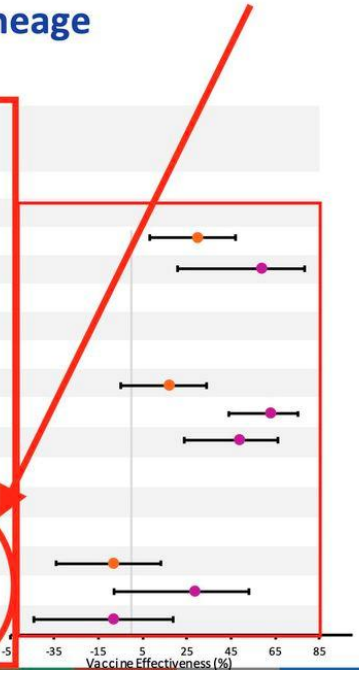


Critical illness defined as admission to intensive care unit or death; case-patients were persons admitted to ICU or who experienced death associated with COVID-19, and control patients were persons hospitalized without COVID-19. VE estimates adjusted for age, sex, race and ethnicity, geographic region, and calendar time. Updated from: Link-Gelles et al., MMWR, https://www.cdc.gov/mmwr/volumes/72/wr/mm7221a3.htm

IVY Network: *Absolute* VE against COVID-19 *hospitalization* among immuno*competent* adults aged *≥18 years* by lineage period — September 8, 2022 – May 24, 2023

	Total Cases and Controls	Cases (%)	Median time since last dose, days (IQR)	Adjusted VE*, % (95% CI)
BA.4/5 (September 8 – November 13, 2022)				
Unvaccinated (Ref)	313	138 (44)	--	**Ref**
Monovalent doses only	1003	398 (40)	304 (188–386)	**30 (8– 47)**
Bivalent booster dose, 7–59 days earlier	83	26 (31)	25 (13–40)	**59 (21–78)**
BQ.1 (November 14, 2022 – January 22, 2023)				
Unvaccinated (Ref)	458	190 (41)	--	**Ref**
Monovalent doses only	1262	504 (40)	386 (297–518)	**17 (-5 to 34)**
Bivalent booster dose, 7–59 days earlier	226	52 (23)	40 (25–52)	**63 (44–75)**
Bivalent booster dose, 60–119 days earlier	225	68 (30)	83 (69–95)	**49 (24–66)**
XBB (January 23 – May 24, 2023)				
Unvaccinated (Ref)	514	209 (41)	--	**Ref**
Monovalent doses only	1246	558 (45)	464 (378–590)	**-8 (-34 to 13)**
Bivalent booster dose, 7–89 days earlier	155	56 (36)	64 (46–78)	**29 (-8 to 53)**
Bivalent booster dose, 90–179 days earlier	478	208 (44)	137 (118–154)	**-8 (-44 to 19)**

*VE adjustments: Age, sex, race, ethnicity, admission date (biweekly), and HHS region

