AFFIDAVIT OF PETER A. MCCULLOUGH, M.D., M.P.H.

1. I swear and affirm that the testimony in this affidavit is true and correct and represents my expert medical opinions in this matter within a reasonable degree of medical certainty.

2. I have been asked to provide expert medical opinions to address the risks and benefits presented by the administration of the Covid 19 vaccine to SD, age 13, and IMD, age 17 years and 10 months, both minor sons of BS-D and DD, and to provide my recommendation to assist the Court in determining what is in the best interests of the children with respect to the subject of whether they should be mandated to take a COVID-19 shot.

3. I will provide my general and specific analysis and focus my general discussion on the demographic that both of these children belong to, which is children under the age of 18.

4. In preparation for this, Affidavit, I have reviewed the Affidavits of DD and ID, as well as the mother's Response and attachments.

As to my background:

5. After receiving a bachelor's degree from Baylor University, I completed my medical degree as an Alpha Omega Alpha graduate from the University of Texas Southwestern Medical School in Dallas. I went on to complete my internal medicine residency at the University of Washington in Seattle, a cardiology fellowship including service as Chief Fellow at William Beaumont Hospital, and a master's degree in public health in the field of epidemiology at The University of Michigan. My curriculum vitae is attached as **Exhibit A**.

6. I am board certified in internal medicine and cardiovascular disease and hold an additional certification in clinical lipidology, and previously echocardiography. I participate in the maintenance of certification programs by the American Board of Internal Medicine for both

Internal Medicine and Cardiovascular Diseases. I practice internal medicine and clinical cardiology as well as teach, conduct research, and I am an active scholar in medicine with roles as an author, editor-in-chief of a peer-reviewed journal, editorialist, and reviewer at dozens of major medical journals and textbooks.

7. I have led clinical, education, research, and program operations at major academic centers (Henry Ford Hospital, Oakland University William Beaumont School of Medicine) as well as academically oriented community health systems. I spearheaded the clinical development of in vitro natriuretic peptide and neutrophil gelatinase associated lipocalin assays in diagnosis, prognosis, and management of heart and kidney disease now used worldwide. I also led the first clinical study demonstrating the relationship between severity of acute kidney injury and mortality after myocardial infarction. I have contributed to the understanding of the epidemiology of chronic heart and kidney disease through many manuscripts from the Kidney Early Evaluation Program Annual Data Report published in the American Journal of Kidney Disease and participated in clinical trial design and execution in cardiorenal applications of acute kidney injury, hypertension, acute coronary syndromes, heart failure, and chronic cardiorenal syndromes. I participated in event adjudication (involved attribution of cause of death) in trials of acute coronary syndromes, chronic kidney disease, heart failure, and data safety and monitoring of antidiabetic agents, renal therapeutics, hematology products, and gastrointestinal treatments. I have served as the chairman or as a member of over 20 randomized trials of drugs, devices, and clinical strategies. Sponsors have included pharmaceutical manufacturers, biotechnology companies, and the National Institutes of Health.

8. I frequently lecture and advise on internal medicine, nephrology, and cardiology to leading institutions worldwide. I am recognized by my peers for my work on the role of chronic

kidney disease as a cardiovascular risk state. I have over 1,000 related scientific publications, including the "Interface between Renal Disease and Cardiovascular Illness" in Braunwald's Heart Disease Textbook. My works have appeared in the New England Journal of Medicine, Journal of the American Medical Association, and other top-tier journals worldwide. I am a senior associate editor of the American Journal of Cardiology. I have testified before the U.S. Senate Committee on Homeland Security and Governmental Affairs, the U.S. Food and Drug Administration Cardiorenal Advisory Panel and its U.S. Congressional Oversight Committee, The New Hampshire Senate, the Colorado House of Commons, Texas Senate Committee on Health and Human Services, and South Carolina Senate Committee on Medical Affairs.

9. I am a Fellow of the American College of Cardiology, the American Heart Association, the, the American College of Chest Physicians, the National Lipid Association, the Cardiorenal Society of America, and the National Kidney Foundation. I am also a Diplomate of the American Board of Clinical Lipidology.

10. In 2013, I was honored with the International Vicenza Award for Critical Care Nephrology for my contribution and dedication to the emerging problem of cardiorenal syndromes. I am a founding member of Cardiorenal Society of America, an organization dedicated to bringing together cardiologists and nephrologists and engage in research, improved quality of care, and community outreach to patients with both heart and kidney disease.[1]

11. I am the current President of the Cardiorenal Society of America, an expert organization dedicated to advancing research and clinical care for patients who have combined heart and kidney disease. Finally, I am the Editor-in-Chief of Reviews in Cardiovascular Medicine, a widely read journal that publishes reviews on

1 http://www.cardiorenalsociety.org/

contemporary topics in cardiology and is also listed by the National Library of Medicine.

12. My appended curriculum vitae further demonstrates my academic and scientific achievements and provides a list of publications authored by me in the past 30 years.

13. Since the outset of the pandemic, I have been a leader in the medical response to the COVID-19 disaster and have published "Pathophysiological Basis and Rationale for Early Outpatient Treatment of SARS-CoV-2 (COVID-19) Infection," the first synthesis of sequenced multidrug treatment of ambulatory patients infected with SARS-CoV-2 in the American Journal of Medicine and updated in Reviews in Cardiovascular Medicine.[2] I have 45 peer-reviewed publications on the COVID-19 infection cited in the National Library of Medicine. Through a window to public policymakers, I have contributed extensively on issues surrounding the COVID-19 crisis in a series of OPED's for The Hill in 2020. I testified on the SARS-CoV-2 outbreak in the U.S. Senate Committee on Homeland Security and Governmental Affairs on November 19, 2020. I testified on lessons learned from the pandemic response in the Texas Senate Committee on Health and Human Services on March 10, 2021, and on early treatment of COVID-19 at the Colorado General Assembly on March 31, 2021. Additionally, I testified in the New Hampshire Senate on legislation concerning the investigational COVID-19 vaccine on April 14, 2020. My expertise on the SARS-CoV-2 infection and COVID-19 syndrome, like that

2 McCullough PA, Kelly RJ, Ruocco G, Lerma E, Tumlin J, Wheelan KR, Katz N, Lepor NE, Vijay K, Carter H, Singh, B, McCullough SP, Bhambi BK, Palazzuoli A, De Ferrari GM, Milligan GP, Safder T, Tecson KM, Wang DD, McKinnon JE, O'Neill WW, Zervos M, Risch HA. Pathophysiological Basis and Rationale for Early Outpatient Treatment of SARS-CoV-2 (COVID-19) Infection. Am J Med. 2021 Jan;134(1):16-22. doi: 10.1016/j.amjmed.2020.07.003. Epub 2020 Aug 7. PMID: 32771461; PMCID: PMC7410805 available at https://pubmed.ncbi.nlm.nih.gov/32771461/; McCullough PA, Alexander PE, Armstrong R, Arvinte C, Bain AF, Bartlett RP, Berkowitz RL, Berry AC, Borody TJ, Brewer JH, Brufsky AM, Clarke T, Derwand R, Eck A, Eck J, Eisner RA, Fareed GC, Farella A, Fonseca SNS, Geyer CE Jr, Gonnering RS, Graves KE, Gross KBV, Hazan S, Held KS, Hight HT, Immanuel S, Jacobs MM, Ladapo JA, Lee LH, Littell J, Lozano I, Mangat HS, Marble B, McKinnon JE, Merritt LD, Orient JM, Oskoui R, Pompan DC, Procter BC, Prodromos C, Rajter JC, Rajter JJ, Ram CVS, Rios SS, Risch HA, Robb MJA, Rutherford M, Scholz M, Singleton MM, Tumlin JA, Tyson BM, Urso RG, Victory K, Vliet EL, Wax CM, Wolkoff AG, Wooll V, Zelenko V. Multifaceted highly targeted sequential multidrug treatment of early ambulatory high- risk SARS-CoV-2 infection (COVID-19). Rev Cardiovasc Med. 2020 Dec 30;21(4):517 doi: 10.31083/j.rcm.2020.04.264. PMID: 33387997 available at https://pubmed.ncbi.nlm.nih.gov/33387997/.

of infectious disease specialists, is approximately 18 months old with the review of hundreds of manuscripts and with the care of many patients with acute COVID-19, post-COVID-19 long-hauler syndromes, and COVID-19 vaccine injury syndromes including neurologic damage, myocarditis, and a variety of other internal medicine problems that have occurred after the mRNA and adenoviral DNA COVID-19 vaccines. I have formed my opinions in close communications with many clinicians around the world based on in part our collective clinical experience with acute and convalescent COVID-19 cases as well as closely following the preprint and published literature on the outbreak. I have specifically reviewed key published rare cases and reports concerning the possible recurrence of SARS-CoV-2 in patients who have survived an initial episode of COVID-19 illness.

14. My compensation rates are as follows: I am working on this case Pro Bono.

As to my expert opinion:

Methodologies and Analysis of COVID-19 Generally

15. The CDC recently reported the lowest number of cases since March of 2020 (the beginning of the COVID-19 pandemic). Sam Baker & Andrew Witherspoon, *COVID-19 cases hit lowest point in U.S. since pandemic began*, AXIOS (June 3, 2021), https://www.axios.com/coronavirus-cases-infections-vaccines-success-fa7673a1-0582-4e69-aefb-3b5170268048.html

16. Further, according to my research, herd immunity is calculated by a specific formula, as follows: ((CC*6) + V + (.15*P)) ÷ P = HIN.

