IN THE HIGH COURT OF NEW ZEALAND
WELLINGTON REGISTRY

I TE KŌTI MATUA O AOTEAROA
TE WHANGANUI-A-TARA ROHE

CIV-2022-485-013

UNDER	the Judicial Review Procedure Act 2016
IN THE MATTER	of an application for judicial review of a decision made under the Medicines Act 1981
BETWEEN	**DCB**
	First to Eighth Applicants
AND	**THE MINISTER OF HEALTH**
	First Respondent
AND	**THE GROUP MANAGER OF THE NEW ZEALAND MEDICAL DEVICES SAFETY AUTHORITY (MEDSAFE)**
	Second Respondent
AND	**THE COVID-19 RESPONSE MINISTER**
	Third Respondent

AFFIDAVIT OF DR PETER MCCULLOUGH IN SUPPORT OF APPLICATION FOR JUDICIAL REVIEW

Dated 25 January 2022

Counsel

David PH Jones QC
P +64 9 357 3566
E david@davidphjones.co.nz

Tom Molloy
P + 64 9 303 3177
E tom@tommolloy.co.nz

Solicitors

Gaze Burt
PO Box 91345
Victoria Street West
Auckland 1142
P +64 9 303 3764
E shelley.eden@gazeburt.co.nz

Solicitor acting:
Shelley Eden

I, **PETER A MCCULLOUGH**, Medical Doctor of Dallas, Texas, United States of America, swear/affirm:

1. I am an Internist, Cardiologist and Epidemiologist.

2. I have been asked to provide my expert opinion In respect to the COVID-19 vaccine for children aged 5-11 years of age, specifically the Pfizer mRNA vaccine.

3. I have read the Code of Conduct for Expert Witnesses in Schedule 4 of the High Court Rules and I agree to comply with it. The evidence which I give is within my area of expertise. The further matters referred to in clause 3 of the Code of Conduct are addressed in my attached report.

4. A copy of my report is annexed hereto **marked "A"**.

Sworn/Affirmed at)
this 25 day of January 2022)
before me:)

[Person of appropriate office or occupation that is able to take oaths or affirmations in the jurisdiction that you are in at the time of swearing/affirming this affidavit]

State: Texas
County: Dallas
Date: 01/25/2022
Notary: Sabastian Stephon Applewhite

SABASTIAN STEPHON APPLEWHITE
Notary Public, State of Texas
Comm. Expires 10-06-2023
Notary ID 13039631-0

Exhibit "A"

Peter A. McCullough, MD, MPH

January 25, 2022

RE: Expert Opinion on Comirnaty vaccine for 5 – 11 year olds

1. You have asked for my expert medical opinion as to the appropriateness of giving the Pfizer/BioNTech (Comirnaty) COVID vaccine (**Vaccine**) to otherwise healthy children aged 5 to 11 years of age.

Background and Expertise

General

2. 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.

3. I am Board Certified in internal medicine and cardiovascular disease and hold and 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 one peer-reviewed journal, editorialist, and reviewer at dozens of major medical journals and textbooks.

4. 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 of my work have included pharmaceutical manufacturers, biotechnology companies, and the National Institutes of Health.

5. I have decades of experience as Principal Investigator of numerous clinical trials[1] and of undertaking post marketing surveillance of drugs newly released to market. I am therefore well qualified to review, analyze and assess the quality of published clinical data.

6. 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, the Texas Senate Committee on Health and Human Services, and the South Carolina Senate.

7. I am a Fellow of the American College of Cardiology, the American Heart Association, 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.

8. 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

[1] The obligations of a Principal Investigator are discussed here: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7122254/

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.[2]

9. 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. I am the Editor-in-Chief of Reviews in Cardiovascular Medicine, a widely read journal that publishes reviews on contemporary topics in cardiology and is also listed by the National Library of Medicine.

COVID-19

10. 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.[3] I have 50 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 Op-ed'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. I have also

[2] http://www.cardiorenalsociety.org/

[3] 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/.

testified in the South Carolina Senate Medical Advisory Committee on the treatment of COVID-19. My expertise on the SARS-CoV-2 infection and COVID-19 syndrome, like that of infectious disease specialists, is approximately 20 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.

Compensation

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

Code of Conduct for Expert Witnesses

12. I confirm that I have read and understand the Code of Conduct for Expert Witnesses in Schedule 4 of the High Court Rules and I agree to comply with it. [4] The evidence which I give is within my area of expertise. The further matters referred to in clause 3 of the Code of Conduct are addressed in my attached report.

[4] https://www.legislation.govt.nz/regulation/public/2016/0225/latest/DLM6953324.html

Structure and contents of Report

13. My report is broken into three parts and addresses the following topics:

PART ONE: COVID-19 risks are significantly lower than they were in 2020 to 2021

a. Methodologies and Analysis of COVID-19 in 2021 (para 14)

b. Risk of Covid-19 for Children and Adolescents (paras 15 - 22)

c. Asymptomatic spread (paras 23 - 27)

d. Herd immunity (paras 28 to 29)

e. Advances in COVID-19 Treatments (paras 30 - 33)

PART TWO: COVID vaccines losing efficacy

f. Pre Omicron variants (paras 34 - 43)

g. Omicron (paras 44 to 49)

PART THREE: Risk/benefit analysis of vaccinating adolescents and children

h. COVID-19 Vaccine Risks to Children and Adolescents (paras 51 - 57)

i. Adverse reactions (para 58 - 74)

j. Treatments for myocarditis (para 75 - 86)

k. Risks of COVID-19 Vaccines for Those Recovered from COVID-19 (paras 87 - 95)

l. Natural Immunity to COVID-19 (para 96 - 101)

m. Conclusion (paras 102 - 104)

PART ONE: COVID-19 risks are significantly lower than they were in 2020 to 2021

Methodologies and Analysis of COVID-19 in 2021

14. In June of 2021, the United States Centers for Disease Control and Prevention (**CDC**) reported the lowest number of COVID-19 cases since March of 2020 (the beginning of the COVID-19 pandemic).[5] Then by the start of October 2021, the U.S. cases of, and hospitalizations from, COVID-19 continued their steady decline, as the country seemed to be moving past a July surge caused by the Delta variant.[6] America's summer wave peaked at an average of nearly 176,000 cases per day, but plummeted 41 percent as of the first week in October 2021. The number of COVID patients in hospitals, a lagging indicator, is down 25 percent since September 4th, and COVID deaths, which lag even further, are now decreasing as well. Further, overall, fewer and fewer COVID tests nationwide in the US have been coming back positive: less than 6.5 percent currently (compared with more than 10 percent in late August). Based upon this data, "experts predict that the U.S. pandemic may finally be starting to peter out, which appears to be the case with the arrival of the Omicron variant (which is less serious than Delta).[7] While the virus may never fully disappear, it is expected to become endemic — just another less dangerous and disruptive threat that humans coexist with."[8]

