From:	Lee Ellen
To:	Ethics Commission, (ETH)
Cc:	Pelham, Leeann (ETH); Thaikkendiyil, Gayathri (ETH); Pierce, Jeffrey (ETH); Massey, Steven (ETH); Contreraz, Ronald (ETH); Gage, Rachel (ETH); Hosey, Johnny; Kim, John (ETH); Petersen, Patricia (ETH); Ford, Patrick (ETH); Field, Tyler (ETH); Flores, Jarrod (ETH); Hodge, Robert (ETH); Lal, Manisha (ETH); ETH_Purge_amy.li_03062021; Braxton, Ernestine; McClain, Thomas (HSA); Willett, Eric (ETH); Zumwalt, Jeffrey (ETH); Taloa, Jen (ETH)
Subject:	Step up to save San Franciscans, workers and families from mandate covid19 vaccination
Date:	Friday, September 24, 2021 4:45:53 PM
Attachments:	09132021 vaccine death 296,640.docx Nuremberg Code.docx 2006 to 2019 data-statistics-report.pdf No mandate in Florida EO-21-81.pdf No mandate 08172021 military-vaccine-mandate-complaint.pdf 06102021 filed 113 pages 1 60c2c0ef2f009a01af1e18be_Doc 10 Original AFLDs Complaint.pdf 07192021 CDC 45,000 Covid 19 Vaccine deaths Law Suit case 2-21-cv-00702-CLM.pdf DOJ 2021-07-06-mand-vax.pdf 07272021 health department has NO right to shut down private business re covid19.pdf CITIZENS+ARREST+-+info+CA+(1).docx US+Civil+Rights+Protection+Card+(3).pdf

Dear SF Ethics Commission Staff,

This is for public information. Please submit for next Ethics Commission Public hearing. Thank you. 11 attachment.

I am writing to you, SF Ethics Commissioners, to request you look into the public codes, laws and regulations, to stop mandate vaccination because covid19 vaccine was meant to reduce symptoms only, never intend to prevent or cure or stop any pandemic, per vaccine application filed with CDC.

I hope things are well with you all. America is in the middle of communism take over, lawlessness happens across our nation, it is evil vs good. More and more Americans forced to die or adverse injuries by forcing a gene therapy, aka covid19 vaccine, see my attached files.

As Behavioral Health Clinician for Public Health, I have the duty to inform our public about politicians abuse and management abuse. Many of the public workers are threat to take the gene therapy or face termination, more than 300,000 Americans died already from taking the covid19 vaccine. Forcing a gene therapy is illegal and un-American. See attached court reports and medical report on illegal mandate. More and more people died from covid19 vaccination.

As some of you, Ethics Commission staff already know from public hearings, I have a track record against government corruption since 2016 to present. I will continue to stand up to protect our children, public workers and families. Yes, SF public employees filed a lawsuit against medical tyranny. If you are being forced, see help, see below public resources for help.

Between July 2021 to present, I gave evidence to public officials and SFDPH DHR and management staff about gene therapy, an experimental drug should NOT be mandated. More and more people died after being vaccinated. See below information my previous email attachments to you. But CCSF DHR Director Carol Isen keeps on sending threaten email to public employees to vaccinate or no job which is illegal, it is crime against humanity. It is against civil, ADA, Medical and religious laws. We are Americans and we have constitutional rights. Medical is a choice, not a force! I am Public Health worker and I am well trained on informed consent for any treatment. For management staff and politicians to lie and cheat on the public on a gene therapy process is a crime.

Ethics Commission staff, as many of you remember that back in December 2015, we have more than 200 public employees spoke in front of Civil Service Commission about government corruption and management corruption across most departments. I believe the majority of public workers are good people. Majority of us, public workers work so hard to keep our public safe.

From March 2020 to present, our city is under attack by the some lawless politicians who sold their souls to communism, globalists, aka One World Order. The pandemic 2019 was planned to take down our nation. Covid19 gene therapy was meant to destroy our economy and our health. Vaccine shot does not heal or cure anyone, it only reduce symptoms, per vaccine application filed with CDC, emergency use authorization, never FDA approved for regular vaccine. The California lockdown was illegal too, lawsuits filed against Gavin Newsom in 2020 and 2021and won by the people, specially people believe in God, that was one of the reasons that we can re-open.

Covid19 survival rate is 99.9%, less than 1% death and most deaths are elderly, people old, expected deaths. The Covid19 death ages beyond life expectancy. Then why CCSF-DHR kept forcing public employees, students, workers and citizens to vaccine??? Who are the people benefit from vaccine? Follow the money NOT the science! It is a crime against humanity for CCSF public officials and management staff to push a bio-weapon, aka gene therapy, aka vaccine on people's body!!! So many people died already from this covid19 shot! Wake up! Wake up America! Wake up San Francisco!

CCSF - SFDPH does NOT have a tracking system for vaccine death nor injuries. It is illegal for SFDPH management staff, specially the Health Officer / health codes, no vaccine card, no indoor eating or indoor activities, all these are violations against civil rights and constitutional rights. These public officers abuse their job title should be removed from their public position. We, the public buildings and public employees do NOT discriminate against any clients based on sex, gender, race, creed, age, religious, vaccinated or un-vaccinated! But why health orders create discrimination against American people? It is illegal for what we face in today's lawless un-American San Francisco. I am a public servant and I am trained to follow the **Mission** of the San Francisco Department of Public Health is to protect and promote the health of all San Franciscans.

We, the Americans are under attack by the evil agenda 21 and now evil agenda 2030. There are more and more people died from vaccination. See my attached files here in this email. We, some of the government employees filed lawsuit against medical tyranny.

You and I know, we, can NOT force any gene therapy or any medical treatment to any patients. Have you ever thought about who are the people behind the no vaccine no job agenda? Why? We have medicine to heal covid19 patients, but why forcing vaccine even so many people died??? In the last 20 years, there are fewer than 5,000 died from vaccine. But from January 2021 to present, more than 300,000 died already, plus millions adverse injuries from covid19 vaccination, but why DPH Health Officer continue to push a gene therapy that has nothing to do with healing patients? Vaccine19 vaccine only meant to reduce symptoms, not to heal any covid19 patients, per vaccine application filed in CDC!

Ethics Commission staff, you and I are public servants and we serve the public with love, hope and faith. We have equal rights and responsibilities to do our job. I stood up against management abuse and this investigation toward me is retaliation! The tax payers pay our paychecks. What the corrupted management staff and politicians do, cheat and lie to our public, I have no control. But, I follow the good public servant codes to report to you and the public. The blood is not on my hand now. I do my part to share the truth with you Ethics Commissioners and I hope you find ways to stop killing more Americans. May God bless you and keep you safe.

May God give courage Ethics Commissioners o stand firm for the truth. No more mandate for gene therapy! No more threats to discriminate anyone!

Ellen Lee Zhou, Behavioral Health Clinician for San Francisco Public Health.
The **Mission** of the San Francisco Department of Public Health is to protect and promote the health of all San Franciscans

See below resources to support what I said. I am sharing you nothing but the truth. The truth shall revive America. Yes, return to God and God will help us to revive San Francisco. I am a firm believer for being a good and faithful public servant. I love my job and I love San Francisco.

296,640 Estimated Dead From the mRNA Vaxxxines in the USA. Yet Dr. Death Fauci is Coming For Your Children. Dr. Zelenko: This is a Worldwide Genocide | Agenda 21 | Before It's News (beforeitsnews.com) : **296,640 Estimated Dead From the mRNA Vaxxxines in the USA. Yet Dr. Death Fauci is Coming For Your Children. Dr. Zelenko: This is a Worldwide Genocide,** Monday, September 13

For those who vaccinated, time to seek medical help, detox
MyFreeDoctor.com's Free Doctor consults all 50 states!

Lawsuits filed across the nation against vaccine mandate:
America's Frontline Doctors (americasfrontlinedoctors.org)

[Advocates For Faith & Freedom (faith-freedom.com)]

[Freedom Of Religion - United Solutions (FOR-US) (forunitedsolutions.org)]

United through religious freedom. Finding solutions to protect it.

Freedom Of Religion - United Solutions (FOR-US) is a coalition of multi-faith religious leaders that aims at pro...

THE HEALTHY AMERICAN™

Non-Profit Legal Defense Organization - Pacific Justice Institute

A Voice for Choice Advocacy – If there is RISK there MUST be CHOICE!

The fruit of the Spirit is love, joy, peace, forbearance, kindness, goodness, faithfulness, gentleness and self-control. Against such things there is no law. (Bible---Galatians 5:22,23)

LEGAL NOTICE

To the Person in Charge of this Establishment

As the person responsible for the operation and management of this place of public accommodation, YOU are criminally and civilly liable for the activities that you allow or prohibit on these premises – regardless of whether you own this establishment or not.

YOU ARE HEREBY NOTIFIED THAT:

(1) **It is UNLAWFUL for you or another employee to require someone to wear a mask.** Even if you are a licensed medical doctor who has examined the patron and you have determined that person to be physically fit enough to restrict their breathing while on your premises, the person still has the right to choose whether to wear a mask or not. Recommending that someone wear a mask, which is designated by the FDA as a "medical device" is the unlicensed practice of medicine, which is a violation of **California Business and Professions Code 2052.**

(2) **It is UNLAWFUL for you or another employee to take someone's temperature**. Gathering vital statistics is a **violation of the 4th Amendment,** which protects a person's right to privacy. Violation of this protection will result in your actions being report to the U.S. Department of Justice, which is required by law to investigate Civil Rights Violations.

(3) **It is UNLAWFUL for you to require proof of vaccination as a condition of entry to this establishment.** State and federal non-discrimination laws protect FREE AND EQUAL ACCESS regardless of my medical condition, which I do not need to disclose to you.

(4) **It is UNLAWFUL for you or another employee to attempt to enforce local ordinances.** You are not a law enforcement officer and impersonating a law enforcement officer is a crime in this state under **California Penal Code 538(d) PC:** Impersonating a peace officer carries the penalty of one year in jail and a $2,000 fine. You will be reported to authorities for this violation.

(5) **It is UNLAWFUL for you or another employee to prohibit someone to enter this establishment, which is a place of public accommodation. U.S. Federal Civil Rights Law, Title II requires free and equal access to all services and facilities WITHOUT DISCRIMINATION**. Having someone else shop for them is not equal. Further, the non-discrimination laws in this State, under **California Civil Code 51** further prohibit you from preventing entry to the full enjoyment of this business establishment. Violation of these laws will result in you being served a NOTICE

OF DISCRIMINATION, which can serve as the basis of a formal complaint against you personally with the California Department of Justice and the U.S. Department of Justice, which is required by law to investigate civil rights violations.

(6) **It is UNLAWFUL for you or another employee to block someone's entry to your establishment.** This is a place of public accommodation and as such, no person may be prevented entry when this establishment is open to the public. FALSE IMPRISONMENT is the "unlawful violation of the personal liberty of another." Attempting to prevent someone's entry to this establishment or to restrict, detain or confine their movement constitutes **FALSE IMPRISONMENT**, under **California Penal Code 236 PC,** which can be a felony and punishable up to three years in jail.

(7) **Any claim of "store policy" or "no mask, no service" is NULL, VOID and UNLAWFUL** as no business may enforce policy that violates established law. This LEGAL NOTICE sets forth the previous five laws (and there may be more) which SUPERCEDE any claim to a "store policy". Any attempt to prohibit the "free and equal access to all services and facilities" of this business establishment will:

a. Be reported to law enforcement as criminal charges of false imprisonment
b. Be reported to the U.S. Department of Justice as a violation of civil rights
c. Be reported to the LEGAL COUNSEL of this establishment
d. Be reported to the DISTRICT ATTORNEY of this jurisdiction for possible criminal charges.

(8) **Neither you nor an employee may prevent the lawful entry of a patron – regardless of whether they are wearing a mask or not.** Attempting to prevent the entry of a patron to your business establishment, which is a place of public accommodation is a violation of an IMPLIED, IRREVOCABLE LICENSE that this business has granted to the public.

(9) **Any attempt by you or an employee to summon law enforcement with a claim of "trespassing" will be reported as ASSAULT by you or your employee.** You or your employee can be charged with and convicted of assault in this state if no one is physically hurt by your behavior. There is **NO VALID CLAIM of TRESPASS** because:

a. your business establishment is open to the public
b. this business has extended an irrevocable license to the public for entry
c. the patron has entered legally and has not interfered with the business
d. there has been no evidence of violation

(10) If you are wearing a mask while engaged in any of the above violations, this may aggravate your crime. You or your employee can be charged with and

convicted of assault in this state under code even if no one is physically hurt by your behavior.

YOU ARE HEREBY NOTIFIED of a potential CITIZEN'S ARREST for violations of the above laws, under California Penal Code 837 PC, which authorizes a private person to make a citizen's arrest in California.

YOU ARE HEREBY NOTIFIED of a POTENTIAL CITIZEN'S ARREST AUTHORIZED BY CA PENAL CODE 837PC

WHEREAS, under the authority of California Penal Code 837 PC, when someone commits a misdemeanor in a citizen's presence, or commits a felony and a citizen has a reasonable cause to believe the perpetrator committed it;

WHEREAS, California courts have recommended that private persons follow certain procedures when making these arrests:

1. The citizen should inform a person that he **intends to arrest him;**

2. The citizen should set for the **cause of the arrest;**

3. If possible, the citizen should indicate **the authority to make the arrest;**

4. If applicable, the citizen should inform the perpetrator that he has **called the police or sheriff;**

5. The citizen should try to **make an arrest as soon as possible,** as a delay may result in the citizen's loss of authority to make an arrest

6. The citizen making the arrest **can use reasonable force** but should consider the safety of all involved

7. The citizen should **consider the safety** of all involved

8. **The citizen should call 911**

9. The citizen should ask for the arrestee's cooperation

10. If needed, the citizen can keep the perpetrator out of harm's way in a secluded location. Initial here: _____

Referenced from https://www.shouselaw.com/ca/defense/penal-code/837/

THEREFORE, you and your employees have hereby been PUT ON NOTICE of potential civil and criminal violations of unlawfully preventing the lawful entry of any member of the public.

YOU ARE AT RISK FOR A CITIZEN'S ARREST, AS AUTHORIZED UNDER CA PENAL CODE 837, WITH LAW ENFORCEMENT BEING SUMMONED FOR YOUR VIOLATIONS OF THE ABOVE LAWS. INITIAL_____.

HOW TO MAKE A CITIZEN'S ARREST IN CALIFORNIA:

1. First, **CALL 911** to report a crime in progress.

2. Inform the perpetrator of the intended arrest, using the following language:

3. "You are hereby informed of my attention to place you under citizen's arrest."

4. "You have willfully and knowingly violated these laws: (read off the list of violations as applicable)"

5. "My authority to arrest you is granted by California Penal Code 837"

6. "I have called law enforcement to the scene"

7. "I am requesting your cooperation until law enforcement arrives".

8. “If you refuse to cooperate or attempt to flee the scene, I have the right to use reasonable force to detain you.”

9. “The law allows for you to be kept out of harm’s way in a secluded location until law enforcement arrives.”

Referenced from https://www.shouselaw.com/ca/defense/penal-code/837/
Prepared by www.THEHEALTHYAMERICAN.ORG

Nuremberg Code - history - Office of NIH History and Stetten Museum

The Nuremberg Code

1. The voluntary consent of the human subject is absolutely essential.
   This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved, as to enable him to make an understanding and enlightened decision. This latter element requires that, before the acceptance of an affirmative decision by the experimental subject, there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person, which may possibly come from his participation in the experiment.
   The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.
2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.
3. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study, that the anticipated results will justify the performance of the experiment.
4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.
5. No experiment should be conducted, where there is an a priori reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the
   experimental physicians also serve as subjects.
6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.
7. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.
8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.

9. During the course of the experiment, the human subject should be at liberty to bring the experiment to an end, if he has reached the physical or mental state, where continuation of the experiment seemed to him to be impossible.
10. During the course of the experiment, the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill and careful judgement required of him, that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.

["Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10", Vol. 2, pp. 181-182. Washington, D.C.: U.S. Government Printing Office, 1949.]

296,640 Estimated Dead From the mRNA Vaxxxines in the USA. Yet Dr. Death Fauci is Coming For Your Children. Dr. Zelenko: This is a Worldwide Genocide

Monday, September 13, 2021

Resource: 296,640 Estimated Dead From the mRNA Vaxxxines in the USA. Yet Dr. Death Fauci is Coming For Your Children. Dr. Zelenko: This is a Worldwide Genocide | Agenda 21 | Before It's News (beforeitsnews.com)

Dr.Zelenko:
"FOR EVERY CHILD THAT DIES OF COVID, 100 DIES FROM THE VACCINE"

https://rumble.com/vmdow5-we-are-witnessing-worldwide-planned-genocide-hitler-on-steroids-w-dr.-zelen.html

Sarah Westall / Dr. Zelenko
We are Witnessing Worldwide Planned Genocide, "Hitler on Steroids" w/ Dr. Zelenko September 11, 2021

World Famous Dr. Zelenko drops some major Bombshells

Patent for the mRNA vaccines that PROVES THEY ARE CAPABLE OF REMOTE BODY MONITORING AND TRACKING

Dr. Zelenko:
"The Vaccine is a Tool of Eugenics,And accomplishes multiple Goals at once.

There are 3 Levels of Death

(About Vladimir Zelenko MD (zstacklife.com)

We are Witnessing Worldwide Planned Genocide, "Hitler on Steroids" w/ Dr. Zelenko

Sarah Westall
September 11, 2021
1,235 Views

SUBSCRIBE

U.S. CIVIL RIGHTS PROTECTION

MY LEGAL RIGHT TO ENTER, SHOP AND BE SERVED AT THIS ESTABLISHMENT -- without covering my face or showing proof of vaccination -- IS PROTECTED BY STATE AND FEDERAL LAW

1. **This private business has a LEGAL CLASSIFICATION as a *"public accommodation"*** according to Title III Reg 28 CFR §36.104. Your private business serves the public and therefore must abide by all state and federal laws. No business policy supersedes the law. No governor's order, health order, emergency or pandemic supersedes Constitutionally-protected rights. This business is open to the public, and I am the public. **Your denial of my service violates several federal laws.**
2. **Federal law 28 CFR §36.202 prohibits *"denial of participation"* from this business** establishment. §36.202(c) states that unless I have been individually assessed as a *"direct threat"* you may not exclude me from the SAME and EQUAL services as others.
3. Denying my service or requiring me to be served outside or be limited to home delivery is a VIOLATION of Title II, III and VII of the U.S. Civil Rights Act of 1964.
4. **Title III, Sections §36.202(a)(b)(c) and §36.203(a)(b)(c)** states that I shall not be denied the same PARTICIPATION and EQUAL ACCESS as everyone else. **The law prohibits you from serving me separately or differently.**
5. **As such, this business is PROHIBITED from unlawful discrimination** by denying the entry of any member of the public who is not disturbing the peace. To do so is a crime of unlawful restraint and interfering with commerce and you will be held personally liable for this crime.
6. These premises are open to the public and thus any charge of "trespass" is a false accusation as **I am complying with all lawful conditions allowing me to remain on these premises and be served by this business without discrimination. I do not need to disclose my condition to you.**

Learn about your rights and how to defend them at www.TheHealthyAmerican.org

SHUTDOWNS ARE ILLEGAL

THERE IS NO LAWFUL AUTHORITY FOR ANY GOVERNOR, MAYOR OR HEALTH OFFICER TO ORDER YOU TO CLOSE YOUR BUSINESS DUE TO COVID

1. There is no evidence of any emergency. Therefore any emergency orders are null, void and unlawful and may be successfully challenged in court, and already have been. (Sutter County 11/13/20; Los Angeles County 12/8/20; Kern County 12/10/20 San Diego County 12/16/20.) Courts ruled the restrictions are unjustified.

2. No governor or health officer has the authority to shut down your business without due process of law. That means no Sheriff or health officer can close your business or revoke your license without a hearing. No emergency or pandemic suspends the law. There needs to be evidence that your business is unsafe.

3. You cannot lose your liquor license unless you serve alcohol to minors or are convicted of a crime. You cannot lose your license for not wearing or requiring masks or distancing.

4. There is no law or regulation requiring you or prohibiting you from serving your patrons indoors or outdoors. **You do not have to limit the number of patrons you serve.**

5. There is no lawful order that requires you or your employees to wear masks, distance, or limit the number of patrons you serve. No emergency orders supersede your rights.

6. You have the legal right to operate your business the way you want to. No government agent has the authority to interfere in the legal operations of your business, as long as you are not in violation of any actual regulations on the books.

7. Your business is your property, and the government ordering you to close or limit your operations, reduce operating hours or limit number of patrons is **THEFT and DEPRIVATION OF RIGHTS, which is a felony. Title 18 §242**

8.You are not licensed to dispense medical advice, and you may not require anyone to wear a mask or use hand sanitizer. Further, requiring physical distancing, denying a patron's entry or restricting their movement, could result in a charge against you of unlawful restraint or false imprisonment.

Learn to defend your rights at www.TheHealthyAmerican.org

LAWS THAT PROTECT YOUR RIGHTS

THE CONSTITUTION DOESN'T GIVE YOU RIGHTS -- IT PROTECTS THE GOVERNMENT FROM TAKING YOUR GOD-GIVEN INALIENABLE RIGHTS

THE BILL OF RIGHTS contains the Amendments to the Constitution

The following Amendments are important to you as a business owner:

Amendment I Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof; or abridging the freedom of speech, or of the press; or **the right of the people peaceably to assemble,** and to petition the government for a redress of grievances. [People have the right to gather, including in your place of business.]

Amendment IV The right of the people to be secure in their persons, houses, papers, and effects, against unreasonable searches and seizures, shall not be violated, and **no warrants shall issue, but upon probable cause,** supported by oath or affirmation, and particularly describing the place to be searched, and the persons or things to be seized. [No government agent can enter your business without your permission, and/or without a warrant.]

Amendment V No person shall be held to answer for a capital, or otherwise infamous crime, unless on a presentment or indictment of a grand jury, except in cases arising in the land or naval forces, or in the militia, when in actual service in time of war or public danger; nor shall any person be subject for the same offense to be twice put in jeopardy of life or limb; nor shall be compelled in any criminal case to be a witness against himself, **nor be deprived of life, liberty, or property, without due process of law;** nor shall private property be taken for public use, without just compensation. [Your business and/or your professional license cannot be taken from you unless a court orders it to be so, after a trial.]

Amendment XIV All persons born or naturalized in the United States, and subject to the jurisdiction thereof, are citizens of the United States and of the State wherein they reside. **No State shall make or enforce any law which shall abridge the privileges or immunities of citizens of the United States; nor shall any State deprive any person of life, liberty, or property, without due process of law;** nor deny to any person within its jurisdiction the equal protection of the laws. [The shutdown orders are unconstitutional, null, void and invalid.]

Learn to defend your rights at www.TheHealthyAmerican.org

(Slip Opinion)

Whether Section 564 of the Food, Drug, and Cosmetic Act Prohibits Entities from Requiring the Use of a Vaccine Subject to an Emergency Use Authorization

Section 564(e)(1)(A)(ii)(III) of the Food, Drug, and Cosmetic Act concerns only the provision of information to potential vaccine recipients and does not prohibit public or private entities from imposing vaccination requirements for a vaccine that is subject to an emergency use authorization.

July 6, 2021

MEMORANDUM OPINION FOR THE
DEPUTY COUNSEL TO THE PRESIDENT

Section 564 of the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 360bbb-3,[1] authorizes the Food and Drug Administration ("FDA") to issue an "emergency use authorization" ("EUA") for a medical product, such as a vaccine, under certain emergency circumstances. This authorization permits the product to be introduced into interstate commerce and administered to individuals even when FDA has not approved the product for more general distribution pursuant to its standard review process. Section 564 directs FDA—"to the extent practicable" given the emergency circumstances and "as the [agency] finds necessary or appropriate to protect the public health"—to impose "[a]ppropriate" conditions on each EUA. FDCA § 564(e)(1)(A). Some of these conditions are designed to ensure that recipients of the product "are informed" of certain things, including "the option to accept or refuse administration of the product." *Id.* § 564(e)(1)(A)(ii)(III).

Since December 2020, FDA has granted EUAs for three vaccines to prevent coronavirus disease 2019 ("COVID-19"). In each of these authorizations, FDA imposed the "option to accept or refuse" condition by requiring the distribution to potential vaccine recipients of a Fact Sheet that states: "It is your choice to receive or not receive [the vaccine]. Should you decide not to receive it, it will not change your standard medical care." *E.g.*, FDA, Fact Sheet for Recipients and Caregivers at 5 (revised June 25, 2021), https://www.fda.gov/media/144414/download

[1] Because it is commonly referred to by its FDCA section number, and for the sake of simplicity, we will refer to this provision as section 564, rather than by its United States Code citation.

("Pfizer Fact Sheet"). In recent months, many public and private entities have announced that they will require individuals to be vaccinated against COVID-19—for instance, in order to attend school or events in person, or to return to work or be hired into a new job. We will refer to such policies as "vaccination requirements," though we note that these policies typically are conditions on employment, education, receipt of services, and the like rather than more direct legal requirements.[2]

In light of these developments, you have asked whether the "option to accept or refuse" condition in section 564 prohibits entities from imposing such vaccination requirements while the only available vaccines for COVID-19 remain subject to EUAs. We conclude, consistent with FDA's interpretation, that it does not. This language in section 564 specifies only that certain information be provided to potential vaccine recipients and does not prohibit entities from imposing vaccination requirements.[3]

I.

A.

Federal law generally prohibits anyone from introducing or delivering for introduction into interstate commerce any "new drug" or "biological product" unless and until FDA has approved the drug or product as safe and effective for its intended uses. *See, e.g.*, FDCA §§ 301(a), 505(a), 21 U.S.C. §§ 331(a), 355(a); 42 U.S.C § 262(a). A vaccine is both a drug and a biological product. *See* FDCA § 201(g), 21 U.S.C § 321(g); 42 U.S.C. § 262(i)(1). Consistent with section 564, we will generally refer to it here as a "product." *See* FDCA § 564(a)(4)(C) (defining "product" to mean "a drug, device, or biological product").

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[2] For an example of the latter, see our discussion in Part II.B of a hypothetical military order to service members.

[3] We do not address whether other federal, state, or local laws or regulations, such as the Americans with Disabilities Act ("ADA"), might restrict the ability of public or private entities to adopt particular vaccination policies. *See, e.g.*, Equal Employment Opportunity Commission, *What You Should Know About COVID-19 and the ADA, the Rehabilitation Act, and Other EEO Laws* (updated June 28, 2021), https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws (discussing the ADA).

In 2003, Congress addressed a problem raised in emergency situations where "the American people may be placed at risk of exposure to biological, chemical, radiological, or nuclear agents, and the diseases caused by such agents," but where, "[u]nfortunately, there may not be approved or available countermeasures to treat diseases or conditions caused by such agents," even though "a drug, biologic, or device is highly promising in treating [such] a disease or condition." H.R. Rep. No. 108-147, pt. 1, at 2 (2003). President George W. Bush had flagged this problem in his 2003 State of the Union Address, in which he proposed Project BioShield, a legislative initiative "to quickly make available effective vaccines and treatments against agents like anthrax, botulinum toxin, Ebola, and plague." *Address Before a Joint Session of the Congress on the State of the Union* (Jan. 28, 2003), 1 Pub. Papers of Pres. George W. Bush 82, 86 (2003). Among the principal components of the proposed Project BioShield legislation were provisions to enable FDA to authorize medical products for use during emergencies even before they are proven to be safe and effective under ordinary FDA review. *See, e.g.*, H.R. 2122, 108th Cong. § 4 (2003). At that time, the only alternative to ordinary FDA approval was 21 U.S.C. § 355(i), which authorizes FDA to exempt drugs from the ordinary approval requirements where the drug is "intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs." Such a cabined investigational new drug ("IND") exemption does not, however, allow the widespread dissemination of a drug for general public use in response to an emergency. *See* H.R. Rep. No. 108-147, pt. 1, at 2.

Congress enacted a version of the Project BioShield legislation's EUA provision in the National Defense Authorization Act for Fiscal Year 2004 as section 564 of the FDCA. *See* Pub. L. No. 108-136, § 1603(a), 117 Stat. 1392, 1684 (2003) (codified at 21 U.S.C. § 360bbb-3).[4] Section 564 authorizes the Secretary of Health and Human Services ("HHS")—who has delegated to FDA the authorities under the statute at issue here—to authorize the introduction into interstate commerce of a drug, device, or biological product intended for use in an actual or potential emergency even though the product has not yet been generally approved as safe and

[4] The statute has been amended since, including when Congress enacted the Project BioShield Act the following year. *See* Pub. L. No. 108-276, § 4(a), 118 Stat. 835, 853 (2004).

effective for its intended use. FDCA § 564(a)(1)–(2); *see also* FDA, *Emergency Use Authorization of Medical Products and Related Authorities: Guidance for Industry and Other Stakeholders* at 3 n.6 (Jan. 2017) ("EUA Guidance") (noting delegation of most of the Secretary's authorities under section 564 to FDA).[5]

The most pertinent part of section 564 for purposes of your question has remained materially the same since Congress first enacted the statute in 2003. Subsection (e)(1)(A),[6] titled "Required conditions," provides:

> With respect to the emergency use of an unapproved product, the Secretary, to the extent practicable given the applicable [emergency] circumstances . . . , shall, for a person who carries out any activity for which the authorization is issued, establish such conditions on an authorization under this section as the Secretary finds necessary or appropriate to protect the public health, including [certain specified conditions].

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[5] The current version of section 564(a)(1) provides in full:

> Notwithstanding any provision of this chapter and section 351 of the Public Health Service Act, and subject to the provisions of this section, the Secretary may authorize the introduction into interstate commerce, during the effective period of a declaration under subsection (b), of a drug, device, or biological product intended for use in an actual or potential emergency (referred to in this section as an "emergency use").

The "declaration under subsection (b)" refers to a declaration by the Secretary "that the circumstances exist justifying" an EUA, which must be made "on the basis" of one or more types of emergencies or threats. FDCA § 564(b)(1). FDA can grant an EUA where, "based on the totality of scientific evidence available to the Secretary, including data from adequate and well-controlled clinical trials, if available," FDA finds that "it is reasonable to believe," among other things, that "the product may be effective in diagnosing, treating, or preventing" a "serious or life-threatening disease or condition" caused by a "biological, chemical, radiological, or nuclear agent or agents" (a standard less onerous than for final approval of the product); that "the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product"; and that "there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition." FDCA § 564(c).

