[redacted]

August 23rd, 2022

Re: [redacted]

To Whom it May Concern,

I am a practicing Emergency Physician, in both academic and community settings, with a doctoral background in computational decision modeling with expertise in the application of mathematical and computational techniques to medical decisions. An updated copy of my Curriculum Vitae is attached. I have reviewed Mr. [redacted] medical history as it pertains to his COVID-19 vaccination status and potential complications from the same including his most recent doppler ultrasound results. Mr. [redacted] had a COVID-19 infection in January 2021 as documented with a formal rapid antigen test. He recovered from that illness without incident. Subsequently, due to mandates issued by Michigan State University, Mr. [redacted] completed a 2 dose Pfizer COVID vaccine series September 5th, 2021. Two months after completion, Mr. [redacted] developed a Deep Venous Thrombosis (DVT) in his leg extending above the knee. There were no other events such as prolonged immobilization or trauma or a prior history of DVT or family history of the same to serve as an adequate explanation for Mr. [redacted] DVT.

From the outset of the latest waves of the dominant Omicron variant, we have had ample evidence that vaccinees who were boosted or had a prior infection enjoyed excellent neutralization of Omicron variants. The Advisory Committee on Immunization Practices (ACIP) specifically acknowledged this over 8 months ago in 11/19/2021 and 12/16/2021 (slide 12 in particular) ACIP meetings.[1,2]

More recent data in a post-Omicron infection sample, shows that those with prior infection, with or without associated vaccination, have a robust rise in neutralizing antibodies after an Omicron infection. Indeed, those who were vaccinated alone with no prior infection had modal titers similar to those who were unvaccinated.[3] In this same study, 47% of the vaccinees had an mRNA vaccination within the preceding 3 months and 40% had been boosted.[3] More recent literature has examined local tissue and mucosal immunity generated by an infection compared to vaccination alone.[4,5] Furthermore, disease severity does not determine the potency or longevity of response with commercially available assay levels correlating with separate neutralizing-antibody titers.[6] A COVID infection, at least once, is an inevitability and may be an immunologic requirement.

What about transmission and vaccination/booster status with Omicron and associated subvariants? An early December 2021 paper in Danish Households demonstrated a roughly 40% reduction in household secondary attack rate (SAR) with boosting when compared to the unvaccinated or vaccinated.[7] Focusing on table 9, during the early December 2021 study period, booster vaccination cut the risk of contracting BA.1 by roughly 45%+ and passing on BA.1 by roughly 40% and then only 20% with BA.2 6 weeks

[1] https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-11-19/06-COVID-Oliver-508.pdf
[2] https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-12-16/06-COVID-Scobie-508.pdf
[3] https://www.nejm.org/doi/full/10.1056/NEJMc2201607
[4] https://www.science.org/doi/10.1126/sciimmunol.add4853
[5] https://www.science.org/doi/10.1126/sciimmunol.abl9105
[6] https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2794167
[7] https://www.medrxiv.org/content/10.1101/2021.12.27.21268278v1.full.pdf

later.[8,9] While this appeared promising, the subsequent ecological waves from late December 2022 forward in heavily boosted countries demonstrated otherwise. Denmark, Iceland, Norway, New Zealand, Australia, Hong Kong, South Korea all experienced per-capital COVID waves larger than any experienced by the United States.[10] So the advantage of boosting, while demonstrable in an 8-week time frame, appears to rapidly devolve over time.