CC= COVID-19 cases in the state

6= the current CDC multiplier[3]

V= number of vaccinated in the state

15% = the number of people in a given state that will not get COVID-19

P=Population of a state

HIN=Herd Immunity Totals

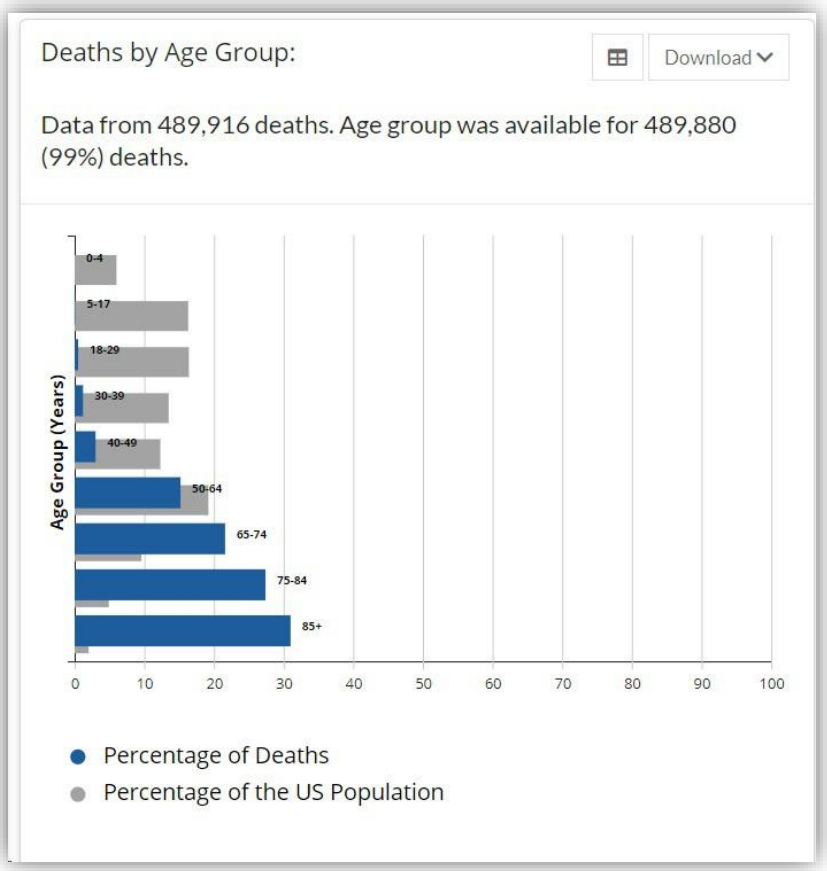
By this method of calculation, the United States has achieved herd immunity meaning that the total of this calculation has achieved a level where there will not be rampant spread. As vaccines continue to fail we can expect more cases of COVID-19. Despite expected incidents and prevalent cases, my opinion is that spread will be minimized and there will be no more large outbreak curves as the country experienced in November through early January before the advent of widely deployed early treatment protocols. Because the randomized trials of all COVID-19 vaccines revealed < 1% absolute risk reductions, and the recent observation of widespread failure of COVID-19 vaccines in countries such as Israel which has a substantial population vaccinated early the pandemic, we can expect more vaccine failures (i.e. "breakthrough cases" that occur in the fully vaccinated) in the United States and no fundamental impact of mass vaccination on the epidemic curves.

Children and Adolescents and COVID-19

17. In addition, in my expert medical opinion and as Table 1 below shows, there is little to no risk for serious injury or hospitalization for COVID-19 among children and adolescents.

Table 1: COVID-19 Deaths by Age Group in the U.S. as of June 27, 2021:

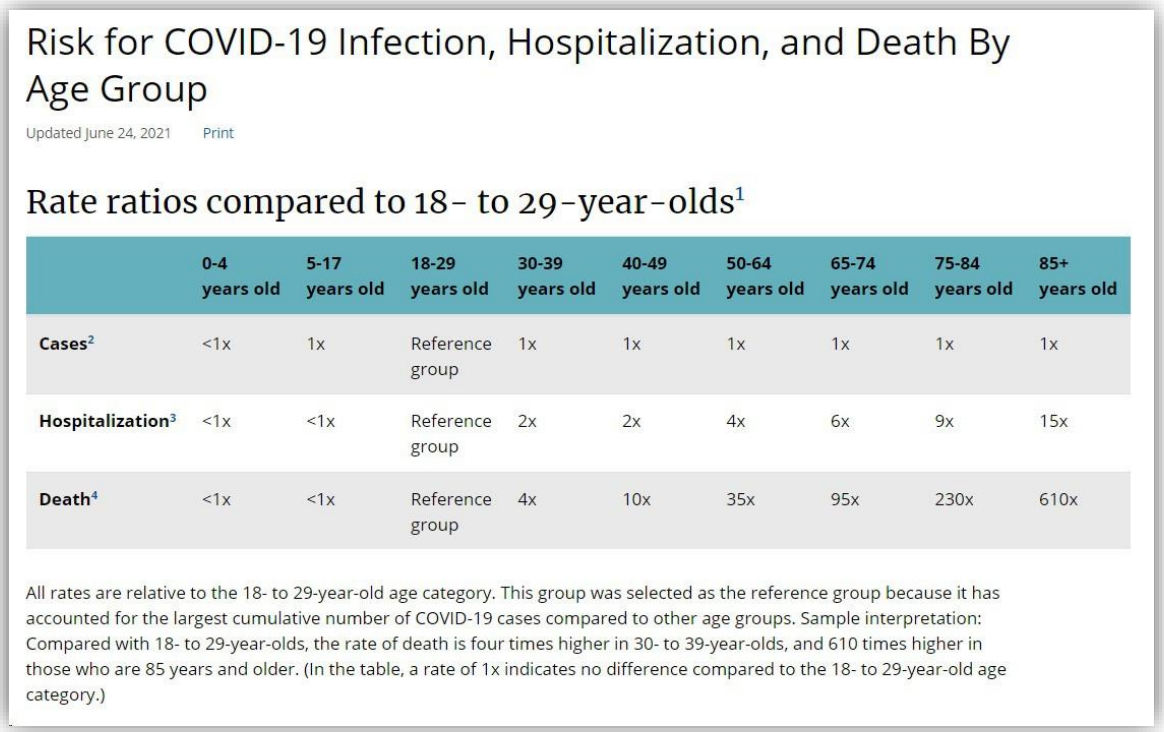
3 Centers for Disease Control and Prevention, Estimated Disease Burden of COVID-19 (May 19, 2021), https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/burden.html



Source: https://COVID-19.cdc.gov/COVID-19-data-tracker/#demographics

Further, the CDC has released charts depicting the risks by age, as shown below.

Table 2: COVID-19 Rate Ratios by Age
Source: https://www.cdc.gov/coronavirus/2019-ncov/COVID-19-data/investigations-discovery/hospitalizationdeath-by-age.html (Last Checked, June 27, 2021).



Risk for COVID-19 Infection, Hospitalization, and Death By Age Group

Updated June 24, 2021 Print

Rate ratios compared to 18- to 29-year-olds[1]

	0-4 years old	5-17 years old	18-29 years old	30-39 years old	40-49 years old	50-64 years old	65-74 years old	75-84 years old	85+ years old
Cases[2]	<1x	1x	Reference group	1x	1x	1x	1x	1x	1x
Hospitalization[3]	<1x	<1x	Reference group	2x	2x	4x	6x	9x	15x
Death[4]	<1x	<1x	Reference group	4x	10x	35x	95x	230x	610x

All rates are relative to the 18- to 29-year-old age category. This group was selected as the reference group because it has accounted for the largest cumulative number of COVID-19 cases compared to other age groups. Sample interpretation: Compared with 18- to 29-year-olds, the rate of death is four times higher in 30- to 39-year-olds, and 610 times higher in those who are 85 years and older. (In the table, a rate of 1x indicates no difference compared to the 18- to 29-year-old age category.)

18. There is negligible risk for children and adolescents across the United States. For example, for each 18-29-year-old that dies from COVID-19, four 30-39 year olds die, ten 40-49 year-olds die, thirty-five 50-64 year-olds die, ninety-five 65-74 year-olds die, 230 75-84 year-olds die, and 610 over 85 years of age die. ***See Table 2***.

19. In my expert medical opinion, the epidemic spread of COVID-19, like all other respiratory viruses, notably influenza,[4] is driven by symptomatic persons; asymptomatic spread is trivial and inconsequential.

20. A meta-analysis of contact tracing studies published in The Journal of the American

4 Eleni Patrozou & Leonard A. Mermel, *Does Influenza Transmission Occur from Asymptomatic Infection or Prior to Symptom Onset?*, 124 Pub. Health Rep. 193 (2009).

Medical Association showed asymptomatic COVID-19 spread was negligible at 0.7%. Zachary J. Madewell, Ph.D.; Yang Yang, Ph.D.; Ira M. Longini Jr, Ph.D.; M. Elizabeth Halloran, MD, DSc; Natalie E. Dean, Ph.D., Household Transmission of SARS-CoV-2: A Systematic Review and Meta-analysis, JAMA Network Open, available at https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2774102 (last visited June 20, 2021).

