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October 4, 2021

Michigan State University
535 Griswold, Suite 1700
Detroit, MI 48226

VIA EMAIL exemptionappeal@msu.edu

Re: Appeal from COVID-19 vaccine exemption request

Dear Sir/Madam:

This office represents [redacted]. This appeal is submitted within five (5) business days of the denial (dated September 29, 2021).

First, your email did not provide a reason for the denial of the COVID-19 vaccine exemption request. Therefore, as an initial matter, the denial is arbitrary and capricious, and provided no reasonable basis in fact. The denial must be overturned for that reason alone.

Second, the denial violates the First Amendment to the Constitution and the Michigan Constitution:

Mich. Const. Art. 1, Section 2: No person shall be denied the equal protection of the laws; nor shall any person be denied the enjoyment of his civil or political rights or be discriminated against in the exercise thereof because of religion, race, color or national origin. The legislature shall implement this section by appropriate legislation.

Mich. Const. Art. 1, Section 4: Every person shall be at liberty to worship God according to the dictates of his own conscience. No person shall be compelled to attend, or, against his consent, to contribute to the erection or support of any place of religious worship, or to pay tithes, taxes or other rates for the support of any minister of the gospel or teacher of religion. No money shall be appropriated or drawn from the treasury for the benefit of any religious sect or society, theological or religious seminary; nor shall property belonging to the state be appropriated for any such purpose. The civil and political rights, privileges and capacities of no person shall be diminished or enlarged on account of his religious belief.

MCL 37.2201 *et seq*. Elliot-Larsen Civil Rights Act: The State of Michigan has advised that The Michigan Department of Civil Rights today cautioned all Michigan healthcare providers,

businesses, law enforcement agencies and others that civil rights laws, including the Elliott-Larsen Civil Rights Act (ELCRA), the Michigan Persons with Disabilities Act and the Americans with Disabilities Act (ADA), remain in full effect during the public health crisis created by COVID-19.

Title VII of the Civil Rights Act of 1964: individuals have the right to be free from discrimination on the basis of religion. As part of their religious beliefs, many individuals object to vaccines.

US Constitution; First Amendment: The Free Exercise Clause protects citizens' right to practice their religion as they please, so long as the practice does not run afoul of a "public morals" or a "compelling" governmental interest. For instance, in *Prince v. Massachusetts*, 321 U.S. 158 (1944), the Supreme Court held that a state could force the inoculation of children whose parents would not allow such action for religious reasons. The Court held that the state had an overriding interest in protecting public health and safety.

As Judge Paul L. Maloney recently stated in *Dahl et al v The Board of Trustees of Western Michigan University*, Case No. 1:21-cv-00757, ECF No. 7 (08/31/2021):

> The The Free Exercise Clause in our Constitution provides protections against a law that "discriminate against some or all religious beliefs or regulates or prohibits conduct because it is undertaken for religious reasons." Church of the Lukumi Babalu Aye, Inc. v. City of Hialeah, 508 U.S. 520, 532 (1993)); see Bible Believers v. Wayne Cty., Michigan, 805 F.3d 228, 255-56 (6th Cir. 2015) (en banc) ("The right to free exercise of religion includes the right to engage in conduct that is motivated by the religious beliefs held by the individual asserting the claim."). "Where a challenged law is neutral and of general applicability and has a merely 'incidental effect' on Plaintiffs' religious beliefs, Defendants need not show a compelling governmental interest." Resurrection Sch. v. Hertel, —F.4th—, 2021 WL 3721475, at *11 (6th Cir. Aug. 23, 2021) (citing City of Hialeah, 508 U.S. at 531).
>
> Laws that discriminate against religious practices will be invalidated unless "justified by a compelling interest and is narrowly tailored to advance that interest." Roberts v. Neace, 958 F.3d 409, 413 (6th Cir. 2020) (quoting City of Hialeah, 508 U.S. at 553). When laws "infringe upon or restrict practices because of their religious motivation, the law is not neutral." City of Hialeah, 508 U.S. at 533. When law forces an individual to choose between following her religious beliefs or forfeiting benefits, the law places a substantial burden on the individual's free exercise of religion. Living Water Church of God v. Charter Twp. Of Meridian, 258 F. App'x 729, 734 (6th Cir. 2007). And, "[a] law is not generally applicable if it 'invite[s]' the government to consider the particular reasons for a person's conduct by providing a 'mechanism for individualized exemptions.'" Fulton v. City of Philadelphia, Pennsylvania, 141 S. Ct. 1868, 1877 (2021) (citation omitted).