[6] Subsection (e)(1) applies to a product that FDA has not approved as safe and effective for any intended use, whereas subsection (e)(2) applies to an unapproved use of an otherwise approved product. The COVID-19 vaccines fall under the former category, but the statute applies the condition at issue here to the latter category as well. *See* FDCA § 564(e)(2)(A).

The statute then lists a number of such conditions, including "[a]ppropriate conditions designed to ensure that individuals to whom the product is administered are informed" of certain information. FDCA § 564(e)(1)(A)(ii). This information includes the fact that FDA "has authorized the emergency use of the product," "the significant known and potential benefits and risks of such use," and "the extent to which such benefits and risks are unknown." *Id.* § 564(e)(1)(A)(ii)(I)–(II). Most relevant here, section 564(e)(1)(A)(ii)(III) directs FDA to impose conditions on an EUA "designed to ensure that individuals to whom the product is administered are informed . . . of the option to accept or refuse administration of the product, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks."

In the same section of the 2004 National Defense Authorization Act, Congress also enacted another provision, codified as 10 U.S.C. § 1107a, which is specific to the U.S. military and which expressly refers to the "option to accept or refuse" condition described in section 564(e)(1)(A)(ii)(III). Pub. L. No. 108-136, sec. 1603(b)(1), § 1107a, 117 Stat. at 1690. Subsection (a) of this law provides that when an EUA product is administered to members of the armed forces, "the condition described in section 564(e)(1)(A)(ii)(III) . . . and required under paragraph (1)(A) or (2)(A) of such section 564(e), designed to ensure that individuals are informed of an option to accept or refuse administration of a product, may be waived only by the President" and "only if the President determines, in writing, that complying with such requirement is not in the interests of national security." 10 U.S.C. § 1107a(a)(1).

B.

In the years after Congress enacted section 564, FDA issued dozens of EUAs in response to various public-health emergencies. *See, e.g.*, Authorization of Emergency Use of the Antiviral Product Peramivir Accompanied by Emergency Use Information; Availability, 74 Fed. Reg. 56,644 (Nov. 2, 2009) (antiviral drug to treat swine flu). The agency's use of EUAs increased dramatically with the onset of the COVID-19 pandemic in 2020. As of January 2021, the agency had issued more than 600 EUAs for products to combat COVID-19, including drugs, tests, personal protective equipment, and ventilators. *See* FDA, *FDA COVID-19 Pandemic*

Recovery and Preparedness Plan (PREPP) Initiative: Summary Report at 6 (Jan. 2021); *cf. id.* at 24 (noting that FDA issued 65 EUAs prior to COVID-19). More importantly for present purposes, the agency has granted EUAs for three COVID-19 vaccines manufactured by Pfizer, Moderna, and Janssen, respectively. *See* Authorizations of Emergency Use of Certain Biological Products During the COVID-19 Pandemic; Availability, 86 Fed. Reg. 28,608 (May 27, 2021) (Janssen); Authorizations of Emergency Use of Two Biological Products During the COVID-19 Pandemic; Availability, 86 Fed. Reg. 5200 (Jan. 19, 2021) (Pfizer and Moderna).

As we have explained, section 564 of the FDCA contemplates that each EUA will be subject to various conditions. For the three COVID-19 vaccines, FDA implemented the "option to accept or refuse" condition described in section 564(e)(1)(A)(ii)(III) in the following manner: In each letter granting the EUA, FDA established as a "condition[] of authorization" that FDA's "Fact Sheet for Recipients and Caregivers" be made available to potential vaccine recipients. *See, e.g.*, Letter for Pfizer Inc. from RADM Denise M. Hinton, Chief Scientist, FDA at 6, 9 (updated June 25, 2021), https://www.fda.gov/media/150386/download ("Pfizer EUA Letter"). The Fact Sheet in question states (to take the Pfizer vaccine as an example): "It is your choice to receive or not receive the Pfizer-BioNTech COVID-19 Vaccine. Should you decide not to receive it, it will not change your standard medical care." Pfizer Fact Sheet at 5. We understand that this approach is consistent with FDA's general practice for EUAs. *See* EUA Guidance at 24–25 (discussing the use of fact sheets to inform recipients of EUA products "[t]hat they have the option to accept or refuse the EUA product and of any consequences of refusing administration of the product").

As access to the COVID-19 vaccines has become widespread, numerous educational institutions, employers, and other entities across the United States have announced that they will require individuals to be vaccinated against COVID-19 as a condition of employment, enrollment, participation, or some other benefit, service, relationship, or access.[7] For

[7] *See, e.g.*, Rukmini Callimachi, *For Colleges, Vaccine Mandates Often Depend on Which Party Is in Power*, N.Y. Times (May 22, 2021), https://www.nytimes.com/2021/05/22/us/college-vaccine-universities.html; Tracy Rucinski, *Delta will require COVID-19*

instance, certain schools will require vaccination in order for students to attend class in person, and certain employers will require vaccination as a condition of employment.

Some have questioned whether such entities can lawfully impose such requirements in light of the fact that section 564 instructs that potential vaccine recipients are to be informed that they have the "option to accept or refuse" receipt of the vaccine.[8] In the past few months, several lawsuits have also been filed challenging various entities' vaccination requirements on the same theory.[9] The only judicial decision to have addressed this issue so far summarily rejected the challenge. *See Bridges v. Houston Methodist Hosp.*, No. 4:21-cv-01774, 2021 WL 2399994, at *1–2 (S.D. Tex. June 12, 2021), *appeal docketed*, No. 21-20311 (5th Cir. June 14, 2021).

II.

A.

We conclude that section 564(e)(1)(A)(ii)(III) concerns only the provision of information to potential vaccine recipients and does not prohibit public or private entities from imposing vaccination requirements for vaccines that are subject to EUAs. By its terms, the provision directs only that potential vaccine recipients be "informed" of certain information, including "the option to accept or refuse administration of the product."

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vaccine for new employees, Reuters (May 14, 2021, 9:16 AM), https://www.reuters.com/world/us/delta-will-require-covid-19-vaccine-new-employees-2021-05-14/.

[8] *See, e.g.*, Letter for Thomas C. Galligan Jr., Interim President, Louisiana State University, from Jeff Landry, Attorney General of Louisiana (May 28, 2021); *see also* Advisory Committee on Immunization Practices, Summary Report at 56 (Aug. 26, 2020), https://www.cdc.gov/vaccines/acip/meetings/downloads/min-archive/min-2020-08-508.pdf (reporting a CDC official as saying that EUA vaccines are not allowed to be mandatory).

[9] *See, e.g.*, Defendant's Notice of Removal, *Bridges v. Methodist Hosp.*, No. 4:21-cv-01774 (S.D. Tex. June 1, 2021), 2021 WL 2221293 (referencing complaint); Complaint, *Neve v. Birkhead*, No. 1:21-cv-00308 (M.D.N.C. Apr. 16, 2021), 2021 WL 1902937; Complaint, *Cal. Educators for Med. Freedom v. L.A. Unified Sch. Dist.*, No. 21-cv-2388 (C.D. Cal. Mar. 17, 2021), 2021 WL 1034618; Complaint, *Legaretta v. Macias*, No. 2:21-cv-00179 (D.N.M. Feb. 28, 2021), 2021 WL 909707; *see also* Complaint, *Health Freedom Defense Fund v. City of Hailey*, No. 1:21-cv-00212-DCN (D. Idaho May 14, 2021), 2021 WL 1944543 (making a similar argument about a face-mask requirement).

FDCA § 564(e)(1)(A)(ii)(III). In the sense used here, the word "inform" simply means to "give (someone) facts or information; tell." *New Oxford American Dictionary* 891 (3d ed. 2010); *see also, e.g.*, *Webster's Third New International Dictionary* 1160 (2002) (similar). Consistent with this understanding, the conditions of authorization that FDA imposed for the COVID-19 vaccines require that potential vaccine recipients receive FDA's Fact Sheet, *see, e.g.*, Pfizer EUA Letter at 6, 9, which states that recipients have a "choice to receive or not receive" the vaccine, *see, e.g.*, Pfizer Fact Sheet at 5. Neither the statutory conditions of authorization nor the Fact Sheet itself purports to restrict public or private entities from insisting upon vaccination in any context. *Cf. Bridges*, 2021 WL 2399994, at *2 (explaining that section 564 "confers certain powers and responsibilities to the Secretary of [HHS] in an emergency" but that it "neither expands nor restricts the responsibilities of private employers").[10]

The language of another provision of section 564 reflects the limited scope of operation of section 564(e)(1)(A)(ii)(III). Section 564(*l*) provides that "this section [i.e., section 564] only has legal effect on a person who carries out an activity for which an authorization under this section is issued." This provision expressly forecloses any limitation on the activities of the vast majority of entities who would insist upon vaccination requirements, because most do not carry out any activity for which an EUA is issued.

To be sure, the EUA conditions effectively require parties administering the products to do so in particular ways—including that they only administer the products to individuals after providing them the informational Fact Sheets that FDA prescribes—and some of those entities,

[10] Earlier-introduced versions of section 564(e)(1)(A)(ii)(III) in 2003 referred to "*any* option to accept or refuse administration of the product" (as opposed to "the" option), a formulation that might have even more clearly conveyed the informational nature of the condition. *See, e.g.*, S. 15, 108th Cong. § 204 (Mar. 11, 2003) (emphasis added). We have not found any explanation for why Congress revised the provision to refer to "the option," so we ascribe little significance to the change—either for or against our reading of the statute. *See Mead Corp. v. Tilley*, 490 U.S. 714, 723 (1989); *Trainmobile Co. v. Whirls*, 331 U.S. 40, 61 (1947) ("The interpretation of statutes cannot safely be made to rest upon mute intermediate legislative maneuvers."). In 10 U.S.C. § 1107a(a), moreover, Congress used the alternative formulation "*an* option to accept or refuse" in referring to the condition in section 564(e)(1)(A)(ii)(III) as it relates to the armed forces. (Emphasis added.) This discrepancy counsels further against assigning interpretive weight to the change from "any" to "the" in the legislative development of section 564.

such as universities, might also impose vaccination requirements (e.g., on their students and employees). There is no indication, however, that Congress intended to regulate such entities except with respect to the circumstances of their administration of the product itself. *See, e.g.*, FDCA § 564(e)(1)(B)(ii) (authorizing FDA to establish "[a]ppropriate conditions on who may administer the product with respect to the emergency use of the product, and on the categories of individuals to whom, *and the circumstances under which, the product may be administered with respect to such use*" (emphasis added)). And it would have been odd for Congress to have done so, for in that case the entities choosing to administer EUA products would be limited in their relations with third parties (e.g., students, employees) in ways that analogous entities that did not administer the products were not.

This reading of the "option to accept or refuse" condition to be informational follows not only from the plain text of the provision, but also from the surrounding requirements in section 564(e)(1)(A)(ii). *See, e.g.*, *Lagos v. United States*, 138 S. Ct. 1684, 1688–89 (2018) (relying on the canon of "*noscitur a sociis*, the well-worn Latin phrase that tells us that statutory words are often known by the company they keep"). In addition to requiring that potential recipients be informed of "the option to accept or refuse administration of the product," the statute also requires that they be informed of "the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks." FDCA § 564(e)(1)(A)(ii)(III). Similarly, the two other provisions in subsection (e)(1)(A)(ii) require that individuals be informed of the fact that FDA "has authorized the emergency use of the product" and of "the significant known and potential benefits and risks of such use, and of the extent to which such benefits and risks are unknown." *Id.* § 564(e)(1)(A)(ii)(I)–(II). These provisions all appear to require only that certain factual information be conveyed to those who might use the product.

Indeed, if Congress had intended to restrict entities from imposing EUA vaccination requirements, it chose a strangely oblique way to do so, embedding the restriction in a provision that on its face requires only that individuals be provided with certain information (and grouping that requirement with other conditions that are likewise informational in nature). Congress could have created such a restriction by simply stating that persons (or certain categories of persons) may not require others to

use an EUA product. *See Kloeckner v. Solis*, 568 U.S. 41, 52 (2012) (rejecting a statutory interpretation positing that Congress took a "roundabout way" and an "obscure path" to reach "a simple result"); *cf. Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 468 (2001) (Congress does not "hide elephants in mouseholes").

Our reading of section 564(e)(1)(A)(ii)(III) does not fully explain why Congress created a scheme in which potential users of the product would be informed that they have "the option to accept or refuse" the product. The legislative history of the 2003 statute does not appear to offer any clear explanation. Perhaps Congress viewed section 564(e)(1)(A)(ii)(III) as a variation on the "informed consent" requirement that applies to human subjects in "investigational drug" settings,[11] the only other context in which FDA may (in a limited fashion) authorize the introduction of unapproved drugs into interstate commerce. Or perhaps Congress included this condition to ensure that potential users of an EUA product would not misunderstand what the likely impact of declining to use that product would be.

The information conveyed pursuant to the "option" clause continues to be a true statement about a material fact of importance to potential vac-

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[11] Section 355(i)(4) of title 21 provides that an IND exemption to the premarket approval requirement may only apply if the manufacturer or sponsor of an expert investigation requires the experts in question to certify

> that they will inform any human beings to whom such drugs, or any controls used in connection therewith, are being administered, or their representatives, that such drugs are being used for investigational purposes and will obtain the consent of such human beings or their representatives, except where it is not feasible, it is contrary to the best interests of such human beings, or the proposed clinical testing poses no more than minimal risk to such human beings and includes appropriate safeguards.

Congress did not include this same "informed consent" requirement as part of the EUA provision in 2003, perhaps out of concern that it would not be practicable in emergency situations. *See Project BioShield: Contracting for the Health and Security of the American Public: Hearing Before the H. Comm. on Gov't Reform*, 108th Cong. 33 (Apr. 4, 2003) (statement of Mark B. McClellan, Commissioner, FDA, and Anthony S. Fauci, Director, National Institute of Allergy and Infectious Diseases) ("Because urgent situations may require mass inoculations and/or drug treatments, such informed consent requirements may prove impossible to implement within the necessary time frame when trying to achieve the public health goal of protecting Americans from the imminent danger."); *see also infra* note 15 (explaining that the informed consent requirements contained in 21 U.S.C. § 355(i)(4) do not apply to EUA products).

cine recipients—virtually all such persons continue to have the "option" of refusing the vaccine in the sense that there is no direct legal requirement that they receive it. *See Bridges*, 2021 WL 2399994, at *2 (noting that an employer's vaccination policy was not "coercive" because an employee "can freely choose to accept or refuse a COVID-19 vaccine; however, if she refuses, she will simply need to work somewhere else"); Wen W. Shen, Cong. Research Serv., R46745, *State and Federal Authority to Mandate COVID-19 Vaccination* at 4 (Apr. 2, 2021) ("[E]xisting vaccination mandates—as they are typically structured—generally do not interfere with . . . an individual's right to refuse in that context. Rather, they impose secondary consequences—often in the form of exclusion from certain desirable activities, such as schools or employment—in the event of refusal." (footnote omitted)); *Black's Law Dictionary* 1121 (7th ed. 1999) (defining "option" as relevant here as "[t]he right or power to choose; something that may be chosen"); *The American Heritage Dictionary of the English Language* 1235 (4th ed. 2000) (similar); *cf.* FDCA § 564(e)(1)(A)(ii)(III) (directing that potential vaccine recipients be informed not only of "the option to accept or refuse administration of the product" but also of "the *consequences*, if any, of refusing administration of the product" (emphasis added)).

Importantly, however, and consistent with FDA's views, we also read section 564 as giving FDA some discretion to modify or omit "the option to accept or refuse" notification, or to supplement it with additional information, if and when circumstances change. As noted above, the statute directs FDA to establish the section 564(e)(1)(A) conditions "to the extent practicable given the applicable [emergency] circumstances" and "as the [agency] finds necessary or appropriate to protect the public health." FDCA § 564(e)(1)(A). Both of these phrases—"to the extent practicable" and "as the [agency] finds necessary or appropriate"—are generally understood to confer discretion on an agency. *See, e.g.*, *Gallegos-Hernandez v. United States*, 688 F.3d 190, 195 (5th Cir. 2012) (per curiam) ("to the extent practicable"); *Madison-Hughes v. Shalala*, 80 F.3d 1121, 1128 (6th Cir. 1996) (collecting cases on "necessary" and "appropriate"). Moreover, the portion of section 564 that deals specifically with informational conditions provides that FDA should establish "[a]ppropriate" conditions designed to ensure that potential vaccine recipients are informed of the "option to accept or refuse" an EUA product. FDCA § 564(e)(1)(A)(ii). These qualifiers indicate that FDA's responsibility to

impose the "option to accept or refuse" condition is not absolute and that the agency has some discretion to modify or omit the condition when the agency finds the notification would not be "practicable" given the emergency circumstances, or to determine that changes to the notification are "necessary or appropriate to protect the public health." *See* EUA Guidance at 24 n.46 (noting circumstances in which the "option to accept or refuse" notification might not be practicable).[12] In addition, section 564 gives FDA the authority to supplement the information that is conveyed to potential vaccine recipients, including information about "the consequences, if any, of refusing administration of the product." FDCA § 564(e)(1)(A)(ii)(III); *see also id.* § 564(e)(1)(B) (noting that FDA has the authority to impose additional conditions as the agency "finds necessary or appropriate to protect the public health"); EUA Guidance at 22 n.40, 26–27 (noting this point). Together, then, these provisions of section 564 give FDA the authority to adapt to changing circumstances and to ensure that the information conveyed to potential users of EUA products is accurate.[13]

Although many entities' vaccination requirements preserve an individual's ultimate "option" to refuse an EUA vaccine, they nevertheless impose sometimes-severe adverse consequences for exercising that option (such as not being able to enroll at a university). Under such circumstances, FDA could theoretically choose to supplement the conditions of authorization to notify potential vaccine recipients of the possibility of such consequences (or to make it even clearer that the consequences described

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[12] Indeed, FDA has recently exercised its discretion not to require certain of the statutorily specified conditions with respect to the current COVID-19 pandemic. We understand that FDA has amended or plans to amend the EUAs for the COVID-19 vaccines so as not to require compliance with several of the conditions—including the "option to accept or refuse" notification—when the vaccines are exported to other countries. *See, e.g.*, Pfizer EUA Letter at 10.

[13] Congress's use of the phrase "Required conditions" in the title of subsection (e)(1)(A) and its specification of certain conditions in the statute suggest that Congress may have presumed that FDA would generally find that the specified conditions are "necessary or appropriate" and thus impose them. As we discuss above, however, the operative text of section 564 indicates that FDA has some discretion to modify, omit, or supplement the conditions in some circumstances. *See Fulton v. City of Philadelphia*, 141 S. Ct. 1868, 1879 (2021) ("[A] title or heading should never be allowed to override the plain words of a text." (quoting A. Scalia & B. Garner, *Reading Law: The Interpretation of Legal Texts* 222 (2012)) (alteration in original)).

in the Fact Sheets are limited to consequences related to medical care). As we have noted, however, section 564 does not limit the ability of entities to impose vaccination requirements, and FDA would not be required to change the Fact Sheets in order to allow them to impose such requirements.[14]

* * * * *

As noted above, FDA agrees with our interpretation of section 564. On a few occasions, however, FDA has made statements that could be understood as saying that the condition described in section 564(e)(1)(A)(ii)(III) prohibits entities (particularly the U.S. military) from requiring the use of EUA products. In 2005, for instance, FDA issued an EUA that permitted the use of a vaccine for the prevention of inhalation anthrax by individuals between 18 and 65 years of age who were deemed by the Department of Defense ("DOD") to be at heightened risk of exposure due to an attack with anthrax. As a condition of that authorization, the agency required DOD to inform potential vaccine recipients "of the option to accept or refuse administration of [the vaccine]." Authorization of Emergency Use of Anthrax Vaccine Adsorbed for Prevention of Inhalation Anthrax by Individuals at Heightened Risk of Exposure Due to Attack With Anthrax; Availability, 70 Fed. Reg. 5452, 5455 (Feb. 2, 2005). That EUA continued:

> With respect to [the] condition . . . relating to the option to accept or refuse administration of [the vaccine], the [immunization program] will be revised to give personnel the option to refuse vaccination. Individuals who refuse anthrax vaccination will not be punished. Refusal may not be grounds for any disciplinary action under the Uniform Code of Military Justice. Refusal may not be grounds for any adverse personnel action. Nor would either military or civilian personnel be considered non-deployable or processed for separation

[14] FDA further informs us that, wholly apart from FDA's own authority to change the Fact Sheet, nothing in the FDCA would prohibit an administrator of the vaccine who also has a relationship with the individuals to whom the vaccine is offered (e.g., students in a university that offers the vaccine) from supplementing the FDA Fact Sheet at the point of administration with factually accurate information about the possible nonmedical consequences of the person choosing not to use the product (e.g., that she might not be permitted to enroll).

> based on refusal of anthrax vaccination. There may be no penalty or loss of entitlement for refusing anthrax vaccination.

Id.; *see also id.* (allowing DOD to inform recipients that "military and civilian leaders strongly recommend anthrax vaccination, but . . . individuals [subject to the vaccination program] may not be forced to be vaccinated" and that "the issue of mandatory vaccination will be reconsidered by [DOD] after FDA completes its administrative process."). FDA included the same information in its later extension of that EUA. *See* Authorization of Emergency Use of Anthrax Vaccine Adsorbed for Prevention of Inhalation Anthrax by Individuals at Heightened Risk of Exposure Due to Attack With Anthrax; Extension; Availability, 70 Fed. Reg. 44,657, 44,659–60 (Aug. 3, 2005).

In addition, although it is less than clear, certain FDA guidance could be read as saying that section 564 confers an affirmative "option" or "opportunity" to refuse EUA products. *See* EUA Guidance at 24 n.46 (implying that the condition in section 564(e)(1)(A)(ii)(III)—which is subject to waiver for the armed forces under 10 U.S.C. § 1107a—protects "the option for members of the armed forces to accept or refuse administration of an EUA product"); *Guidance Emergency Use Authorization of Medical Products*, 2007 WL 2319112, at *15 (July 1, 2007) (stating that "[r]ecipients must have an opportunity to accept or refuse the EUA product").

These statements do not affect our conclusion. Neither the 2005 anthrax vaccine EUA nor the later FDA guidance articulated a legal interpretation of section 564(e)(1)(A)(ii)(III)'s text. And FDA appears to have insisted upon the voluntariness requirement for DOD in the anthrax vaccine EUA because of then-recent litigation in which a court enjoined DOD from implementing a mandatory vaccination program based upon a different statutory provision that is inapplicable to EUAs. *See Doe v. Rumsfeld*, 341 F. Supp. 2d 1 (D.D.C. 2004) (relying on 10 U.S.C. § 1107); *Doe v. Rumsfeld*, 297 F. Supp. 2d 119 (D.D.C. 2003) (same); *see also* 70 Fed. Reg. at 44,660 (requiring DOD to tell vaccine recipients the following: "On October 27, 2004, the U.S. District Court for the District of Columbia issued an Order declaring unlawful and prohibiting mandatory anthrax vaccinations to protect against inhalation anthrax, pending further FDA action. The *Court's injunction* means you have the right to refuse to take the vaccine without fear of retaliation." (emphasis added)); 70 Fed. Reg.

at 5454 (discussing litigation); *see also infra* note 15 (explaining that 10 U.S.C. § 1107(f) is inapplicable to EUAs).

B.

Section 564(e)(1)(A)(ii)(III) also raises a question about how to understand its cognate provision regarding the use of EUA products by the armed forces. As we noted above, in the same 2003 legislation that first created section 564, Congress also added the following provision to title 10 of the United States Code:

> In the case of the administration of [an EUA] product . . . to members of the armed forces, the condition described in section 564(e)(1)(A)(ii)(III) . . . and required under paragraph (1)(A) or (2)(A) of such section 564(e), designed to ensure that individuals are informed of an option to accept or refuse administration of a product, may be waived only by the President only if the President determines, in writing, that complying with such requirement is not in the interests of national security.

10 U.S.C. § 1107a(a)(1).[15] On its own terms, this provision appears to be consistent with—and even to support—our reading of section 564, as it likewise describes the "option to accept or refuse" condition in purely informational terms. The language refers to the President's authority to

[15] Section 1107(f) of title 10—an earlier-enacted provision—contains a similar, but importantly different, waiver authority. Specifically, that provision authorizes the President, "[i]n the case of the administration of an [IND] or a drug unapproved for its applied use to a member of the armed forces in connection with the member's participation in a particular military operation," to waive "the prior consent requirement imposed under [21 U.S.C. § 355(i)(4)]." 10 U.S.C. § 1107(f)(1). That "prior consent requirement," which is imposed for purposes of the human clinical trials for which FDA authorizes "investigational" use of unapproved drugs, *see* 21 U.S.C. § 355(i)(4), does not apply to EUA products, which typically are more widely available, *see* FDCA § 564(k); EUA Guidance at 24 ("informed consent as generally required under FDA regulations is not required for administration or use of an EUA product" (footnote omitted)). Thus, the waiver provision in section 1107(f) is inapplicable to EUA products. *See* 10 U.S.C. § 1107(f)(2) (explaining that this waiver authority applies only in cases in which "prior consent for administration of a particular drug is required" because the Secretary of HHS determines that the drug "is subject to the [IND] requirements of [21 U.S.C. § 355(i)]"); *see also id.* § 1107(f)(4) (defining the relevant consent requirements as those in 21 U.S.C. § 355(i)).

waive a requirement to provide certain information, not to waive any right or affirmative "option" to refuse administration of the product itself.

On the other hand, the conference report on the legislation that created both section 564 of the FDCA and section 1107a of title 10 described the latter provision in the following way:

> [This provision] would authorize the President to waive *the right of service members to refuse administration of a product* if the President determines, in writing, that affording service members the right to refuse the product is not feasible, is contrary to the best interests of the members affected, or is not in the interests of national security.

H.R. Rep. No. 108-354, at 782 (2003) (Conf. Rep.) (emphasis added). This language indicates that the conferees may have believed that section 1107a concerns some "right" of members of the armed forces to refuse the use of EUA products. And that belief may help to explain why section 1107a allows only the President to exercise the waiver authority.

Consistent with this legislative history and the vesting of the waiver authority in the President, DOD informs us that it has understood section 1107a to mean that DOD may not require service members to take an EUA product that is subject to the condition regarding the option to refuse, unless the President exercises the waiver authority contained in section 1107a. *See* DOD Instruction 6200.02, § E3.4 (Feb. 27, 2008) ("In the event that an EUA granted by the Commissioner of Food and Drugs includes a condition that potential recipients *are provided an option* to refuse administration of the product, the President may . . . waive *the option* to refuse for administration of the medical product to members of the armed forces." (emphasis added)). Moreover, we understand that DOD's position reflects the concern that service members, unlike civilian employees, could face serious criminal penalties if they refused a superior officer's order to take an EUA product. *See* 10 U.S.C. § 890; *see also United States v. Kisala,* 64 M.J. 50 (C.A.A.F. 2006) (upholding a soldier's punishment for refusing to take a vaccine). In this way, service members do not have the same "option" to refuse to comply with a vaccination requirement as other members of the public.

As noted above, it does appear that certain members of Congress thought that section 1107a concerned a prohibition against requiring service members to take an EUA product—perhaps on the view that the

waiver authority in section 1107a paralleled the one in 10 U.S.C. § 1107(f), which does effectively prohibit the administration of an IND product in a clinical trial without first obtaining the individual's affirmative, informed *consent*. *See supra* note 15 (distinguishing these waiver authorities).[16] As explained, however, that intent or expectation is not realized in the text of section 564(e)(1)(A)(ii)(III), which section 1107a expressly cross-references. *Cf. Steinle v. City & Cty. of San Francisco*, 919 F.3d 1154, 1164 n.11 (9th Cir. 2019) ("[T]he plain and unambiguous statutory text simply does not accomplish what the Conference Report says it was designed to accomplish."); *Goldring v. Dist. of Columbia*, 416 F.3d 70, 75 (D.C. Cir. 2005) ("A sentence in a conference report cannot rewrite unambiguous statutory text[.]").[17] We therefore conclude that section 1107a does not change our interpretation of section 564 of the FDCA.

As for DOD's concern about service members who would lack a meaningful option to refuse EUA products because of the prospect of sanction, including possibly prosecution, we note that any difference between our view and the assumption reflected in the conference report should have limited practical significance. Given that FDA has imposed the "option to accept or refuse" condition for the COVID-19 vaccines by requiring

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[16] It is possible the conferees assumed that the new EUA legislation would, in effect, carry over from the earlier IND provision of the FDCA, *see supra* Part I.A and note 11, the condition that a covered product may not be administered to an individual without that person's express, informed consent—a condition that applies to the military when it undertakes the sort of clinical trial with an IND that 21 U.S.C. § 355(i) governs, *see supra* note 11. Congress did not include such a consent requirement in section 564, however, perhaps because EUA products are not limited, as INDs are, to use in human clinical trials, but are instead authorized for more widespread use in the case of a declared emergency. *See supra* Part I.A and notes 11 & 15.

[17] Moreover, the legislative history as a whole is not uniform on this point. The earlier House report, for instance, described the condition in purely informational terms. *See* H.R. Rep. No. 108-147, pt. 3, at 33 (2003) ("New section 564(k) [an earlier but similarly worded version of what became 10 U.S.C. § 1107a] pertains to members of the Armed Forces and, among other things, it specifies that the President may waive requirements designed to ensure that such members are *informed* of the option to accept or refuse administration of an emergency use product, upon certain findings[.]" (emphasis added)); *see also Milner v. Dep't of the Navy*, 562 U.S. 562, 574 (2011) (noting that "[l]egislative history, for those who take it into account, is meant to clear up ambiguity, not create it," and thus, "[w]hen presented, on the one hand, with clear statutory language and, on the other, with dueling committee reports, we must choose the language").

distribution of its Fact Sheet containing the "[i]t is your choice to receive or not receive" language, DOD is required to provide service members with the specified notification unless the President waives the condition pursuant to 10 U.S.C. § 1107a. And because DOD has informed us that it understandably does not want to convey inaccurate or confusing information to service members—that is, telling them that they have the "option" to refuse the COVID-19 vaccine if they effectively lack such an option because of a military order—DOD should seek a presidential waiver before it imposes a vaccination requirement.