21. Accordingly, a rational and ethical prevention measure to reduce the spread of COVID-19 is a simple requirement, as part of formal policies, that persons with active symptomatic, febrile (feverish) respiratory illnesses, like COVID-19, should isolate themselves. Indeed, during the H1N1 influenza A pandemic, fully open, unmasked college campuses were advised by federal health officials, *"Flu-stricken college students should stay out of circulation"* and *"if they can't avoid contact they need to wear surgical masks."* Great Falls Tribune, *Advice: Flu-stricken college students should stay out of circulation, August 21, 2009,* page 5, section A, available at https://www.newspapers.com/image/243611045

22. Further, young people are not the spreaders of the virus to the community. A recent study from Dr. Arnold and colleagues that reported the results of a longitudinal serosurvey (blood sampling) of community residents in Centre County, Pennsylvania, home to Pennsylvania State University, University Park campus. See Callum R K Arnold, Sreenidhi Srinivasan, Catherine M Herzog, Abhinay Gontu, Nita Bharti, Meg Small, Connie J Rogers, Margeaux M Schade, Suresh V Kuchipudi, Vivek Kapur, Andrew Read, Matthew J Ferrari, SARS-CoV-2 *Seroprevalence in a University Community: A Longitudinal Study of the Impact of Student Return to Campus on Infection Risk Among Community Members, medRXiv (Feb. 19, 2021), available at https://pubmed.ncbi.nlm.nih.gov/33619497/ (last visited June 20, 2021).*

23. Children and adolescents face little chance of actually catching COVID-19 or developing severe symptoms if it occurs and a negligible chance of spreading it to the greater community.

Advances in COVID-19 Treatments

24. Even if young people contract the virus, the treatment of the infection has improved tremendously since the advent of COVID-19. Studies have shown several different treatment methods, which have proven effective. A combination of medications, supported by the Association of American Physicians and Surgeons, for a minimum of five days and acutely administered supplements used for the initial ambulatory patient with suspected and or confirmed COVID-19 (moderate or greater probability) has proven effective. Brian C Procter, Casey Ross, Vanessa Pickard, Erica Smith, Cortney Hanson, Peter A McCullough, *Clinical outcomes after early ambulatory multidrug therapy for high-risk SARS-CoV-2 (COVID-19) infection*, Reviews in Cardiovascular Medicine (December 30, 2021), available at https://rcm.imrpress.com/EN/10.31083/j.rcm.2020.04.260 (last visited June 26, 2021), summarized in Table 3 below. This approach has resulted in an ~85% reduction in hospitalization and death in high-risk individuals presenting with COVID-19.[5]

Table 3: COVID-19 Treatments

Agent (drug)	Rationale
Zinc	Inhibits SARS-CoV-2 RNA synthesis
Hydroxychloroquine 200 mg po bid	Inhibits endosomal transfer of virions, anti-inflammatory
Ivermectin (200 mcg/kg) usual dose nuclear12 mg po qd x 3 days nucleus	Attenuates importin á/â-mediated transport of SARS-CoV-2 into
Azithromycin 250 mg po bid	Covers respiratory bacterial pathogens insecondary infection
Doxycycline 100 mg po bid	Covers respiratory bacterial pathogens in secondary infection
Inhaled budesonide, Dexamethasone 8 mg IM	Treats cytokine storm

[5] https://ijirms.in/index.php/ijirms/article/view/1100

Folate, thiamine, vitamin B-12	Reduce tissue oxidative stress
Intravenous fluid	Intravascular volume expansion

25. I, along with my colleagues, conducted the study referenced in paragraph 23, which evaluated patients between the ages of 12 and 89 years. The average age was 50.5 and 61.6% were women. The study found that primary care physicians can treat COVID-19 patients resulting in rates of hospitalization and death. The study showed that administration of the medicines and supplements shown in Table 3 produces a less than 2% chance of facing hospitalization or death among high-risk adults (age over 50 with medical problems). As this study was done with mainly higher-risk patients at the peak of the pandemic, this is a highly successful treatment plan and just one of the many new treatments that have been used in the last year including those admitted for COVID-19 which are covered in the NIH COVID-19 Guidelines. *Id.; see also* National Institutes of Health, *Therapeutic Management of Adults With COVID-19* (Updated May 24, 2021), https://www.COVID-1919treatmentguidelines.nih.gov/management/therapeutic-management/ (last visited June 21, 2021).

26. Treatment has improved so drastically for COVID-19 that according to the CDC AH Provisional COVID-19 Death Counts by Age, there were no deaths in Colorado for the 0-17 age group in 2020 or 2021. This is evidence of less virulent strains of SARS-CoV-2 and better treatment and less risk for students and a generally lowered virulence for the SARS-CoV-2 strains as the pandemic progresses over time.

27. In my expert medical opinion, the combination of lowering COVID-19 rates, achievement of herd immunity, the low risk of hospitalization and death among children, and the drastically improved treatment options make the Emergency Use Authorization for the

investigational COVID-19 vaccine sponsored by the US FDA and CDC, unreasonable from a scientific and medical perspective. Contrary to what was expressed by a letter from the pediatrician for S, the 13 year old, attached to Mother's Response, there are NO vaccines which have been "approved" by the FDA for children under 16. The only vaccine for COVID19 that received FDA approval (which is different from being granted Emergency Use Authorization) is the Comirnaty by Pfizer, which is not available in the United States at this time. The investigational studies for ages 12-15 will not be completed until May 31, 2023. Further investigational studies about myocarditis and pericarditis adverse events are also being done post market approval. Therefore, the only vaccines available are those allowed under Emergency Use Authorization, and are therefore, still investigational and experimental.

https://www.fda.gov/vaccines-blood-biologics/comirnaty Aug. 23, 2021 Approval Letter for Comirnaty.

COVID-19 Vaccine Research and Development

28. Pfizer conducted a registrational clinical trial which was randomized, double-blind, placebo-controlled among 2260 adolescents age 12-15 years of age and the trial did not demonstrate a clinically meaningful benefit in COVID-19 outcomes nor did it have any reported impact on child to family or child to teacher spread of the virus.(Frenck RW Jr, Klein NP, Kitchin N, Gurtman A, Absalon J, Lockhart S, Perez JL, Walter EB, Senders S, Bailey R, Swanson KA, Ma H, Xu X, Koury K, Kalina WV, Cooper D, Jennings T, Brandon DM, Thomas SJ, Türeci Ö, Tresnan DB, Mather S, Dormitzer PR, Şahin U, Jansen KU, Gruber WC; C4591001 Clinical Trial Group. Safety, Immunogenicity, and Efficacy of the BNT162b2 Covid-19 Vaccine in Adolescents. N Engl J Med. 2021 Jul 15;385(3):239-250. doi: 10.1056/NEJMoa2107456. Epub 2021 May 27. PMID: 34043894; PMCID: PMC8174030.) Among 1132 who received the Pfizer

BNT162b2 vaccine, the prevention of 18 cases of mild COVD-19 was observed, and there were no cases of severe disease, hospitalizations, or deaths in either group. Approximately 80% and 60% of subjects had local and systemic reactions to the vaccine including pain at the injection site, fatigue, fever, and chills. Approximately 37% of adolescents required medication to control fever with the injections. It is my opinion that the prevention of mild viral upper respiratory-like infections, of which adolescents that age may have four or more times per year, is not worth the risks to the body after an adolescent is injected with one of the COVID-19 vaccines.

29. The COVID-19 genetic vaccines (Pfizer, Moderna, J&J) skipped testing for genotoxicity, mutagenicity, teratogenicity, and oncogenicity. In other words, it is unknown whether or not these products will change human genetic material, cause birth defects, reduce fertility, or cause cancer.

30. The Pfizer, Moderna, and JNJ vaccines are considered "genetic vaccines" or vaccines produced from gene therapy molecular platforms which according to US FDA regulatory guidance are classified as gene delivery therapies and should be under a 15-year regulatory cycle with annual visits for safety evaluation by the research sponsors. FDA. Food and Drug Administration. (Long Term Follow-up After Administration of Human Gene Therapy Products. Guidance for Industry. FDA-2018-D-2173. 2020. Accessed July 13, 2021, at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/long-term-follow-after-administration-human-gene-therapy-products) FDA has "advised sponsors to observe subjects for delayed adverse events for as long as 15 years following exposure to the investigational gene therapy product, specifying that the long-term follow-up observation should include a minimum of **five years of annual examinations**, followed by ten years of annual queries of study subjects, either in person or by questionnaire." Thus, the administration of the

Moderna, Pfizer, and JNJ vaccines should not be undertaken without the proper consent and arrangements for long-term follow-up which are currently not offered in the US. *(See,* EUA briefing documents for commitments as to follow up*:* Moderna[6], Pfizer[7], J&J[8])

They have a dangerous mechanism of action in that they all cause the body to make an uncontrolled quantity of the pathogenic wild-type spike protein from the SARS-CoV-2 virus for at least two weeks, and probably a longer period based on the late emergence of vaccine injury reports. This is unlike all other vaccines where there is a set amount of antigen or live-attenuated virus. This means for Pfizer, Moderna, and J&J vaccines it is not predictable among patients who will produce more or less of the spike protein. The Pfizer, Moderna, and JNJ vaccines because they are different, are expected to produce different libraries of limited antibodies to the now extinct wild-type spike protein. We know the spike protein produced by the vaccines is obsolete because the 17th UK Technical Report on SARS-CoV-2 Variants issued June 25, 2021, and the CDC June 19, 2021, Variant Report both indicate the SARS-CoV-2 wild type virus to which all the vaccines were developed is now extinct.