Indeed, MSU has not provided any compelling reason in this case; but instead denied the application for religious exemption without explanation or justification.

As further stated by Judge Maloney on September 13, 2021 (ECF No. 25):

> The First Amendment to our Constitution provides, in part, that "Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof[.]" U.S. Const. amend I. The latter phrase, the Free Exercise Clause, provides protections against laws that "discriminate against some or all religious beliefs or regulates or prohibits conduct because it is undertaken for religious reasons." *Church of the Lukumi Babalu Aye, Inc. v. City of Hialeah*, 508 U.S. 520, 532 (1993). The Supreme Court has held that the Fourteenth Amendment incorporates the First Amendment's protections against the states. See *Maye v. Klee*, 915 F.3d 1076, 1083 (6th Cir. 2019) (citing *Cantwell v. Connecticut*, 310 U.S. 296, 303 (1940)).
>
> The Sixth Circuit has held that a Free Exercise Clause claim must be "predicated on coercion." *Nikolao v. Lyon*, 875 F.3d 310, 316 (6th Cir. 2017) (quoting *Mozert v. Hawkins Cty. Bd. of Educ*., 827 F.2d 1058, 1066 (6th Cir. 1963)). Plaintiffs can establish a Free Exercise claim by showing that WMU requires them to do an act that would violate their religious beliefs. See *Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. 682, 710 (2014) ("As the Court explained in a later case, the 'exercise of religion' involves 'not only belief and profession but the performance of (or abstention from) physical acts' that are 'engaged in for religious reasons.'") (quoting *Emp't Div., Dep't of Human Res. of Oregon v. Smith*, 494 U.S. 872, 877 (1990)); *Mozert*, 827 F.2d at 1066 ("It is clear that governmental compulsion either to do or refrain from doing an act forbidden or required by one's religion, or to affirm or disavow a belief forbidden or required by one's religion, is the evil prohibited by the Free Exercise Clause."). The belief or conduct must be religious in the plaintiff's own scheme of things and must be sincerely held. See *Maye*, 915 F.3d at 1083.
>
> Courts review Free Exercise claims under both rational and strict scrutiny. See *City of Hialeah*, 508 U.S. at 531. "When a challenged law is neutral and of general applicability and has a merely 'incidental effect' on Plaintiff's religious beliefs," courts review the claim under rational scrutiny. *Resurrection Sch. v. Hertel*, —4th—, 2021 WL 3721475, at *11 (6th Cir. Aug. 23, 2021) (citing *City of Hialeah*, 508 U.S. at 531); accord Agudath Israel of *America v. Cuomo*, 983 F.3d 620, 631 (2d Cir. 2020) (explaining that, for a free exercise claim, a "neutral and generally applicable policy is subject only to rational-basis review"); *Bethel World Outreach Ministries v. Montgomery Cty. Council*, 706 F.3d 548, 561 (4th Cir. 2013) (same). Courts apply strict scrutiny to laws that burden religious practices when the law lacks neutrality or is not generally applicable. *Monclova Christian Acad. v. Toledo-Lucas Cty. Health Dep't*, 984 F.3d 477, 479 (6th Cir. 2020) (quoting *City of Hialeah*, 508 U.S. at 546).