Risks of COVID-19 for Children and Adolescents

15. In my opinion, children and adolescents are at no material risk of serious injury or hospitalization from COVID-19 due to their immunity naturally, as is shown in deaths by age group at Table 1:

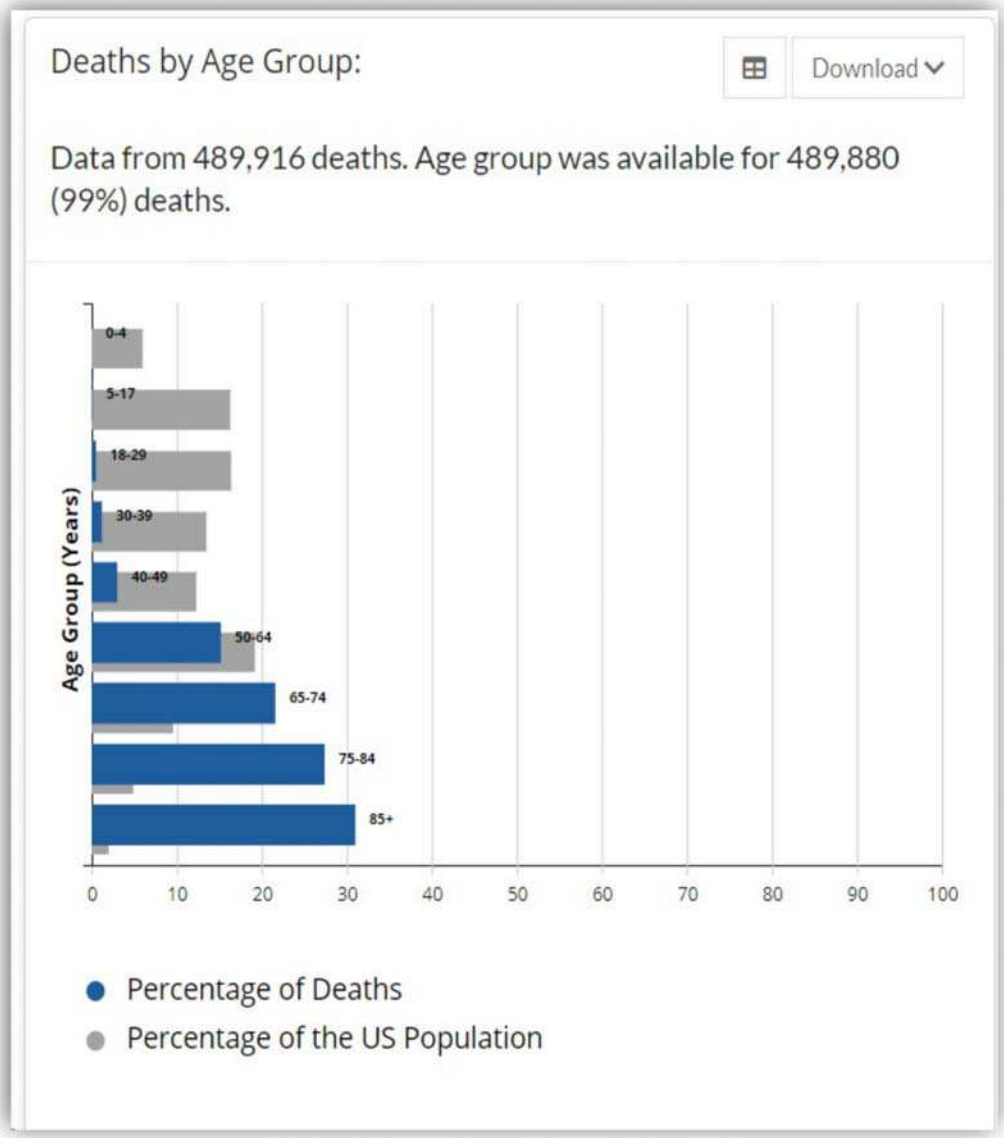
[5] Sam Baker & Andrew Witherspoon, COVID-19 cases hit lowest point in U.S. since pandemic began, AXIOS (June 3, 2021), https://www.axios.com/coronavirus-cases-infections-vaccines-success-fa7673a1-0582-4e69-aefb-3b5170268048.html

[6] https://www.marketwatch.com/story/u-s-covid-19-cases-and-hospitalizations-continue-to-decline-but-experts-lament-preventable-deaths-that-have-pushed-toll-above-700-000-11633358051?siteid=yhoof2

[7] https://www.medrxiv.org/content/10.1101/2021.12.21.21268116v1

[8] https://news.yahoo.com/the-last-major-wave-of-infection-do-falling-covid-cases-signal-the-end-of-the-us-pandemic-203343478.html

Table 1: COVID-19 Deaths by Age Group in the U.S. as of June 27, 2021:[9]



16. This is further confirmed by the CDC that has released charts depicting the risks by age, as shown below:[10]

[9] Source: https://COVID-19.cdc.gov/COVID-19-data-tracker/#demographics.
[10] Source: https://www.cdc.gov/coronavirus/2019-ncov/COVID-19-data/investigations-discovery/hospitalizationdeath-by-age.html (Last Checked, June 27, 2021).

Table 2: COVID-19 Rate Ratios by Age:

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

Updated Nov. 22, 2021 Print

Rate compared to 18-29 years old[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	5x	8x	10x
Death[4]	<1x	<1x	Reference group	4x	10x	25x	65x	150x	370x

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 370 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.)

17. Table 2 shows that 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, twenty-five 50-64-year-olds die, sixty-five 65-74-year-olds die, one-hundred and fifty 75-84-year-olds die, and three-hundred and seventy over 85 years of age die.