III.

For the reasons set forth above, we conclude that section 564 of the FDCA does not prohibit public or private entities from imposing vaccination requirements, even when the only vaccines available are those authorized under EUAs.

DAWN JOHNSEN
Acting Assistant Attorney General
Office of Legal Counsel

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U.S. DISTRICT COURT
N.D. OF ALABAMA

IN THE UNITED STATES DISTRICT COURT FOR

THE NORTHERN DISTRICT OF ALABAMA

AMERICA'S FRONTLINE DOCTORS, et al.,	)	
	)	
Plaintiffs,	)	
	)	
vs.	)	Civil Action No.
	)	2:21-cv-00702-CLM
XAVIER BECERRA, Secretary of the U.S. Department of Health and Human Services, et al.,	)	
	)	
Defendants.	)	
_____	)	

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PLAINTIFFS MOTION FOR

PRELIMINARY INJUNCTION

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TABLE OF CONTENTS

I. INTRODUCTION

Plaintiffs move under Rule 65, Fed.R.Civ.P., for a preliminary injunction against Defendants enjoining them from continuing to authorize the emergency use of the so-called "Pfizer-BioNTech COVID-19 Vaccine,"[1] "Moderna COVID-19 Vaccine"[2] and the "Johnson & Johnson (Janssen) COVID-19 Vaccine"[3] (collectively, the "Vaccines")[4] pursuant to their respective EUAs, and from granting full Food and Drug Administration ("FDA") approval of the Vaccines:

(i) for the under-18 age category;

(ii) for those, regardless of age, who have been infected with SARS-CoV-2 prior to vaccination; and

(iii) until such time as the Defendants have complied with their obligation to create and maintain the requisite "conditions of authorization" under Section 546 of the Food, Drugs and Cosmetics Act, 21 U.S.C. § 360bbb–3(e), thereby enabling Vaccine candidates to give truly voluntary, informed consent.

II. SUMMARY OF FACTS

Plaintiffs reference and incorporate herein the facts contained in their Complaint filed on June 10, 2021 (ECF 10).

A. The Unlawful Vaccine Emergency Use Authorizations

(1) 21 U.S.C. § 360bbb–3(b)(1)(C): There is No Emergency

On February 4, 2020, the Department of Health and Human Services ("DHHS") Secretary declared, pursuant to § 360bbb–3(b)(1)(C), that SARS-CoV-2 created a "public health

[1] Emergency Use Authorization ("EUA") issued December 11, 2020. *See* https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccine.
[2] EUA issued December 18, 2020. *See* https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-19-vaccine.
[3] EUA issued February 27, 2021. *See* https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/janssen-covid-19-vaccine.
[4] For the sake of clarity of reference, Plaintiffs are using the names given to the Pfizer and Moderna EUA medical products by their manufacturers and the Defendants. However, Plaintiffs reject the highly misleading use of the term "vaccine" to describe the Pfizer and Moderna EUA medical products, since they are not vaccines within the settled meaning of the term and instead are more precisely described as a form of genetic manipulation.

emergency." This initial emergency declaration has been renewed repeatedly and remains in force today. The emergency declaration is the necessary legal predicate for the issuance of the Vaccine EUAs, which have allowed the mass use of the Vaccines by the American public, even before the completion of the standard regimen of clinical trials and FDA approval.

The emergency declaration and its multiple renewals are illegal, since in fact there is no underlying emergency. Assuming the accuracy of Defendants' COVID-19 death data, SARS-CoV-2 has an overall survivability rate of 99.8% globally, which increases to 99.97% for persons under the age of 70, on a par with the seasonal flu. However, Defendants' data is deliberately inflated. On March 24, 2020, DHHS changed the rules applicable to coroners and others responsible for producing death certificates and making "cause of death" determinations — **exclusively for COVID-19**. The rule change states: "COVID-19 should be reported on the death certificate for all decedents where the disease caused *or is assumed to have caused or contributed* to death." In fact, DHHS statistics show that 95% of deaths classed as "COVID-19 deaths" involve an average of four additional co-morbidities. The CDC knew "…the rules for coding and selection of the underlying cause of death are expected to result in COVID-19 being the underlying cause more often than not."

Similarly, the actual number of COVID-19 "cases" is far lower than the reported number. DHHS authorized the emergency use of the polymerase chain reaction ("PCR") test as a diagnostic tool for COVID-19, with disastrous consequences. The PCR tests are themselves experimental products, authorized by the FDA under separate EUAs. PCR test manufacturers use disclaimers like this in their product manuals: "[t]he FDA has not determined that the test is safe or effective for the detection of SARS-Co-V-2." Manufacturer inserts furnished with PCR test products include disclaimers stating that the PCR tests should NOT be used to diagnose

COVID-19. This is consistent with the warning issued by the Nobel Prize winning inventor of the PCR test that such tests are not appropriate for diagnosing disease.

The way in which the PCR tests are administered guaranties an unacceptably high number of false positive results. Cycle Threshold Value ("CT value") is essentially the number of times that a sample (usually from a nasal swab) is magnified or amplified before a fragment of viral RNA is detected. The CT Value is exponential, and so a 40-cycle threshold means that the sample is magnified around a trillion times. The higher the CT Value, the less likely the detected fragment of viral RNA is intact, alive and infectious.[5]

Virtually all scientists, including Dr. Fauci, agree that any PCR test run at a CT value of 35-cycles or greater is useless. Dr. Fauci has stated (emphasis below added):

> ***What is now evolving into a bit of a standard is that if you get a cycle threshold of 35 or more that the chances of it being replication competent are miniscule****…We have patients, and it is very frustrating for the patients as well as for the physicians…somebody comes in and they repeat their PCR and it's like 37 cycle threshold…you can almost never culture virus from a 37 threshold cycle. So I think if somebody does come in with 37, 38, even 36, you gotta say, you know, it's dead nucleotides, period. In other words, it is not a COVID-19 infection.*[6]

A study funded by the French government showed that even at 35-cycles, the false positivity rate is as high as 97%. Despite this, a majority of the PCR tests for COVID-19 deployed under EUAs in the United States are run at 35-45 cycles in accordance with manufacturer instructions. Under the EUAs issued by the FDA, there is no flexibility to depart from the manufacturer's instructions and change the way in which the test is administered or interpreted. The chart below shows that all major PCR tests in use in the United States are run at cycles of up to 35 or higher.

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[5] https://www.oralhealthgroup.com/features/the-problems-with-the-covid-19-test-a-necessary-understanding/ (last visited July 15, 2021).

[6] https://1027kearneymo.com/kpgz-news/2020/11/9/covid-tests-may-inflate-numbers-by-picking-up-dead-virus (last visited July 15, 2021).

Manufacturer	Manufacturer's Recommended Cycle Threshold
Xiamen Zeesan SARS-CoV-2 Test Kit (Real-time PCR)	45 cycles
Opti Sars CoV-2 RT-PCR Test	45 cycles
Quest SARS-CoV-2rRT-PCR Test	40 cycles
CDC 2019-Novel Coronavirus Real Time (RT-PCR Diagnostic Panel) Test	40 cycles
Wren Labs COVID-19 PCR Test	38 cycles
LabCorp COVID-19 RT-PCR Test	35 cycles

Further, the Defendants and their counterparts in state governments used the specter of "asymptomatic spread" — the notion that fundamentally healthy people could cause COVID-19 in others — to justify the purported emergency. But there is *no credible scientific evidence* that demonstrates that the phenomenon of "asymptomatic spread" is real. On the contrary, on June 7, 2020, Dr. Maria Von Kerkhov, head of the WHO's Emerging Diseases and Zoonosis Unit, told a press conference that from the known research, asymptomatic spread was "very rare." "From the data we have, it still seems to be rare that an asymptomatic person actually transmits onward to a secondary individual." She added for emphasis: "it's very rare." Researchers from Southern Medical University in Guangzhou, China, published a study in August 2020 concluding that asymptomatic transmission of COVID-19 is *almost non-existent*. "Asymptomatic cases were least likely to infect their close contacts," the researchers found. A more recent study involving nearly 10 million residents of Wuhan, China found that there were no — zero — positive COVID-19 tests amongst 1,174 *close contacts* of asymptomatic cases, *indicating the complete absence of asymptomatic transmission.*

On September 9, 2020, Dr. Fauci was forced to admit in an official press conference:

> *[E]ven if there is some asymptomatic transmission, in all the history of respiratory borne viruses of any type, asymptomatic transmission has never been the driver of outbreaks. The driver of outbreaks is always a symptomatic person,*

even if there is a rare asymptomatic person that might transmit, an epidemic is not driven by asymptomatic carriers.[7]

(2) § 360bbb–3(c)(1): There is in Fact no Serious or Life-Threatening Disease or Condition

Once an emergency has been declared and while it remains in force, the DHHS Secretary can issue and maintain EUAs "**only if**" (emphasis added) certain criteria are met. One of these criteria is that there is in fact (not simply perceived, projected or declared) "a serious or life threatening disease or condition." For the reasons set forth above in the prior section, SARS-CoV-2 and COVID-19 do not constitute a "serious or life threatening disease or condition" within the meaning of the statute. It also bears noting that the legal purpose of an emergency declaration is to bypass checks and balances typically required under law due to a crisis and that the use of such a declaration for such an arbitrary purpose could undermine the balance of power between the various branches of government.

(3) § 360bbb–3(c)(2)(A): The Vaccines Do Not Diagnose, Treat or Prevent SARS-CoV-2 or COVID-19

The DHHS Secretary can issue and maintain the Vaccine EUAs "**only if**" they are "effective" in diagnosing, treating or preventing a disease or condition.

Centers for Disease Control and Prevention ("CDC") data shows that the Vaccines are not effective in treating or preventing SARS-CoV-2 or COVID-19. Deaths from COVID-19 in those who have received the recommended dosages of the Vaccines increased from 160 as of April 30, 2021 to 535 as of June 1, 2021. Further, a total of 10,262 SARS-CoV-2 "breakthrough infections" of those who have already received the full recommended dosage of the Vaccines

[7] https://www.statnews.com/2021/01/23/asymptomatic-infection-blunder-covid-19-spin-out-of-control/ (last visited July 15, 2021).

were reported to the CDC from 46 states and territories between January 1, 2021 and April 30, 2021.

In studying the effectiveness of a medical intervention in randomized controlled trials (often called the gold standard of study design), the most useful way to present results is in terms of Absolute Risk Reduction ("ARR"). ARR compares the impact of treatment by comparing the outcomes of the treated group and the untreated group. In other words, if 20 out of 100 untreated individuals had a negative outcome, and 10 out of 100 treated individuals had a negative outcome, the ARR would be 10% (20 - 10 = 10). **According to a study published by the NIH, the ARR for the Pfizer Vaccine is a mere 0.7%, and the ARR for the Moderna Vaccine is only 1.1%.**

From the ARR, one can calculate the Number Needed to Vaccinate ("NNV"), which signifies the number of people that must be injected before even one person benefits from the vaccine. The NNV for the Pfizer Vaccine is 119, meaning that 119 people must be injected in order to observe the reduction of a COVID-19 case in one person. The reputed journal the *Lancet* reports data indicating that the NNV may be as high as 217.

There are several factors that reduce any purported benefit of the COVID-19 Vaccines. First, it is important to note that the Vaccines were only shown to reduce symptoms – not block transmission. For over a year now, these Defendants and state-level public health authorities have told the American public that SARS-CoV-2 can be spread by people who have none of the symptoms of COVID-19, therefore Americans must mask themselves, and submit to innumerable lockdowns and restrictions, even though they are not manifestly sick. If that is the case, and these officials were not lying to the public, and asymptomatic spread is real, then what is the benefit of a vaccine that merely reduces symptoms? There isn't any.

Secondly, it appears that these Defendants either did lie about asymptomatic spread, or were simply wrong about the science. The theory of asymptomatic transmission — used as the justification for the lockdown and masking of the healthy — was based *solely* upon mathematical modeling. This theory had no actual study participants, and no peer review. The authors made the unfounded assumption that asymptomatic persons were "75% as infectious" as symptomatic persons. But in the real world, healthy false positives turned out to be merely healthy, and were never shown to be "asymptomatic" carriers of anything. Studies have shown that PCR test-positive asymptomatic individuals do not induce clinical COVID-19 disease, not even in a family member with whom they share a home and extended proximity. An enormous study of nearly ten million people in Wuhan, China showed that asymptomatic individuals testing positive for COVID-19 **never** infected others. Since asymptomatic individuals do not spread COVID-19, they do not need to be vaccinated.

(4) § 360bbb–3(c)(2)(B): The Known and Potential Risks of the Vaccine Outweigh their Known and Potential Benefits

The DHHS Secretary can issue and maintain the Vaccine EUAs "**only if**" (emphasis added) the known and potential risks of each Vaccine are outweighed by its known and potential benefits.

The typical vaccine development process takes between 10 and 15 years, and consists of the following sequential stages: research and discovery (2 to 10 years), pre-clinical animal studies (1 to 5 years), clinical human trials in four phases (typically 5 years). Phase 1 of the clinical human trials consists of healthy individuals and is focused on safety. Phase 2 consists of additional safety and dose-ranging in healthy volunteers, with the addition of a control group. Phase 3 evaluates efficacy, safety and immune response in a larger volunteer group, and requires two sequential randomized controlled trials. Phase 4 is a larger scale investigation into longer-

term safety. Vaccine developers must follow this process in order to be able to generate the data the FDA needs in order to assess the safety and effectiveness of a vaccine candidate.

This 10-15 year testing process has been abandoned for purposes of the Vaccines. The first human-to-human transmission of the SARS-CoV-2 virus was not confirmed until January 20, 2020, and less than a year later both mRNA Vaccines had EUAs and for the first time in history this novel mRNA technology was being injected into millions of human beings. As of June 7, 2021, 138 million Americans, representing 42% of the population, have been fully vaccinated.

All of the stages of testing have been compressed in time, abbreviated in substance, and are overlapping, which dramatically increases the risks of the Vaccines. Plaintiffs' investigation indicates that Moderna and Pfizer designed their Vaccines in only two days. It appears that pharmaceutical companies did not independently verify the genome sequence that China released on January 11, 2020. It appears that the Vaccines were studied for only 56 days in macaques, and 28 days in mice, and then animal studies were halted. It appears that the pharmaceutical companies discarded their control groups receiving placebos, squandering the opportunity to learn about the rate of long-term complications, how long protection against the disease lasts and how well the Vaccines inhibit transmission. A number of studies were deemed unnecessary and not performed prior to administration in human subjects, including single dose toxicity, toxicokinetic, genotoxicity, carcinogenicity, prenatal and postnatal development, offspring, local tolerance, teratogenic and postnatal toxicity and fertility. The American public has not been properly informed of these dramatic departures from the standard testing process, and the risks they generate.

Plaintiff America's Frontline Doctors' ("AFLDS") medico-legal researchers have analyzed the accumulated COVID-19 Vaccine risk data, and report as follows:

Migration of the SARS-CoV-2 "Spike Protein" in the Body

The SARS-CoV-2 has a spike protein on its surface. The spike protein is what allows the virus to infect other bodies. It is clear that the spike protein is not a simple, passive structure. The spike protein is a "pathogenic protein" and a toxin that causes damage. The spike protein is itself biologically active, even without the virus. It is "fusogenic" and consequently binds more tightly to our cells, causing harm. If the purified spike protein is injected into the blood of research animals, it causes profound damage to their cardiovascular system, and crosses the blood-brain barrier to cause neurological damage. If the Vaccines were like traditional *bona fide* vaccines, and did not leave the immediate site of vaccination, typically the shoulder muscle, beyond the local draining lymph node, then the damage that the spike protein could cause might be limited.

However, the Vaccines were authorized without any studies demonstrating where the spike proteins traveled in the body following vaccination, how long they remain active and what effect they have. A group of international scientists has recently obtained the "biodistribution study" for the mRNA Vaccines from Japanese regulators. The study reveals that unlike traditional vaccines, this spike protein enters the bloodstream and circulates throughout the body over several days post-vaccination. It accumulates in a number of tissues, such as the spleen, bone marrow, liver, adrenal glands and ovaries. It fuses with receptors on our blood platelets, and also with cells lining our blood vessels. It can cause platelets to clump leading to clotting, bleeding and heart inflammation. It can also cross the blood-brain barrier and cause brain damage. It can be transferred to infants through breast milk. The VAERS system includes reports of infants suckling from vaccinated mothers experiencing bleeding disorders in the gastrointestinal tract.

Increased Risk of Death from Vaccines

The government operated VAERS database is intended to function as an "early warning" system for potential health risks caused by vaccines. It is broadcasting a red alert. Of the 262,000 total accumulated reports in VAERS, only 1772 are not related to COVID-19. The database indicates that the total reported vaccine deaths in the first quarter of 2021 represents a 12,000% to 25,000% increase in vaccine deaths, year-on-year. In ten years (2009-2019) there were 1529 vaccine deaths, whereas in the first quarter of 2021 there have been over 4,000. Further, 99% of all reported vaccine deaths in 2021 are caused by the COVID-19 Vaccines, only 1% being caused by the numerous other vaccines reported in the system. It is estimated that VAERS only captures 1% to at best 10% of all vaccine adverse events.

Reproductive Health

The mRNA Vaccines induce our cells to manufacture (virus-free) "spike proteins." The "spike proteins" are in the same family as the naturally occurring syncytin-1 and syncytin-2 reproductive proteins in sperm, ova and placenta. Antibodies raised against the spike protein might interact with the naturally occurring syncytin proteins, adversely affecting multiple steps in human reproduction. The manufacturers did not provide data on this subject despite knowing about the spike protein's similarity to syncytin proteins for more than one year. There are now a very high number of pregnancy losses in VAERS. A study recently published in the New England Journal of Medicine, "Preliminary Findings of mRNA COVID-19 Vaccine Safety in Pregnant Persons," exposes that pregnant women receiving Vaccines during their first or second trimesters suffer an 82% spontaneous abortion rate, killing 4 out of 5 unborn babies. There are worldwide reports of irregular vaginal bleeding without clear explanation. Scientists are concerned that the Vaccines pose a substantial risk to a woman's reproductive system. This increased risk of sterility stems from an increased concentration of the spike proteins in various

parts of the reproductive system after vaccination. Not enough is known to determine the risk of sterility, but it is beyond question that the risk is increased.

A leaked Pfizer document (excerpted below) exposes that Pfizer Vaccine nanoparticles accumulate in the ovaries at an extraordinarily high rate, in concentrations orders of magnitude higher than in other tissues. Billions of aggressive spike proteins are accumulating in very delicate ovarian tissues, the one place in the human body where females carry a finite number of fertile eggs.

SARS-CoV-2 mRNA Vaccine (BNT162, PF-07302048)
2.6.5 薬物動態試験の概要表

2.6.5.5B. PHARMACOKINETICS: ORGAN DISTRIBUTION CONTINUED **Test Article: [**

Sample	Total Lipid concentration (µg lipid equivalent/g [or mL]) (males and females combined)							%
	0.25 h	1 h	2 h	4 h	8 h	24 h	48 h	0.25 h
Lymph node (mandibular)	0.064	0.189	0.290	0.408	0.534	0.554	0.727	--
Lymph node (mesenteric)	0.050	0.146	0.530	0.489	0.689	0.985	1.37	--
Muscle	0.021	0.061	0.084	0.103	0.096	0.095	0.192	--
Ovaries (females)	0.104	1.34	1.64	2.34	3.09	5.24	12.3	0.001
Pancreas	0.081	0.207	0.414	0.380	0.294	0.358	0.599	0.003
Pituitary gland	0.339	0.645	0.868	0.854	0.405	0.478	0.694	0.000
Prostate (males)	0.061	0.091	0.128	0.157	0.150	0.183	0.170	0.001
Salivary glands	0.084	0.193	0.255	0.220	0.135	0.170	0.264	0.003
Skin	0.013	0.208	0.159	0.145	0.119	0.157	0.253	--
Small intestine	0.030	0.221	0.476	0.879	1.28	1.30	1.47	0.024
Spinal cord	0.043	0.097	0.169	0.250	0.106	0.085	0.112	0.001
Spleen	0.334	2.47	7.73	10.3	22.1	20.1	23.4	0.013
Stomach	0.017	0.065	0.115	0.144	0.268	0.152	0.215	0.006
Testes (males)	0.031	0.042	0.079	0.129	0.146	0.304	0.320	0.007
Thymus	0.088	0.243	0.340	0.335	0.196	0.207	0.331	0.004
Thyroid	0.155	0.536	0.842	0.851	0.544	0.578	1.00	0.000
Uterus (females)	0.043	0.203	0.305	0.140	0.287	0.289	0.456	0.002
Whole blood	1.97	4.37	5.40	3.05	1.31	0.909	0.420	--
Plasma	3.97	8.13	8.90	6.50	2.36	1.78	0.805	--
Blood:Plasma ratio[a]	0.815	0.515	0.550	0.510	0.555	0.530	0.540	--

PFIZER CONFIDENTIAL
Page 7

Each baby girl is born with the total number of eggs she will ever have in her entire life. Those eggs are stored in the ovaries, and one egg is released each month of a normal menstrual cycle. When there are no more eggs, a woman stops menstruating. The reproductive system is

arguably the most delicate hormonal and organ balance of all our systems. The slightest deviation in any direction results in infertility. Even in 2021, doctors and scientists do not know all the variables that cause infertility.

There is evidence to support that the Vaccines could cause permanent autoimmune rejection of the placenta. Placental inflammation resulting in stillbirths mid-pregnancy (second trimester) is seen with COVID-19 and with other similar coronaviruses. There is a case report of a woman with a normally developing pregnancy who lost the otherwise healthy baby at five months during acute COVID-19. The mother's side of the placenta was very inflamed. This "infection of the maternal side of the placenta inducing acute or chronic placental insufficiency resulting in miscarriage or fetal growth restriction was observed in 40% of pregnant women with similar coronaviruses." The mRNA Vaccines may instigate a similar reaction as the SARS-CoV-2 virus. There is a component in the vaccine that could cause the same autoimmune rejection of the placenta, but indefinitely. Getting COVID-19 has been associated with a high risk of mid-pregnancy miscarriage because the placenta fails. The mRNA Vaccines may have precisely the same effect, however, not for just the few weeks of being sick, but forever. Repeated pregnancies would keep failing in mid-pregnancy.

On December 1, 2020, a former Pfizer Vice President and allergy and respiratory researcher, Dr. Michael Yeadon, filed an application with the European Medicines Agency, responsible for approving drugs in the European Union, seeking the immediate suspension of all SARS-CoV-2 Vaccines, citing *inter alia* the risk to pregnancies. As of April 26, 2021, the VAERS database contains over 3,000 reports of failed pregnancies associated with the Vaccines.

Vascular Disease

Salk Institute for Biological Studies researchers in collaboration with the University of San Diego, published in the journal *Circulation Research* that the spike proteins themselves

damage vascular cells, causing strokes and many other vascular problems. All of the Vaccines are causing clotting disorders (coagulopathy) in all ages. The spike proteins are known to cause clotting that the body cannot fix, such as brain thrombosis and thrombocytopenia.

None of these risks has been adequately studied in trials, or properly disclosed to healthcare professionals or Vaccine subjects.

Autoimmune Disease

The spike proteins are perceived to be foreign by the human immune system, initiating an immune response to fight them. While that is the intended therapeutic principle, it is also the case that any cell expressing spike proteins becomes a target for destruction by our own immune system. This is an autoimmune disorder and can affect virtually any organ in the body. It is likely that some proportion of spike protein will become permanently fused to long-lived human proteins and this will prime the body for prolonged autoimmune diseases. Autoimmune diseases can take years to show symptoms and many scientists are alarmed at giving young people such a trigger for possible autoimmune disease.

Neurological Damage

The brain is completely unique in structure and function, and therefore it requires an environment that is insulated against the rest of the body's functioning. The blood-brain-barrier exists so the brain can function without disruption from the rest of the body. This is a complex, multi-layered system, using several mechanisms that keep nearly all bodily functions away from the brain. Three such systems include: very tight junctions between the cells lining the blood vessels, very specific proteins that go between, and unique enzymes that alter substances that do go through the cells. Working together, the blood-brain-barrier prevents almost everything from getting in. Breaching it is generally incompatible with life.

Most unfortunately, the COVID-19 Vaccines — unlike any other vaccine ever deployed — are able to breach this barrier through various routes, including through the nerve structure in the nasal passages and through the blood vessel walls. The resulting damage begins in the arterial wall, extends to the supporting tissue outside the arteries in the brain, and from there to the actual brain nerve cells inside. The Vaccines are programmed to produce the S1 subunit of the spike protein in every cell in every Vaccine recipient, but it is this subunit that causes the brain damage and neurologic symptoms. Elderly persons are at increased risk for this brain damage.

COVID-19 patients typically have neurological symptoms including headache and loss of smell and taste, as well as brain fog, impaired consciousness, and stroke. Researchers have published a paper in the *Journal of Neurological Sciences* correlating the severity of the pulmonary distress in COVID-19 with viral spread to the brain stem, suggesting direct brain damage, not just a secondary cytokine effect. It has been shown recently by Dr. William Banks, professor of Internal Medicine at University of Washington School of Medicine, that the S1 subunit of the spike protein — the part of the SARS-CoV-2 virus that produces the COVID-19 disease and is in the Vaccines — can cross the blood brain barrier. This is even more concerning, given the high number of ACE2 receptors in the brain (the ACE2 receptor is that portion of the cell that allows the spike protein to connect to human tissue). Mice injected with the S1 subunit of the spike protein developed direct damage to the perivascular tissue. In humans, viral spike protein was detected in the brain tissues of COVID-19 patients, but not in the brain tissues of the controls. Spike protein produces endothelial damage.

There are an excessive number of brain hemorrhages associated with COVID-19, and the mechanism suggests that it is the spike protein that is responsible. The federal government's VAERS database shows a dramatic increase in adverse event reporting of neurological damage following injection with the Vaccine.

Year	**Dementia** (reports following injection with Vaccine)	**Brain Bleeding** (reports following injection with Vaccine)
2000	4	7
2010	0	17
2015	0	17
2018	21	31
2019	11	17
2020	12 → (43)	4 → (11)
2021	17 → (251)	0 → (258)

While the full impact of these Vaccines crossing the blood-brain barrier is unknown, they clearly put vaccinated individuals at a substantially increased risk of hemorrhage, neurological damage, and brain damage as demonstrated by the increased instances of such reporting in the VAERS system.

Effect on the Young

The Vaccines are more deadly or harmful to the young than the virus, and that is excluding the unknown future effects on fertility, clotting, and autoimmune disease. Those under the age of 18 face statistically zero chance of death from SARS-CoV-2 according to data published by the CDC, but there are reports of heart inflammation — both myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) — in young men, and at least one documented fatal heart attack of a healthy 15-year old boy in Colorado two days after receiving the Pfizer Vaccine.[8] The CDC has admitted that "[s]ince April 2021, increased cases of myocarditis and pericarditis have been reported in the United States after the mRNA COVID-19 vaccination (Pfizer-BioNTech and Mederna), particularly in adolescents and young adults."

[8] https://archive.is/mEBcV (last visited July 15, 2021).

The Vaccines induce the cells of the recipient to manufacture trillions of spike proteins with the pathology described above. Because immune responses in the young and healthy are more vigorous than those in the old, paradoxically, the vaccines may thereby induce, in the very people least in need of assistance, a very strong immune response, including those which can damage their own cells and tissues, including by stimulating blood coagulation.

See also infra Section II.B.

Chronic Disease

Healthy children whose birthright is decades of healthy life will instead face premature death or decades of chronic disease. We cannot say what percentage will be affected with antibody dependent enhancement, neurological disorders, autoimmune disease and reproductive problems, but it is a virtual certainty that this will occur.

Antibody Dependent Enhancement

Antibody Dependent Enhancement ("ADE") occurs when SARS-CoV-2 antibodies, created by a Vaccine, instead of protecting the vaccinated person, cause a more severe or lethal case of the COVID-19 disease when the person is later exposed to SARS-CoV-2 in the wild.[9] The vaccine *amplifies* the infection rather than *preventing* damage. It may only be seen after months or years of use in populations around the world.

This paradoxical reaction has been seen in other vaccines and animal trials. One well-documented example is with the Dengue fever vaccine, which resulted in avoidable deaths. Dengue fever has caused 100-400 million infections, 500,000 hospitalizations, and a 2.5% fatality rate annually worldwide. It is a leading cause of death in children in Asian and Latin American countries. Despite over 50 years of active research, a Dengue vaccine still has not

[9] https://www.nature.com/articles/s41564-020-00789-5 (last visited July 15, 2021).

gained widespread approval in large part due to the phenomenon of ADE. Vaccine manufacturer Sanofi Pharmaceutical spent 20 years and nearly $2 billion to develop the Dengue vaccine and published their results in the *New England Journal of Medicine*, which was quickly endorsed by the World Health Organization. Vigilant scientists clearly warned about the danger from ADE, which the Philippines ignored when it administered the vaccine to hundreds of thousands of children in 2016. Later, when these children were exposed in the wild, many became severely ill and 600 children died. The former head of the Dengue department of the Research Institute for Tropical Medicine (RITM) was indicted in 2019 by the Phillipines Department of Justice for "reckless imprudence resulting [in] homicide," because he "facilitated, with undue haste," Dengvaxia's approval and its rollout among Philippine schoolchildren.[10]

ADE has been observed in the coronavirus setting. The original SARS-CoV-1 caused an epidemic in 2003. This virus is a coronavirus that is reported to be 78% similar to the current SARS-CoV-2 virus that causes the disease COVID-19. Scientists attempted to create a vaccine. Of approximately 35 vaccine candidates, the best four were trialed in ferrets. The vaccines appeared to work in the ferrets. However, when those vaccinated ferrets were challenged by SARS-CoV-1 in the wild, they became very ill and died due to what we would term a sudden severe cytokine storm. The reputed journals *Science*, *Nature* and *Journal of Infectious Diseases* have all documented ADE risks in relation to the development of experimental COVID-19 vaccines. The application filed by Dr. Yeadon with the European Medicines Agency on December 1, 2020 also mentioned the risk from ADE. ADE is discovered during long-term animal studies, to which the Vaccines have not been subjected.