> Discretionary denials of a request for a religious exemption to an otherwise neutral and generally applicable policy must be reviewed under the strict scrutiny standard. See *Fulton v. City of Philadelphia, Pennsylvania*, 141 S. Ct. 1868, 1877-78 (2021); *Meriwether v. Hartop*, 992 F.3d 492, 515 (6th Cir. 2012). In Fulton, our Supreme Court held that a law is not generally applicable when it "invites the government to consider the particular reasons for a person's conduct by providing a mechanism for individualized exemptions." 141 S. Ct. at 1978 (cleaned up and quoting Smith, 494 U.S. at 884). The provision in dispute in Fulton gave the Commissioner "sole discretion" to grant an exception to an otherwise blanket prohibition. *Id*. The Court applied strict scrutiny to the Free Exercise claim reasoning that the City "may not refuse to extend that exemption system to cases of religious hardship without compelling reason." Id. at 1878 (cleaned up and quoting *Smith*, 949 U.S. at 884).
>
> When courts apply strict scrutiny to a Free Exercise claim, the law must be justified by a compelling governmental interest and must be narrowly tailored to advance that interest. *Fulton*, 141 S. Ct. at 1181; *City of Hialeah*, 508 U.S. at 531-32. Narrow tailoring requires the government to use the "least restrictive means" of achieving its goal. *Roberts v. Neace*, 958 F.3d 409, 415 (6th Cir. 2020); see *Saieg v. City of Dearborn*, 641 F.3d 727, 738 (6th Cir. 2011) (involving a free speech challenge and explaining that for narrow tailoring, the "regulation must not be 'substantially broader than necessary.'") (quoting *Ward v. Rock Against Racism*, 491 U.S. 781, 800 (1989)). The government bears the burden of establishing that its chosen course of action is narrowly tailored to serve a compelling government interest. *McGlone v. Bell*, 681 F.3d 718, 734 (6th Cir. 2012) (involving a free speech claim and explaining which party bears the burden of establishing narrow tailoring).
>
> The Court concludes strict scrutiny applies to the WMU's denial of Plaintiffs' requests for religious exemptions. Defendants do not dispute that Plaintiffs' beliefs are religious in nature. Nor do they dispute that Plaintiffs' beliefs are sincerely held. Nor do they dispute Plaintiffs' contention that getting a COVID-19 vaccination would violate those sincerely held religious beliefs. By exercising discretion and denying the requested exemptions, exemptions identified in the policy, Defendants' policy was no longer generally applicable. Defendants' denials of the requested exemptions thus function to coerce Plaintiffs into violating their sincerely held religious beliefs.

Clearly, the MSU policy [Exhibit 1] that places the burden on the student is unconstitutional. Therefore, the denial must be overturned on this reason alone.

Third, [redacted] has alleged the MSU has discriminated against her based upon religion and has violated and/or restricted her right to the free exercise of religion. [redacted] is a practicing baptized Catholic.

- Vaccines use cell lines derived from a aborted fetus. There is a general moral duty[1] to refuse the use of medical products, including certain vaccines, that are produced using human cells lines derived from direct abortions. It is permissible to use such vaccines only under certain case-specific conditions, based on a judgment of conscience.

- A Catholic may judge it wrong to receive certain vaccines for a variety of reasons consistent with these teachings, and there is no authoritative Church teaching universally obliging Catholics to receive any vaccine. An individual Catholic may invoke Church teaching to refuse a vaccine developed or produced using abortion-derived cell lines. More generally, a Catholic might refuse a vaccine based on the Church's teachings concerning therapeutic proportionality. Therapeutic proportionality is an assessment of whether the benefits of a medical intervention outweigh the undesirable side-effects and burdens in light of the integral good of the person, including spiritual, psychological, and bodily goods.[2]

- The judgment of therapeutic proportionality must be made by the person who is the potential recipient of the intervention in the concrete circumstances, not by public health authorities or by other individuals who might judge differently in their own situations.[3]

- The Roman Catholic Church teaches that a person may be required to refuse a medical intervention, including a vaccination, if his or her informed conscience comes to this sure judgment. While the Catholic Church does not prohibit the use of any vaccine, and generally encourages the use of safe and effective vaccines as a way of safeguarding personal and public health, the following authoritative Church teachings demonstrate the principled religious basis on which a Catholic may determine that he or she ought to refuse certain vaccines:

    - Vaccination is not morally obligatory in principle and so must be voluntary.[4]

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1 https://www.vatican.va/roman_curia/congregations/cfaith/documents/rc_con_cfaith_doc_20081208_dignitas-personae_en.html

2 https://www.usccb.org/about/doctrine/ethical-and-religious-directives/upload/ethical-religious-directives-catholic-health-service-sixth-edition-2016-06.pdf

3 *Id*.

4 https://www.vatican.va/roman_curia/congregations/cfaith/documents/rc_con_cfaith_doc_20201221_nota-vaccini-anticovid_en.html

- A person's informed judgments about the proportionality of medical interventions are to be respected[5] unless they contradict authoritative Catholic moral teachings.

- A person is morally required to obey his or her sure conscience.[6]

- The Moral Reflection On Vaccines published by the Pontifical Academy for Life[7] suggests that these vaccines should be avoided.