18. In the seven-month period of January 2021 to July 2021 (which is comparative to December 2021 in the U.S.), the rate of COVID-19 hospitalization among children (ages 5-11) has ranged from a low of ≤2 per million weekly (July 2021) to moderate level (5 per million per week in mid-August 2021) and high (6 per million per week in January 2021). For adolescents (ages 12-17) it has ranged from a low of ≤ 4 per million weekly (July 2021) to moderate level (15 per million per week in mid-August 2021) and high (21 per million per week in January 2021).[11] In the relevant age groups, a:

    a. healthy child (ages 5-11) might expect a COVID-19 hospitalization risk of 13.3 per million over the next 120 days;

[11] COVID-NET: COVID-19-Associated Hospitalization Surveillance Network, Centers for Disease Control and Prevention. https://gis.cdc.gov/grasp/covidnet/covid19_3.html : Accessed on July 6, 2021; Havers FP, Whitaker M, Self JL, et al. Hospitalization of Adolescents Aged 12–17 Years with Laboratory-Confirmed COVID-19 — COVID-NET, 14 States, March 1, 2020–April 24, 2021. *MMWR Morb Mortal Wkly Rep* 2021;70:851–857 (https://www.cdc.gov/mmwr/volumes/70/wr/mm7023e1.htm)

b. healthy adolescent might expect a COVID-19 hospitalization risk of 44.4 per million over the next 120 days,

assuming disease-related hospitalization prevalence stays at moderate levels.[12]

19. As noted, the risk of death associated with COVID-19 in healthy children is virtually non-existent, as children have significant immunologic advances relative to the older adult population (>65 years) which comprises the high-risk cohort for COVID-19.

20. The peer reviewed paper titled "*Why are we vaccinating children against Covid-19*?"[13] found that "the bulk of the official Covid-19 attributed deaths per capita occur in the elderly with high comorbidities, and the Covid-19 attributed deaths per capita are negligible in children". In contrast, "the normalized post-inoculation [post-vaccination] deaths are small, but not negligible, in children. Critically, the study found that "a novel best-case scenario cost-benefit analysis showed very conservatively that there are five times the number of deaths attributable to each inoculation vs those attributable to COVID-19 in the most vulnerable 65+ demographic. The risk of death from COVID-19 decreases drastically as age decreases, and the longer-term effects of the inoculations on lower age groups will increase their risk-benefit ratio, perhaps substantially".

21. The risk of death and disease in children has become even more rare with Omicron. Yet even prior to the advent of Omicron, the above peer reviewed study clearly demonstrated (using safety data accumulated during past variant circulation) that the genetic COVID-19 vaccines carry a risk/benefit ratio of five deaths in the older, high-risk cohort for every one life saved from COVID-19 (and those data did not account for the reporting bias inherent in US deaths due to COVID-19 consequent to inappropriate use of PCR tests).

22. With Omicron, what was already an inverted risk benefit ratio for genetic vaccination in children and adults (greater risk of death from vaccine than from COVID-19) has become even more inverted since the risks of COVID-19 are further reduced with Omicron. The Omicron variant is different in five essential ways:

    a. More infectious – it is now the dominant variant in the USA

    b. Less pathogenic

[12] Tracy Beth Høeg MD, PhD; Allison Krug, MPH; Josh Stevenson; John Mandrola, MD SARS-CoV-2 mRNA Vaccination-Associated Myocarditis in Children Ages 12-17: A Stratified National Database Analysis (August 30, 2021).

[13] Elsevier, Kostoff, Calina et all Why are we vaccinating children against COVID-19?" (Toxicology Reports, Volume 8, 2021, Pages 1665-1684 (https://www.sciencedirect.com/science/article/pii/S221475002100161X)

c. Poorly matched to currently available vaccines

d. Natural immunity is providing good protection against Omicron

e. Disease symptoms are more similar to the common cold

Asymptomatic spread

23. There has been much discussion around children being asymptomatic spreaders of COVID-19. In my expert medical opinion, the epidemic spread of COVID-19, like all other respiratory viruses, notably influenza,[14] is driven by symptomatic persons; asymptomatic spread is trivial and inconsequential.[15]

24. A meta-analysis of contact tracing studies published in The Journal of the American Medical Association showed asymptomatic COVID-19 spread was negligible at 0.7%.[16]

25. 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 that *"Flu-stricken college students should stay out of circulation"* and *"if they can't avoid contact they need to wear surgical masks."*[17]

26. Further, young people are not the spreaders of the virus to the community, as shown by a 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.[18]

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

[15] Cao et al: https://translational-medicine.biomedcentral.com/articles/10.1186/s12967-021-02762-0; Madewell et al: https://www.lifesitenews.com/opinion/there-is-no-evidence-that-covid-19-is-transmitted-by-asymptomatic-people/

[16] 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 at p5(last visited 11 January, 2021).

[17] 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.

[18] 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

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

Herd immunity

28. The reduction in the risk of COVID-19 in 2021, was in part due to the U.S achieving herd immunity. 'Herd immunity', also known as 'population immunity', is the indirect protection from an infectious disease that happens when a population is immune either through vaccination or immunity developed through previous infection.[19]

29. As COVID-19 vaccines continue to wane, we can expect more cases of COVID-19, meaning more people will develop natural immunity - herd immunity applies to the spread of natural immunity amongst the population. 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 had a substantial population vaccinated early in the pandemic, we can expect more vaccines to wane in the United States and therefore, New Zealand and no fundamental impact of mass vaccination on the epidemic curves.

Advances in COVID-19 Treatments

30. 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.[20] This approach has resulted in an ~85% reduction in hospitalization and death in high-risk individuals presenting with COVID-19.[21]

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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).

[19] https://ia801408.us.archive.org/12/items/gov.uscourts.flmd.395057/gov.uscourts.flmd.395057.1.8.pdfWorl Health Organisation as at 31 December 2020

[20] 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 above.

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

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 12 mg po qd x 3 days	Attenuates importin á/â-mediated transport of SARS-CoV-2 into nuclear nucleus
Azithromycin 250 mg po bid	Covers respiratory bacterial pathogens in secondary infection
Doxycycline 100 mg po bid	Covers respiratory bacterial pathogens in secondary infection
Inhaled budesonide, Dexamethasone 8 mg IM	Treats cytokine storm
Folate, thiamine, vitamin B-12	Reduce tissue oxidative stress
Intravenous fluid	Intravascular volume expansion

31. I, along with my colleagues, conducted the study referenced in paragraph 30, 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 reduced 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 that are covered in the NIH COVID-19 Guidelines.[22] In my experience, the same medicines and supplements can be safely administered to children 5-11 years to the same effect.

32. 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 children and adolescents and a generally lowered virulence for the SARS-CoV-2 strains as the pandemic progresses over time.

33. In my expert medical opinion, despite the current Delta variant outbreak and likely Omicron outbreak in New Zealand (as with the rest of the world), the lowering COVID-19 rates generally, the combination of children's immunity naturally, the achievement of herd immunity, and the drastically improved treatment options

[22] *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).

available, all make the risks inherent in COVID-19 significantly lower than they were in 2020.