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1001354/Variants_of_Concern_VOC_Technical_Briefing_17.pdf
https://COVID-19.cdc.gov/COVID-19-data tracker/?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fcases-updates%2Fvariant-proportions.html#variant-proportions

The spike protein itself has been demonstrated to injure vital organs such as the brain, heart, lungs, as well as damage blood vessels and directly cause blood clots. Additionally, because these vaccines infect cells within these organs, the generation of spike protein within heart and brain cells, in particular, causes the body's own immune system to attach to these organs. This is

[6] https://www.fda.gov/media/144434/download
[7] https://www.fda.gov/media/144245/download
[8] https://www.fda.gov/media/146219/download

abundantly apparent with the burgeoning number of cases of myocarditis or heart inflammation among individuals, and especially males, below age 30 years. *See, infra* ¶ *48 - 54*.

Because the US FDA and CDC have offered no methods of risk mitigation for these serious adverse effects which can lead to permanent disability or death, no child should be pressured, coerced, receive the threat or reprisal, or be mandated to receive one of these investigational products against their will. Because the vaccine centers, CDC, FDA, and the vaccine manufacturers ask for the vaccine recipient to grant indemnification on the consent form before injection, all injuries incurred by children and young adults are at their own cost which can be prohibitive depending on the needed procedures, hospitalizations, rehabilitation, and medications.

31. In general, it is never good clinical practice to widely utilize novel biological products in populations that have not been tested in registrational trials. For COVID-19 vaccines, this includes COVID-19 survivors, those with prior suspected COVID-19 infection, those with positive SARS-CoV-2 serologies, pregnant women, and women of childbearing potential who cannot assure contraception.

32. It is never good research practice to perform a large-scale clinical investigation without the necessary structure to ensure the safety and protection of human subjects. These structures include a critical event committee, data safety monitoring board, and human ethics committee. These groups in large studies work to objectively assess the safety of the investigational product and research integrity. The goal is mitigating risk and protecting human subjects. It is my understanding that the COVID-19 vaccine program is sponsored by the CDC and FDA and has none of these safety structures in place. It is my assessment, that the COVID-19 clinical investigation has provided no meaningful risk mitigation for subjects (restricting groups, a

special assessment of side effects, follow-up visits, or changes in the protocol to ensure or improve the safety of the program).[9]

COVID-19 Vaccine Risks to Children and Adolescents

33. The COVID-19 public vaccination program operated by the CDC and the FDA is a clinical investigation and under no circumstance can any person, particularly a child, should receive pressure, coercion, or threat of reprisal on their free choice of participation. Violation of this principle of autonomy by any entity constitutes reckless endangerment with a reasonable expectation of causing personal injury resulting in damages. The principle of autonomy applies to use of medical products before and after regulatory approval.

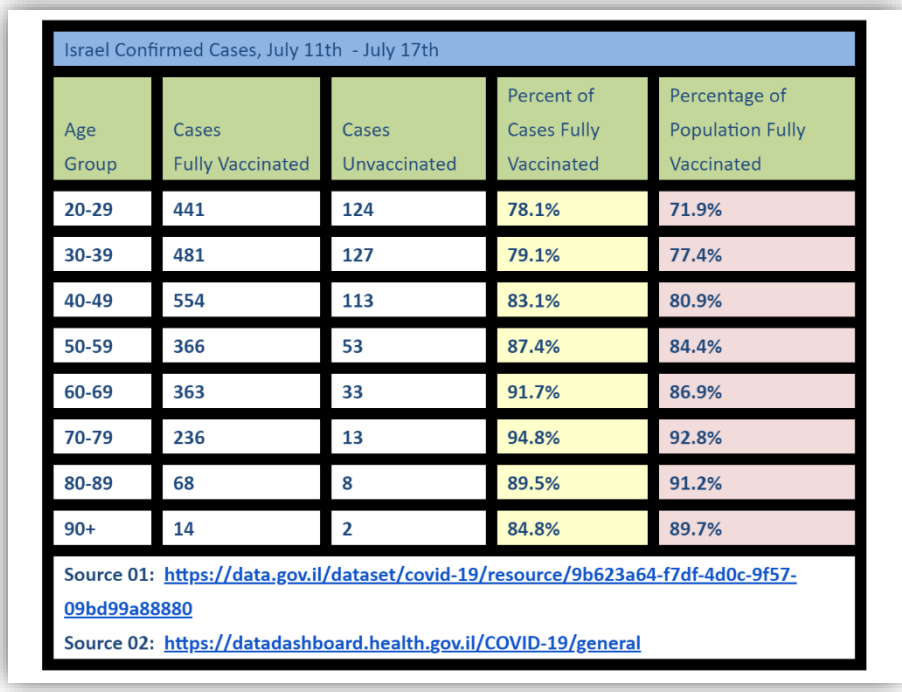
34. The current COVID-19 vaccines are not sufficiently protective against contracting COVID-19 to support its use beyond the current voluntary participation in the CDC-sponsored program. A total of 10,262 SARS-CoV-2 vaccine breakthrough infections had been reported from 46 U.S. states and territories as of April 30, 2021. Among these cases, 6,446 (63%) occurred in females, and the median patient age was 58 years (interquartile range = 40–74 years). Based on preliminary data, 2,725 (27%) vaccine breakthrough infections were asymptomatic, 995 (10%) patients were known to be hospitalized, and 160 (2%) patients died. Among the 995 hospitalized patients, 289 (29%) were asymptomatic or hospitalized for a reason unrelated to COVID-19. The median age of patients who died was 82 years (interquartile range = 71–89 years); 28 (18%) decedents were asymptomatic or died from a cause unrelated to COVID-19. Sequence data were available from 555 (5%) reported cases, 356 (64%) of which were identified as SARS-CoV-2 variants of concern, including B.1.1.7 (199; 56%), B.1.429 (88; 25%), B.1.427

[9] https://www.authorea.com/users/414448/articles/522499-sars-cov-2-mass-vaccination-urgent-questions-on-vaccine-safety-that-demand-answers-from-international-health-agencies-regulatory-authorities-governments-and-vaccine-developers

(28; 8%), P.1 (28; 8%), and B.1.351 (13; 4%). None of these variants are encoded in the RNA or DNA of the current COVID-19 vaccines. In response to these numerous reports, the CDC announced on May 1, 2021, that community breakthrough cases would no longer be reported to the public and only those vaccine failure cases requiring hospitalization will be reported, presumably on the CDC website (https://www.cdc.gov/mmwr/volumes/70/wr/mm7021e3.htm). This overt asymmetric reporting will create the false picture of only unvaccinated individuals developing COVID-19 when in reality patients who are fully vaccinated will be contracting breakthrough infections except for those vaccinated individuals who were previously immune from prior COVID-19 infection.

35. The Delta variant of SARS-CoV-2 accounts for the majority of cases in the United Kingdom, Israel, and the United States. Because of progressive mutation of the spike protein, the virus has achieved an immune escape from the COVID-19 vaccines with the most obvious example being Israel where indiscriminate vaccination achieved 80% immunization rates. ***See Table 4***

This has promoted the emergence of the Delta variant as the dominant strain and because it is not adequately covered by the Pfizer COVID-19 vaccine, >80% of COVID-19 cases have occurred in persons fully vaccinated. This confirms the failure of the vaccines against mutated strains of COVID-19.



Israel Confirmed Cases, July 11th - July 17th

Age Group	Cases Fully Vaccinated	Cases Unvaccinated	Percent of Cases Fully Vaccinated	Percentage of Population Fully Vaccinated
20-29	441	124	78.1%	71.9%
30-39	481	127	79.1%	77.4%
40-49	554	113	83.1%	80.9%
50-59	366	53	87.4%	84.4%
60-69	363	33	91.7%	86.9%
70-79	236	13	94.8%	92.8%
80-89	68	8	89.5%	91.2%
90+	14	2	84.8%	89.7%

Source 01: https://data.gov.il/dataset/covid-19/resource/9b623a64-f7df-4d0c-9f57-09bd99a88880

Source 02: https://datadashboard.health.gov.il/COVID-19/general

Table 4: Israel Confrmed Cases, Vaccinated vs. Unvaccinated

Source: https://datadashboard.health.gov.il/COVID-19019/general

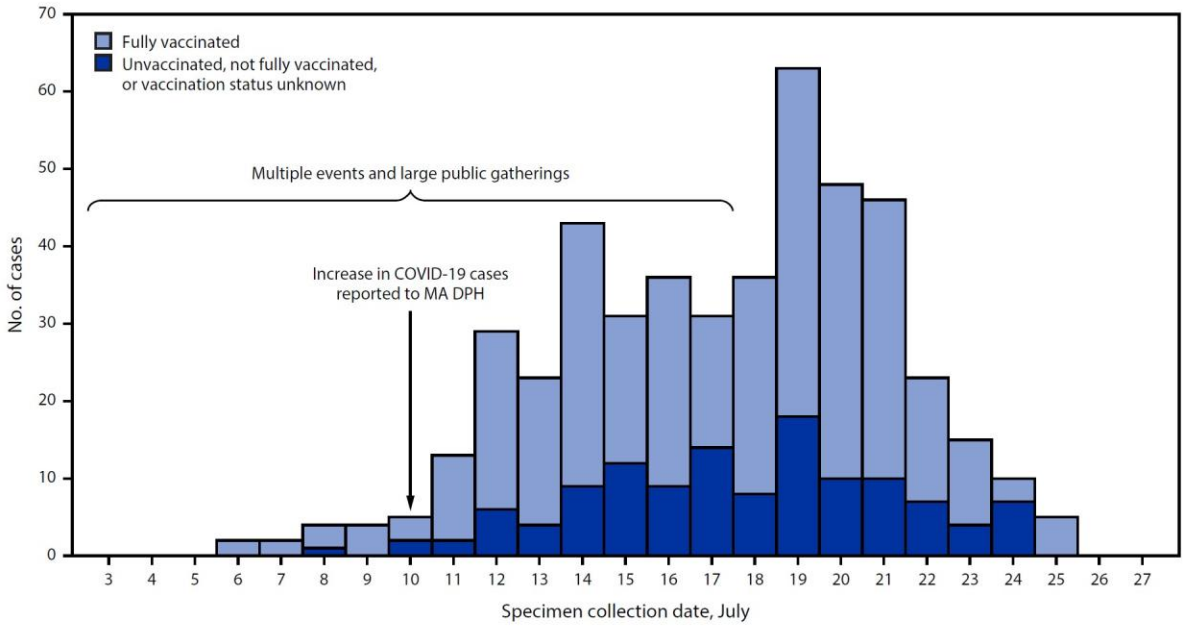
36. In the SARS-CoV-2 variants of concern and variants under investigation in England Technical briefing 17 25 June 2021, 92,056 cases had the Delta variant and 50/7235 fully vaccinated and 44/53,822 of the unvaccinated died. This indicates that the fully vaccinated who contract the Delta variant have an 8.6-fold increased risk for death, (95% CI 5.73-12.91), $p < 0.0001$, as compared to those who chose to remain unvaccinated, https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1001354/Variants_of_Concern_VOC_Technical_Briefing_17.pdf