- The Catholic Church's Magisterium discusses bioethical issues with respect to forbidden sources of human biological materials in two further documents. *Dignitas personae*[8], n. 34-35 speaks of the illicit origin of human sources of biological material, founding its opinions on the dignity of the person, emphasized in the documents *Donum vitae*[9] (I, 4) and *Evangelium Vitae*.[10]

- The Catholic Church treasures its teaching on the sanctity of conscience: "In all his activity a man is bound to follow his conscience in order that he may come to God, the end and purpose of life. It follows that he is not to be forced to act in a manner contrary to his conscience. Nor, on the other hand, is he to be restrained from acting in accordance with his conscience, especially in matters religious."[11]

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[5] https://www.usccb.org/about/doctrine/ethical-and-religious-directives/upload/ethical-religious-directives-catholic-health-service-sixth-edition-2016-06.pdf

[6] https://www.vatican.va/archive/ENG0015/__P62.HTM

[7] Moral reflections on vaccines prepared from cells derived from aborted human fetuses. Pontifical Academy for Life. Natl Cathol Bioeth Q. 2006 Autumn; 6(3):541-37.

[8] Dignitas personae. Congregation for the Doctrine of the Faith. Instruction Dignitas Personae. On Certain Bioethical Questions, 2008. Available from: http://www.vatican.va/roman_curia/congregations/cfaith/documents/rc_con_cfaith_doc_20081208_dignitas-personae_en.html. Accessed: February 10, 2016.

[9] Donum vitae. Congregation for the Doctrine of the Faith, Instruction on Respect for Human Life in Its Origin and on the Dignity of Procreation, 1987. Available from: http://www.vatican.va/roman_curia/congregations/cfaith/documents/rc_con_cfaith_doc_19870222_respect-for-human-life_en.html. Accessed: February 10, 2016.

[10] Evangelium Vitae. John Paul II.1995. Available from: http://*w2.vatican.va/content/john-paul-ii/en/encyclicals/documents/hf_jp-ii_enc_25031995_evangelium-vitae.html*. Accessed: February 10, 2016. 24.

[11] Saint Paul VI, *Dignitatis Humanae*, No. 3.

https://www.vatican.va/archive/hist_councils/ii_vatican_council/documents/vat-ii_decl_19651207_dignitatis-humanae_en.html

- Nobody should violate the sanctity of conscience by forcing a person to do something contrary to his or her conscience. There are many health or ethical reasons why a person may refuse COVID-19 vaccination. Even when someone's decision is contrary to the mandates of the State, conscience does not lose its dignity.[12]

- A well-formed conscience stands not solely upon ecclesiastical authority, but also upon the law of God written in an individual's heart.[13] Therefore, a human being must always obey the certain judgment of his or her conscience.[14]

- Additionally, "the Christian faithful, in common with all other men, possess the civil right not to be hindered in leading their lives in accordance with their consciences."[15]

- At the core of the Church's teaching are the first and last points listed above: vaccination is not a universal obligation and a person must obey the judgment of his or her own informed and certain conscience. In fact, the *Catechism of the Catholic Church* instructs that following one's conscience is following Christ Himself:

  - In all he says and does, man is obliged to follow faithfully what he knows to be just and right. It is by the judgment of his conscience that man perceives and recognizes the prescriptions of the divine law: "Conscience is a law of the mind; yet [Christians] would not grant that it is nothing more; . . . [Conscience] is a messenger of him, who, both in nature and in grace, speaks to us behind a veil, and teaches and rules us by his representatives. Conscience is the aboriginal Vicar of Christ."[16]

- Therefore, someone who in conscience decides that he or she should not receive the COVID-19 vaccine should be granted an exemption based on his or her beliefs or convictions.

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[12] Saint Paul VI, *Gaudium et Spes*, No. 16.

https://www.vatican.va/archive/hist_councils/ii_vatican_council/documents/vat-ii_const_19651207_gaudium-et-spes_en.html

[13] *Id*.

[14] Catechism of the Catholic Church, no. 1800.

[15] Saint Paul VI, *Dignitatis Humanae*, No. 13.

https://www.vatican.va/archive/hist_councils/ii_vatican_council/documents/vat-ii_decl_19651207_dignitatis-humanae_en.html

[16] https://www.vatican.va/archive/ENG0015/__P5Z.HTM

Fourth, as detailed by Dr. Peter A. McCullough, M.D., M.P.H, "in my medical expert opinion, the mandatory, administration of COVID-19 vaccines in students creates unnecessary risk to students, the student body at large, and young persons in the United States of America." [Exhibit 2].