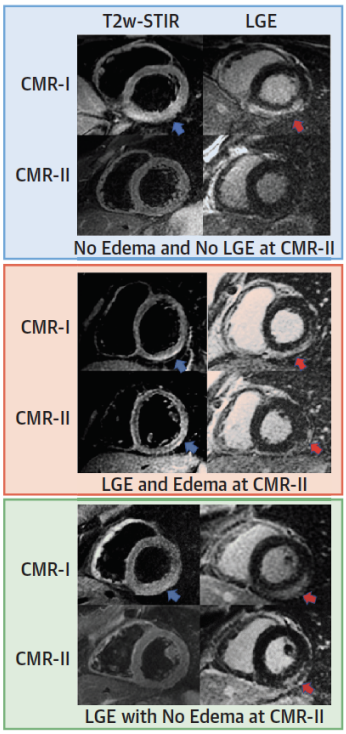


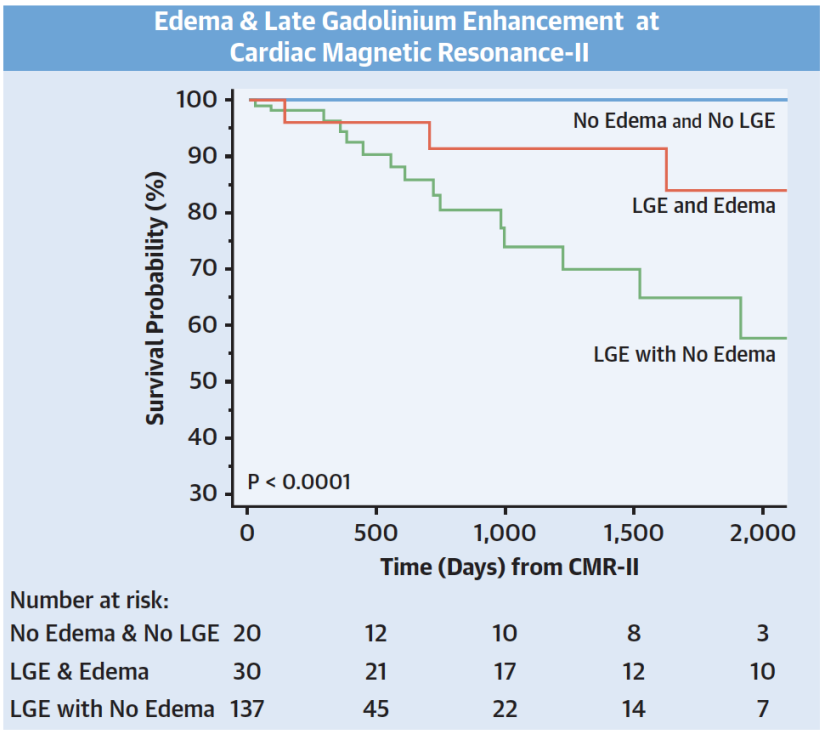
APPENDIX D

Prognostic Role of 6-Month Follow-Up CMR in Myocarditis

https://www.jacc.org/doi/abs/10.1016/j.jacc.2019.08.1061

CENTRAL ILLUSTRATION Prognostic Role of 6-Month Follow-Up CMR in Myocarditis





Aquaro, G.D. et al. J Am Coll Cardiol. 2019;74(20):2439-48.

Cardiac magnetic resonance (CMR) was performed within the first week following symptom onset (CMR-I) and after 6 months (CMR-II). At CMR-II, 3 different presentations were found: 1) the complete absence of edema and late gadolinium enhancement (LGE) (no edema and no LGE, **left top**); 2) the presence of both edema and LGE (LGE and edema, **left middle**); and 3) LGE without edema (LGE with no edema, **left bottom**). The **red arrows** identify the presence of LGE, and the **blue arrows** indicate the presence of edema. **(Right)** The Kaplan-Meier survival curves demonstrate that patients with LGE but without edema at CMR-II had a worse prognosis than those with edema and LGE and than those with complete healing from edema and LGE.

APPENDIX E

CDC's intermediate term follow-up study on myocarditis (Lancet study)