37. The CDC has published a report titled: "Outbreak of SARS-CoV-2 Infections, Including COVID-19 Vaccine Breakthrough Infections, Associated with Large Public Gatherings — Barnstable County, Massachusetts, July 2021" demonstrating complete failure of the COVID-19

in controlled spread of SARS-CoV-2 in congregate settings. My interpretation of this report is that the vaccines are not sufficiently effective to make the elective, investigation vaccine recommended for use beyond individual preference.

https://www.cdc.gov/mmwr/volumes/70/wr/pdfs/mm7031e2-H.pdf

FIGURE 1. SARS-CoV-2 infections (N = 469) associated with large public gatherings, by date of specimen collection and vaccination status* — Barnstable County, Massachusetts, July 2021



Abbreviation: MA DPH = Massachusetts Department of Public Health.
* Fully vaccinated was defined as ≥14 days after completion of state immunization registry–documented COVID-19 vaccination as recommended by the Advisory Committee on Immunization Practices.

38. In 1990, the Vaccine Adverse Event Reporting System ("VAERS") was established as a national early warning system to detect possible safety problems in U.S. licensed vaccines. VAERS is a passive reporting system, meaning it relies on individuals to voluntarily send in reports of their experiences to the CDC and FDA. VAERS is useful in detecting unusual or unexpected patterns of adverse event reporting that might indicate a possible safety problem with a vaccine.

39. The total safety reports in VAERS for all vaccines per year up to 2019 was 16,320. The total safety reports in VAERS for COVID-19 Vaccines alone through Jun 18, 2021, is 387,288.

40. Based on VAERS as of August 13, 2021, there were 13,068 COVID-19 vaccine deaths reported and 36,117 hospitalizations reported for the COVID-19 vaccines (Pfizer, Moderna, JNJ). See VAERS COVID-19 Vaccine Data, attached as **Exhibit B**. By comparison, from 1999, until December 31, 2019, VAERS received 3167 death reports (158 per year) adult death reports for all vaccines combined.[10] Thus, the COVID-19 mass vaccination is associated a massive increase over expected rates of death.

41. COVID-19 vaccine adverse events account for 98% of all vaccine-related AEs from December 2020 through the present in VAERS.

42. The COVID-19 vaccines are not safe for general use and cannot be deployed indiscriminately or supported, recommended, or mandated among any group.

43. There are emerging trends showing that the vaccine is especially risky for those 12-29 in my expert medical opinion with complications in the cardiovascular, neurological, hematologic, and immune systems. (*See, Rose J, et al*)

44. Increasingly the medical community is acknowledging the possible risks and side effects including myocarditis, Bell's Palsy, Pulmonary Embolus, Pulmonary Immunopathology, and severe allergic reaction causing anaphylactic shock. See Chien-Te Tseng, Elena Sbrana, Naoko Iwata-Yoshikawa, Patrick C Newman, Tania Garron, Robert L Atmar, Clarence J Peters, Robert B Couch, Immunization with SARS coronavirus vaccines leads to pulmonary immunopathology on challenge with the SARS virus, https://pubmed.ncbi.nlm.nih.gov/22536382/ (last visited June 21, 2021); Centers for Disease Control and Prevention, Allergic Reactions Including

[10]Pedro L. Moro, Jorge Arana, Mria Cano, Paige Lewis, and Tom T. Shimabukuro, Deaths Reported to the VaccineAdverse Event Reporting System, United States, 1997-2013, VACCINES, CID 2015:61 (September 2015).

Anaphylaxis After Receipt of the First Dose of Pfizer-BioNTech COVID-19 Vaccine — United States, December 14–23, 2020 (Jan 15, 2021), https://www.cdc.gov/mmwr/volumes/70/wr/mm7002e1.htm (last visited June 26, 2021).

45. The Centers for Disease Control has held emergency meetings on this issue and the medical community is responding to the crisis. It is known that myocarditis causes injury to heart muscle cells and may result in permanent heart damage resulting in heart failure, arrhythmias, and cardiac death. These conditions could call for a lifetime need for multiple medications, implantable cardio defibrillators, and heart transplantation. Heart failure has a five-year 50% survival and would markedly reduce the lifespan of a child or young adult who develops this complication after vaccine-induced myocarditis (ref McCullough PA Reach Study)

46. COVID-19 vaccine-induced myocarditis has a predilection for young males below age 30 years.[11] The Centers for Disease Control has held emergency meetings on this issue and the medical community is responding to the crisis and the US FDA has issued a warning on the Pfizer and Moderna vaccines for myocarditis.[12] In the cases reviewed by the CDC and FDA, 90% of children with COVID-19 induced myocarditis developed symptoms and clinical findings sufficiently severe to warrant hospitalization. Myocarditis cannot be dismissed "rare" since all vaccinated subjects are not evaluated for heart injury with ECG and troponin values and there is no systematic followup over a time frame of 3-6 months. Because the risk of heart injury is not predictable and the early reports may represent just the tip of the iceberg, no individual under age 30 under any set of circumstances should feel obliged to take this risk with the current genetic vaccines particularly the Pfizer and Moderna products. https://www.fda.gov/news-events/press-

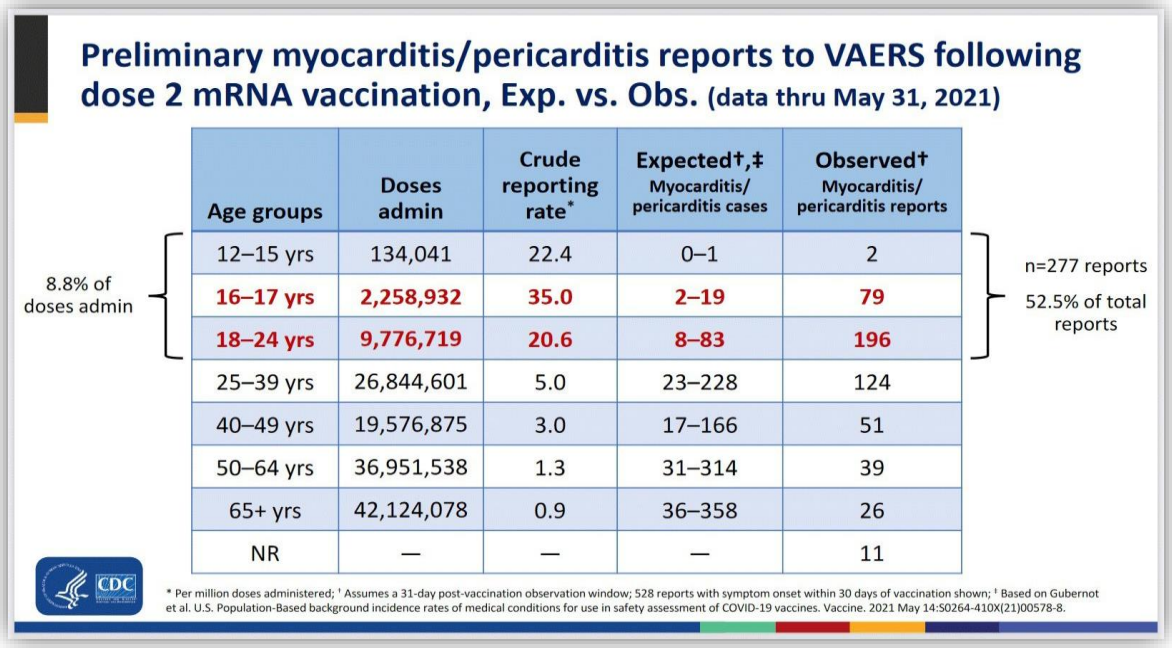
[11] Abu Mouch S, Roguin A, Hellou E, Ishai A, Shoshan U, Mahamid L, Zoabi M, Aisman M, Goldschmid N, Berar Yanay N. Myocarditis following COVID-19 mRNA vaccination. Vaccine. 2021 Jun 29;39(29):3790-3793. doi: 10.1016/j.vaccine.2021.05.087. Epub 2021 May 28. PMID: 34092429; PMCID: PMC8162819.
[12] https://www.fda.gov/news-events/press-announcements/coronavirus-COVID-19-update-june-25-2021

announcements/coronavirus-COVID-19-update-june-25-2021

Multiple recent studies and news reports detail people 18-29 dying from myocarditis after receiving the COVID-19 vaccine. According to the CDC, 475 cases of pericarditis and myocarditis[13] have been identified in vaccinated citizens aged 30 and younger. See FDA, Vaccines and Related Biological Products Advisory Committee June 10, 2021, Meeting Presentation, https://www.fda.gov/media/150054/download#page=17 (last visited June 21, 2021).