PART TWO: COVID vaccines losing efficacy

Pre Omicron variants

34. The current COVID-19 vaccines are not sufficiently protective against contracting COVID-19 to support their use beyond the current voluntary participation in the CDC-sponsored program. A total of 10,262 SARS-CoV-2 vaccine failures or breakthrough infections[23] 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 - Alpha (199; 56%), B.1.429 - Epsilon (88; 25%) and B.1.427 (28; 8%), P.1 -Gamma (28; 8%), and B.1.351 – Beta (13; 4%).

35. 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.[24] 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.

36. The Delta variant of SARS-CoV-2 until recently accounted 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 which achieved population vaccination rates of 80%" or similar but has continued to suffer from multiple waves of COVID-19.[25]

37. This promoted the emergence of the Delta variant as the dominant strain and because it was not adequately covered by the Pfizer COVID-19 vaccine, >80% of COVID-19

[23] A vaccine breakthrough infection happens when a fully vaccinated person gets infected with COVID-19. People with vaccine breakthrough infections may spread COVID-19 to others. Vaccine Breakthrough Infections: The Possibility of Getting COVID-19 after Getting Vaccinated (cdc.gov)
[24] https://www.cdc.gov/mmwr/volumes/70/wr/mm7021e3.htm
[25] https://datadashboard.health.gov.il/COVID-19019/general

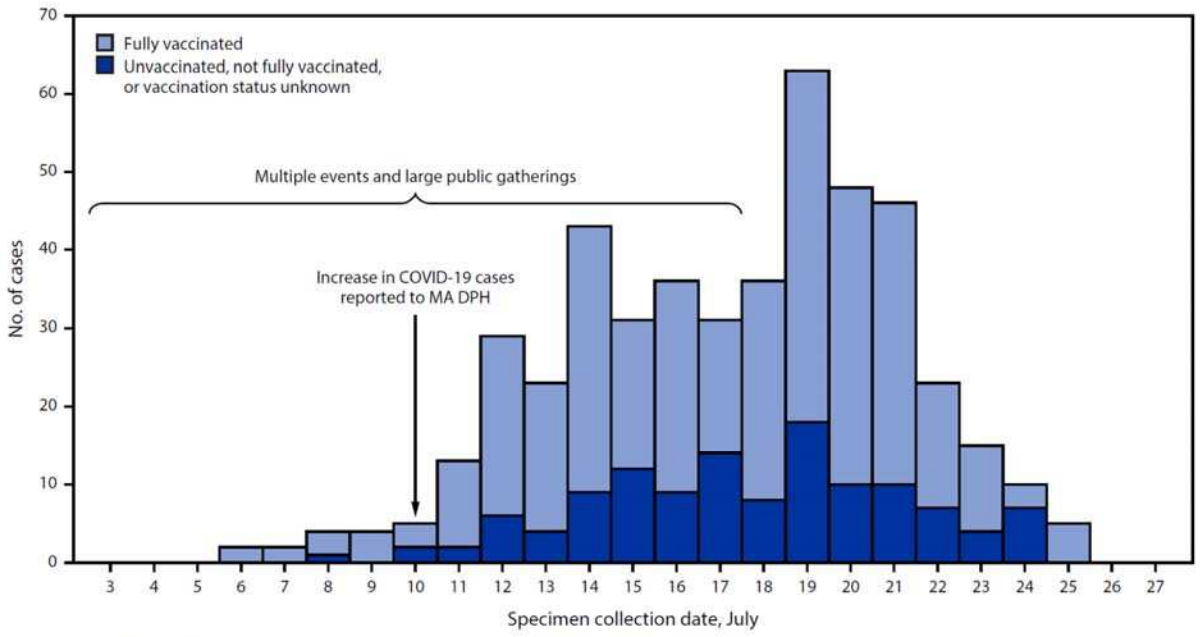
cases have occurred in persons fully vaccinated, some now with failed boosters. This confirms the failure of the vaccines against COVID-19.

38. In the SARS-CoV-2 variants of concern and variants under investigation in England in 25 June 2021, 92,056 cases had the Delta variant and 50 out of 7235 fully vaccinated and 44 out of 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.[26]

39. 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 vaccines in controlled spread of SARS-CoV-2 in congregate settings (as can be seen in Table 4 below).[27]

Table 4 – COVID-19 infections amongst vaccinated and unvaccinated following large public gatherings

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.

[26] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1001354/Variants_of_Concern_VOC_Technical_Briefing_17.pdf
[27] https://www.cdc.gov/mmwr/volumes/70/wr/pdfs/mm7031e2-H.pdf

40. My interpretation of the CDC report is that the vaccines are not sufficiently effective to recommended them for use beyond individual preference.

41. Further, the Wisconsin Department of Public Health reported that vaccinated are carrying the Delta variant in high viral loads and are equally infectious as the unvaccinated with Delta, implying that vaccination of one individual does not protect another individual against COVID-19.

42. Among those tested, the vaccinated have similar viral loads to the unvaccinated, and thus, the vaccinated cannot be considered "more protected" than those who have declined vaccination.[28]

43. It is my expert medical opinion that the COVID-19 vaccines are progressively losing efficacy and have become obsolete with antigenic escape or resistance to variants (e.g. Delta and Omicron) that have evolved to infect persons who were vaccinated against the now extinct wild-type SARS-CoV-2 strain[29].

Omicron

44. The SARS-CoV-2 Omicron variant was only recently discovered in southern Africa and, by November 2021, had almost completely displaced other COVID variants. The first case of Omicron in the US was detected on 1 December 2021 and is now being detected in most US cities.[30] It is likely to quickly become the dominant worldwide SARS-CoV-2 variant.

45. Recent data from countries including Scotland, Denmark and the United Kingdom suggest the current COVID-19 vaccines may have negative vaccine efficacy (**VE**) against Omicron. In other words, vaccinated persons are more likely to be infected with Omicron than non-vaccinated persons. This data should be a serious concern to all public health authorities.

46. By way of example, Public Health Scotland's most recent COVID-19 report dated 12 January 2022 records that Omicron now accounts for > 90% of COVID cases.[31] Since 9 January 2022, Scotland has had 32,305 confirmed Omicron cases with 9 Omicron related ICU/HDU admissions and 15 Omicron deaths (p7).