[10] https://trialsitenews.com/philippine-dengue-vaccine-criminal-indictments-includes-president-of-sanofi-pasteur-their-fda (last visited July 15, 2021).

Vaccine-Driven Disease Enhancement in the Previously Infected

See infra section II. C.

More Virulent Strains

Scientists are concerned that universal inoculation may create more virulent strains. This has been observed with Marek's Disease in chickens.[11] A large number of chickens not at risk of death were vaccinated, and now all chickens must be vaccinated or they will die from a virus that was nonlethal prior to widespread vaccination. The current policy to pursue universal vaccination regardless of risk may exert the same evolutionary pressure toward more highly virulent strains.

Blood Supply

Presently, the vaccinated are permitted to donate their spike protein laden blood into the blood supply, which projects all of the risks discussed *supra* onto the general population of unvaccinated blood donees.

Scientists and healthcare professionals all over the world are sounding the alarm and frantically appealing to the FDA to halt the Vaccines. They have made innumerable public statements. Fifty-seven top scientists and doctors from Central and South America are calling for an immediate end to all Vaccine COVID-19 programs. Other physician-scientist groups have made similar calls, among them: Canadian Physicians, Israeli People's Committee, Frontline COVID-19 Critical Care Alliance, World Doctors Alliance, Doctors 4 Covid Ethics, and Plaintiff America's Frontline Doctors. These are healthcare professionals in the field who are seeing the catastrophic and deadly results of the rushed Vaccines, and reputed professors of science and medicine, including the physician with the greatest number of COVID-19 scientific citations

[11] https://en.wikipedia.org/wiki/Marek%27s_disease (last visited July 15, 2021).

worldwide. They accuse the government of deviating from long-standing policy to protect the public. In the past, government has halted vaccine trials based on a tiny fraction — far less than 1% — of the number of unexplained deaths already recorded. The scientists all agree that the spike protein (produced by the Vaccines) *causes disease even without the virus*, which has motivated them to lend their imprimatur to, and risk their reputation and standing on, these public objections.

(5) § 360bbb–3(c)(3): There Are Adequate, Approved and Available Alternatives to the Vaccines

The DHHS Secretary can issue and maintain the Vaccine EUAs "**only if**" (emphasis added) there is no adequate, approved and available alternative to the Vaccines.

There are numerous alternative safe and effective treatments for COVID-19. These alternatives are supported by over 300 studies, including randomized controlled studies. Tens of thousands of physicians have publicly attested, and many have testified under oath, as to the safety and efficacy of the alternatives. Globally and in the United States, treatments such as Ivermectin, Budesonide, Dexamethasone, convalescent plasma and monoclonal antibodies, Vitamin D, Zinc, Azithromycin, Hydroxychloroquine, Colchicine and Remdesivir are being used to great effect, and they are far safer than the COVID-19 Vaccines.[12]

Doctors from the Smith Center for Infectious Diseases and Urban Health and the Saint Barnabas Medical Center have published an *Observational Study on 255 Mechanically Ventilated COVID Patients at the Beginning of the USA Pandemic*, which states: "Causal modeling establishes that weight-adjusted HCQ [Hydroxychloroquine] and AZM [Azithromycin] therapy improves survival by over 100%."[13]

[12] Numerous studies can be reviewed here: https://c19early.com (last visited June 7, 2021).
[13] https://www.medrxiv.org/content/10.1101/2021.05.28.21258012v1 (last visited July 15, 2021).

Observational studies in Delhi and Mexico City show dramatic reductions in COVID-19 case and death counts following the mass distribution of Ivermectin. These results align with those of a study in Argentina, in which 800 healthcare professionals received Ivermectin, while another 400 did not. Of the 800, not a single person contracted COVID-19, while more than half of the control group did contract it. Dr. Pierre Kory, a lung specialist who has treated more COVID-19 patients than most doctors, representing a group of some of the most highly published physicians in the world, with over 2,000 peer reviewed publications among them, testified before the U.S. Senate in December 2020.[14] He testified that based on 9 months of review of scientific data from 30 studies, Ivermectin obliterates transmission of the SARS-CoV-2 virus and is a powerful prophylactic (if you take it, you will not contract COVID-19). Four large randomized controlled trials totaling over 1500 patients demonstrate that Ivermectin is safe and effective as a prophylaxis. In early outpatient treatment, three randomized controlled trials and multiple observational studies show that Ivermectin reduces the need for hospitalization and death in statistically significant numbers. In inpatient treatment, four randomized controlled trials show that Ivermectin prevents death in a statistically significant, large magnitude. Ivermectin won the Nobel Prize in Medicine in 2015 for its impacts on global health.[15]

Inexplicably, the Defendants never formed or assigned a task force to research and review existing alternatives for preventing and treating COVID-19. Instead, the Defendants and others set about censoring both concerns about the Vaccines, and information about safe and effective alternatives.

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[14] https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=&ved=2ahUKEwji38elkuPxAhWeAp0JHZhzAeMQFnoECAIQAA&url=https%3A%2F%2Fwww.hsgac.senate.gov%2Fdownload%2Fkory12-08-2020&usg=AOvVaw3z2a7PpDLWgyfSrp3miF1y (last visited July 15, 2021).

[15] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4692067/ (last visited July 15, 2021).

(6) § 360bbb–3(e)(1)(A)(i) and (ii): Healthcare Professionals and Vaccine Candidates are Not Adequately Informed

Once an EUA has been issued, § 360bbb–3(e) mandates that the DHHS Secretary "shall [ ] establish" conditions "designed to ensure" that both healthcare professionals and Vaccine candidates receive certain minimum required information that is necessary in order to make voluntary, informed consent possible. The required disclosures that the DHHS Secretary are designed to ensure include inter alia (i) that the Vaccines are only authorized for emergency use and not FDA approved, (ii) the significant known and potential risks of the Vaccines, (iii) available alternatives to the Vaccines, (iv) the option to accept or refuse the Vaccines.

The Vaccines are Not Approved by the FDA, but Merely Authorized for Emergency Use

Defendants have failed to educate the American public that the FDA has not actually "approved" the Vaccines, and that the DHHS Secretary has *not* in fact determined that the Vaccines are "safe and effective," and on the contrary has merely determined, in accordance with the proverbial "weasel language" of the EUA statute, that "**it is reasonable to believe**" that the Vaccines "**may be**" effective and that the benefits outweigh the risks. Instead of being so educated, the public is barraged with unqualified "safe and effective" messaging from all levels of federal and state government, the private sector and the media. They hear from no higher authority than the President himself that: "The bottom line is this: I promise you they are safe. They are safe. And even more importantly, they're extremely effective. If you're vaccinated, you are protected."

The public are also unaware of the serious financial conflicts-of-interest that burden Dr. Fauci, the National Institute of Allergies and Infectious Diseases, and the Vaccines and Related Biological Products Advisory Committee which advises and consults Defendants with respect to the Vaccine EUAs, as outlined in the Complaint (ECF 10, ¶¶ 250-256). Without the information

regarding conflicts-of interest, the public cannot assess for themselves the reliability and objectivity of the analysis underpinning the EUAs.

The Significant Known and Potential Risks of the Vaccines

Perhaps the first step in understanding the potential risks of the Vaccines is to understand exactly what they are, and what they are not. The CDC defines a "vaccine" as: "A product that stimulates a person's immune system to produce immunity to a specific disease, protecting the person from that disease. Vaccines are usually administered through needle injections, but can also be administered by mouth or sprayed into the nose."[16] The CDC defines "immunity" as: "Protection from an infectious disease. If you are immune to a disease, you can be exposed to it without becoming infected."[17]

However, the "Pfizer-BioNTech COVID-19 Vaccine" and the "Moderna COVID-19 Vaccine" do not meet the CDC's own definitions. They do not stimulate the body to produce immunity from a disease. They are a synthetic fragment of nucleic acid embedded in a fat carrier that is introduced into human cells, not for the purpose of inducing immunity from infection with the SARS-CoV-2 virus, and not to block further transmission of the virus, but in order to lessen the symptoms of COVID-19. No published, peer-reviewed studies prove that the "Pfizer-BioNTech COVID-19 Vaccine" and the "Moderna COVID-19 Vaccine" confer immunity or stop transmission.

Further, the "Pfizer-BioNTech COVID-19 Vaccine" and the "Moderna COVID-19 Vaccine" are not "vaccines" within the common, lay understanding of the public. Since vaccines were first discovered in 1796 by Dr. Edward Jenner, who used cowpox to inoculate humans against smallpox, and called the process "vaccination" (from the Latin term *vaca* for cow), the

[16] *See* https://www.cdc.gov/vaccines/vac-gen/imz-basics.htm (last visited July 9, 2021).
[17] Id.

public has had an entrenched understanding that a vaccine is a microorganism, either alive but weakened, or dead, that is introduced into the human body in order to trigger the production of antibodies that confer immunity from the targeted disease, and also prevent its transmission to others. The public are accustomed to these traditional vaccines and understand them.

The public are fundamentally uninformed about the gene therapy technology behind the "Pfizer-BioNTech COVID-19 Vaccine" and the "Moderna COVID-19 Vaccine." Referring to the "mRNA technology" in its Vaccine, Moderna admits the "novel and unprecedented nature of this new class of medicines" in its Securities and Exchange Commission filings.[18] Further, it admits that the FDA classes its Vaccine as a form of "gene therapy." No dead or attenuated virus is used in the "Pfizer-BioNTech COVID-19 Vaccine" and the "Moderna COVID-19 Vaccine." Rather, instructions, via a piece of lab-created genetic code (the mRNA) are injected into your body that tell your body how to make a certain "spike protein" that is purportedly useful in attacking the SARS-CoV-2 virus.

By referring to the "Pfizer-BioNTech COVID-19 Vaccine" and the "Moderna COVID-19 Vaccine" as "vaccines," and by allowing others to do the same, the Defendants knowingly seduce and mislead the public, short-circuit independent, critical evaluation and decision-making by the consumers of these products, and vitiate their informed consent to this novel technology which is being deployed in the unsuspecting human population for the first time in history.

Meanwhile, the federal government is orchestrating a nationwide media campaign funded with $1 billion — not to ensure that the Defendants meet their statutory disclosure obligations, but solely to promote the purported benefits of the Vaccines. Simultaneously, the Associated Press, Agence France Press, British Broadcasting Corporation, CBC/Radio-Canada, European

[18] *See* www.sec.gov/Archives/edgar/data/1682852/000168285220000017/mrna-20200630.htm (last visited July 6, 2021).

Broadcasting Union (EBU), Facebook, Financial Times, First Draft, Google/YouTube, The Hindu Times, Microsoft, Reuters, Reuters Institute for the Study of Journalism, Twitter, The Washington Post and The New York Times all participate in the "Trusted News Initiative" which has agreed to not allow any news critical of the Vaccines.

Individual physicians are being censored on social media platforms (e.g., Twitter, Facebook, Instagram, TikTok), the modern day "public square." Plaintiff AFLDS has recorded innumerable instances of social media deleting scientific content posted by AFLDS members that runs counter to the prevailing Vaccine narrative, and then banning them from the platform altogether as users. Facebook has blocked the streaming of entire events at which AFLDS Founder Dr. Simone Gold has been an invited guest, prior to her uttering a word. Other doctors have been banned for posting or tweeting screenshots of government database VAERS.

The censorship also extends to medical journals. In an unprecedented move, the four founding topic editors for the *Frontiers in Pharmacology* journal all resigned together due to their collective inability to publish peer reviewed scientific data on various drugs for prophylaxis and treatment of COVID-19.

Dr. Philippe Douste-Blazy, a cardiology physician, former France Health Minister, 2017 candidate for Director of the WHO and former Under-Secretary-General of the United Nations, described the censorship in chilling detail:

> *The Lancet boss said "Now we are not going to be able to, basically, if this continues, publish any more clinical research data, because the pharmaceutical companies are so financially powerful today and are able to use such methodologies, as to have us accept papers which are apparently, methodologically perfect but in reality, which manage to conclude what they want to conclude." … one of the greatest subjects never anyone could have believed … I have been doing research for 20 years in my life. I never thought the boss of The Lancet could say that. And the boss of the New England Journal of Medicine too. He even said it was "criminal" — the word was used by him. That is, if you will, when there is an outbreak like the COVID-19, in reality, there are people … us,*

> *we see "mortality" when you are a doctor or yourself, you see "suffering." And there are people who see "dollars" — that's it.*

In many instances, highly publicized attacks on early treatment alternatives seem to be done in bad faith. For example, one study on Hydroxychloroquine overdosed study participants by administering a multiple of the standard prescribed dose, and then reported the resulting deaths as though they were not a result of the overdose, but from the medication itself administered in the proper dosages. The twenty-seven physician-scientist authors of the study were civilly indicted and criminally investigated, and still the Journal of the American Medical Association has not retracted the article.[19]

The Available Alternatives to the Vaccines

Information regarding available alternatives to the Vaccines has been suppressed and censored equally with information regarding the risks of the Vaccines, as aforesaid.

The Option to Accept or Refuse the Vaccines

The idea of using fear to manipulate the public is not new, and is a strategy frequently deployed in public health. In June 2020, three American public health professionals, concerned about the psychological effects of the continued use of fear-based appeals to the public in order to motivate compliance with extreme COVID-19 countermeasures, authored a piece for the journal *Health Education and Behavior* calling for an end to the fear-mongering. In doing so, they acknowledged that fear has become an accepted public health strategy, and that it is being deployed aggressively in the United States in response to COVID-19:

> *"… behavior change can result by increasing people's perceived severity and perceived susceptibility of a health issue through heightened risk appraisal coupled by raising their self-efficacy and response-efficacy*

[19] https://www.medrxiv.org/content/medrxiv/early/2020/04/16/2020.04.07.20056424.full.pdf (last visited July 15, 2021).

about a behavioral solution. In this model, fear is used as the trigger to increase perceived susceptibility and severity."

In 1956, Dr. Alfred Biderman, a research social psychologist employed by the U.S. Air Force, published his study on techniques employed by communist captors to induce individual compliance from Air Force prisoners of war during the Korean War. The study was at the time and to some extent remains the core source for capture resistance training for the armed forces. The chart below compares the techniques used by North Korean communists with the fear-based messaging and COVID-19 countermeasures to which the American population has been subjected over the last year.

"COMMUNIST COERCIVE METHODS FOR ELICITING INDIVIDUAL COMPLIANCE".*
The Biderman Report of 1956 and COVID-19

Chart of Coercion	COVID-19
Isolation • Deprives individual of social support of his ability to resist • Makes individual dependent upon the captor • Individual develops an intense concern with self.	***Isolation*** • Social distancing • Isolation from loved ones, massive job loss • Solitary confinement semi-isolation • Quarantines, containment camps
Monopolization of Perception • Fixes all attention upon immediate predicament; • Frustrates all actions not consistent with compliance • Eliminates stimuli competing with those controlled by the captor	***Monopolization of perception*** • Restrict movement • Create monotony, boredom • Prevent gathering, meetings, concerts, sports • Dominate all media the 24/7, censor information
Induced Debility and Exhaustion • Weakens mental and physical ability to resist • People …become worn out by tension and fear	***Induced debility*** • Forced to stay at home, all media is negative • not permitted to exercise or socialize
Threats • Cultivates anxiety and despair • Gives demands and consequences for non compliance	***Threats and Intimidation*** • Threaten to close business, levy fines • Predict extension of quarantine, force vaccines • Create containment camps
Occasional Indulgences • Provides motivation for compliance • Hinders adjustment to deprivation. • Creates hope for change, reduces resistance • This keeps people unsure of what is happening.	***Occasional Indulgences*** • Allow reopening of some stores, services • Let restaurants open but only at a certain capacity • Increase more people allowed to gather • Follow concessions with tougher rules
Demonstrate Omnipotence • Demonstrates futility of resistance • Shows who is in charge • Provides positive motivation for compliance	***Demonstrate Ominpotence*** • Shut down entire economies across the world • Create money out of nowhere, force dependency • Develop *total* surveillance with nanochips and 5G
Degradation • Makes resistance seem worse than compliance • Creates feelings of helplessness. • Creates fear of freedom, dependence upon captors	***Humiliation or Degradation techniques*** • Shame people who refuse masks, don't distance • Make people stand on circles and between lines • Make people stand outside and wait in queues • Sanitation stations in every shop
Enforcing trivial demands • Develops habit of compliance • Demands made are illogical and contradictory • Rules on compliance may change • Reinforces who is in control	***Enforcing trivial demands*** • Family members must stand apart • Masks in home and even when having sex • Random limits on people allowed to be together • Sanitizers to be used over and over in a day

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The Chart of Coercion above is drawn from the Biderman Report on communist brainwashing techniques used by the Chinese and North Koreans on captured American servicemen to make them psychological as well as physical prisoners. Dr. Alfred D. Biderman M.A. and presented his Report at the New York Acadamy of Medicine Nov 13, 1956. Compare right column with your experience this year.

After a year of sustained psychological manipulation, the population is now weakened, frightened, desperate for a return of their freedoms, prosperity and normal lives, and especially vulnerable to pressure to take the Vaccine. The lockdowns and shutdowns, the myriad rules and regulations, the confusing and self-contradictory controls, the enforced docility, and the consequent demoralization, anxiety and helplessness are typical of authoritarian and totalitarian conditions. This degree of systemic and purposeful coercion means that Americans cannot give truly free and voluntary informed consent to the Vaccines.

At the same time, the population is being subjected to an aggressive, coordinated media campaign promoting the Vaccines funded by the federal government with $1 billion. The media campaign is reinforced by a system of coercive rewards and penalties designed to induce vaccination. The federal government is offering a range of its own incentives, including free childcare. The Ohio Governor rewarded those Ohio residents accepting the Vaccines by allowing them to enter into the "Vaxamillion" lottery with a total $5 million prize and the chance to win a fully funded college education, while barring entry for residents who decline the Vaccines. In New York, metro stations offer free passes to those receiving the Vaccine in the station. West Virginia is running a lottery exclusively for the vaccinated with free custom guns, trucks and lifetime hunting and fishing licenses, a free college education, and cash payments of $1.5 million and $600,000 as the prizes. Previously, the state offered a $100 savings bond for each injection with a Vaccine. New Mexican residents accepting the Vaccines will be entered into weekly drawings to take home a $250,000 prize, and those fully vaccinated by early August could win the grand prize of $5 million. In Oregon, the vaccinated can win $1 million, or one of 36 separate $10,000 prizes through the state's "Take Your Shot" campaign. Other state and local governments are partnering with fast food chains to offer free pizza, ice cream, hamburgers and other foods to the vaccinated. Many people are desperate following the last year of economic

destruction and deprivation of basic freedoms, and they are especially vulnerable to this coercion.

The penalties take many forms, among them:

- Using guilt and shame to make unvaccinated children and adults feel badly about themselves for refusing the Vaccines.

- Threatening the unvaccinated with false fears and anxieties about COVID-19, especially children who are at no risk statistically.

- Removing the rights of those who are unvaccinated, including:
  - Being prohibited from working
  - Being prohibited from attending school or college
  - Being limited in the ability to travel in buses, trains and planes
  - Being prohibited from traveling outside the United States
  - Being excluded from public and private events, such as performing arts venues.

Most recently, the President has announced an aggressive campaign to visit the homes of the unvaccinated, not for the purpose of ensuring that they have all of the information they might need in order to make fully informed, voluntary decisions about the Vaccines (the information required by § 360bbb–3(e)(1)(A)(i) and (ii)), but instead for the purpose of pressuring them to be injected with the Vaccine so that the Administration can reach its goal of having 70% of the American population vaccinated. He said: "Now we need to go to community by community, neighborhood by neighborhood, and oftentimes, door to door — literally knocking on doors — to get help to the remaining people protected from the virus."[20] The White House press secretary referred to the door-knockers who would enter our communities to pressure us to accept the Vaccines using the language of war, as "strike forces." Then, after Dr. Fauci stated his opinion in mainstream media news outlets that "at the local level . . . there should be more mandates,

[20] *See* "Biden admin launching door-to-door push to vaccinate Americans, sparks major backlash," https://www.foxnews.com/media/biden-admin-door-to-door-coronavirus-vaccines (last visited July 15, 2021).

there really should be", the press secretary announced that the Biden Administration would support state and local Vaccine mandates.[21]

A study recently published in the International Journal of Clinical Practice, "Informed Consent Disclosure to Vaccine Trial Subjects of Risk of COVID-19 Vaccines Worsening Clinical Disease,"[22] concludes:

> *COVID-19 vaccines designed to elicit neutralising antibodies may sensitise vaccine recipients to more severe disease than if they were not vaccinated. Vaccines for SARS, MERS and RSV have never been approved, and the data generated in the developmentand testing of these vaccines suggest a serious mechanistic concern: that vaccines designed empirically using the traditional approach (consisting of the unmodified or minimally modified coronavirus viral spike to elicit neutralising antibodies), be they composed of protein, viral vector, DNA or RNA and irrespective of delivery method, may worsen COVID-19 disease via antibody-dependent enhancement (ADE).* ***This risk is sufficiently obscured in clinical trial protocols and consent forms for ongoing COVID-19 vaccine trials that adequate patient comprehension of this risk is unlikely to occur, obviating truly informed consent by subjects in these trials.***

(emphasis added).

Plaintiffs' expert Dr. Lee Merritt is a fully licensed, board certified surgeon, and has been actively engaged in medical practice for over 35 years. As Chief of Staff, Chief of Surgery and Chief of Credentialing at a regional medical center, she participated in hospital administration and education with respect to *inter alia* informed consent. She states: "I have read the Complaint and Motion for Preliminary Injunction in the above captioned matter, specifically the allegations related to informed consent. I agree with the informed consent allegations contained in the Complaint and Motion for Preliminary Injunction" (*see* Declaration of Dr. Lee Merritt at Exhibit A). Dr. Merritt has provided an example of some of the language that she would recommend using for the purpose of obtaining voluntary, informed consent to the Vaccines.

[21] *See* "Biden will back local vaccine mandates," https://thehill.com/changing-america/well-being/prevention-cures/562622-biden-will-back-local-vaccine-mandates (last visited July 15, 2021).
[22] *See* https://onlinelibrary.wiley.com/doi/epdf/10.1111/ijcp.13795 (last visited July 17, 2021).

The combined effect of (i) the suppression and censorship of information regarding the risks of the Vaccines, (ii) the failure to inform the public regarding the novel and experimental nature of the mRNA Vaccines, (iii) the suppression and censorship of information regarding alternative treatments, (iv) the failure to inform and properly educate the public that the Vaccines are not in fact "approved" by the FDA, (v) the failure to inform and properly educate the public that the DHHS Secretary has *not* determined that the Vaccines are "safe and effective" and on the contrary has merely determined that "it is reasonable to believe" that the Vaccines "may be effective" and that the benefits outweigh the risks, (vi) the sustained psychological manipulation of the public through official fear-based messaging regarding COVID-19, draconian countermeasures and a system of rewards and penalties, is to remove any possibility that Vaccine recipients are giving voluntary informed consent to the Vaccines. They have no real option to accept or refuse the Vaccines. They are unwitting, unwilling participants in a large scale, ongoing non-consensual human experiment.[23]

(7) § 360bbb–3(e)(1)(A)(iii): Monitoring and Reporting of Adverse Events

VAERS was established in 1986 in order to facilitate public access to information regarding adverse events potentially caused by vaccines. This system is inadequate to the present circumstances, for the following reasons:

- neither healthcare professionals nor Vaccine recipients are being informed by the Defendants, and conditions do not exist ensuring that others will inform them, that the DHHS Secretary "has authorized the emergency use of the [Vaccines]" since they are not being informed of the true meaning of the EUAs, specifically, that the Secretary has *not* determined that the Vaccines are "safe and effective" (notwithstanding the President's widely publicized statements to the contrary, which are amplified daily by countless other governmental and private sector statements that the Vaccines are "safe and effective"), and that instead the DHHS Secretary has only determined that he

[23] https://en.wikipedia.org/wiki/Unethical_human_experimentation_in_the_United_States (last visited July 15, 2021).

has "reason to believe" that the Vaccines "may be effective" in treating or preventing SARS-CoV-2 and COVID-19, based on trials of the Vaccines that are not being conducted like any previous trials and are compressed, overlapping, incomplete and in many instances conducted by the Vaccine manufacturers themselves;

- neither healthcare professionals nor Vaccine recipients are being informed by the Defendants, and conditions do not exist ensuring that others will inform them, of "the significant known and potential [ ] risks" of the Vaccines, since there is a coordinated campaign funded with $1 billion to extol the virtues of the Vaccines, and a simultaneous effort to censor information about the inefficacy of the Vaccines in preventing or treating SARS-CoV-2 and COVID-19, Vaccine risks, and injuries and deaths caused by the Vaccine;
- Vaccine recipients are not being informed by the Defendants, who have a financial stake in the intellectual property underlying at least one Vaccine, and who have other financial conflicts of interest, and conditions do not exist ensuring that others will inform them, that there are alternatives to the Vaccines and of their benefits;
- Vaccine recipients are not being informed by the Defendants, and conditions do not exist ensuring that others will inform them, of their "option to accept or refuse" the Vaccines, since they have been saturated with unjustified fear-messaging regarding SARS-CoV-2 and COVID-19, psychologically manipulated, and coerced by a system of rewards and penalties that render the "option to [ ] refuse" meaningless; and
- Appropriate conditions do not exist for "the monitoring and reporting of adverse events" since only a fraction (as low as 1%) of adverse events are reported to VAERS by physicians fearing liability, and the Defendants have established a parallel reporting system for COVID-19 that is not accessible by Plaintiffs or the rest of the public.

A 2011 report by Harvard Pilgrim Healthcare for DHHS stated that fewer than 1% of all vaccine adverse events are reported to Defendants: "[F]ewer than 1% of vaccine adverse events are reported. Low reporting rates preclude or slow the identification of "problem" drugs and vaccines that endanger public health. New surveillance methods for drug and vaccine adverse effects are needed."[24]

To illustrate, while the CDC claims that "Anaphylaxis after COVID-19 vaccination is rare and occurred in approximately 2 to 5 people per million vaccinated in the United States

[24] Harvard Pilgrim Health Care, Inc., Electronic System for Public Health Vaccine Adverse Event Reporting System, *AHRQ* 2011.

based on events reported to VAERS,"[25] a recent study by Mass General Brigham found "severe reactions consistent with anaphylaxis occurred at a rate of 2.47 per 10,000 vaccinations."[26] This is 50 to 120 times more cases than reported by VAERS and the CDC, meaning that only between 0.8% and 2% of all anaphylaxis cases are being reported by the Defendants. The underreporting is inexplicable, since it is mandatory for healthcare professionals to report this reaction to the Vaccines,[27] and the reactions typically occur within 30 minutes of vaccination.[28]

Uniquely for COVID-19, the CDC has developed a parallel system called "V-Safe." V-Safe is an app on a smart phone which people can use to report adverse events. Plaintiffs' investigation indicates that vaccine subjects who are provided with written information are given the V-Safe contact information. Plaintiffs cannot access V-Safe data, since it is controlled exclusively by the CDC. Plaintiffs are concerned that the information in V-Safe exceeds that in VAERS, in terms of volume and kind, defying Congressional intent in creating VAERS.

In summation, VAERS is inaccurate, and the federal government is failing to provide data from other sources such as V-Safe, Medicare/Medicaid, the military, etc. Informed consent cannot be given without an understanding of risk and Plaintiffs cannot help but wonder why the Defendants would fail to disclose this critical information related to risk to the public, particularly in light of the fact that they have had the time and resources to study and extend the authorizations on the Vaccines, build an enormous Vaccine marketing machine, and roll out Vaccine clinics all over the nation.

[25] *See* https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html.
[26] *See* https://jamanetwork.com/journals/jama/fullarticle/2777417.
[27] *See* https://www.fda.gov/media/144413/download.
[28] *See* https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html.

B. The Under-18 Age Category

In the United States, those younger than 18 years of age accounted for just 1.7% of all COVID-19 cases.[29] Essentially no severe cases of COVID-19 were observed in those aged 10 through 18 years. This group accounted for just 1% of reported cases, almost all of which were very mild.[30] A study recently published in the British Medical Journal concludes: "In contrast to other respiratory viruses, children have less severe symptoms when infected with the novel severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)."[31] Hospitalization due to COVID-19 is incredibly rare among youth, and overstated. The American Academy of Pediatrics[32] reported:

> *…these studies underscore the importance of clearly distinguishing between children hospitalized with SARS-Co-V-2 found on universal testing versus those hospitalized for COVID-19 disease. Both demonstrate that reported hospitalization rates greatly overestimate the true burden of COVID-19 disease in children.*

Professor Hervé Seligmann, an infectious disease expert and biomedical researcher with over 100 peer-reviewed international publications, of the University of Aix-Marseille, has scrutinized the official COVID-19 statistics and figures of Israel, which has vaccinated 63% of its population, and fully vaccinated 57% of its population. Professor Seligmann sees no benefit in vaccinating those under 18, and significant risk of harm:

> *There are several theories about why the risk of death is so low in the young including that the density of the ACE2 receptors that the virus uses to gain entry into cells is lower in the tissue of immature animals and this is expected to be true also in humans. However, the vaccines induce the cells of the recipient to*

[29] Coronavirus Disease 2019 in Children - United States, February 12-April 2, 2020. *MMWR. Morbidity and Mortality Weekly Report* 69:422-426.
[30] Tsabouri, S. et al. (2021), Risk Factors for Severity in Children with Coronavirus Disease 2019: A Comprehensive Literature Review. *Pediatric Clinics of North America* 68:321-338.
[31] Zimmermann P, Curtis N Why is COVID-19 less severe in children? A review of the proposed mechanisms underlying the age-related difference in severity of SARS-CoV-2 infections Archives of Disease in Childhood 2021;106**:**429-439.
[32] Ioannidis, J.P.A. (2020) Infection fatality rate of COVID-19 inferred from seroprevalence data. Bull. World Health Organ. -:BLT.20.265892.