47. The FDA found that people 12-24 account for 8.8% of the vaccines administrated, but 52% of the cases of myocarditis and pericarditis were reported. *Id.*

Table 5: VAERS Report



Age groups	Doses admin	Crude reporting rate*	Expected†,‡ Myocarditis/ pericarditis cases	Observed† Myocarditis/ pericarditis reports
12–15 yrs	134,041	22.4	0–1	2
16–17 yrs	**2,258,932**	**35.0**	**2–19**	**79**
18–24 yrs	**9,776,719**	**20.6**	**8–83**	**196**
25–39 yrs	26,844,601	5.0	23–228	124
40–49 yrs	19,576,875	3.0	17–166	51
50–64 yrs	36,951,538	1.3	31–314	39
65+ yrs	42,124,078	0.9	36–358	26
NR	—	—	—	11

48. Further, the CDC just announced that the vaccine is "likely linked" to myocarditis. Advisory Board, CDC panel reports 'likely association' of heart inflammation and mRNA

[13] Myocarditis is inflammation of the heart muscle, whereas pericarditis is inflammation of the sac-like tissue around the heart called the pericardium.

COVID-19 vaccines in young people, (June 24, 2021) https://www.advisory.com/daily-briefing/2021/06/24/heart-inflammation.

49. The CDC recently released data stating that there have been 267 cases of myocarditis or pericarditis reported after receiving one dose of the COVID-19 vaccines and 827 reported cases after two doses through June 11. There are 132 additional cases where the number of doses received is unknown. *Id.*

50. There have been 6812 reported cases of myocarditis that have occurred, and the median age is thirty. *Id.* https://www.openvaers.com/COVID-19-data (accessed October 7, 2021, **Exhibit B**)

51. I have seen and examined adolescent patients with post-COVID-19 myocarditis which typically occurs two days after the injection, most frequently after the second injection of mRNA products (Pfizer, Moderna). The clinical manifestations can be chest pain, signs and symptoms of heart failure, and arrhythmias. The diagnosis usually requires a clinical or hospital encounter, 12-lead electrocardiogram, blood tests including cardiac troponin (test for heart muscle damage), ECG monitoring, and cardiac imaging with echocardiography or cardiac magnetic resonance imaging. Given the risks for either manifest or future left ventricular dysfunction, patients are commonly prescribed heart failure medications (beta-blockers, renin-angiotensin system, inhibitors), and aspirin. More complicated patients require diuretics and anticoagulants. For post-COVID-19 vaccine myocarditis, I follow current position papers on the topic[14] and restrict

[14] Myocarditis References:
Rose, Jessica. A Report on the U.S. Vaccine Adverse Events Reporting System (VAERS) of the COVID-19 Messenger Ribonucleic Acid (mRNA) Biologicals. Science, Public Health Policy, and The Law: Volume 2:59-80 May, 2021.; Sinagra G, Merlo M, Pinamonti B, editors. Dilated Cardiomyopathy: From Genetics to Clinical Management [Internet]. Cham (CH): Springer; 2019; ESC Textbook of Cardiovascular Medicine, 3rd edition; Libby P, Swirski FK, Nahrendorf M. The Myocardium: More Than Myocytes. J Am Coll Cardiol. 2019 Dec 24;74(25):3136-3138. doi: 10.1016/j.jacc.2019.10.031. PMID: 31856970.; Banerjee I, Fuseler JW, Price RL, Borg TK, Baudino TA. Determination of cell types and numbers during cardiac development in the neonatal and adult rat

and mouse. Am J Physiol Heart Circ Physiol. 2007 Sep;293(3):H1883-91. doi: 10.1152/ajpheart.00514.2007. Epub 2007 Jun 29. PMID: 17604329.; M.F. Wendt-Gallitelli, G. Isenberg. Electrophysiology and Microinjection. Methods in Neurosciences, 1991.; Harris KM, Mackey-Bojack S, Bennett M, Nwaudo D, Duncanson E, Maron BJ. Sudden Unexpected Death Due to Myocarditis in Young People, Including Athletes. Am J Cardiol. 2021 Mar 15;143:131-134. doi: 10.1016/j.amjcard.2020.12.028. Epub 2020 Dec 19. PMID: 33347841.; https://www.mayoclinic.org/diseases-conditions/myocarditis/symptoms-causes/syc-20352539; Myocarditis Education Updates and How to Potentially Diagnose the Disease. Aug 4, 2020. Myocarditis Foundation; Myocarditis in children: incidence, clinical characteristics and outcomes. Jul 29, 2020. Myocarditis Foundation; https://www.cdc.gov/dhdsp/myocarditis.htm; https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/myocarditis.html; Siripanthong B, Nazarian S, Muser D, et al. 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Outcomes of Cardiovascular Magnetic Resonance Imaging in Patients Recently Recovered From Coronavirus Disease 2019 (COVID-19). JAMA Cardiol. 2020 Nov 1;5(11):1265-1273. doi: 10.1001/jamacardio.2020.3557. Erratum in: JAMA Cardiol. 2020 Nov 1;5(11):1308. PMID: 32730619; PMCID: PMC7385689.; Gregorio Tersalvi, MD, Marco Vicenzi, MD, Davide Calabretta, MD, Luigi Biasco, MD, PhD, Giovanni Pedrazzini, MD, Dario Winterton, MD. Elevated Troponin in Patients with Coronavirus Disease 2019: Possible Mechanisms. Review article| Volume 26, ISSUE 6, P470-475, June 01, 2020. Published:April 18, 2020DOI:https://doi.org/10.1016/j.cardfail.2020.04.009.; Nascimento JHP, Gomes BFO, Oliveira GMM. Cardiac Troponin as a Predictor of Myocardial Injury and Mortality from COVID-19. Arq Bras Cardiol. 2020 Oct;115(4):667-668. English, Portuguese. doi: 10.36660/abc.20200862. PMID: 33111867.; Ucar FM, Ozturk C, Yılmaztepe MA. 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Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine. N Engl J Med. 2020 Dec 31;383(27):2603-2615. doi: 10.1056/NEJMoa2034577. Epub 2020 Dec 10. PMID: 33301246; PMCID: PMC7745181.; IPAK Report 2021-1. 2021. Post-vaccination Death Causality Likely Given Temporal Distribution of Deaths Following COVID19 Vaccinations. Interim results.; Tinari S. The EMA covid-19 data leak, and what it tells us about mRNA instability BMJ 2021; 372 :n627 doi:10.1136/bmj.n627; Corbett, K.S., Edwards, D.K., Leist, S.R. et al. SARS-CoV-2 mRNA vaccine design enabled by prototype pathogen preparedness. Nature 586, 567–571 (2020). https://doi.org/10.1038/s41586-020-2622-0.; Nalca A, Zumbrun EE. ACAM2000: the new smallpox vaccine for United States Strategic National Stockpile. Drug Des Devel Ther. 2010

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physical activity and continue medications for approximately three months before blood biomarkers and cardiac imaging are reassessed. If there is concurrent pericarditis, non-steroidal anti-inflammatory agents and colchicine may additionally be prescribed. Multiple medical studies are starting to come out detailing this problem.[15]

52. The US FDA has given an update on the JNJ vaccine concerning the risk of cerebral venous sinus thrombosis and thrombosis with thrombocytopenia in patients ages 18-48 associated with low platelet counts.[16] This complication causes a variety of stroke-like syndromes that can involve the cranial nerves, vision, and coordination. Blood clots in the venous sinuses of the brain are difficult to remove surgically and require blood thinners sometimes with only partial recovery. As a result of this reported adverse effect, "CDC will

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Merritt LD, Orient JM, Oskoui R, Pompan DC, Procter BC, Prodromos C, Rajter JC, Rajter JJ, Ram CVS, Rios SS, Risch HA, Robb MJA, Rutherford M, Scholz M, Singleton MM, Tumlin JA, Tyson BM, Urso RG, Victory K, Vliet EL, Wax CM, Wolkoff AG, Wooll V, Zelenko V. Multifaceted highly targeted sequential multidrug treatment of early ambulatory high-risk SARS-CoV-2 infection (COVID-19). Rev Cardiovasc Med. 2020 Dec 30;21(4):517-530. doi: 10.31083/j.rcm.2020.04.264. PMID: 33387997. McCullough PA, Vijay K. SARS-CoV-2 infection and the COVID-19 pandemic: a call to action for therapy and interventions to resolve the crisis of hospitalization, death, and handle the aftermath. Rev Cardiovasc Med. 2021 Mar 30;22(1):9-10. doi: 10.31083/j.rcm.2021.01.301. PMID: 33

[15] *See, e.g.,* Tommaso D'Angelo MD, Antonino Cattafi MD, Maria Ludovica Carerj MD, Christian BoozMD, Giorgio Ascenti MD, Giuseppe Cicero MD, Alfredo Blandino MD,