47. The report records Omicron cases per 100,000 people by week and by vaccination status (unvaccinated, 1 dose vaccinated, 2 doses vaccination, and 3 dose vaccinated). Between 11 December 2021 to 7 January 2022, 1 and 2 dose vaccinated persons have consistently had materially higher rates of Omicron infection than unvaccinated

[28] https://www.medrxiv.org/content/10.1101/2021.07.31.21261387v3
[29] See footnote 4.
[30] https://www.cdc.gov/coronavirus/2019-ncov/variants/omicron-variant.html
[31] https://www.publichealthscotland.scot/media/11076/22-01-12-covid19-winter_publication_report.pdf

persons. In addition, between 25 December 2021 and 7 January 2022, 3 dose vaccinated persons have had materially higher rates of Omicron infection than unvaccinated persons. This is illustrated by Table 5 below:[32]

Table 5 – Age-standardized case rate per 100,000 individuals by week and vaccination status 11 December 2021 to 7 January 2022

	Unvaccinated		1 Dose	
Week	No. tested positive by PCR	Age Standardised case rate per 100,000 with 95% confidence intervals	No. tested positive by PCR	Age Standardised case rate per 100,000 with 95% confidence intervals
11 December - 17 December 2021	6,545	**482.87** (464.41 - 501.34)	2,952	**574.16** (538.46 - 609.85)
18 December - 24 December 2021	9,070	**721.39** (698.44 - 744.34)	4,639	**958.62** (911.03 - 1,006.20)
25 December - 31 December 2021	14,465	**1,242.10** (1,209.27 - 1,274.94)	7,657	**1,693.71** (1,631.31 - 1,756.11)
01 January 2022 – 07 January 2022	12,485	**1,092.80** (1,063.90 - 1,121.71)	6,702	**1,527.57** (1,462.52 - 1,592.63)
	2 Doses		Booster or 3rd Dose	
Week	No. tested positive by PCR	Age Standardised case rate per 100,000 with 95% confidence intervals	No. tested positive by PCR	Age Standardised case rate per 100,000 with 95% confidence intervals
11 December - 17 December 2021	20,788	**826.49** (809.83 - 843.16)	3,926	**458.39** (400.49 - 516.29)
18 December - 24 December 2021	35,123	**1,527.87** (1,501.86 - 1,553.88)	10,193	**902.02** (841.06 - 962.98)
25 December - 31 December 2021	54,860	**2,897.58** (2,859.92 - 2,935.23)	30,327	**1,755.69** (1,701.98 - 1,809.40)
01 January 2022 – 07 January 2022	35,119	**2,499.52** (2,462.50 - 2,536.53)	33,415	**1,466.76** (1,418.18 - 1,515.33)

Date are only based on PCR results. Vaccination status is determined as at the date of positive PCR test according to the definitions described in Appendix 6. The data displayed within the greyed-out section are considered preliminary and are subject to change as more data is updated. Age-standardised case rates are per 100,000 people per week, standardised to the 2013 European Standard Population (see Appendix 6). On average, unvaccinated individuals are younger than individuals with two or more doses of COVID-19 vaccine. To compare across vaccination statuses (unvaccinated, 1 dose, 2 doses or booster/3 doses), age-standardised case rates are calculated to adjust for differences in age distribution. COVID-19 cases included in this table for the *age-standardised rates only includes individuals 10 years old and over. Although the majority of 10 and 11 year olds are currently not eligible for vaccination, the five-year age band standardised to the 2013 European Standard Population used in this analysis ranges from 10-14 years and therefore cases and denominators for these age groups are included.*

48. Evidence of negative VE with respect to Omicron is also reflected in data from Public Health England[33] and Denmark. Table 6, below, records that in the period 22 November 2021 to 11 December 2021 there were 14,188 Omicron infections and 96,868 Covid infections (other variants) in Denmark. However, of the people infected with Omicron, 79.3 percent were fully vaccinated whereas only 8.5 percent were unvaccinated:

[32] Table 5 from page 30 of the report.
[33] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1046431/Vaccine-surveillance-report-week-2-2022.pdf

Table 6 – Omicron infections in Denmark between 22 November 2021 and 15 December 2021 by vaccination status[34]

Vaccination status (12+ year olds)	Other variants (No. of cases)	Other variants (%)	Omicron (No. of cases)	Omicron (%)
Booster vaccinated	7,768	8.0	1,460	10.3
Fully vaccinated	63,543	65.6	11,252	79.3
Not vaccinated	22,490	23.2	1,205	8.5
Received first dose	3,067	3.2	271	1.9
Total	96,868	100.0	14,188	100.0

Individuals aged 5-11 years have recently been invited for COVID-19 vaccination, hence the vaccination coverage is relatively low in this age group and not included in Table 4.

Personer i aldersgruppen 5-11 år er fornyligt blevet inviteret til covid-19-vaccination, hvorfor vaccinationstilslutningen i denne aldersgruppe foreløbigt er begrænset. Denne aldersgruppe er derfor ikke inkluderet i Tabel 4.

49. Why might this be occurring? In part, this appears to be because Omicron has many spike protein mutations that make it markedly resistant to neutralization with the current mRNA vaccines.[35] However, the abovementioned data also suggests that the mRNA vaccines may be negatively impacting a vaccinated person's ability to mount a proper immune response to Omicron, potentially by way of original antigenic sin or vaccine associated enhanced disease. This is another reason why children should not be vaccinated given they are not at any material risk from COVID-19.

50. As at the date of this report, Europe has confirmed it does not support boosters[36] and the United Kingdom has dropped almost all restrictions and mandates[37].

[34] https://files.ssi.dk/covid19/omikron/statusrapport/rapport-omikronvarianten-18122021-wj25
[35] https://www.biorxiv.org/content/10.1101/2021.12.14.472719v1
[36] https://www.euractiv.com/section/coronavirus/news/eu-drug-regulator-expresses-doubt-on-need-for-fourth-booster-dose/
[37] https://www.voanews.com/a/britain-to-drop-covid-19-restrictions-/6403604.html

PART THREE: Risk/benefit analysis of vaccinating adolescents and children

COVID-19 Vaccine Risks to Children and Adolescents

51. 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.

52. 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.[38] The 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." (*emphasis added*). 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 United States. *(See,* EUA briefing documents for commitments as to follow up*:* Moderna[39], Pfizer[40], J&J[41]).

53. These vaccines 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, 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,

[38] 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).
[39] https://www.fda.gov/media/144434/download
[40] https://www.fda.gov/media/144245/download
[41] https://www.fda.gov/media/146219/download

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.[42]

54. 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 abundantly apparent with the burgeoning number of cases of myocarditis or heart inflammation among individuals below age 30 years. *See, infra ¶ 43 – 53.*

55. Because the U.S. FDA and CDC have offered no methods of risk mitigation for these serious adverse effects that can lead to permanent disability or death, it is my opinion no child should be pressured, coerced, receive the threat or reprisal, or be mandated to receive one of these investigational products. 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. I am instructed that New Zealand has a public health system and accident compensation scheme which may cover costs and care.