Medial Issues.

Fifth, [redacted] also has medical reasons to not take the COVID-19 vaccine. She has an immune deficiency disorder. The Americans with Disabilities Act (ADA), and other state and federal laws, do not permit MSU to force vaccination on [redacted].

If you have any questions, please contact me.

Very truly yours,

DePERNO LAW OFFICE, PLLC

Matthew S. DePerno

Exhibit 1

Vaccine Exemption Appeal Process

Michigan State University requires all faculty, students, and staff to be fully vaccinated against COVID-19 with limited exemptions. Those limited exemptions are (1) medical; (2) religious; and (3) for students who are taking all online classes during the fall 2021 semester. The exemptions are set forth in detail in the Covid-19 Directives.

Faculty, students, and staff who applied for, but were denied, an exemption from the mandatory vaccine requirement may appeal the denial determination by following this appeal process.

Timeframe for Submitting Appeal

Appeals of a vaccine exemption denial are filed in writing and must specify the basis for appeal in sufficient detail. Appeals must be submitted within five (5) calendar days of the vaccine exemption denial. If a deadline falls on a weekend or university holiday, the deadline will be extended to the next day on which the university is open for business.

The appeal deadline may be extended for good cause, as determined by the Appeal Officer. Good cause is typically found where circumstances outside of an individual's control would prevent them from complying with the deadline. Requests for extensions should be made to the Appeal Officer before the deadline has expired and explain why there is good cause for the extension.

Appeal Standard

Appeals must demonstrate that the vaccine exemption denial had no reasonable basis in fact. The party filing the appeal bears the burden of proof.

Appeals will be decided by an Appeal Officer. The Appeal Officer may request more information if needed.

The Appeal Officer will issue a decision within five (5) calendar days of receiving all information required by the Appeal Officer for the appeal. The Appeal Officer may uphold the vaccine exemption denial determination or determine the decision had no reasonable basis in fact. The decision of the Appeal Officer is final and is not subject to further appeal.

Electronic Submission of Appeal

Appeals of vaccine exemption denial determinations should be submitted electronically to the Appeal Officer at exemptionappeal@msu.edu (mailto:exemptionappeal@msu.edu).

MICHIGAN STATE
UNIVERSITY
(https://msu.edu/)

Exhibit 2

AFFIDAVIT OF DR. PETER MCCULLOUGH, MD, MPH

BEFORE ME, the undersigned person, duly authorized to administer oaths, personally appeared, Dr. Peter McCullough, MD, MPH, to me well known, who, after being first duly cautioned and sworn, deposed and stated as follows:

1. My name is Dr. Peter McCullough, MD, MPH, I am over eighteen years of age, and I am not suffering under any mental disability and am competent to give this sworn affidavit. I am able to read and write and to give this affidavit voluntarily and on my own free will and accord. No one has used any threats, force, pressure, or intimidation to make me sign this affidavit. I understand that I am swearing or affirming under oath to the truthfulness of the claims made in this affidavit under penalties of perjury; that I have read these statements in this affidavit; and these statements are my understanding of the facts and that my opinion provided is based on a reasonable degree of medical certainty. I am working on this case Pro Bono; and have not been paid by Mr. Kenneth Ferguson Esq., Plaintiffs, or anyone else to provide this opinion. I am providing this affidavit as I have serious, grave concerns for students and the public-at-large.

2. I have personal knowledge and understanding of these matters and I make this affidavit in support of the truth of the contents contained herein. In short: I believe within a reasonable degree of medical certainty that the COVID-19 vaccine(s) are not safe generally; and particularly dangerous for students. It is my belief based on a reasonable degree of medical certainty that the vaccine could cause the death of students and that their lives are in danger should they be administered the vaccine and participate in online or on campus activities. I believe within a reasonable degree of medical certainty that the data upon which United Airlines has based its mandate upon is flawed and/or inaccurate; and imposing this vaccine is not only dangerous and could cause harm to the students, but to their student bodies and the public-at-large. In support, I submit the following for the Court's consideration:

3. 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. 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 am on the active medical staff at Baylor University Medical Center and Baylor Jack and Jane Hamilton Heart and Vascular Hospital, in Dallas, Texas. 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 two peer-reviewed journals, editorialist, and reviewer at dozens of major medical journals and textbooks. I am a Professor of Medicine, Texas Christian University and the University of North Texas Health Sciences Center School of Medicine.