Silvio Mazziotti MD, *Myocarditis after SARS-CoV-2 Vaccination: A Vaccine-induced Reaction?*, Pre-proof, Canadian Journal of Cardiology, https://www.onlinecjc.ca/article/S0828-282X(21)00286-5/fulltext (last visitedJune 26, 2021); Jeffrey Heller, *Israel sees probable link between Pfizer vaccine and myocarditis cases* (June 2, 2021), https://www.reuters.com/world/middle-east/israel-sees-probable-link-between-pfizer-vaccine-small-number-myoca rditis-cases-2021-06-01/(last visited June 26, 2021); Tschöpe C, Cooper LT, Torre-Amione G, Van Linthout S. Management of Myocarditis-Related Cardiomyopathy in Adults. Circ Res. 2019 May 24;124(11):1568-1583. doi: 10.1161/CIRCRESAHA.118.313578. PMID: 31120823. Caforio AL, Pankuweit S, Arbustini E, Basso C, Gimeno-Blanes J, Felix SB, Fu M, Heliö T, Heymans S, Jahns R, Klingel K, Linhart A, Maisch B, McKenna W, Mogensen J, Pinto YM, Ristic A, Schultheiss HP, Seggewiss H, Tavazzi L, Thiene G, Yilmaz A, Charron P, Elliott PM; European Society of Cardiology Working Group on Myocardial and Pericardial Diseases. Current state of knowledge on aetiology, diagnosis, management, and therapy of myocarditis: a position statement of the EuropeanSociety of Cardiology Working Group on Myocardial and Pericardial Diseases. Eur Heart J. 2013 Sep;34(33):2636-48, 2648a-2648d. doi: 10.1093/eurheartj/eht210. Epub 2013 Jul 3. PMID: 23824828.

[16] https://www.fda.gov/news-events/press-announcements/joint-cdc-and-fda-statement-johnson-johnson-COVID-19-vaccine

convene a meeting of the Advisory Committee on Immunization Practices (ACIP) on Wednesday to further review these cases and assess their potential significance. …Until that process is complete, we (the FDA) are recommending a pause in the use of this vaccine out of an abundance of caution."

53. Additionally, the US FDA has an additional warning for Guillen-Barre Syndrome or ascending paralysis for the JNJ vaccine which is not predictable and when it occurs can result in ascending paralysis, respiratory failure, the need for critical care, and death. Not all cases completely resolve, and some vaccine victims may require long term mechanical ventilation or become quadra- or paraplegics. Prolonged neurological rehabilitation is commonly required, and this will call for time away from school and studies for those children injured from the JNJ vaccine with Guillen-Barre Syndrome. https://www.fda.gov/media/150723/download

54. The vaccine is also far less safe than previous vaccines like the meningococcal meningitis vaccine that is typically required on college campuses which in 2019 recorded zero deaths. The COVID-19 vaccines since their EUA approval on May 10, 2021, have already claimed the lives of 15 children and 79 young individuals under age 30 (VAERS).

55. For example, the VAERS (Vaccine Adverse Event Reporting System) data from the CDC shows, for 18-29-year-olds, there have been no deaths from the meningococcal vaccine from 1999 - 2019. See, United States Department of Health and Human Services (DHHS), Public Health Service (PHS), Centers for Disease Control (CDC)/Food and Drug Administration (FDA), Vaccine Adverse Reporting System (VAERS) 1990 - 06/11/2021, CDC WONDER On-line Database. Accessed at https://wonder.cdc.gov/vaers.html on June 23, 2021, 1:43:33 PM, ("Query Criteria").

56. The main side effects people reported from the meningitis vaccine are headache, injection site pain, nausea, chills, and a fever, and even these were limited as no more than fifteen of each were reported. *Id.* The student population and their parents, in general, accept the requirements for meningococcal vaccination because the vaccines are safe, effective, and do not pose a risk of death, unlike the COVID-19 vaccines.

57. In the brief time the COVID-19 vaccines have been available, there have been many more serious symptoms and even a death of a healthy 13-year-old boy[17]. (See Nationwide VAERS COVID-19 Vaccine Data through September 24, 2021, attached as **Exhibit B**)[18]

58. The World Health Organization said that children should not be vaccinated for the moment before they faced tremendous backlash. WHO, COVID-19 Advice for the public: Getting vaccinated, (Archived from April 8, 2021), https://web.archive.org/web/20210408183900/https:/www.who.int/emergencies/diseases/novel-coronavirus-2019/COVID-19-vaccines/advice.

59. Rachael K. Raw, Clive Kelly, Jon Rees, Caroline Wroe, David R. Chadwick, Previous COVID-19 infection but not Long-COVID-19 is associated with increased adverse events following BNT162b2/Pfizer vaccination, (pre-print) https://www.medrxiv.org/content/10.1101/2021.04.15.21252192v1 (last visited June 26, 2021).

60. Recent studies from Tess Lawrie, a highly respected evidence-based professional, on the UK's equivalent of the VAERS systems concluded that the vaccines were unsafe for use in humans due to the extensive side effects they are causing. Tess Lawrie, *Re. Urgent preliminary*

[17] https://www.newsweek.com/13-year-old-dies-sleep-after-receiving-pfizer-COVID-19-vaccine-cdc-investigating-1606529

[18] VAERS may be publicly accessed at https://www.openvaers.com/COVID-19-data

report of Yellow Card data up to 26th May 2021, (June 9, 2021), http://www.skirsch.com/COVID-19/TessLawrieYellowCardAnalysis.pdf

Risks of COVID-19 Vaccines for Those Recovered from COVID-19

61. There is recent research on the fact that the COVID-19 vaccine is dangerous for those who have already had COVID-19 and have recovered with inferred robust, complete, and durable immunity. Many adolescents and children have had minimally symptomatic COVID-19 and do not have the infection documented with diagnostic testing. These patients were excluded from the FDA-approved clinical trials performed by Pfizer, Moderna, and J&J. From these trials the safety profile was unknown when the products for approved for Emergency Use Authorization in 2020. There has been no study demonstrating clinical benefit with COVID-19 vaccination in those who have well documented or even suspected prior COVID-19 illness.

62. A medical study of United Kingdom healthcare workers who had already had COVID-19 and then received the vaccine found that they suffered higher rates of side effects than the average population. Rachel K. Raw, et al., Previous COVID-19 infection but not Long-COVID-19 is associated with increased adverse events following BNT162b2/Pfizer vaccination, medRxiv (preprint), https://www.medrxiv.org/content/10.1101/2021.04.15.21252192v1 (last visited June 21, 2021).

63. The test group experienced more moderate to severe symptoms than the study group that did not previously have COVID-19. Id.

64. The symptoms included fever, fatigue, myalgia-arthralgia, and lymphadenopathy. Id. Raw found that in 974 individuals who received the BNT162b2/Pfizer vaccine, those with a prior

history of SARS-CoV-2 or those who had positive antibodies at baseline had a higher rate of vaccine reactions than those who were COVID-19 naive. Id.

65. Mathioudakis et al. reported that in 2020 patients who underwent vaccination with either mRNA-based or vector-based COVID-19 vaccines, COVID-19-recovered patients who were needlessly vaccinated had higher rates of vaccine reactions.[19]

66. Krammer et al. reported on 231 volunteers for COVID-19 vaccination, 83 of whom had positive SARS-CoV-2 antibodies at the time of immunization. The authors found: "Vaccine recipients with preexisting immunity experience systemic side effects with a significantly higher frequency than antibody naïve vaccines (e.g., fatigue, headache, chills, fever, muscle or joint pains, in order of decreasing frequency, $P < 0.001$ for all listed symptoms, Fisher's exact test, two-sided)." (https://www.medrxiv.org/content/10.1101/2021.01.29.21250653v1).

Natural Immunity to COVID-19

67. To my knowledge, there are no studies that demonstrate the clinical benefit of COVID-19 vaccination in COVID-19 survivors or those with suspected COVID-19 illness or subclinical disease who have laboratory evidence of prior infection.

68. It is my opinion that SARS-CoV-2 causes an infection in humans that results in robust, complete, and durable immunity, and is superior to vaccine immunity which by comparison has demonstrated massive failure including over 10,000 well-documented vaccine failure cases as reported by the CDC before tracking was stopped on May 31, 2021. There are no studies demonstrating the clinical benefit of COVID-19 vaccination in COVID-19 survivors and there are three studies demonstrating harm in such individuals. Thus, it is my opinion that the COVID-

[19] *See* https://www.medrxiv.org/content/10.1101/2021.02.26.21252096v1

19 vaccination is contraindicated in COVID-19 survivors many of whom are in the student population.

69. Multiple laboratory studies conducted by highly respected U.S. and European academic research groups have reported that convalescent mildly or severely infected COVID-19 patients who are unvaccinated can have greater virus-neutralizing immunity—especially more versatile, long-enduring T- cell immunity—relative to vaccinated individuals who were never infected. See Athina Kilpeläinen, et al., *Highly functional Cellular Immunity in SARS-CoV-2 Non-Seroconvertors is associated with immune protection*, bioRxiv (pre-print), https://www.biorxiv.org/content/10.1101/2021.05.04.438781v1 (last visited June 26, 2021); Tongcui Ma, et al., Protracted yet coordinated differentiation of long-lived SARS-CoV-2-specific CD8+ T cells during COVID-19 convalescence, bioRxiv (pre-print), https://www.biorxiv.org/content/10.1101/2021.04.28.441880v1 (last visited June 26, 2021); Claudia Gonzalez, et al., *Live virus neutralisation testing in convalescent patients and subjects vaccinated against 19A, 20B, 20I/501Y.V1 and 20H/501Y.V2 isolates of SARS-CoV-2*, medRxiv (pre-print), https://www.medrxiv.org/ content/10.1101/2021.05.11.21256578vl (last visited June 21, 2021); Carmen Camara, et al. *Differential effects of the second SARS-CoV-2 mRNA vaccine dose on T cell immunity in naïve and COVID-19 recovered individuals*, bioRxiv (pre-print), https://www.biorxiv.org/content/10.1101/2021.03.22.436441v1 (last visited June 26, 2021); Ellie N. Ivanova, et al., *Discrete immune response signature to SARS-CoV-2 mRNA vaccination versus infection*, medRxiv (pre-print), https://www.medrxiv.org/content/10.1101/2021.04.20.21255677v1 (last visited June 26, 2021); Catherine J. Reynolds, et al, *Prior SARS-CoV-2 infection rescues B and T cell responses to variants after first vaccine dose*, (pre-print), https://pubmed.ncbi.nlm.nih.gov/33931567/ (last

visited June 21, 2021); Yair Goldberg, et al., *Protection of previous SARS-CoV-2 infection is similar to that of BNT162b2 vaccine protection: A three-month nationwide experience from Israel*, medRxiv (pre-print), https://www.medrxiv.org/content/10.1101/2021.04.20.21255670vl (last visited June 26, 2021).