56. 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.

57. 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).[43]

[42] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1001354/Variants_of_Concern_VOC_Technical_Briefing_17.pdf.

[43] 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

Adverse reactions

58. In 1990, in the United States, 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 (I am instructed that Medsafe in New Zealand has a similar reporting system called CARM). VAERS is useful in detecting unusual or unexpected patterns of adverse event reporting that might indicate a possible safety problem with a vaccine.

59. 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 October 1, 2021, is 778,683, up over 400,000 since June 18, 2021.

60. Based on VAERS as of October 1, 2021, there were 16,310 COVID-19 vaccine deaths reported for the COVID-19 vaccines (Pfizer, Moderna, JNJ.[44] By comparison, from 1999, until December 31, 2019, VAERS received 3167 death reports (158 per year) for all vaccines combined.[45] Thus, in the United States, the COVID-19 mass vaccination is associated with at least a 101-fold increase in annualized vaccine deaths reported to VAERS.

61. COVID-19 vaccine adverse events account for 99% of all vaccine-related adverse events from December 2020 through the present in VAERS.

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

63. There are emerging trends showing that the vaccine is especially risky for those aged12-29 in my expert medical opinion, with complications in the cardiovascular, neurological, hematologic, and immune systems. (*See, Rose J, et al*) There is nothing to suggest that this would be any different in the age group 5-11 age group.

64. Increasingly the medical community is acknowledging the possible risks and side effects of COVID mRNA vaccines including myocarditis, Bell's Palsy, Pulmonary Embolus, Pulmonary Immunopathology, and severe allergic reaction causing anaphylactic shock.[46]

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[44] https://www.openvaers.com/COVID-19-data

[45]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).

[46] 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

65. 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.[47]

66. In New Zealand, Medsafe (the New Zealand Medicines and Medical Devices Safety Authority) has recently issued an "Alert Communication" to remind people that the Comirnaty vaccination (Pfizer COVID-19 vaccine) can cause myocarditis and pericarditis, which it describes "as a as a new but rare side effect of vaccination with Comirnaty vaccine (Pfizer COVID-19 vaccine)."[48]

67. COVID-19 vaccine-induced myocarditis has a predilection for young males below age 30 years.[49] The Centers for Disease Control has held emergency meetings on this issue and the medical community is responding to the crisis and the U.S. FDA has issued a warning on the Pfizer and Moderna vaccines for myocarditis.[50] 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. Because this risk is not predictable and the early reports may represent just the tip of the iceberg, in my opinion 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.[51]

Prevention, Allergic Reactions Including 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).

[47] McCullough PA, Philbin EF, Spertus JA, Kaatz S, Sandberg KR, Weaver WD; Resource Utilization Among Congestive Heart Failure (REACH) Study. Confirmation of a heart failure epidemic: findings from the Resource Utilization Among Congestive Heart Failure (REACH) study. J Am Coll Cardiol. 2002 Jan 2;39(1):60-9. doi: 10.1016/s0735-1097(01)01700-4. PMID: 11755288.)

[48] https://www.medsafe.govt.nz/safety/Alerts/comirnaty-myocarditis-reminder.htm. This alert was an update from its earlier "Alert Communication" on 21 July: https://www.medsafe.govt.nz/safety/Alerts/comirnaty-myocarditis-alert.htm and was released the day after the Ministry of Health issued a media release on 20 December 2021 that noted the death of a 26-year-old man who died within two weeks of his first dose of the Pfizer vaccine, for which myocarditis was identified as the probable cause of death: https://www.health.govt.nz/news-media/media-releases/statement-covid-19-vaccine-independent-safety-monitoring-board.

[49] 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.

[50] https://www.fda.gov/news-events/press-announcements/coronavirus-COVID-19-update-june-25-2021

[51] https://www.fda.gov/news-events/press-announcements/coronavirus-COVID-19-update-june-25-2021.

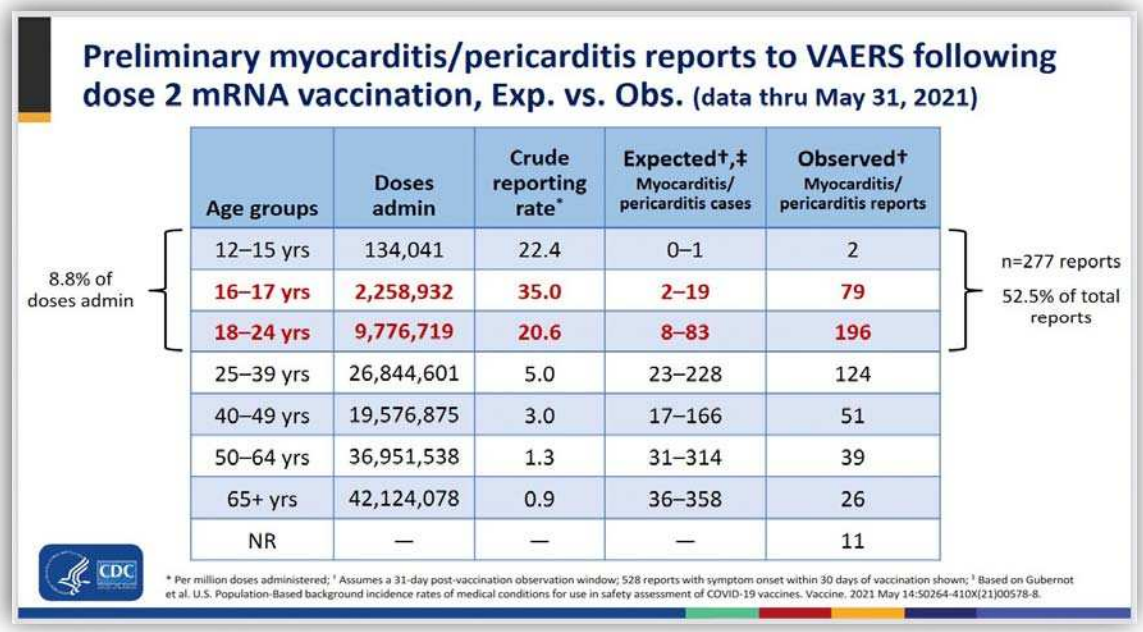
68. Multiple recent studies and news reports detail people aged 18-29 dying from myocarditis after receiving the COVID-19 vaccine. According to the CDC, 475 cases of pericarditis and myocarditis[52] have been identified in vaccinated citizens aged 30 and younger.[53] This number has significantly increased over time, and as of September 24, 2021, the CDC reported there were 6,812 cases of myocarditis/pericarditis.[54]