The Relevance and Importance of Prior SARS-CoV-2 Infection: SARS-CoV-2 was new to our immune systems in early 2020. But as of August 2022, at least 97 percent of Americans have some protective immunity, from either vaccination or infection.[11] COVID vaccines likely saved many lives by priming immune systems before exposure, **yet it is clear that neither vaccination nor mass testing will stop transmission or infection**.[12] The vaccine's transmission reduction was never studied, as Dr. Patrick Moore of the University of Pittsburgh Cancer Institute pointed out (page 342 of transcript) in an open FDA meeting.[13,14] **As with influenza, cases of COVID-19 will continue to appear, but the number and severity of those infections will be significantly reduced.**[15] The most recent CDC update to infection induced seroprevalence was published on August 22nd. 2022 and measured antibodies induced by infection alone through June 26th, 2022 estimated the presence of detectable prior infection at 80% in the under-18-year-oldgroup.[16] Given an additional ~8% cumulative infections since June 26th, 2022, likely 90% of the pediatric and young adult population has had a prior infection.[17] Consequently, when considering the general population, at this point. is clear that neither vaccination or mass testing will stop COVID-19, both vaccination and prior infection will confer resistance to severe disease. Furthermore, a large CDC study with data from New York and California found no extra benefit against severe disease from vaccination following infection,[18] and immunity following infection is durable: post-infection antibody response has now been measured out to 20 months and counting.[19]

Durability Over Time of Immune Memory to SARS-CoV-2 Infection: A healthy immune system mounts an effective response to SARS-CoV-2 infection and this response persists over time. A recent July 2022 publication where 96.7% of study participants had mild or asymptomatic infection shows that children and young adults mount a robust antibody response that will fade with time, but remains measurably present.[20] Once again this speaks to an expected pattern of less severe disease with any subsequent infection. This study reinforced prior research that measured these responses up to 12 months. The stimulation of an immune response after a mild infection can even be demonstrated in the absence of actual seroconversion (detectable prior infection by antibodies) at the level of T-cells.[21] The presence of effective immune memory, both humoral (antibody) and cellular components, after even a mild SARS-CoV-2 infection is no longer a matter of debate.

[8] https://www.medrxiv.org/content/10.1101/2021.12.27.21268278v1
[9] https://www.medrxiv.org/content/10.1101/2022.01.28.22270044v1
[10] https://tinyurl.com/2sn4xcze
[11] https://covid19serohub.nih.gov/
[12] https://www.inquirer.com/health/expert-opinions/covid-19-pandemic-immunity-boosters-normal-20220304.html
[13] https://www.fda.gov/media/148542/download#page=38
[14] https://www.fda.gov/media/144859/download (page 342)
[15] https://www.eurekalert.org/news-releases/694958
[16] https://www.cdc.gov/mmwr/volumes/71/wr/mm7117e3.htm?s_cid=mm7117e3_w
[17] https://tinyurl.com/bdd5tntr
[18] https://www.cdc.gov/mmwr/volumes/71/wr/mm7104e1.htm
[19] https://jamanetwork.com/journals/jama/fullarticle/2788894
[20] https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2794167
[21] https://www.sciencedirect.com/science/article/pii/S0092867420310084

One might be tempted to argue that repeated boosting can permanently suppress infection. Unfortunately, all available evidence suggests that the increased protection from infection is transient. A recent publication from Iceland has offered unique insights into what we can expect with post-Omicron reinfections in different vaccination categories.[22] While I felt there were significant problems with possible ascertainment bias and grouping of unvaccinated with 1 dose recipients, the authors found:

> Surprisingly, 2 or more doses of vaccine were associated with a slightly higher probability of reinfection compared with 1 dose or less. This finding should be interpreted with caution because of limitations of our study, which include the inability to adjust for the complex relationships among prior infection, vaccine eligibility, and underlying conditions.

A more robust nationwide study from Qatar, once again, provides corroborating evidence for the potency of prior infection.[23] Per the authors:

> No discernable differences in protection against symptomatic BA.1 and BA.2 infection were seen with previous infection, vaccination, and hybrid immunity. Vaccination enhanced protection among persons who had had a previous infection. Hybrid immunity resulting from previous infection and recent booster vaccination conferred the strongest protection. [All provided excellent protection against severe outcomes].

But as pertaining to the absolute risk reduction of a recent booster or vaccination on top of a prior infection, a detailed examination of the data tables reveals a striking pattern. In addition to robust protection from severe disease afforded by prior infection in patients with little difference after subsequent vaccination, symptomatic infection rate differences after a prior infection with various doses of vaccine corroborate the authors' conclusion.