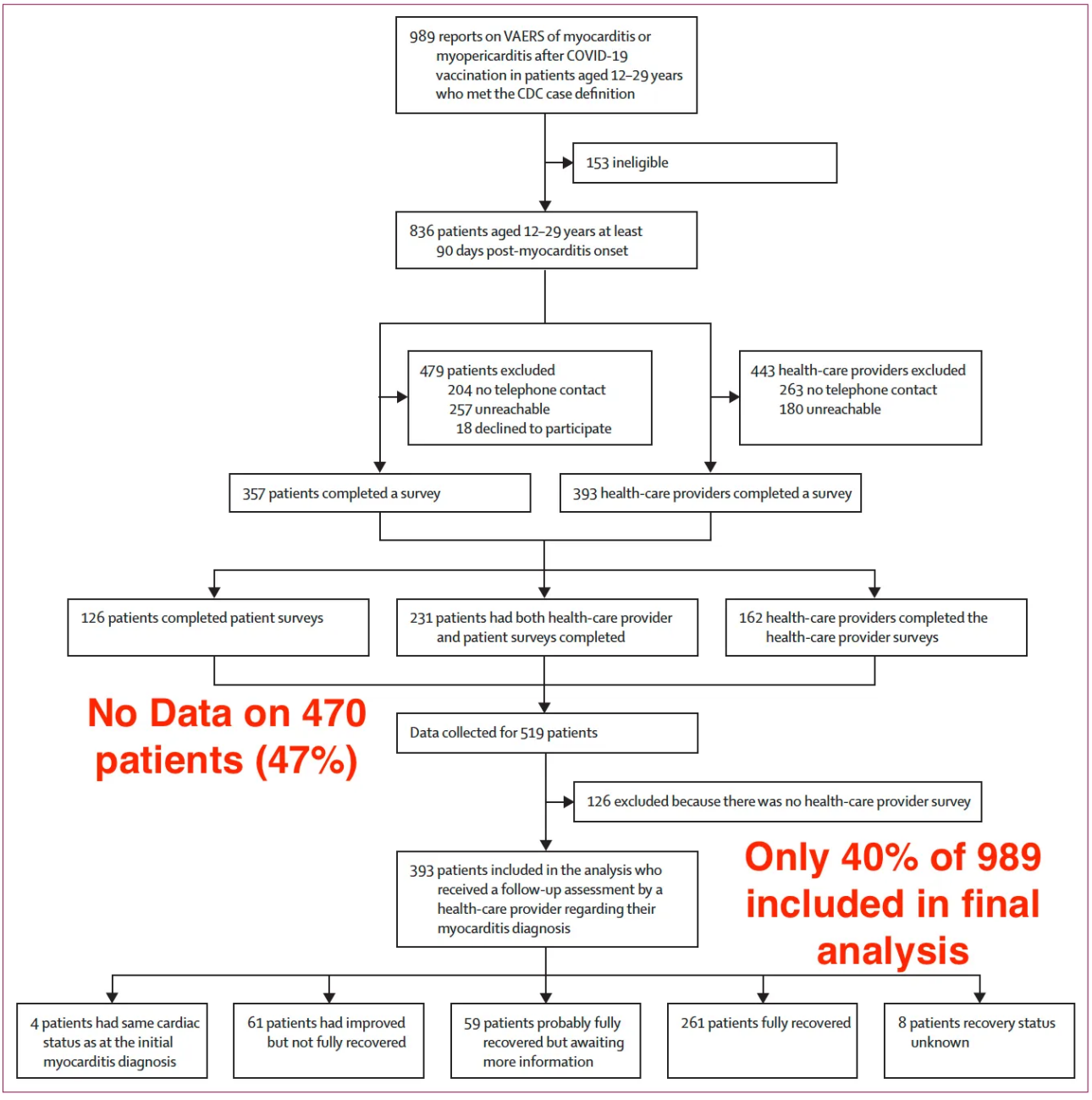


Figure 1: **Survey participation of patients with myocarditis after mRNA COVID-19 vaccination reported to VAERS at least 90 days since symptom onset**
CDC=US Centers for Disease Control and Prevention. VAERS=Vaccine Adverse Event Reporting System.

	Patients fully or probably fully recovered (n=320)	Patients not recovered (n=65)	All patients (n=519)	p value
(Continued from previous page)				
Patient-reported symptoms in the patient survey	n=195§	n=28§	n=357	..
At least one symptom	94 (48%)	18 (64%)	178 (50%)	0·16
Chest pain or discomfort	55 (28%)	13 (46%)	113 (32%)	0·082
Chest pain or discomfort while resting	45 (23%)	11 (39%)	92 (26%)	0·011
Fatigue	40 (21%)	12 (43%)	89 (25%)	0·018
Fatigue while resting	28 (14%)	10 (36%)	63 (18%)	0·012
Shortness of breath	38 (19%)	9 (32%)	80 (22%)	0·28
Shortness of breath while resting	15 (8%)	4 (14%)	38 (11%)	0·42
Heart palpitations	36 (18%)	6 (21%)	77 (22%)	0·71
Heart palpitations while resting	28 (14%)	5 (18%)	59 (17%)	0·84

~50% still had symptoms of myocarditis!