69. A recent study found even the CDC's reported adverse events numbers for adolescents were low.[55] It is not clear whether the same could be said for children, given the length of time the vaccine has been administered in the 5-11 year age group in the U.S. Instead, the post-second-dose-vaccination rates of cardiac adverse events among adolescent boys aged 12-15 was 162.2/million, which exceeded the rates reported by the CDC by (1.4-2.8 times). Among boys aged 16-17, the estimate was 94.0/million, 31.5-41% higher than the CDC estimate. For girls 12-15 years old, the rate was 13.0/million, which was 43-100% higher that the CDC's estimate. Among girls 16-17, the estimate was 13.4/million, which was 47-65% higher than the CDC's estimate. Additionally, another recent study[56] found a 4-fold increased risk of post-vaccination myocarditis in those who had previously been infected with SARS-CoV-2. The recent Hoeg analysis demonstrates that for a young person the risk of being hospitalized with vaccine-induced myocarditis is greater than the risk of contracting COVID-19 and later becoming hospitalized. [57]

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

[52] Myocarditis is inflammation of the heart muscle, whereas pericarditis is inflammation of the sac-like tissue around the heart called the pericardium.
[53] 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).
[54] https://openvaers.com/covid-data.
[55] https://www.cdc.gov/mmwr/volumes/70/wr/pdfs/mm7031e1-H.pdf
[56] Barda N, Dagan N, Ben-Shlomo Y, et al. Safety of the BNT162b2 mRNA Covid-19 Vaccine in a Nationwide Setting. *NEJM*. August 25, 2021. Accessed August 27, 2021. DOI: 10.1056/NEJMoa2110475
[57] Tracy Beth Høeg MD, PhD; Allison Krug, MPH; Josh Stevenson; John Mandrola, MD, SARS-CoV-2 mRNA Vaccination-Associated Myocarditis in Children Ages 12-17: A Stratified National Database Analysis (August 30, 2021).

Table 7: VAERS Report



Preliminary myocarditis/pericarditis reports to VAERS following dose 2 mRNA vaccination, Exp. vs. Obs. (data thru May 31, 2021)

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

8.8% of doses admin

n=277 reports

52.5% of total reports

CDC

* Per million doses administered; † Assumes a 31-day post-vaccination observation window; 528 reports with symptom onset within 30 days of vaccination shown; ‡ Based on Gubernot et al. U.S. Population-Based background incidence rates of medical conditions for use in safety assessment of COVID-19 vaccines. Vaccine. 2021 May 14:S0264-410X(21)00578-8.

71. Further, the CDC has announced that the vaccine is "likely linked" to myocarditis.[58]

72. 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.

73. There have been 6812 reported cases of myocarditis that have occurred, and the median age is thirty.[59]

74. A report from Rose and McCullough has found that following the global rollout and administration of the Pfizer Inc./BioNTech BNT162b2 and Moderna mRNA-1273 vaccines on December 17, 2020, in the United States, and of the Janssen Ad26.COV2.S product on April 1st, 2021, in an unprecedented manner, hundreds of thousands of individuals have reported adverse events using VAERS. We used VAERS data to examine cardiac adverse events, primarily myocarditis, reported following injection of the first or second dose of the COVID-19 injectable products. Myocarditis rates reported in VAERS were significantly higher in youths between the ages of 13 to 23 ($p<0.0001$) with ~80% occurring in males. Within 8 weeks of the public offering of COVID-19 products to the 12-15-year-old age group, we found 19 times the expected number of myocarditis cases in the vaccination volunteers over background

[58] Advisory Board, CDC panel reports 'likely association' of heart inflammation and mRNA COVID-19 vaccines in young people, (June 24, 2021) https://www.advisory.com/daily-briefing/2021/06/24/heart-inflammation.

[59] https://www.openvaers.com/COVID-19-data (last accessed Oct 4, 2021)

myocarditis rates for this age group. In addition, a 5-fold increase in myocarditis rate was observed subsequent to dose 2 as opposed to dose 1 in 15-year-old males. A total of 67% of all cases occurred with Pfizer Inc./BioNTech BNT162b2. Of the total myocarditis adverse event reports, 6 individuals died (1.1%) and of these, 2 were under 20 years of age - 1 was 13. These findings suggest a markedly higher risk for myocarditis subsequent to COVID-19 injectable product use than for other known vaccines, and this is well above known background rates for myocarditis. In my opinion, COVID-19 injectable products are novel and have a genetic, pathogenic mechanism of action causing uncontrolled expression of SARS-CoV-2 spike protein within human cells. When one combines this fact with the temporal relationship of adverse events occurrence and reporting, biological plausibility of cause and effect, and the fact that these data are internally and externally consistent with emerging sources of clinical data, it supports a conclusion that the COVID-19 biological products are deterministic for the myocarditis cases observed after injection.[60]

Treatments for myocarditis

75. I have seen and examined adolescent patients with post-COVID-19 vaccine 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 and restrict 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.[61] No myocarditis or pericarditis is mild or to be taken lightly.

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[60] Rose J, McCullough PA. A Report on Myocarditis Adverse Events in the U.S. Vaccine Adverse Events Reporting System (VAERS) in Association with COVID-19 Injectable Biological Products. Curr Probl Cardiol. 2021 Sep 30:101011. doi: 10.1016/j.cpcardiol.2021.101011. Epub ahead of print. PMID: 34601006.) (Jessica Rose PhD, MSc, BSc , Peter A. McCullough MD, MPH , A Report on Myocarditis Adverse Events in the U.S. Vaccine Adverse Events Reporting System (VAERS) in Association with COVID-19 Injectable Biological Products, *Current Problems in Cardiology* (2021), doi: https://doi.org/10.1016/j.cpcardiol.2021.101011.

[61] *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

76. On October 5, 2021, Sweden and Denmark announced they are pausing the use of Moderna's COVID-19 vaccine for younger age groups due to these cardiovascular side effects. The Swedish health agency said it would pause using the shot for people born in 1991 and later, as data pointed to an increase of myocarditis and pericarditis among youths and young adults that had been vaccinated. Denmark said that it had decided to pause giving the Moderna vaccine to people below 18 according to a "precautionary principle".[62]

77. With respect to other COVID-19 vaccines available on the market, the FDA has given an update on the JNJ vaccine concerning the risk of cerebral venous sinus thrombosis and thrombosis with thrombocytopenia in women ages 18-48 associated with low platelet counts.[63] 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. In some cases, special glasses are required to correct vision and these young adults can be expected to miss considerable time away from school, undergoing neurological rehabilitation. Because this risk is not predictable, in my opinion no woman under age 48 under any set of circumstances should feel obliged to take this risk with the JNJ vaccine.[64]

78. In addition, the U.S. 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

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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.