> *manufacture trillions of spike proteins with the pathology described above. Because immune responses in the young and healthy are more vigorous than those in the old, paradoxically, the vaccines may thereby induce, in the very people least in need of assistance, strong immune responses, including those which can damage their own cells and tissues as well as by stimulating blood coagulation. Experts predict that vaccination will greatly increase the very low COVID-19 risks experienced by the younger population … vaccination-associated mortality risks are expected at least 20 times greater below age 20 compared to the very low COVID19-associated risks for this age group.*[33]

CDC data indicates that children under 18 have a 99.998% COVID-19 recovery rate with no treatment. This contrasts with over 45,000 deaths (*see* below) and hundreds of thousands of adverse events reported following injection with the Vaccines. The risk of harm to children may be as high as 50 to 1. Thus, children under 18 are at no statistically significant risk of harm from SARS-CoV-2 and COVID-19. Administering Vaccines to this age group knowingly and intentionally exposes them to unnecessary and unacceptable risks.

Plaintiffs' expert Dr. Angelina Farella is a fully licensed, board certified pediatrician, actively practicing for over 25 years, and has vaccinated in excess of 10,000 patients (see Declaration of Angelina Farella, MD at Exhibit B). Dr. Farella states, in her professional medical opinion: "There are 104 children age 0-17 who have died from Covid-19 and 287 from Covid + Influenza out of roughly 72 million children in America. This equals ZERO risk. There is NO public interest in subjecting children to experimental vaccination programs, to protect them from a disease that does not threaten them." Dr. Farella also opines, with respect to the lack of testing designed to ensure the safety of this subpopulation:

> *Vaccines take years to safely test. It's not only the number of people tested but the length of time that is important when creating new vaccines. Emergency Use Authorization was granted prematurely for adolescents, before ANY trials were completed. Moderna is scheduled to complete trials on October 31, 2022, and Pfizer is scheduled to complete trials on April 27, 2023. There were no trial*

[33] Seligmann, H., (2021), Expert Evaluation on Adverse Effects of the Pfizer COVID-19 Vaccination. *See* https://www.researchgate.net/publication/351441506_Expert_evaluation_on_adverse_effects_of_the_Pfizer-COVID-19_vaccination (last visited July 8, 2021).

> *patients under the age of 18. The FDA and these pharma companies are currently allowing children 12 years old to receive this shot, when they were never studied in the trials.* ***Never before in history have we given medications that were not FDA approved to people who were not initially studied in the trial.***

Section 360bbb–3(c)(2) requires the Secretary to base decisions on "data from adequate and well-controlled clinical trials". Clearly, the Secretary has exceeded his statutory authority with respect to the under-18 subpopulation.

Meanwhile, local governments are hastily passing laws eliminating the requirement for parental consent, and even parental knowledge, of medical treatments administered to children as young as 12. This is intended to pave the way for children to be vaccinated at school, without parental knowledge or consent.

Children in the 12-18 age group are not developmentally capable of giving voluntary, informed consent to the Vaccines. Their brains are rapidly changing and developing, and their actions are guided more by the emotional and reactive amygdala and less by the thoughtful, logical frontal cortex. Hormonal and body changes add to their emotional instability and erratic judgment. Children also have a well-known and scientifically studied vulnerability to pressure from peers and adults. This age group is particularly susceptible to pressure to do what others see as the right thing to do — in this case, to be injected with the Vaccine "for the sake of other people and society."

Injecting this under-18 subpopulation with the Vaccines threatens them with immediate, potentially life-threatening harm. The documented risks of injecting this subpopulation with the Vaccines far outweigh the purported benefits.

C. Those Previously Infected with SARS-CoV-2

Medical studies show that those with preexisting immunity have long lasting and robust natural immunity to SARS-CoV-2.[34] A recent Cleveland Clinic study[35] demonstrates that natural immunity acquired through prior infection with COVID-19 is stronger than any benefit conferred by a Vaccine, rendering vaccination unnecessary for those previously infected. A comparative study by Goldberg *et al* "questioned the need to vaccinate previously-infected individuals" and noted that previously infected individuals had 96.4% immune protection from COVID-19, versus 94.4% in those injected with the Vaccine.[36]

The Israeli Ministry of Health has released data showing that Israelis who had been previously infected with SARS-CoV-2 (and were not also vaccinated) were far less likely to become re-infected with the virus than those in the population who had been injected with the Vaccines.[37] Of the more then 7,700 new cases detected during the recent wave that commenced in May 2021, only 72, or less than 1%, were people who had previously been infected with SARS-CoV-2 and were never vaccinated. By contrast, over 3,000 cases, or 40%, were people who became infected for the first time, in spite of being vaccinated. The 72 instances of re-infection represent a mere 0.0086% of the 835,792 Israelis who are known to have recovered from the virus.

The immutable laws of immunology continue to function during COVID-19 (meaning those who are previously recovered from such an infection have acquired the ability to recognize disease and can effectively neutralize the infection before it takes hold), as evidenced by the fact

[34] *See* https://www.nature.com/articles/d41586-021-01442-9, and https://www.thelancet.com/journals/lancet /article/PIIS0140-6736(21)00782-0/fulltext (last visited July 14, 2021).
[35] Shrestha, N., Burke, P., Nowacki, A., Terpeluk, P., Gordon, S. (2021), Necessity of COVID-19 Vaccination in Previously Infected Individuals. See https://www.medrxiv.org/content/ 10.1101/2021.06.01.21258176v2 (last visited July 8, 2021).
[36] *See* https://www.medrxiv.org/content/10.1101/2021.04.20.21255670v1.full.pdf (last visited July 13, 2021).
[37] *See* https://www.israelnationalnews.com/News/News.aspx/309762 (last visited July 15, 2021).

that persons who have had SARS-CoV-1, a virus which is 22% dissimilar to the current strain, are still immune from SARS-CoV-2 18 years later.[38] Laypersons are misled to believe that when antibodies gradually diminish as expected, immunity is gone when in fact, immunity remains[39] quiescent deeper in the body, in the bone marrow[40], plasma, ready to be activated should the threat reemerge. This is normal immunology.

Not only is a Vaccine unnecessary in this subpopulation, it is more likely to cause harm. Scientists have observed vaccine-driven disease enhancement in the previously infected. The FDA admits that many people receiving a Vaccine either are or were previously infected with SARS-CoV-2, or have or previously had COVID-19.[41] Upon injection with the Vaccines, this population has reported serious medical harm, including death.[42] There is an immediately higher death rate worldwide upon receiving a Vaccine, generally attributed to persons having recently been infected with COVID-19. A person who previously had SARS-CoV-2, and then receives a Vaccine, mounts an antibody response to the Vaccine that is between 10 and 20 times stronger than the response of a previously uninfected person. The antibody response is far too strong and overwhelms the Vaccine subject. Medical studies show severe Vaccine side effects in persons previously infected with COVID-19.[43] A study published in the New England Journal of Medicine noted antibody titers 10-45 times higher in those with preexisting COVID-19 immunity after the first Vaccine injection, **with 89% of those seropositive reporting adverse side-effects.**[44] This substantial risk is suppressed in mainstream national news. Groups of scientists are demanding improved pre-assessment due to "Vaccine-driven disease enhancement"

[38] See https://www.nature.com/articles/s41586-020-2550-z (last visited July 14, 2021).
[39] https://www.medpagetoday.com/infectiousdisease/covid19/92836 (last visited July 14, 2021).
[40] https://www.nature.com/articles/s41586-021-03647-4 (last visited July 14, 2021).
[41] *See* https://www.fda.gov/media/144245/download (last visited July 13, 2021).
[42] *See* https://www.bridgemi.com/michigan-health-watch/three-michigan-people-who-died-after-vaccine-actually-had-earlier-covid; https://www.bmj.com/content/bmj/373/bmj.n1372.full.pdf (last visited July 13, 2021).
[43] See https://www.medrxiv.org/content/10.1101/2021.01.29.21250653v1.full.pdf (last visited July 13, 2021).
[44] See https://www.nejm.org/doi/10.1056/NEJMc2101667 (last visited July 13, 2021).

in the previously infected, a subpopulation which has been excluded from clinical trials. The failure to protect a subpopulation at higher risk, such as this one, is unprecedented. Injecting this subpopulation with the Vaccines, without prescreening, threatens them with immediate, potentially life-threatening harm.

Plaintiffs' expert Dr. Richard Urso is a fully licensed, board certified, practicing medical doctor (see Declaration of Dr. Richard Urso at Exhibit C). Dr. Urso has treated over 300,000 patients in his career, including over 450 COVID-19 recovered patients. In his professional medical opinion:

> *COVID recovered patients are at extremely high risk to a vaccine. They retain an antigenic fingerprint of natural infection in their tissues. They have all the requisite components of immune memory. Vaccination may activate a hyperimmune response leading to a significant tissue injury and possibly death.*
>
> *I have read the Complaint and Motion for Preliminary Injunction in the above captioned matter, specifically the allegations related to the dangers to members of the population who have already had Covid-19. I agree with the allegations contained in the Complaint and Motion for Preliminary Injunction.*

Pre-screening can be accomplished in the traditional way by (1) obtaining relevant personal and family medical history including prior COVID-19 symptoms and test results, (2) obtaining antibody and T-Detect testing from indeterminate persons, (3) obtaining rapid PCR screening testing on all persons (using at least the standard cycle thresholds set forth *infra*). If the prescreening results are positive, the Vaccine candidate must be excluded. The documented risks of indiscriminately injecting this subpopulation with the experimental Vaccines far outweigh the purported benefits.

For additional support of the foregoing sections, and this Motion for Injunctive Relief generally, please see the duly sworn Declaration of Dr. Peter A. McCullough, attached hereto and incorporated herein with reference to Exhibit L.

D. Whistleblower Testimony: 45,000 Deaths Caused by the Vaccines

Plaintiffs' expert Jane Doe[45] is a computer programmer with subject matter expertise in the healthcare data analytics field, and access to Medicare and Medicaid data maintained by the Centers for Medicare and Medicaid Services (CMS) (*see* Declaration of Jane Doe at Exhibit D). Over the last 20 years, she has developed over 100 distinct healthcare fraud detection algorithms for use in the public and private sectors. In her expert opinion, VAERS under-reports deaths caused by the Vaccines by a conservative factor of at least 5. As of July 9, 2021, VAERS reported 9,048 deaths associated with the Vaccines. Jane Doe queried data from CMS medical claims, and has determined that the number of deaths occurring with 3 days of injection with the Vaccines exceeds those reported by VAERS by a factor of at least 5, indicating that **the true number of deaths caused by the Vaccines is at least 45,000.** She notes that in the 1976 Swine Flu vaccine campaign (in which 25% of the U.S. population at that time, 55 million Americans, were vaccinated), the Swine Flu vaccine was deemed dangerous and unsafe, and removed from the market, even though the vaccine resulted in only 53 deaths.

The gross and willful under-reporting of Vaccine-caused deaths, which is substantiated by Jane Doe's Declaration, and also by other independent data points considered as part of Plaintiffs' due diligence, is profoundly important on a number of levels. This evidence increases the likelihood of Plaintiffs' success on the merits by: (1) making it impossible (a) that the DHHS Secretary can reasonably conclude, as required by § 360bbb–3(c)(2)(B), that "the known and potential benefits of [the Vaccines] outweigh the known and potential risks of [the Vaccines]",

[45] Plaintiffs' expert Jane Doe is a whistleblower who fears for her personal safety and that of her family, and reprisal, including termination and exclusion from her chosen profession for the duration of her working life, for disclosing the evidence contained in her Declaration at Ex. D. Plaintiffs will present the Court with a motion for an appropriately tailored protective order seeking to preserve the confidentiality of Jane Doe's identity. In the meantime, Defendants are not prejudiced, since they can respond to the substance of Jane Doe's Declaration and challenge her expert qualification without knowing her true identity. Plaintiffs' counsel have in their possession a copy of this same Declaration of Jane Doe, signed by the witness in her actual name.

(b) that the DHHS Secretary has succeeded in creating conditions, as required by § 360bbb–3(e)(1)(A)(i)(II) and (ii)(II), that ensure that healthcare professionals and Vaccine candidates are informed of the "significant known and potential [ ] risks" of the Vaccines, and (c) that the DHHS Secretary has succeeded in creating conditions, as required by § 360bbb–3(e)(1)(A)(iii), for the monitoring and reporting of adverse events; and (2) sealing Plaintiffs' argument that the FDA's "citizen petition" process (discussed *infra* in section III(1)) is "inadequate and not efficacious" and that its pursuit by Plaintiffs would have been a "futile gesture" by showing Defendants' bad faith. The evidence makes it irrefutable that Plaintiffs and others in the public will suffer irreparable injury (discussed *infra* in section III(2)) if this Motion is denied. Finally, the evidence tilts the balance of hardships and public interest (discussed *infra* in Section III(3) decisively in favor of Plaintiffs.

III. LAW AND ANALYSIS

In the 11th Circuit, a district court may grant preliminary injunctive relief when:

> *"a party establishes each of four separate requirements: (1) it has a substantial likelihood of success on the merits; (2) irreparable injury will be suffered unless the injunction issues; (3) the threatened injury to the movant outweighs whatever damage the proposed injunction may cause the opposing party; and (4) if issued, the injunction would not be adverse to the public interest."*

Jones v. Governor of Fla., 950 F.3d 795, 806 (11th Cir. 2020). However, the court has "considerable discretion…in determining whether the facts of a situation require it to issue an injunction." eBay, Inc. v. MercExchange, L.L.C., 547 U.S. 388, 391 (2006) (internal quotations and citations omitted).

A. Likelihood of Success on the Merits

As a threshold matter, parties seeking a preliminary injunction "are not required to prove their claim, but only to show that they [are] likely to succeed on the merits." Glossip v. Gross, 135 S. Ct. 2726, 2792 (2015); Winter v. Nat. Res. Def. Council, Inc., 555 U.S. 7, 22 (2008).

While the burden of persuasion remains with the Plaintiffs, the "burdens at the preliminary injunction stage track the burdens at trial." Gonzales v. O Centro Espírita Beneficente Uniã do Vegetal, 546 U.S. 418, 428–30 (2006). For the purposes of a preliminary injunction, this burden of proof can be shifted to the party opposing the injunctive relief after a *prima facie* showing, and the movant should be deemed likely to prevail if the non-movant fails to make an adequate showing. Id.

(1) Plaintiffs Have Standing

Plaintiffs have standing to assert these claims. They have demonstrated that they have "(1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that it is likely to be redressed by a favorable decision." Lujan v. Defs. of Wildlife, 504 U.S. 555, 560-61 (1992).

Plaintiffs have alleged specific physical injuries caused by the Vaccines, death caused by the Vaccines, actual and threatened loss of employment, and violations of their constitutionally protected rights to personal autonomy, bodily integrity, and to work in a profession of their choosing, each of which constitutes "an invasion of a legally protected interest" that is "concrete," "particularized," and "actual or imminent, not conjectural or hypothetical" as required under Spokeo, Inc. v. Robins, 136 S.Ct. 1540, 1548 (2016). Their pleadings are supported by Declarations made under oath.

The participation of third parties in the chain of causation does not defeat Plaintiffs' claims or their standing, since their injuries are "fairly traceable" to the Defendants. *See* Simon

v. Eastern Kentucky Welfare Rights Org., 426 U.S. 26, 45 n.25 (1976) (noting cases providing that privately inflicted injury is traceable to government action if the injurious conduct "would have been illegal without that action"); National Wildlife Federation v. Hodel, 839 F.2d 694, 705 (D.C. Cir. 1988) ("The Supreme Court's decisions on this point show that mere indirectness of causation is no barrier to standing, and thus, an injury worked on one party by another through a third party intermediary may suffice."); Telephone and Data Systems, Inc. v. FCC, 19 F.3d 42, 47 (D.C. Cir. 1994) ("injurious private conduct is fairly traceable to the administrative action contested in the suit if that action authorized the conduct or established its legality" . . . "the relief sought would constitute a 'necessary first step on a path that could ultimately lead to relief fully redressing the injury'" . . . "the relief requested 'will produce tangible, meaningful results in the real world.'"); Motor & Equip. Mfrs. Ass'n v. Nichols, 142 F.3d 449, 457-58 (D.C. Cir. 1998) (petitioner had standing to challenge government action based on the independent conduct of third parties where evidence demonstrated that the challenged action "resulted in an almost unanimous decision" by those third parties to take action that harmed the petitioner); America's Community Bankers v. FDIC, 200 F.3d 822, 827-28 (D.C. Cir. 2000) ("an agency does not have to be the direct actor in the injurious conduct, but that indirect causation through authorization is sufficient to fulfill the causation requirement for Article III standing."); Consumer Federation of America v. F.C.C., 348 F.3d 1009, 1012 (D.C. Cir. 2003) ("When an agency order permits a third-party to engage in conduct that allegedly injures a person, the person has satisfied the causation aspect of the standing analysis.").

A favorable decision of this Court will likely redress Plaintiffs' injuries. The Vaccine-injured Plaintiffs continue to suffer the adverse effects of the Defendants' wrongdoing, and their physical injuries are still unfolding. Their personal injuries can be redressed in the usual way, by

an award of civil money damages for pain and suffering, emotional distress, economic loss and medical monitoring.

(2) Defendants' Actions are Reviewable

Plaintiffs have alleged that there is no real emergency as required by § 360bbb–3(b), that Defendants have willfully failed to satisfy the statutory criteria for issuing the Vaccine EUAs required by § 360bbb–3(c), and that Defendants have failed to create and maintain the conditions of authorization for the Vaccine EUAs required by § 360bbb–3(e) (Counts I, II, III and VI).

The Administrative Procedures Act ("APA") imposes four requirements that must be met before a federal court can review agency action: (1) the alleged injury must "arguably" be within the "zone of interests" protected or regulated by the statute in question, (2) no statute precludes judicial review, (3) the agency action is "final" and (4) the agency action is not "committed to agency discretion" by law.

i. Plaintiffs' Injuries are Within the Zone of Interests

The "zone of interests" test is "*not* 'especially demanding'" Lexmark Int'l, Inc. v. Static Control Components, Inc., 572 U.S. 118, 130 (2014) (quoting Match-E-Be-Nash-She-Wish Band of Pottawatomi Indians v. Patchak, 567 U.S. 209, 225 (2012)). The Supreme Court has "conspicuously included the word 'arguably' in the test to indicate that the benefit of any doubt goes to the plaintiff. " Id. The test "'forecloses suit only when a plaintiff's interests are so marginally related to or inconsistent with the purposes implicit in the statute that it cannot reasonably be assumed that' Congress authorized that plaintiff sue." Collins v. Mnuchin, 938 F.3d 553, 574 (5th Cir. 2019) (quoting Lexmark, 572 U.S. at 130.). The Vaccine injuries and death, and the violations of the constitutionally protected right to bodily integrity and personal autonomy that Plaintiffs assert in the Complaint, are within the zone of interests protected by these statutory provisions, the purpose of which is to tightly limit the circumstances in which

potentially harmful medical products can be placed in the stream of commerce and used by the American public prior to their full approval by the FDA.

ii. No Statutory Preclusion

Plaintiffs can locate no valid statute purporting to preclude judicial review of this agency action, either categorically, or prior to the exhaustion of administrative remedies.

Defendants may cite to 42 U.S.C. § 247d-6d(b)(7), a provision of the Public Readiness and Emergency Preparedness Act ("PREP Act"), which states: "No court of the United States, or of any State, shall have subject matter jurisdiction to review, whether by mandamus or otherwise, any action by the Secretary under this subsection." However, a "strong presumption in favor of judicial review of administrative action" governs the construction of potentially jurisdiction-stripping provisions like § 247d-6d(b)(7). INS v. St. Cyr, 533 U.S. 289, 298 (2001). "Even when the ultimate result is to limit judicial review, the Court cautions that as a matter of the interpretive enterprise itself, the narrower construction of a jurisdiction-stripping provision is favored over the broader one." ANA Inti'l Inc. v. Way, 393 F.3d 886, 891 (2004) (citing to Reno v. American-Arab Anti-Discrimination Committee, 525 U.S. 471, 480-482 (1999)); see also Patel v. United States AG, 917 F.3d 1319, Fn. 4 (11th Cir. 2019) ("We are also mindful that there is a strong presumption in favor of interpreting statutes to allow judicial review of administrative actions; consequently, jurisdiction stripping is construed narrowly."), (citing to Kucana v. Holder, 558 U.S. 233, 251-252 (2010).

Thus the prohibition on judicial review in § 247d-6d(b)(7) must be construed narrowly so as to apply exclusively and specifically to declarations conferring the PREP Act "immunity" described in § 247d-6d(a), which are the only declarations made by the Secretary under "this subsection." Section 247d-6d(b)(1) refers to the Secretary's having first and beforehand made a declaration that a public health emergency exists (a declaration that is made under an entirely

different statute, 21 U.S.C. § 360bbb–3(b)), and states that if such a public health emergency declaration has been made, then the Secretary may confer PREP Act immunity by publishing a notice of same in the Federal Register.

Any broader interpretation of § 247d-6d(b)(7) — and in particular, any broader interpretation that purports to categorically eliminate judicial review of actions taken under § 360bbb–3 — is an unconstitutional delegation of legislative power by Congress to the executive branch. It is unconstitutional for three reasons. First, it is unconstitutional because it is devoid of any "'intelligible principle' on which to judge the conformity of agency action to the congressional grant of power." Florida v. Becerra, 2021 U.S. Dist. LEXIS 114297 (M.D. Fl. 2021) (quoting J.W. Hampton, Jr., & Co. v. Unitd States, 276 U.S. 394, 409 (1928)). Further, it purports to categorically exclude, rather than merely limiting, all judicial review. Finally, it is unconstitutional because it purports to eliminate judicial review in that most constitutionally perilous of situations, a state of emergency unilaterally declared and sustained by an executive branch official.

In Home Building and Loan Association v. Blaisdell, 290 U.S. 398 (1934), the U.S. Supreme Court stated: "Whether an emergency exists upon which the continued operation of the law depends is always open to judicial inquiry." 290 U.S. at 442, citing Chastleton Corp. v. Sinclair, 264 U.S. 543 (1924). In Sinclair, the Supreme Court stated: "A law depending upon the existence of emergency or other certain state of facts to uphold it may cease to operate if the emergency ceases or the facts change." 264 U.S. at 547. Both Blaisdell and Sinclair are clear authority that an emergency and the rules promulgated thereunder must end when the facts of the situation no longer support the continuation of the emergency. They also forbid this Court to merely assume the existence of a "public health crisis" based on the pronouncements of the Executive Defendants. They are clear authority that it is the duty of the court of first instance to

grapple with this question and conduct an inquiry. "[A] Court is not at liberty to shut its eyes to an obvious mistake when the validity of the law depends upon the truth of what is declared." Id. The Sinclair court instructed lower court's to inquire into the factual predicate underlying a declaration of emergency, where there appears to have been a change of circumstances: "the facts should be gathered and weighed by the court of first instance and the evidence preserved for consideration by this Court if necessary." 264 U.S. at 549.

In Sterling v. Constantin. 287 U.S. 378 (1932), the Supreme Court reviewed the actions of the Texas Governor in declaring martial law and interfering with oil well production in a manner that impaired private drilling rights. In holding that the question whether an emergency existed justifying such interference with the plaintiffs' property rights was subject to judicial inquiry and determination, the Court stated:

> *If this extreme position could be deemed to be well taken, it is manifest that the fiat of a state governor, and not the Constitution of the United States, would be the supreme law of the land; that the restrictions of the federal Constitution upon the exercise of state power would be but impotent phrases, the futility of which the state may at any time disclose by the simple process of transferring powers of legislation to the Governor to be exercised by him, beyond control, upon his assertion of necessity. Under our system of government, such a conclusion is obviously untenable. There is no such avenue of escape from the paramount authority of the federal Constitution. When there is a substantial showing that the exertion of state power has overridden private rights secured by that Constitution, the subject is necessarily one for judicial inquiry in an appropriate proceeding directed against the individuals charged with the transgression.*

287 U.S. at 397-98.

Similarly, the actions of the Secretary must be subject to judicial review. Under 21 U.S.C. § 355(q)(1)(A), the DHHS Secretary

> *shall not delay approval of a pending application [ ] because of any request to take any form of action relating to the application, either before or during consideration of the request, unless — (i) the request is in writing and is a petition submitted to the Secretary pursuant to section 10.30 or 10.35 of title 21, Code of Federal Regulations . . .*

21 C.F.R. § 10.30 in turn provides for so called "citizen petitions" which are a form of administrative redress. However, a close reading of the statutory language and due consideration of the underlying policies compel the conclusion that Congress did not intend to preclude judicial review of this particular agency action.

Section 355(q) could easily state that interested parties "shall not pursue" (or the equivalent) lawsuits prior to the completion of the citizen petition process. It does not. Instead, the only mandatory language in § 355(q) is directed at the Secretary, not at citizens, and it states that the Secretary "shall not delay". This language is intended to target the predominant, anti-competitive mischief marring the FDA approval process at the time the statute was enacted. Entrenched market participants abused the citizen petition process by soliciting citizenry to file petitions for the improper purpose of delaying applications for new drug approval submitted by new market entrants.[46] Senator Edward Kennedy explained: "The citizen petition provision is designed to address attempts to derail generic drug approvals. Those attempts, when successful, hurt consumers and the public health."[47] The statutory language should be read narrowly in accordance with that purpose, to apply only to the "approval of a pending application" which should not be delayed.

Plaintiffs here are seeking first and foremost the **revocation** or **termination** of the declared emergency and existing Vaccine EUAs, and not for anti-competitive purposes, but in order to respond to unlawful agency action driven by financial conflicts of interest, political pressure and fear, the substantial risk of widespread personal injury and death, and constitutional infractions.

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[46] See *Citizen Petitions: An Empirical Study*, 34 Cardozo L. Rev. 249, 252 (2012) ("The study finds that brand drug companies file 68% of petitions, far more than generic firms or other parties such as universities, doctors or hospitals. Of the petitions by brand firms, more than 75% target generic entrants.").

[47] 153 Cong. Rec. 25,047 (2007).

Further, neither 21 U.S.C. § 355 nor 21 C.F.R. § 10.30 expressly references § 360bbb–3, the statute pursuant to which the emergency has been declared and the Vaccines released to the public. Conversely, § 360bbb–3 does not expressly refer to 21 U.S.C. § 355 nor 21 C.F.R. § 10.30. If Congress had intended for the citizen petition process — designed to address the specific mischief of anti-competitive behavior — to apply to the very particular and very different circumstances of an emergency use authorization of highly experimental and potentially dangerous medical interventions with the potential to rapidly injure or kill large swathes of the American populace, surely it would have said so. Plaintiffs are the current and future Vaccine-injured in a time of purported emergency, complaining of gross agency malfeasance and conflicts of interest, not profit-seeking market participants.

Neither should the judicial doctrine of "exhaustion of administrative remedies" bar judicial review. "[J]udicially created exhaustion requirements are 'subject to numerous exceptions.'" Georgia v. United States, 398 F.Supp. 1330, 1343 (S.D. Ga. 2019) (quoting Kentucky v. United States ex rel. Hagel, 759 F.3d 588, 599 (6th Cir. 2014)). In their discretion, the district courts

> *"…have recognized at least three prudential exceptions to exhaustion requirements. [ ] Exhaustion may be excused if a litigant can show: (1) that requiring exhaustion will result in irreparable harm; (2) that the administrative remedy is wholly inadequate; or (3) that the administrative body is biased, making recourse to the agency futile."*

Id. (quoting Kansas Dept. for Children and Families v. SourceAmerica, 874 F.3d 1226, 1250 (10th Cir. 2017) ("We permit district courts to excuse a failure to exhaust where '(1) the plaintiff asserts a colorable constitutional claim that is collateral to the substantive issues of the administrative proceedings, (2) exhaustion would result in irreparable harm, and (3) exhaustion would be futile.'")).

Courts have recognized exceptions to the requirement of administrative exhaustion in the specific context of the FDCA and 21 C.F.R. § 10.30. *See, e.g.*, Biotics Research Corp. v. Heckler, 710 F.2d 1375, 1378 (9th Cir. 1983) ("Biotics and Seroyal admit failing to take advantage of this available administrative remedy, but argue that the administrative remedy is 'inadequate and not efficacious' and that its pursuit would have been a 'futile gesture.' **Although we recognize an exception to the exhaustion requirement in these circumstances**, there is nothing in the record to indicate that a citizens petition to the Commissioner would have been ineffective or futile." (emphasis added)) (citing to AMP Inc. v. Gardiner, 275 F.Supp. 410 (S.D.N.Y. 1967), aff'd, 389 F.2d 825 (2d Cir. 1968), cert. denied, 393 U.S. 825 (1968); Premo Pharmaceutical Laboratories, Inc. v. United States, 629 F.2d 795, 801 (2d Cir. 1980), Natick Paperboard Corp. v. Weinberger, 498 F.2d 125, 128-29 (1st Cir. 1974).

The record in this case contains abundant evidence that the citizen petition process is both "inadequate and not efficacious". First and most importantly, the FDA need not respond to a citizen petition for 5 months, and in fact as a practical matter the "deadline" is more honored in the breach than the observance. When the FDA does respond, its response may be indeterminate. The chart below constructed from VAERS data shows that the American public cannot afford to wait for 5 months, while physical injuries and deaths due to the Vaccine skyrocket. Jane Doe's expert testimony that the true number of deaths caused by the Vaccine is in excess of 45,000 (*see* Declaration at Ex. D) renders the Defendants' likely argument that Plaintiffs must muddle through the citizen petition process before bringing this litigation not just legally absurd, but inhumane.