Data are n (%) unless specified otherwise. Data are based on the completion of 357 patient surveys, 393 provider surveys, and 231 linked surveys, resulting in 519 patients for which data were collected. Health-care provider determination of patient myocarditis recovery was provided for 393 patients, of whom 320 were considered fully or probably fully recovered and 65 were not considered recovered (and eight patients had an undetermined recovery status; figure 1). Based on the last patient encounter, health-care providers reported that 62 (16%) of 393 patients had at least one symptom that might occur with myocarditis. *Previous SARS-CoV-2 infection before the diagnosis of myocarditis, as determined by a positive laboratory-confirmed test; the interval from a positive SARS-CoV-2 test result to mRNA COVID-19 vaccination was a median of 139 days (IQR 92–198; n=15 with a date provided). †Asthma, for which prescription medicine within the past 2 years was needed; if asthma was only with exercise, it was not recorded. ‡BMI was calculated using measurements obtained at the earliest follow-up visit: the formula weight (pounds) / [height (inches)]² × 703. The denominators reflect the number of individuals with data available to calculate BMI. §All patients who self-reported symptoms in the patient survey and had a provider-reported recovery status.

Table 1: **Demographic characteristics and symptoms of patients by provider-reported recovery status from myocarditis after mRNA COVID-19 vaccination**

APPENDIX F

From "Effectiveness of Coronavirus Disease 2019 Bivalent Vaccine"

- Risk of COVID-19 infection *increases* with each additional COVID-19 vaccine dose
- https://academic.oup.com/ofid/article/10/6/ofad209/7131292
- https://pubmed.ncbi.nlm.nih.gov/37274183/