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

5. 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, and the Texas Senate Committee on Health and Human Services. I am a Fellow of the American College of Cardiology, the American Heart Association, the American College of Physicians, the American College of Chest Physicians, the National Lipid Association, the Cardiorenal Society of America, and the National Kidney Foundation; and I am also a Diplomate of the American Board of Clinical Lipidology. 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. 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 Cardiorenal Medicine, a primary research journal listed by the National Library of Medicine which is the only publication with a primary focus on research concerning patients with 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 contemporary topics in cardiology and is also listed by the National Library of Medicine.

6. 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. 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 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.

As to my Expert Opinion

7. 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

8. 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
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 exceeds 100%. As vaccines continue to fail, we can expect cases of COVID-19 and the meaning of herd immunity applies to spread. 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 in the United States and no fundamental impact of mass vaccination on the epidemic curves.

Table 1: COVID-19 Deaths by Age Group in the U.S. as of June 27, 2021: Source: https://COVID-19.cdc.gov/COVID-19-data-tracker/#demographics

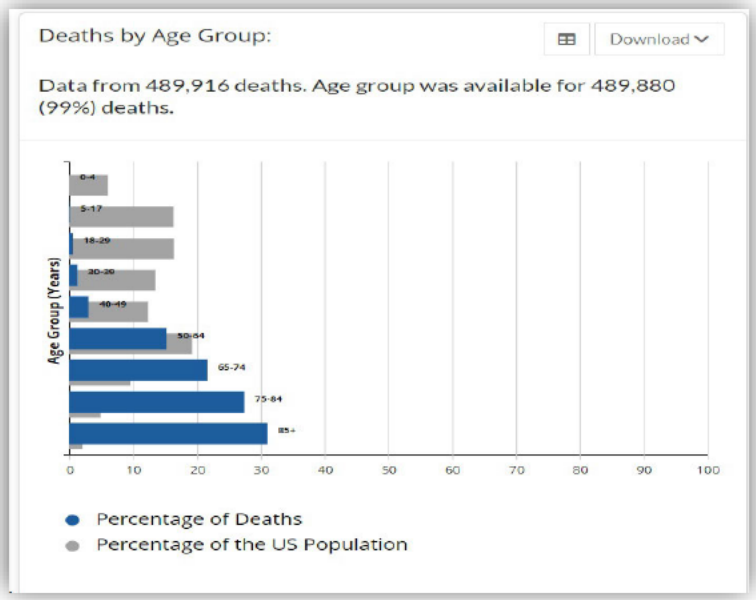


Table 2: COVID-19 Rate Ratios by Age. Source https://www.cdc.gov/coronavirus/2019-ncov/COVID-19-data/investigations-discovery/hospitalizationdeath-by-age.html

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.)

9. There is negligible risk for adults younger than the age of 60. For example, for each 18-29-year-old that dies from COVID-19, four 30-39year 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.

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

11. 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%. 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).

12. 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

Advances in COVID-19 Treatments

13. Even if the virus is contracted, 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 (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 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
Folate, thiamine, vitamin B-12	Reduce tissue oxidative stress
Intravenous fluid	Intravascular volume expansion

14. 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).

15. 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.

16. In my expert medical opinion, the combination of lowering COVID-19 rates, achievement of herd immunity, 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.

COVID-19 Vaccine Research and Development

17. 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.

18. 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.

19. 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 US. (See, EUA briefing documents for commitments as to follow up: Moderna , Pfizer , J&J). 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 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%2F2019ncov%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 abundantly apparent with the burgeoning number of cases of myocarditis or heart inflammation among individuals below age 30 years. See, infra ¶ 48 - 54.

Because the US FDA and CDC have offered no interpretation of overall safey of the COVID-19 vaccines according to the manufacturer or as a group, nor have they offered methods of risk mitigation for these serious adverse effects which can lead to permanent disability or death, no one 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 the person are at their own cost which can be prohibitive depending on the needed procedures, hospitalizations, rehabilitation, and medications.