VAERS DATA		
APRIL 23, 2021	**JULY 2, 2021**	**% INCREASE**
118,902 ADVERSE EVENTS	438,441 ADVERSE EVENTS	72.88%
3,544 DEATHS	9,048 DEATHS	60.83%
12,619 INJURIES	41,015 INJURIES	69.23%

Plaintiff AFLDS' experience with the citizen petition process to date substantiates the argument. The Complaint alleges that Defendants are suppressing information regarding the availability of safe and effective alternative prophylaxis and treatments for COVID-19, including for example hydroxychloroquine (ECF 10, ¶¶ 219-228). Plaintiff AFLDS filed a citizen petition regarding hydroxychloroquine on October 12, 2020, requesting that the FDA exempt hydroxychloroquine-based drugs from prescription-dispensing requirements and make them available to the public over-the counter (*see* Citizen Petition at Exhibit E). The FDA acknowledged receipt of the petition on October 13, 2020. (*see* FDA Acknowledgment Letter at Exhibit F). Then on April 8, 2021, the FDA wrote to AFLDS to say that it "has been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by Agency officials." (*see* FDA Delay Letter at Exhibit G). As recently as June 21, 2021 the FDA has confirmed by email that it has no substantive response to the Citizen's Petition, responding to AFLDS' request for an update by referring back to the FDA's April 8 delay letter! The issues raised in the Complaint and in this Motion would almost certainly be claimed to be equally or more complex, and there is no reason whatsoever to believe that the FDA will respond substantively to them within the statutory deadline, or in any amount of time shorter than the 10 months that have passed since the hydroxychloroquine petition was filed. All of this is becomes

even more relevant in light of the fact that while a response to a citizen's petition is put off for many months, the vaccines were approved with no delay.

Not only is the citizen petition process fatally slow, the FDA is ultimately powerless to award civil money damages for the physical injury and death that have invaded Plaintiffs' constitutional right to personal autonomy and bodily integrity. These are irreparable injuries. Winck v. England, 327 F.3d 1296, 1304 (11th Cir. 2003) (("[exhaustion] is not required where no genuine opportunity for adequate relief exists, **irreparable injury** will result if the complaining party is compelled to pursue administrative remedies, or an administrative appeal would be futile") (emphasis added)).

The pursuit of a citizen petition is also a "futile gesture" since the FDA will not grant the relief requested by Plaintiffs. An empirical study has shown that the mean and median citizen petition grant rates fluctuated between 0% and 16% in the eight years from 2003 through 2010, and the mean and median denial rates were both 92%.[48] The real and substantial financial conflicts of interest compromising the Defendants and their key officials involved in the § 360bbb–3 process (*see* Complaint, ECF 10, ¶¶ 250-256), combined with the immense pressure[49] placed on the FDA by industry and politicians to fast track the approval process, and Jane Doe's revelation that the Defendants have intentionally concealed from the public that the true number of deaths caused by the Vaccines is at least 45,000 not the approximately 9,000 reported by VAERS (*see* Declaration at Ex. D), destroy any pretense that the FDA could adjudicate such a citizen petition with fairness and impartiality.

The policy justification traditionally cited by those courts that have required compliance with the citizen petition process do not apply here. *See, e.g.*, Garlic v. United States Food &

[48] *Citizen Petitions: An Empirical Study*, 34 Cardozo L. Rev. at 275.
[49] Gardner, L., "Calls Mount on FDA to Formally Endorse COVID Vaccines as Delta Surges" (July 8, 2021). *See* https://news.yahoo.com/calls-mount-fda-formally-endorse-182622109.html (last visited July 12, 2021).

Drug Administration, 783 F.Supp. 4, 5 (D. D.C. 1992) ("Allowing 'interested parties' to bypass the administrative remedies would undermine the entire regulatory process. Drug manufacturers could circumvent the FDA's procedures by soliciting private citizens to sue for judicial approval new medications."). Plaintiffs are not attempting to circumvent the substantive provisions of § 360bbb–3 in order to force the approval and release of a new experimental drug, rather they are trying to force the FDA, its officials riddled with serious conflicts of interests, to comply with these provisions in order prevent widespread personal injury and death and egregious violations of the constitutionally protected rights to personal autonomy and bodily integrity.

Count VI of the Complaint seeks mandamus, since there is "'practically no other remedy.'" Collin v. Berryhill, 2017 U.S. Dist. LEXIS 78222 at *9 (quoting Helstoski v. Meanor, 442 U.S. 500, 505 (1979). Courts have held that the perceived medical urgencies created by COVID-19 itself, and also those created by the decisions, orders and actions of authorities responding to COVID-19, can make it impractical and inappropriate to force a plaintiff seeking *mandamus* to wait for alternative processes to run their course:

> *Moreover, given the broader context of the COVID-19 pandemic, we agree with the Fifth Circuit that "[i]n mill-run cases, it might be a sufficient remedy to simply wait for the expiration of the TRO, and then appeal an adverse preliminary injunction. In other cases, a surety bond may ensure that a party wrongfully enjoined can be compensated for any injury caused. Those methods would be woefully inadequate here."*

In re Rutledge, 956 F.3d 1018, 1026 (8th Cir. 2020), quoting In re Abbott, 2020 U.S. App. LEXIS 10893 at *14.[50]

[50] The Supreme Court subsequently vacated the judgment in In re Abbott, and remanded to the Fifth Circuit with instructions to dismiss the case as moot, following the Texas Governor's relaxation of his order restricting abortion as a non-essential surgical procedure, however the decision did not turn on an analysis of mandamus. *See*, Planned Parenthood Ctr. for Choice v. Abbott, 2021 U.S. LEXIS 647.

iii. The Emergency Declaration and the EUAs are "Final" Agency Action

In order to be deemed "final", an agency action (1) "must mark the consummation of the agency's decision-making process — it must not be of a merely tentative or interlocutory nature" and (2) "must be one by which rights or obligations have been determined, or from which legal consequences will flow." United States Corps of Eng'rs v. Hawkes Co., 136 S.Ct. 1807, 1813 (2016) (quoting Bennett v. Spear, 520 U.S. 154, 177-178 (1997)).

After fact-finding and consultation, the DHHS Secretary declared, under § 360bbb–3(b), that there is an emergency. Once issued, his declaration remained valid for a period of time and was serially renewed. The declaration is not merely "advisory in nature." Id. It represents the "consummation of the decision-making process" with respect to whether or not an emergency exists. The declaration also gives rise to "'direct and appreciable legal consequences.'" Id. at 1814. The declaration paved the way for Pfizer, Moderna and Janssen to apply for EUAs for their experimental Vaccines, for the DHHS Secretary and his designee the FDA Commissioner to adjudicate and approve their EUA applications, and for the Vaccines to be released into interstate commerce and injected into millions of Americans.

The FDA Commissioner engaged in fact-finding and made vital determinations that the statutory criteria for issuing the Vaccine EUAs required by § 360bbb–3(c) were met, and that the conditions of authorization for the Vaccine EUAs required by § 360bbb–3(e) were also met. On that basis, the Vaccine EUAs were issued. The issuance of the Vaccine EUAs represents the "consummation of the decision-making process" with respect to whether or not EUAs will be granted, and also gave rise to "'direct and appreciable legal consequences'" since millions of people have been injected with these experimental Vaccines while their manufacturers have made billions of dollars in revenues under an immunity shield.

iv. Not "Committed to Agency Discretion"

The emergency declaration is not committed to agency discretion by law. Section 360bbb–3(b)(1) states that the DHHS Secretary "may" make a declaration, but then proceeds to enumerate in detail the limited bases upon which the declaration may be made, at least three of which prohibit unilateral declarations by the Secretary by requiring consultation with or the prior decisions of other cabinet-level executive branch officials. Section 360bbb–3(b)(3) prohibits the Secretary from unilaterally terminating the declaration. This is not a broad grant of discretion, but even if it were, "[t]he fact that a statute grants broad discretion to an agency does not render the agency's decisions completely unreviewable unless the statutory scheme, taken together with other relevant materials, provides absolutely no guidance to how that discretion is to be exercised." Louisiana v. Biden, 2021 U.S. Dist. LEXIS 112316 * 40-41 (W. D. La. 2021).

Section 360bbb–3(b)(1)(c) is the sole ground for an emergency that does not seem to require consultation with or the prior decisions of other cabinet-level executive branch officials, and it provides guidance to the Secretary by requiring him to make a 4-pronged finding that (parsing the statute): (i) there is a "public health emergency" (ii) that "affects, or has a significant potential to affect" (iii) (a) "national security" or (b) "the health and security United States citizens living abroad", and (iv) that "involves" (a) "a biological, chemical, radiological, or nuclear agent or agents" or (b) "a disease or condition that may be attributable to such agent or agents."

Similarly, the EUAs are not committed to agency discretion by law. Under § 360bbb–3(c), the Secretary "may issue an authorization" but "only if" after consultation with three other executive branch officials, he is able to make at least four different findings. Under § 360bbb–3(e), the Secretary "shall" ensure that certain "required conditions" of authorization, set forth in detail in the statute, are met. Since the Secretary does not have unfettered discretion to issue

EUAs, he must follow detailed guidance as to how any discretion granted to him by the statute is exercised. Id.

In addition to their Counts seeking judicial review of agency action and mandamus, Plaintiffs have also alleged physical injury, death and loss of employment proximately caused, aided and abetted by Defendants' actions, justifying an award of civil money damages under Bivens v. Six Unknown Named Agents of Federal Bureau of Narcotics, 403 U.S. 388 (1971) (Count VII). By issuing and maintaining the EUAs in these circumstances, the Defendants are enabling the shipment of the Vaccines in interstate commerce, and their use by third parties who actually administer them to the public. Defendants, as joint tortfeasors, are purposefully aiding and abetting the infliction of physical injury and death on Plaintiffs and countless other Americans, all in violation of their constitutionally protected right to personal autonomy and bodily integrity.

Guertin v. Michigan, 912 F.3d 907 (6th Cir. 2019) is a case arising out of the infamous Flint Water Crisis. 912 F.3d at 907-915. The City of Flint Michigan instituted cost-saving measures, and used outdated equipment to treat water before delivering it to residents. Id. Residents consumed the water, now contaminated with lead and *e coli* bacteria. Id. Their hair fell out and they developed rashes. Id. Some died from an associated spike in Legionnaire's disease. Id. Children tested positive for dangerously high blood levels. Id.

The 6th Circuit Court of Appeals upheld the district court's denial of defendants' motion to dismiss 42 U.S.C. § 1983 substantive due process claims based on qualified immunity, because plaintiffs had plead a plausible Fourteenth Amendment violation of their right to bodily integrity, where the City's knowing decision to use outdated equipment and mislead the public about the safety of its water shocked the conscience. Id. The Court admonished:

> ***[K]nowing the Flint River water was unsafe for public use, distributing it without taking steps to counter its problems, and assuring the public in the meantime that it was safe*** *"is conduct that would alert a reasonable person to the likelihood of liability." [ ] [T]aking affirmative steps to systematically contaminate a community through its public water supply with deliberate indifference is a government invasion of the highest magnitude. Any reasonable official should have known that doing so constitutes conscience-shocking conduct prohibited by the substantive due process clause. These "actions violate the heartland of the constitutional guarantee" to the right of bodily integrity…*

Id. at 933 (emphasis added).

The language of this decision ought to send a chill through each of the individually named Defendants, for their conduct — albeit distributing dangerous experimental Vaccines, rather than contaminated water — is effectively a mirror image. This is indisputably so with respect to the under-18 age category, and those previously infected with SARS-CoV-2. Since SARS-CoV-2 / COVID-19 present no statistically significant threat to these subpopulations, the Vaccines can have no therapeutic benefits for them. At the same time, the experimental Vaccines, which have known, dangerous side effects and in some cases are even fatal, expose them to unnecessary and dangerous risks.

B. Irreparable Injury

The test does not require that harm actually occur, or that it be certain to occur. *See* Whitaker v. Kinosha Unified School District, 858 F.3d 1034, 1044 (7th Cir. 2017). Rather, "[w]e have indicated that the injury suffered by a plaintiff is 'irreparable only if it cannot be undone through monetary remedies.'" Siegel v. LePore, 234 F.3d 1163, 1191 at Fn. 4 (11th Cir. 2000), quoting Cunningham v. Adams, 808 F.2d 815, 821 (11th Cir. 1987).

The actual or threatened violation of core constitutional rights is presumed irreparable. Id., citing *inter alia* Deerfield Med. Ctr. v. City of Deerfield Beach, 661 F.2d 328 (5th Cir. 1981) (irreparable injury presumed based on threats to access to abortion services implicating the 14th Amendment right to privacy); Robinson v. Attorney General, 957 F.3d 1171, 1177 (11th Cir.

2020) (denying motion for stay of preliminary injunction enjoining public health order issued in response to COVID-19 pandemic because it invaded constitutionally protected 14th Amendment rights); Jolly v. Coughlin, 76 F.3d 468, 473 (2d Cir. 1996) ("In any event, it is the alleged violation of a constitutional right that triggers a finding of irreparable harm."); Mitchell v. Cuomo, 748 F.2d 804, 806 (2d Cir. 1984) ("'When an alleged deprivation of a constitutional right is involved, most courts hold that no further showing of irreparable injury is necessary.'").

In Planned Parenthood v. Casey, 505 U.S. 833, 857 (1992), the U.S. Supreme Court stated:

> *Roe, however, may be seen not only as an exemplar of Griswold liberty, but as a rule (whether or not mistaken) of personal autonomy and bodily integrity, with doctrinal affinity to cases recognizing limits on governmental power to mandate medical treatment or to bar its rejection. If so, our cases since Roe accord with Roe's view that a State's interest in the protection of life falls short of justifying any plenary override of individual liberty claims.* Cruzan v. Director, Mo. Dept. of Health, *497 U.S. 261, 278, 111 L. Ed. 2d 224, 110 S. Ct. 2841 (1990); cf., e. g.,* Riggins v. Nevada, *504 U.S. 127, 135, 118 L. Ed. 2d 479, 112 S. Ct. 1810 (1992);* Washington v. Harper, *494 U.S. 210, 108 L. Ed. 2d 178, 110 S. Ct. 1028 (1990); see also, e. g.,* Rochin v. California, *342 U.S. 165, 96 L. Ed. 183, 72 S. Ct. 205 (1952);* Jacobson v. Massachusetts, *197 U.S. 11, 24-30, 49 L. Ed. 643, 25 S. Ct. 358 (1905).*

To reiterate: "a State's interest in the protection of life falls short of justifying any plenary override of individual liberty claims." *See also* Washington v. Glucksberg, 521 U.S. 702, 720 (1997) ("the 'liberty' protected by the Due Process Clause [of the Fourteenth Amendment] includes the right[] . . . to bodily integrity"); Shillingford v. Holmes, 634 F.2d 263, 265 (5th Cir.1981) ("the right to be free of state-occasioned damage to a person's bodily integrity is protected by the fourteenth amendment guarantee of due process."); Doe v. Moore, 410 F.3d 1337, 1343 (11th Cir. 2005) ("The Supreme Court has recognized that fundamental rights include those guaranteed by the Bill of Rights as well as certain 'liberty' and privacy interests implicit in the due process clause and the penumbra of constitutional rights. These special

'liberty' interests include 'the rights to marry, to have children, to direct the education and upbringing of one's children, to marital privacy, to use contraception, to bodily integrity, and to abortion.'").

Further, the Supreme Court has stated that the protected liberty claims inherent in personal autonomy and bodily integrity include both the right *to be free from* unwanted medical intervention, and the right *to obtain* medical intervention:

> *As the joint opinion acknowledges, ante, 505 U.S. at 857, this Court has recognized the vital liberty interest of persons in refusing unwanted medical treatment. Cruzan v. Director, Mo. Dept. of Health, 497 U.S. 261, 111 L. Ed. 2d 224, 110 S. Ct. 2841 (1990). Just as the Due Process Clause protects the deeply personal decision of the individual to refuse medical treatment, it also must protect the deeply personal decision to obtain medical treatment, including a woman's decision to terminate a pregnancy.*

Casey, 505 U.S. at 927.

In the Supreme Court's seminal "right to die" case, Cruzan v. Director, Missouri Dept. of Health, 497 U.S. 261 (1990), it addressed whether an individual in a persistent vegetative state could require a hospital to withdraw life-sustaining medical care based on her right to bodily integrity. 479 U.S. at 265-69. Chief Justice Rehnquist noted that "[b]efore the turn of this century, [the Supreme Court] observed that 'no right is held more sacred, or is more carefully guarded, by the common law, than the right of every individual to the possession and control of his own person, free from all restraint or interference of others, unless by clear and unquestionable authority of law.'" Id. at 269 (quoting Union Pacific R. Co. v. Botsford, 141 U.S. 250, 251 (1891). He continued: "This notion of bodily integrity has been embodied in the requirement that informed consent is generally required for medical treatment," Id. at 269, "generally encompass[es] the right of a competent individual to refuse medical treatment," Id. at 277, and is a right that "may be inferred from [the Court's] prior decisions." Id. at 278-79 (citing Jacobson v. Massachusetts, 197 U.S. 11 (1905); Breithaupt v. Abram, 352 U.S. 432 (1957);

Washington v. Harper, 494 U.S. 210 (1990); Vitek v. Jones, 445 U.S. 480 (1980); Parham v. J.R., 442 U.S. 584 (1979).).

In Deerfield, the case relied upon by the 11th Circuit in Siegel, a medical group attempted to establish a medical facility to provide abortion services. 661 F.2d at 330-332. The city denied their application for an occupational license on various grounds. Id. The medical group sued the city alleging that the city's actions violated the "right to privacy" in the due process clause of the 14th Amendment by depriving women of access to abortion services, even though any potential constitutional violation was minimized by the presence of other abortion facilities operating in the area. Id. The medical group moved for a preliminary injunction, and the district court denied the motion. Id.

The 5th Circuit reversed, adopting an aggressive, prophylactic approach to the protection of the constitutional right to privacy. "[T]he right of privacy must be carefully guarded for once an infringement has occurred it cannot be undone by monetary relief." Id. at 338, citing to Kennan v. Nichol, 326 F. Supp. 613, 616 (W.D.Wis.1971), aff'd mem., 404 U.S. 1055, 92 S. Ct. 735, 30 L. Ed. 2d 743 (1972) ("to withhold a temporary restraining order is to permit the (constitutional right of privacy) to be lost irreparably with respect to the physician and those women for whom he would otherwise perform the operation in the meantime."). It continued: "We have already determined that the constitutional right of privacy is 'either **threatened** or in fact being impaired', and **this conclusion mandates a finding of irreparable injury**" (emphasis added). Id. at 338, citing to Elrod v. Burns, 427 U.S. 347, 373 (1976).

The Defendants are both violating, and threatening the violation of, the core constitutional right to personal autonomy and bodily integrity held by Plaintiffs and all Americans. Plaintiffs Brittany Galvin (*see* Declaration of Brittany Galvin at Exhibit J), Aubrey Boone, Snow Mills, Angelia Deselle (*see* Declaration of Angelia Deselle at Exhibit H), Kristi

Simmonds, Vidiella A/K/A Shawn Skelton (*see* Declaration of Shawn Skelton at Exhibit I) and the Estate of Dovi Sanders Kennedy have alleged that their rights to personal autonomy and bodily integrity were violated when they were subjected to Vaccines without first having given voluntary, informed consent. Plaintiffs have also attached the Declaration of Diana Hallmark, a resident of Blount County, Alabama, containing the same allegations (*see* Declaration of Diana Hallmark at Exhibit K).[51] These victims testify under penalty of perjury to their physical injuries caused by the Vaccines, and to facts and circumstances that establish that they did not give, and could not possibly have given, their voluntary, informed consent. By way of example, Plaintiff Deselle states (Ex. H):

> *No one ever provided me with any information regarding possible adverse reactions, nor did they provide me with any information regarding alternative treatments. I did not understand this was gene therapy rather than a traditional vaccine. Again, I also did not understand that the Vaccines were not "approved" by the FDA. No one told me, and I did not understand that the Vaccines were not determined to be "safe and effective" by anyone — only that it was "reasonable to believe" that they were.*

In addition to constitutional infringements, physical injury and death may constitute irreparable harm justifying preliminary injunctive relief. *See* Chastain v. Northwest Ga. Hous. Auth., 2011 U.S. Dist. LEXIS 135712 (N.D. Ga. 2011) (possibility of worsening health following eviction from public housing); Garcia v. Google, Inc., 766 F.3d 929, (9th Cir. 2014), aff'd on rehearing en banc, 786 F.3d 733 (9th Cir. 2015) ("[I]t is not irrelevant that the harm Garcia complains of is death or serious bodily harm, which the dissent fails to mention. Death is an 'irremediable and unfathomable' harm, and bodily injury is not far behind. To the extent the irreparable harm inquiry is at all a close question, we think it best to err on the side of life."); Seniors Civil Liberties Ass'n v. Kemp, 761 F.Supp. 1528, 1537 (M.D. Fla. 1991) (possibility of

[51] Plaintiffs anticipate amending the Complaint for the purpose of *inter alia* adding Diana Hallmark to it as a named Plaintiff.

physical injury or death arising from police chokeholds). Plaintiffs Brittany Galvin (Ex. J), Aubrey Boone, Snow Mills, Angelia Deselle (Ex. H), Kristi Simmonds, Vidiella A/K/A Shawn Skelton (Ex. I) and the Estate of Dovi Sanders Kennedy have alleged that the Vaccines have caused them grave physical injury and, in the case of Dovi Sanders, also death. Diana Hallmark has made the same allegations (Ex. K).

The court may consider the harm to the public in assessing whether irreparable injury would result from the denial of an injunction. In Hornbeck Offshore Servs., LLC v. Salazar, 696 F.Supp. 2d 627 (E.D. La. 2010) the court granted a motion for preliminary injunction enjoining a federal agency decision to suspend drilling operations in the Gulf of Mexico, finding irreparable harm based on the harm to the public generally:

> *The defendants trivialize [Plaintiffs' losses] by characterizing them as merely a small percentage of the drilling rigs affected [ ] [C]ourts have held that in making the determination of irreparable harm, "both harm to the parties and to the public may be considered. The effect on employment, jobs, loss of domestic energy supplies caused by the moratorium as the plaintiffs (and other suppliers, and the rigs themselves) lose business, and the movement of the rigs to other sits around the world will clearly ripple throughout the economy in this region.*

696 F.Supp. 2d at 638-639 (internal citations omitted).

In In re Northwest Airlines Corp., 349 B.R. 338, 384 (S.D.N.Y. 2006), aff'd, 483 F.3d 160 (2d Cir. 2007), the court granted a motion for preliminary injunction enjoining a flight attendants' union from carrying out threats to engage in a labor strike, finding irreparable harm based on the harm to the public generally:

> *"[I]n making the determination of irreparable harm, both harm to the parties and to the public may be considered."* * * Here, the record also demonstrates that the public will be harmed: as the Bankruptcy Court found, Northwest carries 130,000 passengers per day, has 1,200 departures per day, is the one carrier for 23 cities in the country, and provides half all airline services to another 20 cities.*

349 B.R. at 384 (quoting Long Island R. Co. v. Int'l Ass'n of Machinists, 874 F.2d 901, 910 (2d Cir. 1989)).

Like Plaintiffs Brittany Galvin (Ex. J), Aubrey Boone, Snow Mills, Angelia Deselle (Ex. H), Kristi Simmonds, Vidiella A/K/A Shawn Skelton (Ex. I), and the Estate of Dovi Sanders Kennedy, and like Diane Hallmark (Ex. K), millions of Americans have already suffered an outrageous violation of their constitutionally protected right to personal autonomy and bodily integrity, and millions more are vulnerable. According to the VAERS data, there have been 438,441 reported adverse events following injection with the Vaccines, including 9,048 deaths and 41,015 serious injuries, between December 14, 2020 and July 2, 2021. The evidence suggests the VAERS system reports only between 0.8% and 2% of all Vaccine adverse events. Plaintiffs' expert and whistleblower Jane Doe has testified that the true number of deaths caused by the Vaccines is at least 45,000 not the approximately 9,000 reported by VAERS (*see* Declaration at Ex. D). By contrast, the Swine Flu vaccine was removed from the market even though it caused only 53 deaths.

C. Balance of Equities (Hardships) and Public Interest

In each case involving a request for pretrial injunctive relief, the court "must consider the effect on each party of the granting or withholding of the requested relief." Winter, 555 U.S. at 24. The plaintiff "must establish . . . that the balance of hardships tips in his favor." Id. at 20.

"'[W]here the government is the party opposing the preliminary injunction, its interest and harm merge with the public interest.' Thus the Court proceeds with analyzing whether the threatened injury to Plaintiffs outweighs the harm that the preliminary injunction would cause Defendants and the public." Brown v. Azar, 497 F. Supp. 3d 1270, 1298 (N.D. Ga. 2020), quoting Swain v. Junior, 958 F.3d 1081, 1091 (11th Cir. 2020).

"[I]t is always in the public interest to prevent the violation of a party's constitutional rights." G & V Lounge, Inc. v. Mich. Liquor Control Comm'n, 23 F.3d 1071, 1079 (6th Cir. 1994). "The vindication of constitutional rights and the enforcement of a federal statute serve the public interest almost by definition." League of Women Voters of Fla. v. Browning, 863 F. Supp. 2d 1155, 1167 (N.D. Fla. 2012). On the other hand, "[t]here is generally no public interest in the perpetuation of unlawful agency action." League of Women Voters v. Newby, 838 F.3d 1, 12 (D.C. Cir. 2016).

Defendants themselves suffer no conceivable harm from the grant of the requested injunctions. A disease that has an overall survivability rate exceeding 99% — comparable to the seasonal flu and countless other ailments — does not create a public health emergency within the meaning of § 360bbb–3. SARS-CoV-2 and COVID-19 do not give rise to any countervailing public interest that justifies overriding the constitutionally protected right to personal autonomy and bodily integrity. This is so with respect to the entire American public, but even more acutely with respect to the under-18 age category and those previously infected with SARS-CoV-2.

IV. CONCLUSION

Accordingly, and for all of the foregoing reasons, Plaintiffs move under Rule 65, Fed.R.Civ.P., for a preliminary injunction against Defendants enjoining them from continuing to authorize the emergency use of the so-called "Pfizer-BioNTech COVID-19 Vaccine," "Moderna COVID-19 Vaccine" and the "Johnson & Johnson (Janssen) COVID-19 Vaccine" pursuant to their respective EUAs, and from granting full FDA approval of the Vaccines:

(i) for the under-18 age category;

(ii) for those, regardless of age, who have been infected with SARS-CoV-2 prior to vaccination; and

(iii) until such time as the Defendants have complied with their obligation to create and maintain the requisite "conditions of authorization" under Section 546 of the Food, Drugs and Cosmetics Act, 21 U.S.C. § 360bbb–

3(e), thereby enabling Vaccine candidates to give truly voluntary, informed consent.

Dated: July 19, 2021.

RESPECTFULLY SUBMITTED BY:

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CERTIFICATE OF SERVICE

I hereby certify that on this date, July 19, 2021, I electronically transmitted this pleading to the Clerk of the Court using the CM/ECF system for filing, which will send notification of such filing to the following counsel for the Defendants:

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FILED
2021 Jun-10 PM 02:52
U.S. DISTRICT COURT
N.D. OF ALABAMA

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ALABAMA

AMERICA'S FRONTLINE DOCTORS; and

JOEL WOOD, RPH; and

BRITTANY GALVIN; and

ELLEN MILLER,
Individually and as Guardian of
3 Minor Siblings; and

AUBREY BOONE; and

JODY SOBCZAK,
Individually and as Father of
2 Minor Children; and

DEBORAH SOBCZAK,
Individually and as Mother of
2 Minor Children; and

SNOW MILLS; and

JENNIFER MCCRAE, RN; and

ANGELLIA DESELLE; and

KRISTI SIMMONDS; and

VIDIELLA, A/K/A SHAWN SKELTON; and

SALLY GEYER; and

MARIA MEYERS; and

KARI HIBBARD; and

JULIE ROBERTS, RN; and

AMY HUNT; and

RICHARD KENNEDY, individually and as
Administrator of the Estate of his mother Dovi

Civil Action No.
2:21-cv-00702-CLM

COMPLAINT

Jury Trial Demanded

Sanders Kennedy; and)
)
ESTATE OF DOVI SANDERS KENNEDY, by)
and through its Administrator Richard Kennedy; and)
)
LYLE BLOOM,)
Individually and as Father of)
2 Minor Children; and,)
)
JULIE BLOOM,)
Individually and as Mother of)
2 Minor Children; and)
)
ANDREA MCFARLANE, RN,)
Individually and as Mother of)
4 Minor Children; and)
)
JENNIFER GREENSLADE,)
Individually and as Mother of)
2 Minor Children; and)
)
STEVEN M. ROTH, MD,)
Individually; and)
)
MATT SCHWEDER,)
Individually and as Father of)
a Minor Child.)
)
Plaintiffs,)
)
vs.)
)
XAVIER BECERRA, Secretary of the U.S.)
Department of Health and Human Services, in his)
official and personal capacities, DR. ANTHONY)
FAUCI, Director of the National Institute of)
Allergies and Infectious Diseases, in his official and)
personal capacities, DR. JANET WOODCOCK,)
Acting Commissioner of the Food and Drug)
Administration, in her official and personal)
capacities, U.S. DEPARTMENT OF HEALTH)
AND HUMAN SERVICES, the FOOD AND)
DRUG ADMINISTRATION, the CENTER FOR)
DISEASE CONTROL AND PREVENTION,)
NATIONAL INSTITUTE OF HEALTH,)
NATIONAL INSTITUTE OF ALLERGIES AND)

INFECTIOUS DISEASES, and JOHN AND JANE DOES I-V.)
)
)
Defendants.)
)

COMPLAINT[1]

I. NATURE OF THE CASE

1. On February 4, 2020, Alex M. Azar, II, the then serving Secretary of the Department of Health and Human Services ("DHHS"), exercising his authority under Section 546 of the Food, Drugs and Cosmetics Act, 21 U.S.C. § 360bbb-3, declared that the SARS-Cov-2 virus created a "public health emergency" that had a "significant potential to affect national security" (the "Emergency Declaration").

2. Based on the Declaration, the DHHS Secretary's designee, the Commissioner of the Food and Drug Administration ("FDA"), issued a series of Emergency Use Authorizations ("EUA") under § 360bbb-3. EUAs allow medical products that have not been fully tested and approved by the FDA to be sold to American consumers, in order to meet the exigencies of an emergency. Initially, the EUA medical products included various polymerase chain reaction ("PCR") tests marketed as COVID-19 diagnostic tools. Later, EUAs (collectively, the "Vaccine EUAs") were issued for the so-called "Pfizer-BioNTech COVID-19 Vaccine,"[2] "Moderna COVID-19 Vaccine"[3] and the "Johnson & Johnson (Janssen) COVID-19 Vaccine"[4] (collectively, the "Vaccines").[5]

[1] Plaintiffs filed a Motion for Temporary Restraining Order on May 19, 2021 (ECF 1). The Court denied the Motion on May 24, 2021 (ECF 3).
[2] Issued December 11, 2020. *See* https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccine.