70. Cleveland Clinic studied their employees for the effects of natural immunity in unvaccinated people. Nabin K. Shrestha, Patrick C. Burke, Amy S. Nowacki, Paul Terpeluk, Steven M. Gordon, *Necessity of COVID-19 vaccination in previously infected individuals*, medRxiv (pre-print), https://www.medrxiv.org/content/10.1101/2021.06.01.21258176v2 (last visited June 21, 2021). They found zero SARS-CoV-2 reinfections during a 5-month follow-up among n=1359 infected employees who were naturally immune remained unvaccinated and concluded such persons are "*unlikely to benefit from COVID-19 vaccination."* Among those who were vaccinated, unlike the naturally immune, there were vaccine failure or breakthrough cases of COVID-19. Id.

71. An analysis by Murchu et al demonstrated in 615,777 individuals which included well-documented COVID-19 as well as subclinical infections with positive serologies, there was a negligible incidence (<1%) of COVID-19 over the long term. Murchu found no evidence of waning immunity over time suggesting no possibility that future vaccination would be indicated for any reason. https://onlinelibrary.wiley.com/doi/10.1002/rmv.2260

72. A recently published article in Nature reported that prior infection induces long-lived bone marrow plasma cells which means the antibodies to prevent reinfection of COVID-19 are long-lasting. Jackson S. Turner et. al. *SARS-CoV-2 infection induces long-lived bone marrow plasma cells in humans*, (May 24, 2021) https://www.nature.com/articles/s41586-021-03647-4

73. A recent study, which can be found at :

https://www.medrxiv.org/content/10.1101/2021.07.31.21261387v4#F2m titled *Shedding of Infectious SARS-CoV2 Despite Vaccination,* indicates strongly that the vaccines do not protect others from getting ill, especially from a variant. In fact, the mother of the children is at greater risk of getting ill after her sons get vaccinated, than if they did not receive the shot. See Table below from the study:

Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent - Wisconsin, July 2021

Kasen K. Riemersma, DVM, PhD[1]; Brittany E. Grogan, MPH[2]; Amanda Kita-Yarbro, MPH[2]; Peter Halfmann, PhD[1]; Anna Kocharian, MS[3]; Kelsey R. Florek, PhD[4]; Ryan Westergaard, MD, PhD[3,5]; Allen Bateman, PhD[4]; Gunnar E. Jeppson, BS[6]; Yoshihiro Kawaoka, DVM, PhD[1]; David H. O'Connor, PhD[7]; Thomas C. Friedrich, PhD[1]; Katarina M. Grande, MPH[2]

[1] Department of Pathobiological Sciences, University of Wisconsin-Madison, Madison, WI, USA; [2] Public Health Madison & Dane County, Madison, WI, USA; [3] Wisconsin Department of Health Services; [4] Wisconsin State Laboratory of Hygiene; [5] Department of Medicine, University of Wisconsin School of Medicine and Public Health, Madison, Wisconsin; [6] Exact Sciences, Madison, WI, USA; [7] Department of Pathology and Laboratory Medicine, University of Wisconsin-Madison, Madison, WI, USA.

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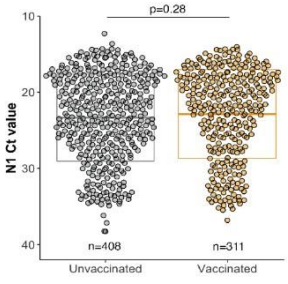

Figure 1. Distributions of SARS-CoV-2 PCR cycle threshold (Ct) values at the time of testing do not differ by vaccination status. N1 PCR Ct values for SARS-CoV-2-positive specimens grouped by vaccination status. Boxplots represent mean N1 Ct values +/- one standard deviation. P-values were calculated by comparing mean Ct values between the groups by Welch two-sample t-test.

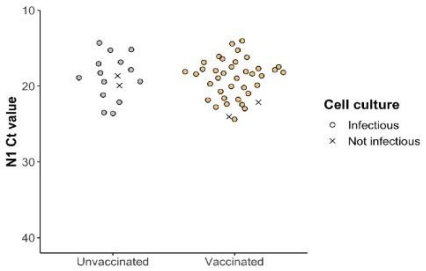

Figure 2. Infectious virus detected in nasal swab specimens from unvaccinated and fully vaccinated cases with Ct values < 25. Infectiousness was determined by the presence of cytopathic effects (CPE) after 5 days of replication in Vero E6 TMPRSS2 cells. Specimens with visually apparent CPE under a light microscope are represented by filled circles, and specimens without apparent CPE are represented by 'X'.

CONCLUSION

In my expert medical opinion, despite the current Delta variant outbreak, increasing likelihood of herd immunity to COVID-19, the low risk to children and adolescents of serious complications or death due to COVID-19, the negligible risk of asymptomatic spread of COVID-

19, and the vastly improved COVID-19 treatments currently available all make the risks inherent in COVID-19 significantly lower than they were in 2020.

It is my expert medical opinion that the Pfizer vaccine as tested in adolescents age 12-15 does not offer a significant clinical benefit and has a poor benefit to risk ratio. Children with any form of pre-existing heart disease in my opinion as a board-certified cardiologist, are at an unacceptable risk of harm with COVID-19 vaccines. Vaccination of children to prevent mild viral upper respiratory symptoms in a small fraction (1.6%) of subjects is not justified given the short and longer-term risks of the vaccines.

It is my expert medical opinion that the COVID-19 vaccines are progressively losing efficacy over the prevention of COVID-19 and in widely vaccinated countries up to 80% of COVID-19 cases have been previously vaccinated implying the vaccines have become obsolete with antigenic escape or resistance to variants (e.g., Delta) that have evolved to infect persons who were vaccinated against the now extinct wild-type SARS-CoV-2 strain.

It is my expert medical opinion that it is not good research or clinical practice to widely utilize novel biologic therapy (mRNA, adenoviral DNA COVID-19 vaccines) in populations where there is no information generated from the registrational trials with the FDA, specifically, children and adolescents, COVID-19 survivors, suspected COVID-19-recovered, pregnant or women who could become pregnant at any time after investigational vaccines. In my expert medical opinion, the risks associated with the investigational COVID-19 vaccines, especially those more prevalent among children and adolescents far outweigh any theoretical benefits, are not minor or unserious, and many of those risks are unknown or have not been adequately quantified nor has the duration of their consequences been evaluated or is calculable. Therefore, in my expert medical opinion, the Emergency Use Authorization and administration of COVID-

19 vaccines for children and adolescents aged 12-17 creates an unethical, unreasonable, clinically unjustified, unsafe, and poses an unnecessary risk to children.

It is my concern as a cardiologist, that 4861 cases of vaccine induced myocarditis reported by the CDC to the public in the VAERS system as of August 13, 2021 (**Exhibit B**), will rise as young persons are coerced into vaccination. This number is not small and COVID-19 vaccine-induced myocarditis is not "rare".

In the rare event of either minor son acquiring the COVID-19 respiratory illness, it is expected to mild and self-limited. Severe symptoms can be readily treated with available medications similar to that in a child with asthmatic bronchitis in order to avoid hospitalization and death. The very rare cases of elevations of troponin that have occurred in adults with the COVID-19 respiratory illness represent mild cardiac injury as a result of prolonged hospitalization and have not led to heart block, heart failure, or complications. These cases cannot be conflated with vaccine-induced myocarditis where the pathogenic spike protein is produced within the heart and or circulates to the heart resulting direct damage and incipient left ventricular dysfunction and heart failure.

It is my expert opinion that the risks associated with the Covid 19 vaccine, particularly to otherwise healthy 13 and 17 year old males, far outweigh any negligible benefit the vaccination might provide to them, and the magnitude of the risks, should they be realized, are unacceptably high.

I do not believe that receiving the Covid 19 vaccine is in the best interests of the minor children involved here. I am of the opinion that vaccinating the children would offer no benefit to their Mother in terms of her risk of getting COVID. She is actually at greater risk of getting ill from a variant from the shedding that occurs following vaccination.

I am willing to present myself in open Court to testify consistent with this affidavit and answer any further questions or concerns that the Court or any counsel may have on the topics contained herein.

I certify that the foregoing is true and correct, within a reasonable degree of medical certainty, under penalty of perjury and as provided by law under 735 ILCS 5/1-109.

Date: October 7 , 2021

7-OCT-2021

Dr. Peter A. McCullough, MD, MPH