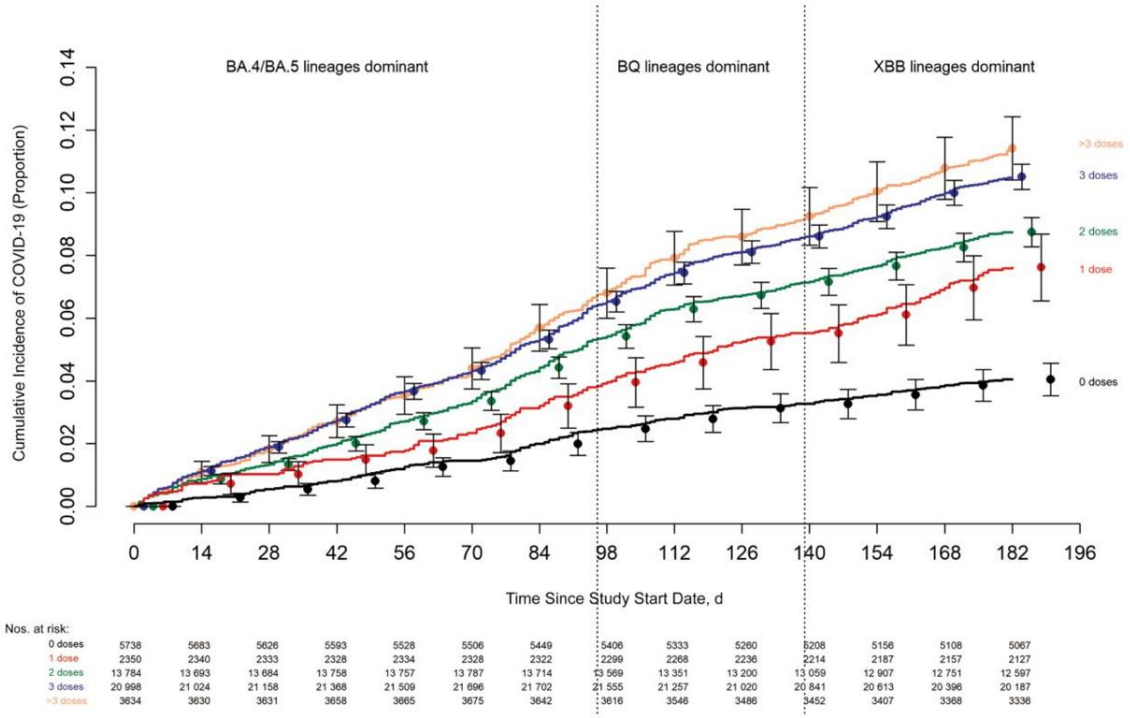
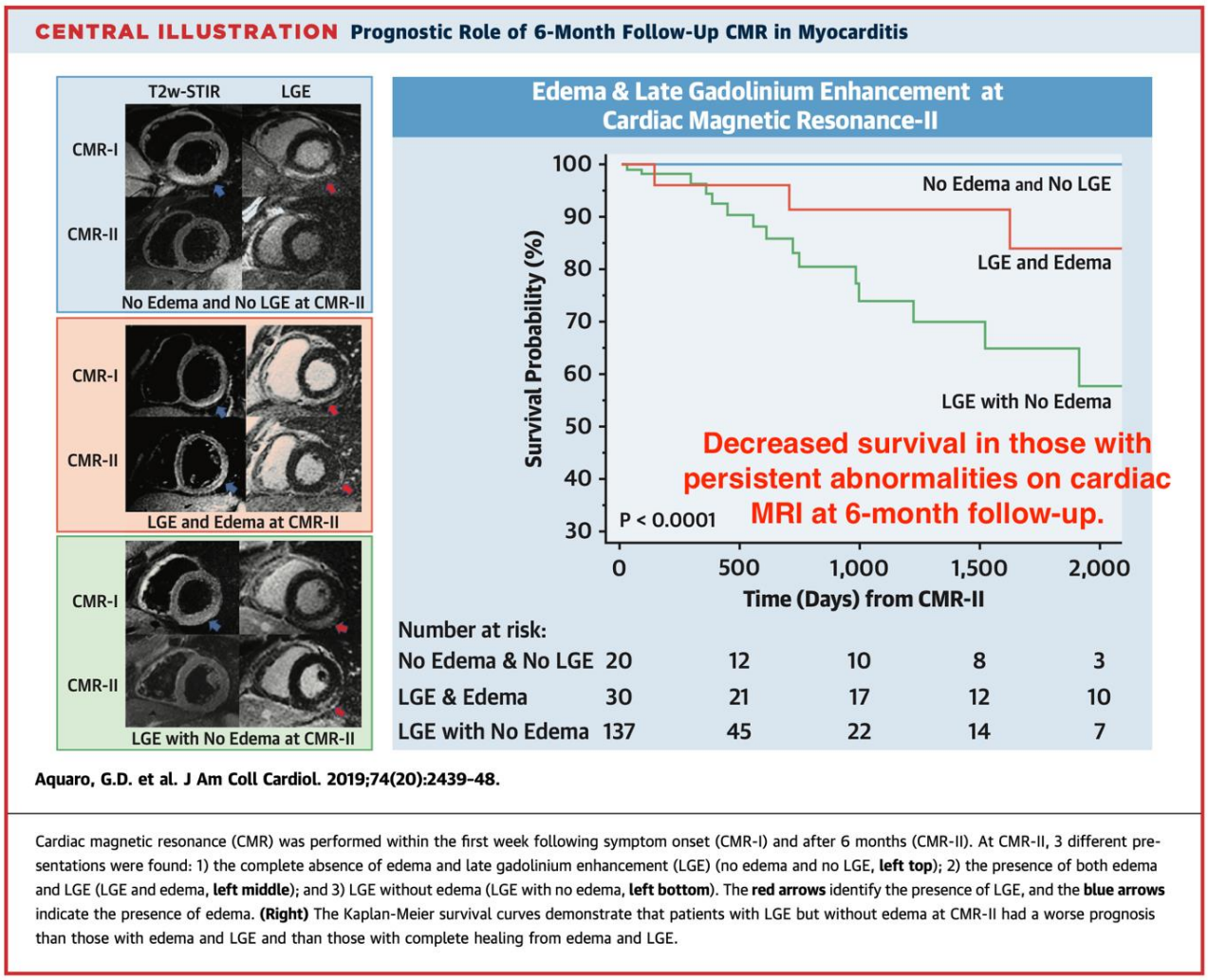


Figure 2. Cumulative incidence of coronavirus disease 2019 (COVID-19) for study participants stratified by the number of COVID-19 vaccine doses previously received. Day 0 was 12 September 2022, the date the bivalent vaccine was first offered to employees. Point estimates and 95% confidence intervals are jittered along the x-axis to improve visibility.

APPENDIX G

Decreased survival in those with persistent abnormalities on cardiac MRI at 6-month follow-up after myocarditis

- https://www.sciencedirect.com/science/article/pii/S0735109719377368?via%3Dihub



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