3. The Emergency Declaration and the Vaccine EUAs were the keys that unlocked the profit potential of the COVID-19 crisis. They enabled the Vaccine manufacturers to open the door to the vast American market, enter and reap billions of dollars in profit by exploiting the fears of the American people. In the first quarter of 2021 alone, Pfizer has earned $3.5 billion, and Moderna has earned $1.7 billion, in revenues generated from the sale of their respective EUA Vaccines. Plaintiffs' investigation has revealed that the Defendants appear to have numerous disclosed and undisclosed conflicts-of-interest that should deeply trouble any reasonable observer concerned about the integrity of the EUA process. For instance, Defendant the National Institutes of Health ("NIH") appears to be a co-creator and co-owner of the intellectual property in the "Moderna COVID-19 Vaccine."

4. The Vaccines are unapproved, inadequately tested, experimental and dangerous biological agents that have the potential to cause substantially greater harm than the SARS-CoV-2 virus and the COVID-19 disease itself. According to data extracted from the Defendants' Vaccine Adverse Events Reporting System ("VAERS"), 99% of all deaths attributed to vaccines in the first quarter of 2021 are attributed to the COVID-19 Vaccines, and only 1% are attributed to all other vaccines. The number of vaccine deaths reported in the same period constitutes a 12,000% to 25,000% increase in vaccine deaths, year-on-year. The Vaccines appear to be linked to a range of profoundly

[3] Issued December 18, 2020. *See* https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-19-vaccine.
[4] Issued February 27, 2021. *See* https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/janssen-covid-19-vaccine.
[5] For the sake of clarity of reference, Plaintiffs are using the names given to the Pfizer and Moderna EUA medical products by their manufacturers and the Defendants. However, Plaintiffs reject the highly misleading use of the term "vaccine" to describe the Pfizer and Moderna EUA medical products, since they are not vaccines within the settled meaning of the term and instead are more precisely described as a form of genetic manipulation.

serious medical complications, among them myocarditis, miscarriage, irregular vaginal bleeding, clotting disorders, strokes, vascular damage and autoimmune disease. Meanwhile, Pfizer, Moderna and Janssen enjoy statutorily conferred immunity from liability for any harm caused by their experimental products.

5. The Vaccine EUAs are unlawful on multiple different grounds and must be terminated immediately. First, the Emergency Declaration upon which they are all based was unjustified. As Plaintiffs allege in detail and will show at trial with expert medical and scientific evidence, including the Defendants' own data and studies, there is not now, and there never has been, a *bona fide* "public health emergency" due to the SARS-Cov-2 virus or the disease COVID-19. Virtually all of the PCR tests were calibrated to produce false positive results, which has enabled the Defendants and their counterparts in state governments to publish daily reports containing seriously inflated COVID-19 "case" and "death" counts that grossly exaggerate the public health threat. Even assuming the accuracy of these counts, we now know that COVID-19 has a fatality rate far below that originally anticipated - 0.2% globally, and 0.03% for persons under the age of 70. According to the CDC, 95% of "COVID-19" deaths involve at least four additional co-morbidities.

6. The DHHS Secretary has failed to satisfy the "criteria for issuance" of the EUAs set forth in § 360bbb-3(c). The Vaccines are not effective in diagnosing, treating or preventing COVID-19. Absolute Risk Reduction ("ARR") is a critical measure of the impact of a medical intervention, reached by comparing outcomes in a treated group with outcomes in an untreated group in a randomized controlled trial. The NIH has published a study that indicates the ARR for the Pfizer-BioNTech COVID-19 Vaccine is just 0.7%,

and the ARR for the Moderna COVID-19 Vaccine is 1.1%. The benefits of the Vaccines when used to diagnose, prevent or treat COVID-19, do not outweigh the risks of these experimental agents. This is particularly so for children, for whom COVID-19 presents 0% risk of fatality statistically. There are multiple adequate, approved and available alternative products that have been used safely and effectively for decades. For example, the evidence suggests that Ivermectin consistently has an ARR that far exceeds that of the Vaccines.[6]

7. The DHHS Secretary has failed to meet the "conditions of authorization" mandated by § 360bbb-3(e)(1)(A). Healthcare professionals administering the Vaccines and Vaccine subjects alike are being deprived of basic information regarding the nature and limitations of the EUAs, the known risks of the Vaccines and the extent to which they are unknown, available alternative products and their risks and benefits, and the right to refuse the Vaccines. Not only is this information not being presented, it is being actively suppressed. There is no reliable system for capturing and reporting all adverse events associated with the Vaccines. The Defendants have created a new reporting system dedicated to the Vaccines parallel to VAERS, and Plaintiffs have been unable to obtain any information from this system.

8. At the same time, the American public, desperate for a return to normalcy following a year of relentless psychological manipulation through fear-messaging regarding SARS-CoV-2/COVID-19 and associated unprecedented deprivations of their constitutional and human rights, are being told in a carefully orchestrated public messaging campaign that the Vaccines are "safe and effective" and a "passport" back to

[6] *See* https://c19ivermectin.com.

the freedoms they once enjoyed. Dissenting medical opinion is systematically censored. Private sector employers and all levels of government are offering dramatic incentives to accept the Vaccines, and jarring penalties for refusing them. In these conditions, it is not possible for Vaccine subjects to give voluntary informed consent to the Vaccines, and the "warp speed" rollout of these dangerous, untested biological agents to the American population constitutes non-consensual human experimentation in violation of customary international law.

9. Plaintiffs are healthcare professionals whose rejection of the Vaccines and promotion of alternative products has resulted in the termination of their employment or the suspension of their professional license, or has placed them in an untenable ethical bind that interferes with their ability to practice their chosen profession and threatens their livelihood and employment; parents and children under extreme pressure to accept the Vaccines; and the Estate and loved ones of an elderly woman whose life was cut short after she received a Vaccine, without having given voluntary, informed consent; and a number of individuals seriously injured by a Vaccine, without having given voluntary, informed consent.

10. As a threshold matter, Plaintiffs are asking the Court to scrutinize, under the authority of Home Building and Loan Association v. Blaisdell, 290 U.S. 398 (1934) and Chastleton Corp. v. Sinclair, 264 U.S. 543 (1924), whether the exigencies that justify a declaration of a "public health emergency" under § 360bbb-3(b) exist, and to declare that since they do not exist, the DHHS Secretary's declaration of a public health emergency and repeated renewals thereof are unlawful, and the Vaccine EUAs which are based on the "public health emergency" are also unlawful.

11. Plaintiffs are seeking additional declaratory relief including *inter alia* determinations that the Defendants have violated § 360bbb-3(c) by failing to meet the criteria for issuing the Vaccine EUAs, that they have violated § 360bbb-3(e) by failing to establish and maintain the conditions for the EUAs, that they have violated customary international law by engaging in non-consensual human medical experimentation, and that they have violated 45 CFR Part 46 by failing to implement protections for human subjects in medical experimentation. They are also asking the Court to enjoin *inter alia* the enforcement of the challenged declaration of a "public health emergency" and further renewals thereof, enforcement of the Vaccine EUAs and further extensions of the Vaccine EUAs to children under the age of 16. Finally, the Vaccine-injured Plaintiffs are seeking civil money damages from the Defendants' key officials.

II. THE PARTIES

Plaintiffs

12. AMERICA'S FRONTLINE DOCTORS ("AFLDS") is a non-partisan, not-for-profit organization of hundreds of member physicians that come from across the country, representing a range of medical disciplines and practical experience on the front lines of medicine. AFLDS' programs focus on a number of critical issues including:

- Providing Americans with science-based facts about COVID-19;
- Protecting physician independence from government overreach;
- Combating the "pandemic" using evidence-based approaches without compromising Constitutional freedoms;
- Fighting medical cancel culture and media censorship;
- Advancing healthcare policies that protect the physician-patient relationship;
- Expanding COVID-19 treatment options for all Americans who need them; and
- Strengthening the voices of front-line doctors in the national healthcare conversation.

13. AFLDS' core beliefs, shared by each of its member health care professionals, include the following:

- That the American people have the right to accurate information using trusted data derived from decades of practical experience, not politicized science and Big Tech-filtered public health information.
- That critical public health decision-making should take place away from Washington and closer to local communities and the physicians that serve them. They are steadfastly committed to protecting the physician-patient relationship.
- That front-line and actively practicing physicians should be incorporated into the nation's healthcare policy conversation.
- That safe and effective, over-the-counter COVID preventative and early treatment options should be made available to all Americans who need them. They reject mandatory government lockdowns and restrictions not supported by scientific evidence. They support focused care for the nation's at-risk population, including seniors and the immune-compromised.

14. AFLDS, through its member physicians, is deeply committed to maintaining the physician-patient relationship in the face of government encroachment.

15. Each of AFLDS' member physicians is also deeply committed to the guiding principle of medicine, "FIRST, DO NO HARM". They take gravely their ethical obligations to their patients. It is axiomatic that a physician's duty is to his or her patient.

16. AFLDS has recommended that the experimental Covid-19 vaccines be prohibited for use in the under-20 age category, and strongly discouraged for use in the healthy population above the age of 20 through the age of 69. These recommendations have two sound and broadly scientific foundations upon which they are based. First, there is the undeniable fact that the Covid-19 vaccines are experimental and either lack clinical testing or have presented serious risks for young people in the 12 to 15 age group. The risks and safety evidence based upon such trials as there are, cannot justify the use of

these vaccines in younger persons. Because AFLDS has taken the science-based position that it is unethical even to advocate for Covid-19 vaccine administration to persons under the age of 50, its and its membership cannot administer it or support any agency that attempted to do so for juvenile persons in the 12 to 15 age category.

17. It should be noted here that AFLDS is NOT against vaccines generally as a class of medical interventions. It has praised the speedy progress of the vaccine development program. It has taken care to ensure clarity in its position regarding support of the proper use of approved vaccines and the proper application of emergency use authorizations. It holds sacrosanct the relationship between doctor and patient where truly informed decisions are to be made, taking into consideration all of the factors relating to the patients' health, risks, co-morbidities and circumstances.

18. Given these considerations it would be grossly unethical and therefore impossible for AFLDS members to stand idly by while their patients and their patients' families are subjected to the imminent risk of experimental COVID-19 vaccine injections being administered to minor children. If the EUAs are allowed to stand unrestrained and extended to young children in the 12-to-15-year age group, AFLDS member physicians will be forced into further untenable positions of unresolvable conflict between their ethical and moral duties to their patients, and the demands of many of the hospitals in which they work. AFLDS is aware of doctors around the Country to whom this has already been done and who have lost their medical licenses and/or their jobs over these issues.

19. Many of AFLDS member physician's employers subscribe to and follow the recommendations of the American Medical Association ("AMA"). In a special

meeting in November of 2020, the AMA's Council on Ethical and Judicial Affairs, updated a previously published Ethics Opinion in the AMA Code of Medical Ethics as opinion 8.7, "Routine Universal Immunization of Physicians."

20. In this updated opinion, the astonishing position was taken that not only do physicians have an ethical and moral obligation to inject themselves with the experimental COVID-19 vaccination, but they also have an ethical duty to encourage their patients to get injected with the experimental COVID-19 vaccination. The ethics opinion repeatedly uses the phrase "safe and effective" as a descriptor for the experimental COVID-19 vaccination. The AMA's ethics opinion goes on to state that institutions may have a responsibility to require immunization of all staff!

21. "Physicians and other health care workers who decline to be immunized with a safe and effective vaccine, without a compelling medical reason, can pose an unnecessary medical risk to vulnerable patients or colleagues," said AMA Board Member Michael Suk, MD, JD, MPH, MBA. "Physicians must strike an ethical balance between their personal commitments as moral individuals and their obligations as medical professionals."

22. The ethical opinion adopted by the AMA House of Delegates says that doctors:

> *have an ethical responsibility to encourage patients to accept immunization when the patient can do so safely, and to take appropriate measures in their own practice to prevent the spread of infectious disease in health care settings. Physician practices and health care institutions have a responsibility to proactively develop policies and procedures for responding to epidemic or pandemic disease with input from practicing physicians, institutional leadership, and appropriate specialists. Such policies and procedures should include robust infection-control practices, provision and required use of appropriate protective equipment, and a process for making appropriate immunization readily available to staff.*

> *During outbreaks of vaccine-preventable disease for which there is a safe, effective vaccine, institutions' responsibility may extend to requiring immunization of staff.*

23. It is clear from this ethics opinion that AFLDS member physicians would be considered by their employers to be both morally and ethically bound by a duty to encourage 12–15-year-old minors to receive the experimental COVID-19 vaccination injection.

24. The AMA even offers a "COVID-19 vaccine script for patient inquiries". Despite being styled as a script for inquiries, the script clearly intends for phone messages and office websites to lead with the following message for every caller, not simply those who wish to inquire about vaccines. The proposed script reads: "We are encouraging our patients to receive the COVID-19 vaccine when it is available and offered to them."

25. To the extent that the AFLDS member physicians either lack control of their office website or telephone system or are simply unaware of the message that has been placed there absent their knowledge and consent, the member physicians will have been forced unwittingly into an utterly untenable position. Such would create an unresolvable conflict for the member physicians, and deep confusion for their patients, who would thereby be receiving irreconcilable and contradictory messages from the same office.

26. To illustrate just how unresolvable these conflicts are, it is necessary to consider the massive power of big pharmaceutical companies over the institutions who employ the physicians and the ease with which a physician's career can be destroyed through widely unregulated reporting which opens an investigation that can and often does render the physician virtually unemployable. Not only do physicians have to choose

between their ethical obligations to their patient to do no harm and their current job; the reality is that many of them will be choosing between their patients and their medical career.

27. It is critical to point out that for AFLDS member physicians, the practice of medicine is not simply a job. Neither is it merely a career. Rather, it is a sacred trust. It is a true high calling that often requires a decade or more of highly focused sacrificial dedication to achieve. The depth and the horror of the bind that this ethics opinion places the member physicians of AFLDS in, simply cannot be overstated.

28. To grasp the irreparable nature of the harm they face, one must consider the ease with which even an anonymous report can be made that may injure or haunt a physician's career. The National Physicians Database ("NPDB") was created by Congress with the intent of providing a central location to obtain information about practitioners. However, as Darryl S. Weiman, M.D., J.D. pointed out, the "black mark of a listing in the NPDB may not accomplish what the law was meant to do; identify the poor practitioner." Weiman goes on to point out that "It is the threat of a NPDB report which prevents the open discussion, fact-finding, and broad-based analysis and problem solving which was the intent of the meaningful peer-review of the HCQIA."

29. The gross imbalance of equities between an individual physician and the various large institutions and pharmaceutical companies which exert tremendous sway over his or her professional calling has many physicians fearful of pushing back against such ethical binds as have been described above. Many physicians have a family and medical school debts to consider and should never be forced into such a bitter double bind.

30. The types of harm the AFLDS member physicians are inevitably subjected to by this extension of the EUAs to inject 12–15-year-old minors with the experimental COVID-19 vaccine is truly irreparable. Such harm strikes at the moral and ethical underpinnings of their calling as a physician and drives irreparable wedges into the sacred doctor-patient relationship that cannot be healed and certainly cannot be addressed with monetary damages. None of the adverse information that this Plaintiff has discovered about the Vaccines, and none of the information about alternatives, was supplied by the Defendants or as a result of their efforts.

31. JOEL WOOD, RPH, of Berkshire, New York, is a licensed registered pharmacist who was named an essential worker, and who worked throughout the entire Covid-19 pandemic for Kinney Drugs Corporation.

32. Joel personally administered over 500 COVID-19 Vaccines to adults through his employment with Kinney Drugs Corporation, beginning in January 2021. When Joel first began to administer the Vaccines, he was under the impression that these Vaccines were necessary to get us through this awful time in history.

33. As time went on, Joel started to be concerned more with what the Vaccines were doing to people, and he started to change his opinion. As a pharmacist, Joel is trained to assess the risk of treatment against the risk of the disease state. Through his research into the experimental COVID-19 Vaccines, Joel learned that the risks associated with the injection outweigh the risks associated with contracting COVID-19. In Joel's professional opinion regarding people below the age of 65, the risks associated with the Vaccines outweigh the risks associated with getting COVID-19. COVID-19 poses almost no health risk to any healthy individual under the age of 50.

34. There is no long-term data regarding possible benefits of the experimental Vaccines. Even with the experimental Vaccines, you can still transmit and become infected with the virus. Coronaviruses has been around for decades; they are part of what causes the common cold. The vaccination site where Joel worked did not ensure full informed consent. Joel has personal knowledge that his former employer, as well as other COVID-19 vaccination sites around the country, are not ensuring study participants give full informed consent as defined in the Code of Federal Regulations §46.116 General Requirements for Informed Consent. In fact, no one can give proper informed consent for the COVID-19 Vaccines, because the package inserts are blank.

35. Joel heard from many staff members and patients that they did not know that the Vaccine was not FDA approved. He personally observed staff administering this Vaccine while not disclosing to people that it is not an FDA-approved Vaccine. How many people would get the shot if they knew they could still get and spread COVID- 19? While Joel was administering the Vaccines, he observed many people coming in to get the shot only because they believed the shot would be required to get back to "normal life," -- take the mask off, attend a wedding or attend a sports game.

36. When Joel became aware that the EUA had been extended to include administration of the Vaccine to children ages 12 to 15, he felt compelled to take a stand. On May 5, 2021, Joel placed an anonymous call to the Kinney Drugs ethics line in order to express deep concern over two issues: Vaccine shedding and the experimental injection of youth.

37. On May 9, 2021, Joel followed up by sending a letter via email expressing the concerns raised in his telephone call and advising his employer that he would contact

OSHA if he did not receive a response. In his letter, Joel inquired about what Kinney Drugs would be doing to address the safety concern of Vaccine shedding in the workplace. The Pfizer Trial Investigational Protocol, 1 at page 67, addresses "environmental exposure" or Vaccine shedding. He also inquired about the lack of patient safety and informed consent he had observed, his issues with many staff members and patients not knowing the shots were **not** FDA approved, and staff administering the shot while failing to advise people the shot is not FDA approved.

38. On May 10, 2021, when Joel's communication with Kinney Drugs was unanswered, he sent an email complaint to OSHA. In his Complaint, he expressed his concern with exposure and his knowledge of vaccine shedding. Joel expressed his concern that there are no long-term studies for the experimental vaccines and his conviction that staff working in retail pharmacies are exposed to vaccine spike protein shedding as described in the Pfizer Trial Investigational Protocol.

39. On May 11, 2021, Joel received a response from OSHA which stated: "At this time OSHA has no standards or jurisdiction when it comes to COVID-19 concerns or complaints." Joel was additionally provided with phone numbers for the New York Governor, the New York State COVID-19 Hotline, and the New York City COVID-19 Violations Hotline.

40. On May 12, 2021, Joel had a verbal discussion with his boss after being advised by human resources that no accommodation was going to be made to address his concerns and that he would be required to give shots to kids. Joel's boss gave him until May 14, 2021 to decide whether he would give the shots. On May 14, 2021, Joel verbally advised his boss that he had a legal right under religious moral, and ethical concerns to

not provide a service. He advised his boss that he could not ethically administer the experimental Vaccines to adolescents, nor could he ethically administer the Vaccines without providing informed consent. Joel further advised his boss that it is not possible to provide full informed consent as the Vaccine manufacturer's package inserts are blank, and there is no long-term data. Joel's boss explained that in that case he would be terminated. Joel was then fired from his job.

41. According to the Nuremberg Code, voluntary consent is absolutely essential to medical experimentation. The Vaccines are medical experimentation. It has been Joel's professional opinion based on direct observation that his former employer, along with other Vaccine clinics has failed, and continue to fail to provide proper informed consent for the Vaccine. None of the adverse information that this Plaintiff has discovered about the Vaccines, and none of the information about alternatives, was supplied by the Defendants or as a result of their efforts.

42. BRITTANY GALVIN, of Tampa, Florida, is Vice President of Sales for a professional employer organization, and the primary breadwinner for her family. She is a 35-year-old wife and mother of three children. She has a history of Rheumatoid Arthritis, diagnosed four years ago, in remission for a couple of years. Before the COVID injections, she did not take any regular medications.

43. Before the spring of 2020, she traveled extensively for work. Just prior to the reporting of the COVID outbreak in the United States, when she returned from Las Vegas in late February of 2020, she got extremely sick. The Urgent Care doctor she saw told her there was no way she could have COVID because she had not been to China.

Between March and June 2020, she was tested at least ten times for COVID-19. None of these tests were positive. However, she was sick for almost three months.

44. By June of 2020, Brittany had become extremely ill. She went to the ER and was transferred to Advent Carrollwood Hospital where she was admitted to a Covid unit for 6 days as "positive" for COVID-19. She never saw positive test results. On the first day of her hospital admission, she was treated with Hydroxychloroquine. By the third day she had improved significantly. Nothing helped before the Hydroxychloroquine. Several months later, she had a positive antibody test.

45. Brittany experienced tremendous pressure to get "vaccinated" so she requested a medical exemption from the shot from her rheumatologist. However, she was advised by his assistant that they were recommending that all patients get the injections. She was further advised that her doctor would not provide a recommendation against the shot, but that instead, he would write a letter stating she should get the shot. This incident was extremely alarming to Brittany.

46. After her doctor failed to support her medically, and needing to get back to work, Brittany reluctantly took the first Moderna injection on March 28, 2021. Within 4-5 hours of receiving the shot, she experienced chills all over her body and felt terrible. She felt unsteady and when she walked it felt like her legs were moving through wet cement.

47. She received her second Moderna injection on May 4, 2021, at her local Publix pharmacy. She filled out a form that asked me if she had a prior autoimmune disease. She checked the box on the form indicating that she had, and that she would

need to be seen by a pharmacist. No pharmacist saw her and she reluctantly accepted the injection.

48. A couple of days after the shot metal started sticking to her body. Brittany had learned more about the shots and was alarmed. She asked the pharmacist why he provided shots with a blank package insert and he could not tell her what was in the shots.

49. On May 22, 2021, about 13 days after her second shot, Brittany seized up unable to walk, and fainted on the floor. Her head was tingling and her ears were hot. She had a terrible headache. Coming to, she was able to call 911. By the time paramedics arrived, her body had fully seized up. She was transported to Memorial Hospital of Tampa by ambulance where the staff asked her immediately if she had had the COVID shot, which ones, and when. She overheard a conversation at that emergency room that alerted her that similar side effects were coming into the hospital regularly. She overheard hospital staff talking about seeing a lot of heart conditions, chest pains, and leg numbness from the COVID shots.

50. At Memorial Hospital, the hospital staff took x-rays with a spoon stuck to her body. In fact, the MRI technician tried it, and the spoon stuck to him as well.

51. She was ultimately released with the reason for admission in her chart noted as “anxiety.”

52. A few days later, on May 25, 2021, she was admitted to the emergency room at Advent Carrollwood Hospital in Tampa, Florida for the same symptoms: unsteadiness, numbness, tingling, headaches, nausea, chest pain. The next day she was

released, and her chart noted that she was admitted for "anxiety." After this hospital stay, she made a report to VAERS.

53. On May 30, 2021, Brittany was again admitted to Advent Carrollwood Hospital. She was there fighting for her life as of, June 8, 2021. She has undergone multiple tests, including without limitation blood tests, neurology tests, brain MRIs, and a spinal tap. The hospital was prepared to release her with another diagnosis of "anxiety" when her neurology team arrived in her room with results from her lumbar puncture. Her neurologist advised her that her problems arose from the COVID shot. He also advised her that she was not the first patient he has seen with these problems. He then diagnosed her with Guillain Barre Syndrome, Acute Neuropathic POTS, pericarditis, gastroparesis and aseptic meningitis and, as she was told, made a report to VAERS.

54. As of June 8, 2021, Brittany has a very stiff neck and her head pain is extreme. She cannot use the bathroom unassisted. She is experiencing pressure in her head like her brain is swollen. She has recently been running a fever and throwing up. She is getting worse, not better. Her family and husband need her.

55. Brittany feels very strongly about using her experience to warn and help others so this does not happen to them. She posted her experiences on Instagram at @brit_galvin. Her videos have been censored on social media.

56. When Brittany took the COVID-19 experimental injections, she did not know they were experimental and not approved by the FDA. She was highly confused by the media asserting that they were "safe and effective."

57. Brittany believes the COVID-19 vaccines should all be immediately pulled from use. She stands strong in her conviction to make a difference with her life by

stopping these experimental injections. None of the adverse information that this Plaintiff has discovered about the Vaccines, and none of the information about alternatives, was known to this Plaintiff prior to sustaining Vaccine injury, and none was supplied by the Defendants or as a result of their efforts.

58. ELLEN MILLEN, a resident of Huntsville, Alabama, is the Guardian of three siblings ages 5, 4 and 4. These children have been entrusted to her by Child Protective Services and she is responsible for making medical decisions for them. Ellen has obtained a medical exemption for vaccines and neither she nor their biological parents wish the children to receive the experimental COVID-19 vaccination. Ellen stands not only for the children currently in her care but for those who may be placed in her care in the future. She stands for her 22-year-old son and four other children who are unable to stand for themselves in opposing the application of the experimental COVID-19 vaccination to children of all ages who are at NO statistical risk of death from COVID-19. Ellen knows that the children in her care will face overwhelming pressure to receive the experimental COVID-19 vaccination injection from friends, parents of friends, sports organizations, summer camps, schools and colleges. The fear and pressure that this fragile at-risk population of children will be subjected to if the requested injunctive relief is not granted is greater than that which is often faced by children from intact nuclear families. The nature of their placement outside of their home and away from their biological family leaves them particularly susceptible to the pressures and the fear mongering that they will receive from peers and authority figures. The harm that they will undergo emotionally, mentally, and/or physiologically is precisely the type of harm considered irreparable by the law in this case. The trauma that is created in this type

of a situation will quite likely be carried for life, and no monetary damage award can possibly erase the effects. Ellen recently watched an interview with the mother of a young man named Everest Romney. Everest was a healthy top-level athlete. Everest took the injection, followed by his father and his pregnant mother, who each took a vaccine in the same day. One took the Pfizer injection and the other took the Moderna injection. Everest and his father were hospitalized within days with blood clots on their brain. Ellen is terrified that something similar or worse will happen to her family. None of the adverse information that this Plaintiff has discovered about the Vaccines, and none of the information about alternatives, was supplied by the Defendants or as a result of their efforts.

59. AUBREY BOONE, of Lubbock, Texas, is 39 years old and studying to be a colon hydro-therapist. She also works as a caregiver for her retired father, who is a disabled Veteran and unable to care for himself due to service-related injuries and significant cognitive decline. Additionally, she is the single mother of two minor children ages twelve and sixteen. She has always been healthy and had no medical problems prior to being injected with the experimental agents in the Covid-19 “vaccine”.

60. Aubrey took the first Moderna shot on March 18, 2021, and the second shot on April 15, 2021. She registered for the vaccine appointment online and showed up at Lubbock Civic Center with her father. When she arrived, staff searched for her name on the roster, where it happened to appear twice. Her identification was never checked, nor was her father’s. They then were escorted to a table and asked only if they were getting the first or second shot.

61. The first shot was given by an EMT. He told Aubrey that it was the first shot, and she should experience no side effects. They were not at any time provided with disclosures, papers or directives. They were only provided a proof of vaccine card.

62. Aubrey cannot attest to the position of the person who administered the second shot, because the woman giving the shot did not wear a uniform. Aubrey and her father were once again only asked if it was the first or second shot. This time, they were asked which brand of shot we had received. The woman giving Aubrey the injection told her she may get a fever and if it persists to go to the emergency room. Once again, Aubrey and her father were never given any paperwork on the actual vaccine and never warned of potential side effects.

63. After the shot Aubrey became extremely ill very quickly. Within 12 hours she had a fever of 103, severe migraine, unbearable body aches, stomach issues, and what seemed to be arthritic pain in every joint on her body. The fever lasted four days, but the severe migraine continued for 17 days. Aubrey became so ill that she could barely function. During the first four days, she had someone assist her by bringing her items that she needed. This person became terribly ill with the same symptoms she was experiencing, within 24 hours of contacting her.

64. Aubrey was never informed that she could get this sick from the vaccine. She could not function for 17 days and this was extremely difficult for her. If she would have known that she was going to become that sick with the vaccine she would have been able to make a somewhat informed decision for herself, and for her family that depends solely on Aubrey's care. Aubrey heard that the experimental injection is going to be given to children aged 12 to 15 and she believes that is wrong. She does not want her

children to get this experimental Covid-19 vaccine injection. Aubrey felt enormous pressure to get vaccinated. She believes the pressure on children is even stronger. Children are not old enough to be pressured about their health decisions and they are not old enough to make a potentially life changing medical decision. None of the adverse information that this Plaintiff has discovered about the Vaccines, and none of the information about alternatives, was known to this Plaintiff prior to sustaining Vaccine injury, and none was supplied by the Defendants or as a result of their efforts.

65. JODY SOBCZAK, of Huntsville, Alabama, is the father of two minor children ages 15 and 17. Jody has researched the experimental COVID-19 vaccines and fiercely opposes their use in healthy children of any age. He knows that his own children are placed at immediate and irreparable risk of harm by extending the EUAs for the experimental COVID-19 Vaccines to adolescents. Jody recently watched a video showing an interview of a young woman named Alicia Smith. Ms. Smith is a 34-year-old hair stylist who has uncontrollable essential tremors and facial palsy since she received her COVID-19 shot on April 15, 2021. She took the vaccine because a lot of her clients pressured her into it and she did not want to lose clients. Ms. Smith's story is heartbreaking. The doctors are telling her that it is an anxiety problem. She does not know if she will ever be able to work as a hairstylist again. It is very upsetting to Jody that this young woman trusted the shot was safe, even though she really did not want to get it. She has now been adversely affected in a serious and possibly permanent way. She is a grown woman, and she succumbed to pressure to take the shot. Teens are far more susceptible to peer pressure than adults, and Jody is afraid for his own children, absent the relief requested. People simply do not know any better and they are trusting the drug

companies and the government. Jody is well aware that there are safe and effective alternative treatments readily available, and he adamantly opposes the suppression of those treatments in favor of experimental and potentially life-threatening agents. None of the adverse information that this Plaintiff has discovered about the Vaccines, and none of the information about alternatives, was supplied by the Defendants or as a result of their efforts.