[62] https://news.yahoo.com/sweden-pauses-moderna-covid-vaccine-113809877.html?guccounter=1 (7 October 2021).

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

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

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.[65]

79. The mRNA COVID-19 vaccines are 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. As of August, the COVID-19 vaccines, since their EUA approval on May 10, 2021, had already claimed the lives of 15 children and 79 young individuals under age 30 (VAERS).

80. For example, the VAERS data from the CDC shows, for 18-29-year-olds, there have been no deaths from the meningococcal vaccine from 1999 - 2019.[66]

81. 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.

82. 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.[67] (See Nationwide VAERS COVID-19 Vaccine Data through October 1, 2021)[68]

83. As at April 2021, the World Health Organization stated that children should not be vaccinated. They have since changed their position after they faced tremendous backlash.[69]

84. Further, milder side effects from the vaccine include changes in hormone and menstrual cycles in women, fever, and swelling at the injection site.[70] As a result, after-

[65] https://www.fda.gov/media/150723/download
[66] 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").
[67] https://www.newsweek.com/13-year-old-dies-sleep-after-receiving-pfizer-COVID-19-vaccine-cdc-investigating-1606529
[68] VAERS may be publicly accessed at https://www.openvaers.com/COVID-19-data
[69] 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.
[70] Jill Seladi-Schulman, Ph.D., Can COVID-19 or the COVID-19 Vaccine Affect Your Period? (May 25, 2021), https://www.healthline.com/health/menstruation/can-COVID-19-affect-your-period#COVID-19-and-men%20strual-cycles (last visited June 26, 2021); 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).

the-fact research monies have been awarded to explore potential links between COVID-19 vaccination and menstrual change.[71]

85. Recent studies from Tess Lawrie, a highly respected evidence-based professional, 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.[72]

86. It is my opinion that the prevention of mild viral upper respiratory-like infections, of which children (5-11 years) and adolescents (12-15 years) may have four or more times per year, is not worth the risks to the body after a child or adolescent is injected with one of the COVID-19 vaccines.

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

87. 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. This situation is arising more with boosters, or third or fourth of a COVID-19 vaccine.

88. 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 were 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.

89. 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.[73]

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

91. The symptoms included fever, fatigue, myalgia-arthralgia, and lymphadenopathy. 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.

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[71] https://www.nichd.nih.gov/newsroom/news/083021-COVID-19-vaccination-menstruation.

[72] Tess Lawrie, *Re. Urgent preliminary report of Yellow Card data up to 26th May 2021,* (June 9, 2021), http://www.skirsch.com/COVID-19/TessLawrieYellowCardAnalysis.pdf

[73] 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).

92. 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.[74]

93. 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:[75] "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)."

94. Block has summarized 20 studies that confirm natural immunity is robust, complete and durable and cannot be improved upon by vaccination. Natural immunity is far superior to vaccine immunity, which has led to large numbers of vaccine failures, hospitalizations, and death.[76]

95. In my opinion, the Emergency Use Authorization for the investigational COVID-19 vaccine, sponsored by the US FDA and CDC, and provisionally approved by Medsafe in New Zealand, is unreasonable from a scientific and medical perspective.

Natural Immunity to COVID-19

96. 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.

97. 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 vaccination is contraindicated in COVID-19 survivors, many of whom may be in the school aged population.

98. 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—

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[74] *See* https://www.medrxiv.org/content/10.1101/2021.02.26.21252096v1
[75] https://www.medrxiv.org/content/10.1101/2021.01.29.21250653v1.
[76] Block J. Vaccinating people who have had covid-19: why doesn't natural immunity count in the US? BMJ. 2021 Sep 13;374:n2101. doi: 10.1136/bmj.n2101. Erratum in: BMJ. 2021 Sep 15;374:n2272. PMID: 34518194.)

especially more versatile, long-enduring T- cell immunity—relative to vaccinated individuals who were never infected.[77]

99. Cleveland Clinic studied their employees for the effects of natural immunity in unvaccinated people.[78] They found zero SARS-CoV-2 reinfections during a 5-month follow-up among 1359 infected employees who were naturally immune and 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.

100. An analysis by Murchu et al demonstrated in 615,777 individuals that 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.[79]

101. 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.[80]

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[77] 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).

[78] Nabin K. Shrestha, Patrick C. Burke, Amy S. Nowacki, Paul Terpeluk, Steven M. Gordon, *Necessity of COVID-19 vaccination in previously infected individual*s now summarized by Block (Block J. Vaccinating people who have had covid-19: why doesn't natural immunity count in the US? BMJ. 2021 Sep 13;374:n2101. doi: 10.1136/bmj.n2101. Erratum in: BMJ. 2021 Sep 15;374:n2272. PMID: 34518194.)

[79] https://onlinelibrary.wiley.com/doi/10.1002/rmv.2260.

[80] 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

CONCLUSION

102. In my expert medical opinion, despite the current Delta variant outbreak and likely Omicron outbreak in New Zealand, the 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, the vastly improved COVID-19 treatments currently available, all make the risks inherent in COVID-19 significantly lower than they were in 2020.

103. It is my expert medical opinion that the Pfizer vaccine as tested in adolescents age 12-15 and children 5-11 does not offer a significant clinical benefit and has a poor benefit to risk ratio as tested in randomized trials in the era of the now extinct SARS-CoV-2 wild-type, alpha, beta, and gamma variants. Vaccination to prevent mild viral upper respiratory symptoms in a small fraction (1.6%) of subjects is not justified given the short and unknown longer-term risks of the vaccines.

104. It is my expert medical opinion that it is dangerous 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 mRNA 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 administration of COVID-19 vaccines for children aged 5-11 and adolescents aged 12-15 creates an unethical, unreasonable, clinically unjustified, unsafe, and poses an unnecessary risk to the children of the United States of America and New Zealand.

Dr. Peter A. McCullough

State: Texas
County: Dallas
Date: 01/25/2022
Notary: Sabastian Stephon Applewhite

SABASTIAN STEPHON APPLEWHITE
Notary Public, State of Texas
Comm. Expires 10-06-2023
Notary ID 13039631-0