20. 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.

21. 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).

COVID-19 Vaccine Risks

22. The COVID-19 public vaccination program operated by the CDC and the FDA is a clinical investigation and under no circumstance can any person 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.

23. 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 (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.

24. 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 COVID-19.

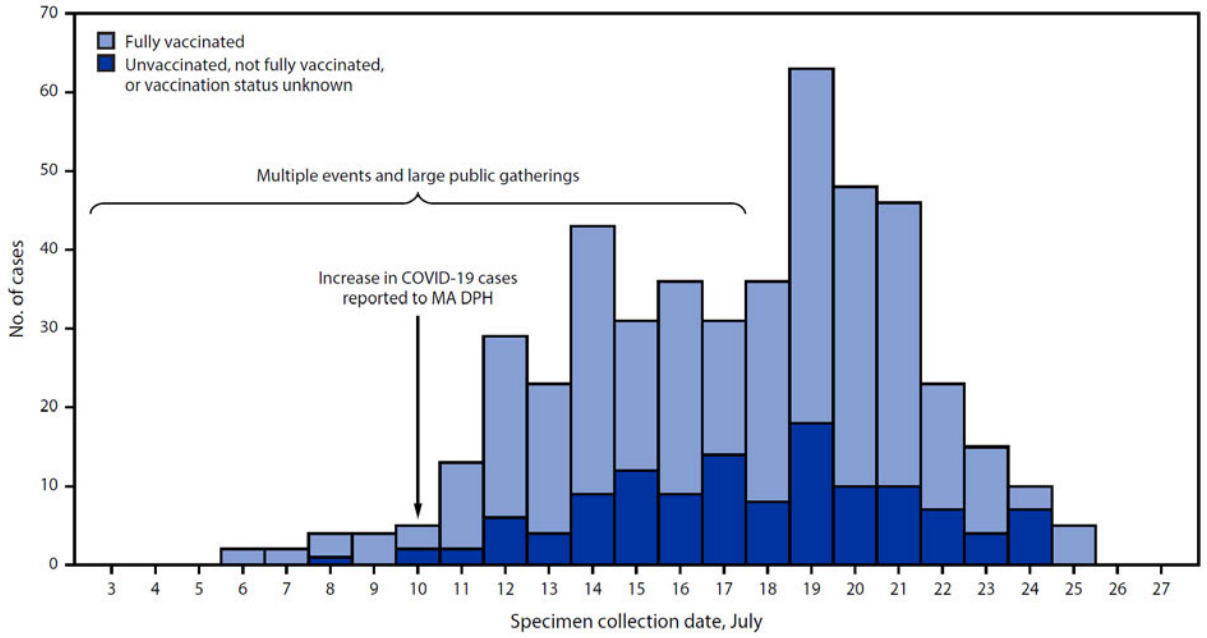
Table 4: Israel Confirmed Cases, Vaccinated vs. Unvaccinated

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

25. 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

26. 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.

27. 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.

28. 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 June 18, 2021, is 387,288. Based on VAERS as of July 16, 2021, there were 11,405 COVID-19 vaccine deaths reported and 36,117 hospitalizations reported for the COVID-19 vaccines (Pfizer, Moderna, JNJ). By comparison, from 1999, until December 31, 2019, VAERS received 3167 death reports (158 per year) adult death reports for all vaccines combined. Thus, the COVID-19 mass vaccination is associated with at least a 39-fold increase in annualized vaccine deaths reported to VAERS.

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

30. The COVID-19 vaccines are not safe for general use and cannot be deployed indiscriminately or supported, recommended, or mandated among any group – this is particularly dangerous for students given their lack of benefit and special risks when administered the COVID-19 vaccines.

31. 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). 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 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).

32. 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).