From another large Qatari study:[24]

> "BNT162b2 effectiveness was highest at 46.6% (95% CI: 33.4–57.2%) against symptomatic BA.1 and at 51.7% (95% CI: 43.2–58.9%) against symptomatic BA.2 infections in the first three months after the second dose, but declined to ~10% or below thereafter. Effectiveness rebounded to 59.9% (95% CI: 51.2–67.0%) and 43.7% (95% CI: 36.5–50.0%), respectively, in the first month after the booster dose, before declining again."

Waning was also confirmed by a large nationwide Israeli study with the booster:[25]

> "These results suggest that there is a significant waning of vaccine effectiveness against the Omicron variant of the third dose of the BNT162b2 vaccine within a few months after administration."

With over 90% of the campus vaccinated **and** boosted, Cornell concluded that:[26,27]

> "While vaccination protected against severe illness, it was not sufficient to prevent rapid

[22] https://jamanetwork.com/journals/jamanetworkopen/article-abstract/2794886
[23] https://www.nejm.org/doi/full/10.1056/NEJMoa2203965
[24] https://www.nature.com/articles/s41467-022-30895-3
[25] https://www.nature.com/articles/s41467-022-30884-6
[26] https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2792382
[27] https://covid.cornell.edu/testing/dashboard/

spread, even when combined with other public health measures including widespread surveillance testing."

Per an NIH study, Omicron specific boosters did not elicit increases in Omicron specific neutralizing antibodies which is a concerning finding for a process called "imprinting".[28] This is not a fringe opinion as it was even cited by Dr. Paul Offit in a New England Journal of Medicine editorial.[29] NIH re-analysis of the Moderna trial data indicated that 93% of subsequently infected placebo participants formed anti-N (anti-nucleocapsid) antibodies while only 40% of vaccine recipients formed these same antibodies.[30] We don't know the long-term significance of this finding, but we have known since mid-2021 that the presence of anti-N antibodies correlates with a reduced risk of reinfection.[31]

mRNA Vaccine Associated Adverse Events

While myocarditis/myopericarditis is not the only known adverse event signal with mRNA vaccines, it has garnered the most attention and is the most relevant to Mr. Chenevert's demographics. Consequently, it serves as a helpful canonical example. mRNA vaccine associated myocarditis/myopericarditis is an uncommon, but well-documented issue with COVID vaccines in young adults, particularly after 2nd or 3rd doses, and particularly in otherwise healthy males.

That said, the oft cited statistic that COVID associated myocarditis is more frequent than myocarditis/pericarditis (myopericarditis) from mRNA vaccination carries its own exaggerations and inaccuracies. They are distinct entities occurring in different populations and different clinical circumstances.

In adolescents and young adults, vaccine-induced myocarditis occurs at a rate of between 1/10,000 and 1/3300 with the highest rates in adolescent boys and young adult males.[32,33] A Kaiser chart review demonstrated that official reporting undercounted cases.[34] These cases would constitute clear violations of the "first, do no harm" principle. There has always been a standing concern about asymptomatic post-vaccine myocarditis: this is not unique to the COVID vaccines. In May 2003, there was some evidence that Smallpox vaccination could be associated with myocarditis, but CDC, at that time, still noted that "signal" was not clearly abnormal.[35] 12 years later, a subsequent study published a 60-fold increased rate of myocarditis when active screening of asymptomatic cases was added to normal passive surveillance.[36] After initial CDC denial of any evidence of post-vaccine myocarditis with the COVID-19 vaccines, they had to backtrack on this premature proclamation. In fact, the FDA tasked Pfizer with studying the rate of asymptomatic myocarditis from booster vaccination with study completion September 2023.[37,38] A recent Thai pre-print that performed active surveillance for asymptomatic myopericarditis is the first of its kind. Out of 301 13-year-old to 18-year-old enrollees, 3 had symptomatic myocarditis/myopericarditis and 7 of the 301 enrollees had asymptomatic troponin elevations such that the additional 4 were classified as having myocarditis/pericarditis. Important caveats:

[28] https://www.biorxiv.org/content/10.1101/2022.02.03.479037v1.full.pdf
[29] https://www.nejm.org/doi/full/10.1056/NEJMe2203329
[30] https://www.medrxiv.org/content/10.1101/2022.04.18.22271936v1.full.pdf
[31] https://www.thelancet.com/journals/lanhl/article/PIIS2666-7568(21)00093-3/fulltext
[32] https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciab989/6445179?login=true
[33] https://www.epi-phare.fr/rapports-detudes-et-publications/myocardite-pericardite-vaccination-covid19/
[34] https://www.medrxiv.org/content/10.1101/2021.12.21.21268209v1
[35] https://www.cidrap.umn.edu/news-perspective/2003/03/link-between-smallpox-vaccine-and-myocarditis-looks-more-likely
[36] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4368609/
[37] https://www.fda.gov/media/151710/download (page 8)
[38] https://clinicaltrials.gov/ct2/show/NCT04955626?term=C4591031&draw=2&rank=1

- all patients had resolution of symptoms and, for the one patient who had a cardiac MRI, resolution of imaging abnormalities at 5 months.
- Additionally, we don't know the long-term clinical significance, if any, of subclinical myocarditis/myopericarditis.

It would be reckless to completely dismiss any concerns about myopericarditis and potential long-term consequences. In the near term, it is a known cause of Sudden Cardiac Death in those under 50-years-old even while it is chronically under-investigated and incompletely reported.[39] "COVID myocarditis" is a "critical care cardiomyopathy" seen in those who are very ill with COVID. This is "critical are cardiomyopathy" is seen in a wide variety of illnesses and is not just limited to COVID. Cardiac enzymes measured in the blood, which serve as a proxy for amount cardiac damage, are uniformly lower with critical care cardiomyopathy of COVID compared to mRNA induced myopericarditis.[40] **Risking vaccine-induced myocarditis in otherwise healthy young adults and teens, most of which could be avoided given the majority have immunity from prior infection, is imprudent regardless of the presumed clinical course of such a complication**.[41,42]

As a physician and a data-scientist, the current controlled experimental evidence and revealed ecological epidemic waves globally, locally, and even within our hospital do not support the position that boosting on top of robust "hybrid immunity" will further decrease Mr. [redacted]'s risk of contracting or transmitting SARS-CoV-2 to any potential contacts at Michigan State University or the surrounding community regardless of their age or vaccination status. It certainly confers no additional protection from severe disease for him. He is fit and young and this alone decreases his risk of transmission given that we have known for some time that infectious aerosol generation and "breakthrough infection" are both elevated in high BMI and older age cohorts.[43,44] To that end, Mr. [redacted] would entertain risks, some known and others unknown, without incurring any benefits to his immediate contacts in the community.

In summary, for the reasons noted above, ongoing insistence on COVID-19 booster vaccination for Mr. [redacted] is not only a violation of his autonomy, but medically risky without any clear benefit to him or any of his contacts. While one cannot definitively link his extensive leg DVT to his 2nd vaccination, the absence of another explanation raises some concern. If there is an underlying and yet undetected proclivity to clotting in Mr. [redacted] potentially exacerbated by the mRNA vaccine, given no sustained community benefit to him receiving a COVID-19 booster, insisting that he do so is, at the very least, medically, and epidemiologically unwarranted and potentially dangerous.

Respectfully,

[redacted]

[39] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6713107/
[40] https://www.medrxiv.org/content/10.1101/2021.10.05.21264581v1
[41] https://onlinelibrary.wiley.com/doi/10.1111/eci.13759
[42] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6713107/
[43] https://www.pnas.org/doi/10.1073/pnas.2021830118
[44] https://www.nature.com/articles/s41574-021-00608-9