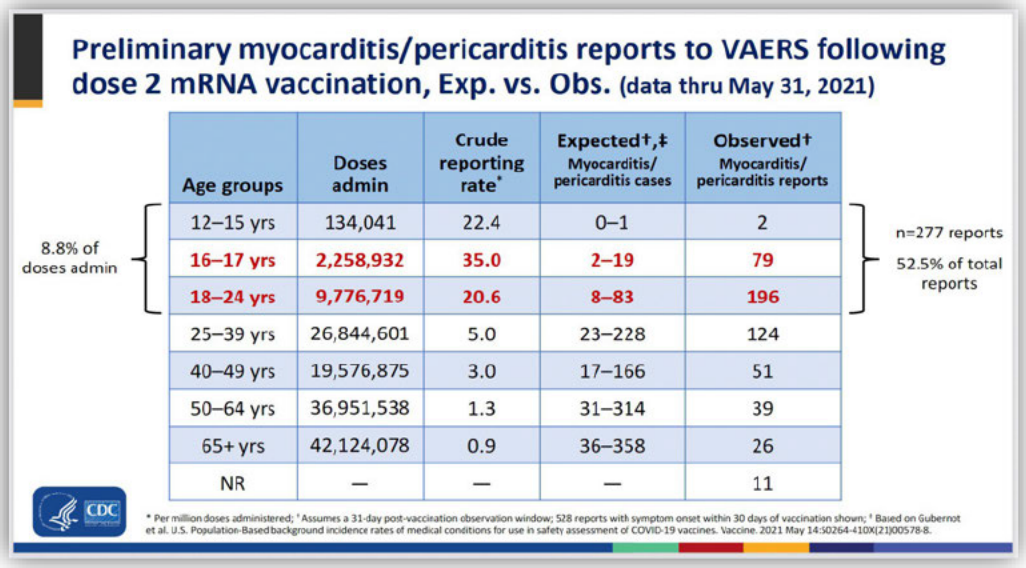
33. COVID-19 vaccine-induced myocarditis has a predilection for young males below age 30 years. The Centers for Disease Control has held emergency meetings on this issue and the medical community is responding to the crisis and the US FDA has issued a warning on the Pfizer and Moderna vaccines for myocarditis. In the cases reviewed by the CDC and FDA, 90% of young persons 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, 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-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 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).

34. 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



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.

35. 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

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

36. 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. There have been 2466 reported cases of myocarditis that have occurred, and the median age is thirty. Id. https://www.openvaers.com/COVID-19-data (accessed July 17, 2021)

37. 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 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[1]. Acute myocarditis could lead to heart failure and sudden deaths in students.

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[1] See, e.g., Tommaso D'Angelo MD, Antonino Cattafi MD, Maria Ludovica Carerj MD, Christian Booz MD, 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 visited June 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-myocarditis-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 European Society 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.

38. The US 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. 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 no woman under age 48 under any set of circumstances should feel obliged to take this risk with the JNJ vaccine. Such catastrophic neurologic thrombotic events could occur in students while in or outside the classroom. https://www.fda.gov/news-events/press-announcements/joint-cdc-and-fda-statement-johnson-johnson-COVID-19-vaccine

39. 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 young persons injured from the JNJ vaccine with Guillen-Barre Syndrome. This syndrome is unpredictable and could occur in a student during enrollment or after graduation. https://www.fda.gov/media/150723/download

40. 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).

41. 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"), Attached as Exhibit C.

42. 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.

43. 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 . (See Nationwide VAERS COVID-19 Vaccine Data through June 18, 2021, attached as Exhibit B). Further, milder side effects from the vaccine include changes in hormone and menstrual cycles in women, fever, swelling at the injection site, etc. 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).

44. Recent studies from Tess Lawrie, MBBS, PhD, 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 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

45. 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. 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.

46. 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).

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

48. 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.

49. 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

50. 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.

51. 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 student population.

52. 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 06/26 21).

53. 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.

54. 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

55. 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

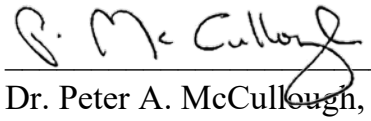
CONCLUSION

In my expert medical opinion, which is and is within a reasonable degree of medical certainty, despite the current Delta variant outbreak, the increasing likelihood of herd immunity to COVID-19, the low risk to students 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.

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 (Israel, Iceland, Singapore) 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 COVID-19 survivors, suspected COVID-19-recovered, pregnant or women who could become pregnant at any time after investigational vaccines; and especially in students. In my expert medical opinion, the risks associated with the investigational COVID-19 vaccines 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 students creates an unethical, unreasonable, clinically unjustified, unsafe, and poses an unnecessary risk to the students of the United States of America. Likewise, in my medical expert opinion, the mandatory, administration of COVID-19 vaccines in students creates unnecessary risk to students, the student body at large, and young persons in the United States of America.



August 13, 2021

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