66. DEBORAH SOBCZAK is the wife of JODY SOBCZAK, and the mother of minor children ages 15 and 17. The allegations in the preceding paragraph are incorporated herein by reference. None of the adverse information that this Plaintiff has discovered about the Vaccine was supplied by the Defendants or as a result of their efforts.

67. SNOW MILLS, of Lubbock, Texas, is a 49-year-old grandmother with no serious health issues prior to the experimental COVID-19 vaccine injection. Snow took the first dose of the experimental Moderna injection on March 8, 2021, after registering online with a CVS Pharmacy. When she arrived at CVS on March 8, she checked in on her phone. She then went inside, checked in with someone, and proceeded to a table to receive the injection. She was not provided with any information about side effects or warnings whatsoever. Later that evening she started feeling very achy and sick to her stomach.

68. Approximately two weeks after the shot Snow contracted a fever and a large knot appeared at the injection site for about four days. On April 4, 2021, Snow received the second Moderna shot. She dreaded it because of the terrible reaction she had

with the first vaccine. Several hours after the second injection, Snow began to experience horrible flu-like symptoms that kept her bed-ridden for two days.

69. At no time was Snow ever given any information about risks or side effects of the experimental COVID-19 Vaccine injection before or after they were administered to her. Snow strongly objects to the COVID-19 shots being given to children. There is no way to know the risks to young people, with their entire lives ahead of them. Snow is mentally and emotionally distressed at the thought of any child, who is statistically at no risk of death or serious injury, going through the awful side effects she experienced. None of the adverse information that this Plaintiff has discovered about the Vaccines, and none of the information about alternatives, was known to this Plaintiff prior to sustaining Vaccine injury, and none was supplied by the Defendants or as a result of their efforts.

70. JENNIFER MCCRAE, RN, of Wichita, Kansas, is an RN working at a county health department vaccination clinic. For many years she did transfusion therapy for patients and therefore she has extensive experience with the process of informed consent. Jennifer is deeply concerned that COVID-19 vaccination sites around the country, such as the one where she works, are also not providing study participants full informed consent as defined in the 45 CFR §46.116, General Requirements for Informed Consent. Jennifer finds this extremely troubling given that legal guardians are enrolling children as young as 12 years old in the COVID-19 vaccination clinical trial without understanding they are participating in a clinical trial. According to the guidance provided by DHHS:

> *Informed consent is a process, not just a form. Information must be presented to enable persons to voluntarily decide whether or not to*

> *participate as a research subject. It is a fundamental mechanism to ensure respect for persons through provision of thoughtful consent for a voluntary act. The procedures used in obtaining informed consent should be designed to educate the subject population in terms that they can understand. Therefore, informed consent language and its documentation (especially explanation of the study's purpose, duration, experimental procedures, alternatives, risks, and benefits) must be written in "lay language", (i.e., understandable to the people being asked to participate). The written presentation of information is used to document the basis for consent and for the subjects' future reference. The consent document should be revised when deficiencies are noted or when additional information will improve the consent process.*

71. Jennifer's opinion as a medical professional with extensive experience studying and providing informed consent to those who are being asked to participate in clinical trials, is that her clinic is providing the experimental COVID-19 experimental Vaccine injections in direct violation of 45 CFR §46.116, General Requirements for Informed Consent. When a vaccine recipient walks into the clinic they are asked a few simple screening questions. They are not counseled by any staff member about risk vs benefits of participating in this clinical trial. Many believe the vaccines are fully FDA approved and that this Vaccine is mandatory or will be soon. Many have even asked Jennifer if they need to have their vaccination card on them at all times. Jennifer interprets this at minimum as a lack of understanding, but also as coercion.

72. A Vaccine recipient is given the manufacturer's information sheet at check in but is not asked if they understand what they are reading. If that person does not speak English as a first language and/or cannot read at an adequate reading level to comprehend the information they are not receiving informed consent. Additionally, no one assesses a Vaccine recipient's level of understanding at any part of the process. The manufacturer's information sheet is not informed consent. For example, it does not contain any information about the individual's risk. For a patient aged 12 to 15, it is relevant risk

information that a person under age 18 has statistically zero percent chance of death from COVID-19. None of the adverse information that this Plaintiff has discovered about the Vaccines, and none of the information about alternatives, was supplied by the Defendants or as a result of their efforts.

73. ANGELLIA DESELLE, of Marrero, Louisiana, was a surgery center manager until the devastating health effects of the experimental COVID-19 Vaccine injection changed her life forever and cost her that job. As an essential worker, Angelia worked throughout the entire Covid-19 pandemic. Before January 5, 2021, she was a healthy 45-year-old woman with absolutely no health issues. She did not take any regular medications. However, she took the experimental Pfizer Vaccine on January 5, 2021, because she was exposed to COVID-19 regularly at work and did not want to endanger her aging parents. She drove herself to the vaccination center during her lunch hour on Tuesday, January 5, 2021. Within 2 hours of receiving the shot, Angelia got a severe headache, and the headache has not gone away since.

74. On Wednesday, January 6, 2021, Angelia slept for 15 hours straight when she got home from work.

75. On Thursday morning, January 7, 2021, she woke up and felt very dizzy, and almost passed out. However, she took Ibuprofen and went on to work.

76. By Friday night, January 8, 2021, Angelia was having problems with her legs. At about 11:30 PM, she got out of bed and could not feel or use her left leg. Initially, she just thought it would pass and went back to bed.

77. By Saturday morning, January 9, 2021, she could not use either of her legs and could not walk unassisted. About two hours later, she started having full-body

convulsions. Her husband took her to the emergency room, and she was admitted to Ochsner Medical Center, where a hospitalist came in to see her. He told her, "Ms. Desselle, I heard you were coming. I know what is going on and I know this is the vaccine. We are going to research this until we figure it out." That doctor never came into Angelia's room again and that was the last time she ever saw him. She was in Ochsner Medical Center Hospital for five days. She was never treated for convulsions, nor was any testing done for convulsions or seizures. Her spine was studied, and an MRI was done. The hospital documented her problems on discharge as "bilateral leg weakness."

78. Angelia's severe health problems have persisted for five months and not only continue unabated, but have grown worse, as detailed below. She has been shuffled from doctor, to doctor, to doctor. She has seen numerous neurologists. Unfortunately, all her testing has taken place at the same hospital where she was administered the experimental vaccine injection. The last five months have been a nightmare for Angelia. She has neurological issues, as well as memory loss and brain fog. As manager of a surgery center, Angelia was very sharp and could think fast and easily make decisions. The mental acuity she possessed before receiving the experimental injection is gone. In addition, Angelia's job is gone. Gone as well is her ability to drive along with the ability to go out in public for fear of a convulsion starting.

79. Angelia recently testified in support of Louisiana State Bill 498 which makes it illegal to discriminate against unvaccinated people and keeps the vaccine off the required list of immunizations for the upcoming school year. Her testimony helped the bill pass through the House. She then testified in front of the State Senate via written

statement and video. She was unable to attend in person because she has a new problem with her vision, preliminarily diagnosed as a detached retina.

80. When the experimental COVID-19 injection was administered, Angelia had no idea it was experimental and NOT approved by the FDA. Her employer provided her with a "Covid-19 Vaccine Consent Form" which appeared to be merely a standard consent form for the "Inactivated Seasonal Influenza Vaccine" with the word "influenza" replaced with "COVID-19." The form does not address potential neurological problems or any of the health issues she has experienced since she was injected. None of the adverse information that this Plaintiff has discovered about the Vaccines, and none of the information about alternatives, was known to this Plaintiff prior to sustaining Vaccine injury, and none was supplied by the Defendants or as a result of their efforts.

81. KRISTI SIMMONDS, of Bakersville, North Carolina, was a healthy 40-year-old, who worked as a Registered Nurse and Clinical Manager for a home health agency prior to January 20, 2021. The only pre-existing conditions she had prior to receiving the experimental Vaccine were related to Barrett's Esophagus and acid reflux. Believing that the experimental injection was an approved vaccine, Kristi only accepted the injection to encourage her clinicians by showing them it was safe. She received the COVID-19 Vaccine at her local health department. When she arrived at her appointment, after her name was confirmed to be on the list, she was simply asked if she wanted the Vaccine in the right or left arm. She signed a document that was presented as a "consent" but was not provided a copy. Kristi is familiar with consent documents and recalls that the consent mentioned flu-like symptoms and a potential for anaphylaxis. It contained no

warning of neurological risks. She was never informed the Vaccine was merely approved under an EUA and was not approved by the FDA.

82. Kristi received the experimental Moderna Vaccine on Tuesday, January 19, 2021. Two days later, she went to the emergency room for swelling in her mouth and throat. She was given Benadryl, Tylenol, and a steroid, which she took round the clock, every four hours, for five days.

83. The following Tuesday, January 26, 2021, Kristi returned to work where she experienced severe fatigue and exhaustion together with unusual difficulty concentrating. That evening, after work, Kristi went straight to bed and immediately started having convulsions. Her entire body drew up into a fetal position with her hands and feet distorted and curled in. She was rushed to a local emergency room, where she was discharged with no diagnosis or change in condition. Her sister immediately drove me to another emergency room, where she received the same response. She was advised that the hospitals did not know what was happening and to follow up with neurology.

84. This cycle repeated continuously for over 3 months. The neurologist and her primary care physician were unable to diagnose the cause of her convulsions, or the cause of other conditions which were developing. Her primary care physician verbalized a concern that the Vaccine has caused autoimmune disorders. Between January 26, 2021, and May 21, 2021, Kristi experienced up to 16 convulsions a day.

85. Kristi has battled these terrible convulsions, body tremors, memory loss, fatigue, brain fog, and pain for almost half a year. Although some conditions have partially relented, new debilitating conditions continue to present. Since the injection, in her desperate quest for medical help, Kristi has been to six different Emergency Rooms,

two different neurologists, and has seen her primary care physician numerous times. Kristi used to ride a Harley Davidson motorcycle for enjoyment, but now she cannot even drive a car. She was terminated from her job on April 28, 2021 and lost her medical insurance and benefits. None of the adverse information that this Plaintiff has discovered about the Vaccines, and none of the information about alternatives, was known to this Plaintiff prior to sustaining Vaccine injury, and none was supplied by the Defendants or as a result of their efforts.

86. VIDIELLA, A/K/A SHAWN SKELTON, of Oakland City, Indiana, has been a Certified Nursing Assistant ("CAN") for 25 years. As an essential worker, Shawn worked throughout the entire Covid-19 pandemic. Prior to January 4, 2021, Shawn was a healthy 42-year-old woman with no underlying health conditions. She took no medication except Effexor (75mg- 1x day).

87. On Jan 4, 2021, she was at work at Good Samaritan Nursing Home and Rehabilitation owned by American Senior Communities (ASC). Her employer was holding a "vaccine" clinic that day. Personnel from CVS pharmacy came in to administer the Vaccines. Corporate representatives were on site attempting to coerce staff into getting injected. Shawn was approached five times that day and pressured to accept the experimental injection. Her employer further coerced staff with the offer of a $50.00 bonus for "getting vaccinated", and the promise that everyone "vaccinated" would be entered into a raffle to win $500, if 70% of staff, or more, were injected.

88. The last time Shawn was approached on January 4, 2021, she was told "Shawn, you are the biggest patient care advocate here. I can't believe you aren't going to take the shot to protect the residents you care so much about!" At 1:45 PM, Shawn

relented to the pressure and guilt and accepted the experimental Vaccine that changed her life forever. The next day, Shawn experienced flu-like symptoms, which worsened as the day progressed. On January 6, 2021, she was barely able to lift her head from her pillow and called in sick. By mid-morning, her tongue began to spasm out of control at a resting state so severely that her teeth rubbed it raw. That afternoon she called her primary care physician, who recommended Benadryl and Pepcid, and called in a prescription for some oral steroids.

89. On January 7, 2021, Shawn woke up in full-body convulsions. She was rushed by ambulance to the Emergency Room. The ER doctor slammed her hand into the side of the bed, told her she was having a panic attack, and instructed her to settle down. Her husband immediately took her to another hospital in Evansville, Indiana. This second ER doctor stated that she was clearly experiencing a Vaccine injury and advised her not to take the second dose. He discharged her with a diagnosis of coarse tremors from the vaccine and advised her to follow up with a neurologist. That was the first and only time she was advised that she had suffered a Vaccine injury.

90. In her desperate and unsuccessful quest for medical help, Shawn visited five emergency rooms as far away from her home as Vanderbilt in Nashville, Tennessee. Doctors suggested a variety of different problems including psychogenic movement disorder, convulsion disorder, panic attack, PTSD, and even stress.

91. On January 11, 2021, she was finally admitted into Deaconess Gateway Neurology. She was examined by a psychologist before she was permitted to be seen by a neurologist, who ordered an MRI. The MRI was deemed normal, and Shawn was discharged. Her full-body convulsions continued without ceasing for 12 days.

92. Shawn currently experiences tremors and uncontrollable body movements almost daily. She experiences convulsions several times a week and sometimes several times a day. In mid-May 2021, her convulsions progressed until she was gripped by six seizures in a single day. Since receiving the experimental injection, Shawn also suffers from severe headaches, high blood pressure and must now take multiple medications a day. She can no longer drive. Her primary care physician has deemed her unable to work and that her condition could persist for years. She was denied worker's compensation and then fired from her job. Shawn is currently being treated experimentally by doctors who cannot provide her with a diagnosis.

93. She knows she is not the only victim of the experimental Vaccines, suffering deeply, injured beyond comprehension. Hundreds of people reached out to her for help since she went public with her story. She speaks to COVID-19 Vaccine victims every day with symptoms similar to her, and no medical diagnosis. None of the adverse information that this Plaintiff has discovered about the Vaccines, and none of the information about alternatives, was known to this Plaintiff prior to sustaining Vaccine injury, and none was supplied by the Defendants or as a result of their efforts.

94. SALLY GEYER, of Muskegon, Michigan, is the grandmother of ten grandchildren ages 18, 16, 12, 12, 11, 9, 9, 6, 6 and 5. She is keenly aware of a Vaccine incident of one of her grandchildren as witnessed by his mother, her daughter. About 7 years ago, when Sally's grandson was about 18 months old, he received the polio/pneumococcal vaccine. That same night he started to bang his head repeatedly on the floor, something he had never done before. As a result of this extremely disturbing incident, Sally and her daughter have educated themselves on many of the adverse

reactions with vaccines and the alarming number of new vaccines that the CDC recommends each year. Sally has strong objections to the experimental COVID-19 Vaccine for children, as well as to it being forced on people of any age. It has not been studied long enough and children are at virtually no risk of dying from COVID-19.

95. As a mother and grandmother, Sally is truly terrified of the futures her grandchildren now face. The testing for the Vaccines was not adequate, and nobody knows what this medical experiment may do to children, who have long lives ahead of them. Sally has faced extreme social pressure to take the experimental injection herself, despite the fact that she is an adult able to make my own decisions. Children are susceptible to peer pressure and authority and are also not old enough to make their own decisions about participating in an experimental, risky clinical trial. Sally is further aware and deeply concerned by the fact effective and safe treatments are available to treat COVID-19, which have been kept from people in order to roll out the experimental COVID-19 Vaccine injections. None of the adverse information that this Plaintiff has discovered about the Vaccines, and none of the information about alternatives, was supplied by the Defendants or as a result of their efforts.

96. MARIA MEYERS, of Traverse City, Michigan, is the mother of two boys, ages 6 and 8 years old. When her first born received his polio/pneumococcal vaccine at 18 months old, he spiked a fever of 102.5 for 2.5 days. After the fever finally broke, he started banging his head on the hardwood floor as hard as he could and did not stop until Maria grabbed him. He did not cry after this head banging incident. Head banging continued a few more times over the next week. Maria never gave him another vaccine. She opposes emergency use authorizations of the experimental COVID-19 injections for

people of any age. Even more strongly, she opposes emergency use authorizations for children and adolescents ages 12-15 and older. She believes her children face substantial risk of harm if emergency use of the experimental COVID-19 Vaccine injections is extended to adolescents. From her own studies, she is aware that the experimental Vaccines have not been studied long enough and that children are at no statistical risk of dying from COVID-19. Nobody knows what could happen to young people, who have long lives ahead of them, if they are experimented on with these untested and experimental agents. Furthermore, Maria believes there could be effective and safe treatments available to treat COVID-19 and strongly opposes suppression of those treatments in favor of using untested, experimental and potentially life-threatening agents. She has serious concerns that these medical experiments will be mandated, which means the loss of medical privacy for her and her boys. Maria believes it should remain her informed choice to decide whether or not to take a Vaccine, after being fully informed about the risks and benefits. None of the adverse information that this Plaintiff has discovered about the Vaccines, and none of the information about alternatives, was supplied by the Defendants or as a result of their efforts.

97. KARI HIBBARD, of North Shores, Michigan, is a Transplant Call Coordinator/Preservationist. She works for a heart and lung transplant program. She receives, reviews, and screens all donor organ offers to help determine whether or not it is a good organ for the intended recipient. Since the experimental Vaccines received EUA, Kari has witnessed that multiple donors have died from a stroke within days or weeks of receiving the Vaccine. Her heart is broken for families losing loved ones to these experimental agents, especially as she knows they are being told it is safe and 95%

effective. Kari believes that they are being lied to because the Vaccines have efficacy with respect to minimizing symptoms, not at stopping transmission of COVID-19.

98. Kari is painfully aware that people are not being provided with information about the terrible risks connected with these medical experiments, nor are they informed that these "vaccine" manufacturers have been granted immunity from liability. The experimental agents have been subjected to no long-term safety studies, yet disturbingly, people are now being told it is safe for 12- to 15-year-olds and pregnant women.

99. Kari has two boys, ages 9 and 11. She is terrified her children will eventually be required to get the Vaccine in order to attend public school. She is deeply disturbed at the implications of forcing dangerous medical experiments on children who face no risk of death from COVID-19, or on adults who have a 99.97% chance at recovering from COVID-19, if they get it. She is disturbed that the Vaccines are fraudulently presented to people as a means of protecting others when they cannot stop transmission. She is aware that thousands who are considered "fully vaccinated" are still getting Covid. She is deeply concerned for her transplant recipients who are being advised to get the Vaccine even though it has never been tested on the immuno-compromised. She is deeply concerned for all the young children and what this could possibly do to their reproductive systems. As a medical professional, she is concerned that in the future we are going to face an increase in childhood auto-immune disorders and cancer.

100. Kari believes that our rights to choose what is best for our bodies are being deliberately stripped away though a campaign of lies and misinformation.

101. Kari's nephew once experienced a vaccine reaction that was so alarming his mother stopped giving vaccines to him and his younger brother. Kari also has a vaccine injured niece who is on the autism spectrum, but high functioning. This vaccine injured niece just allowed herself to be injected with the Vaccine because she was told it is a vaccine that would help protect her father who is going through chemotherapy. Kari believes informed consent and medical health freedom have been ignored. None of the adverse information that this Plaintiff has discovered about the Vaccines, and none of the information about alternatives, was supplied by the Defendants or as a result of their efforts.

102. JULIE ROBERTS, RN, of Niles, Michigan, works for a physician service for homebound people. She works primarily in triaging phone calls. Her organization is involved in scheduling and administering COVID-19 Vaccines. Julie is also the grandmother of three boys ages 4, 7 and 8. As a concerned grandparent, a medical professional and citizen, she deeply opposes EUAs of the experimental COVID-19 Vaccines for any age of the population. It makes her especially ill to see EUAs granted for children and adolescents ages 12 to 15. She believes that her own grandchildren and their young peers are at dire risk.

103. As a medical professional, she knows very well that the experimental COVID-19 Vaccines have been rushed out without enough time to study them. Children have a 100% chance of living through COVID-19. Nobody knows what could happen to young people, who have long lives ahead of them, if they are experimented on with these untested experimental agents.

104. She has heard about a lot of injuries and deaths from the COVID-19 Vaccines and personally experienced a horrifying situation at work recently. She examined an elderly woman who had received the COVID-19 Vaccine sometime at the end of February or the beginning of March, 2021. Julie recalls that the woman was one of the first recipients to have received both of the 2-part Pfizer Vaccine from the organization where she works. Julie assessed her on a Friday because she had not been feeling well. When Julie examined her, she did not present emergent. She was weak but alert and conversing without any problems. Her lung sounds were good. Julie was a bit concerned that she could not get an accurate oxygen reading but the woman was in no respiratory distress during the visit and had a history of being difficult to get readings from. Her husband stated that he had noticed that she had been having some difficulty breathing at times. Julie texted the woman's provider about medications and advised her husband to take her to the ER if needed. When Julie came into work that following Monday, she was told that the woman's husband had her taken to the ER that Sunday but she died, testing positive for COVID and having multiple pulmonary emboli. Julie was shocked that she had pulmonary emboli, and also shocked that the woman tested positive after already receiving the Vaccine. Julie conducted research and discovered that the experimental Vaccine can affect the pulmonary lining. Julie became convinced that the woman passed away as a result of the Vaccine.

105. Julie had to give one of the experimental COVID-19 Vaccines to an elderly woman who was not alert. The woman's daughter had insisted she receive the Vaccine when she moved into a nursing home. Julie did not want to give the injection but was in the area of the nursing home and accepted the assignment. Julie felt terrible doing

it and afterward. Julie would refuse to give the Vaccine to a young person, and never wants to give another one to anybody. Julie's adult son in Maryland was bullied into taking the vaccine by his employer. After he received the Vaccine, he told Julie he would not have done it, but felt it was necessary to get back into the office.

106. The truly eye-opening moment for Julie came when her research led her to discover that in order to obtain an EUA for a Vaccine, there has to be no treatment available. As a medical professional, Julie is aware that there are multiple effective and safe treatments for COVID-19. Julie cannot understand why harmful and experimental injections are being pushed so strongly in favor of the safe, effective and readily available treatments. Julie has never witnessed anything so disturbing in her nursing career. None of the adverse information that this Plaintiff has discovered about the Vaccines, and none of the information about alternatives, was supplied by the Defendants or as a result of their efforts.

107. AMY HUNT, of Grand Rapids, Michigan, is a mother of two minor children ages 11 and 13. As a mother, she opposes EUAs of experimental COVID-19 Vaccines for any age of the population. In our current climate, she is very hesitant to allow her children to be involved in activities where they may be subjected to pressure to take the Vaccine. She worries that their summer camp will try to require the Vaccine. She recently watched a podcast that depicted a teenage boy with injuries he had received from the COVID-19 Vaccine. The boy was shaking uncontrollably. The video made impacted her deeply with incredibly sadness for that boy who had his whole life ahead of him, and fear for her own children. She firmly believes her children are at dire risk if EUA is granted to allow medical experimentation on adolescents through these COVID-19

Vaccines. There is no circumstance under which Amy will allow her children to receive the experimental COVID-19 Vaccine.

108. Amy knows that there has not been proper testing for the experimental COVID-19 Vaccine. She knows that no other vaccination ever created was introduced into humans until after extensive animal testing. Amy also discovered that animal testing was initiated with these experimental Vaccines, but the animals died. Now, she has learned, the VAERS data says there are more adverse reactions to this injection than in the previous 20 years combined for all vaccinations. Amy wonders how many thousands of deaths it will take before the Vaccines are taken off the market. In doing extensive research about the COVID Vaccine, Amy has learned that children have a 100% chance of living through COVID-19. None of the adverse information that this Plaintiff has discovered about the Vaccines, and none of the information about alternatives, was supplied by the Defendants or as a result of their efforts.

109. RICHARD KENNEDY is a resident of Dallas, Louisiana. His mother Dovi Sanders Kennedy lived in an assisted living facility called Savannah Grand in Bossier City, Louisiana. She was 89 years old and in good health, until she was killed by the experimental COVID-19 Vaccine that was forced on her despite a direct refusal of the Vaccine by her Guardian. Richard visited his mom on Christmas Day, December 25, 2020, one month before her birthday, and she looked great. Like always she was in a great mood. She was reading her Bible. The next time Richard visited his mom was on January 25, 2021. It was her birthday and Richard, with his youngest daughter, visited her around 10:00 am. As soon they walked in Richard sensed something was not right. His mom was always smiling and in good spirits and never complained about anything. On

this day, however, she had her comforter curled up on one side of her in a way that Richard had never seen before, and she just did not look right. But it was her birthday so Richard and his daughter did what they could to cheer her up. They took several pictures and stayed with her for a little over an hour.

110. Richard later learned through another resident's daughter that the facility, Savannah Grand, had made it mandatory for all residents to get the experimental Covid-19 Vaccine and that the first dose was given on January 25. Richard's older brother, who is their mother's medical decision maker, informed Richard that Savannah Grand contacted him and asked about giving his mother the experimental Covid-19 Vaccine and he told them not to. They administered the experimental Covid-19 Vaccine anyway.

111. Richard took pictures on his mom's birthday and was disturbed at her sad face, and the way she was holding her right arm and the heavy bruising on her neck in the lymph node area. His Mom was paralyzed on her left side from a stroke 20 years ago. She had some movement, but she always used her right hand to do everything. Looking at the pictures taken on her birthday Richard noticed she was not using her right hand and that it was tightened up almost closed. She was clearly in pain from getting the shot on her right side. She was trying to hold on to a cup cake with her index finger on her left side, the side that she had little movement on.

112. Richard's mother had a bit of Alzheimer's, so he believes she did not know what was going on when they gave her the Vaccine. She certainly could not have given informed consent. But she was in pain and bruised heavily on the right side, which Richard did not discover until after she died when he began to examine his pictures of her. His mom was administered a second dose of the Vaccine on February 22, 2021,

according to another resident's daughter. Richard and his brother, their mom's guardian, were never told that their mother received the Vaccine, on either the first or second dosage. Richard next visited his mother on February 1 or 2, and again on February 7. He spent a few hours with her on the February 7, and it was clear to Richard that she was not the same person anymore.

113. On March 1, Richard's brother called him around 6:00 PM and told him that their mother was almost dead. Stunned, Richard rushed to the home where their mother was in bed near death. Curiously, however, her heart rate was normal. They stayed with their mother until 9:00 PM that night on Monday and were told she would not make it until Tuesday.

114. Richard could not understand how this happened to her so quickly. His mother had no underlying medical problems with internal organs and her heart was beating fine but she was laying there dehydrated and unable not talk. Nevertheless, his mother was never taken to the hospital. She did survive that night and Richard spent most of the day Tuesday, March 2 sitting beside her bed holding her hand. The staff had already written up a death certificate. She died on March 5. None of the adverse information that this Plaintiff has discovered about the Vaccines, and none of the information about alternatives, was known to this Plaintiff prior to his mother sustaining Vaccine injury, and none was supplied by the Defendants or as a result of their efforts.

115. ESTATE OF DOVI SANDERS KENNEDY, is represented by its Administrator Richard Kennedy. The allegations of the preceding paragraph are incorporated herein by reference. None of the adverse information that this Plaintiff has discovered about the Vaccines, and none of the information about alternatives, was

known to this Plaintiff prior to sustaining Vaccine injury, and none was supplied by the Defendants or as a result of their efforts.

116. LYLE BLOOM, of Huntsville, Alabama, is the father of two children ages 10 and 16, and the father of one young adult aged 21. Lyle has researched the Vaccines and fiercely opposes their use in healthy children of any age. Lyle recently watched the podcast interview where Robert F. Kennedy Jr. interviewed the mother of a young man named Everest Romney. Everest was a healthy top-level athlete from Utah. Everest took the Vaccine, followed by his father and his pregnant mother, who each took a Vaccine the same day. One took the Pfizer Vaccine and the other took the Moderna Vaccine. Everest and his father were hospitalized within days with blood clots on their brain. Lyle is afraid of what will happen to his own children if the Vaccine experiments are not stopped immediately.

117. Lyle knows that his own children are placed at immediate and irreparable risk of harm by the extension of the Vaccine EUAs to adolescents. Lyle is well aware that there are safe and effective alternative treatments readily available, and he adamantly opposes the suppression of those treatments in favor of experimental and potentially life-threatening agents. None of the adverse information that this Plaintiff has discovered about the Vaccines, and none of the information about alternatives, was supplied by the Defendants or as a result of their efforts.

118. JULIE BLOOM, of Huntsville, Alabama, is the wife of Lyle Bloom and the mother of their two children ages 10 and 16, and the mother of their young adult aged 21. The allegations of the preceding paragraph are incorporated by reference. None of the adverse information that this Plaintiff has discovered about the Vaccines, and none of

the information about alternatives, was supplied by the Defendants or as a result of their efforts.

119. ANDREA MCFARLANE, RN, of Huntsville, Alabama, currently works as a trauma/ICU nurse at Vanderbilt. She is the mother of 4 children, 10, 12, 14 and 16. As a nurse Andrea has seen tremendous pressure placed on staff to get the experimental COVID-19 Vaccines. Even medical staff that have had COVID-19 are pressured relentlessly to take the experimental Vaccines. It is well known among the staff that taking the experimental Vaccines will leave you sick for days, and they accommodate for the expected sick reactions in their staffing plans. Andrea is also in school and as a student she is pressured and incentivized to get vaccinated. As a mother, Andrea knows only too well the tremendous pressure her boys will be under to get vaccinated. They will be under social and school pressure and Andrea deeply fears for their safety. She has studied the Vaccines. She knows that they are experimental and that they have proven harmful in many cases. She knows that her children are not at risk from COVID-19 and believes it should be illegal and that it is immoral to give an experimental and untested Vaccine to children who are not at risk. She believes that if the relief sought herein is not granted, not only will her children be at grave risk of irreparable harm, but she will be subjected to pressure in her profession to comply with an immoral policy. The AMA, through an updated ethics opinion, has already opined that medical institutions will likely have an obligation to require that their staff get injected with the Vaccines. When this happens, Andrea will be unable to work because she will not follow a policy that she believes is immoral. None of the adverse information that this Plaintiff has discovered

about the Vaccines, and none of the information about alternatives, was supplied by the Defendants or as a result of their efforts.

120. JENNIFER GREENSLADE, of Remlap, Alabama, has an autoimmune disorder for which she takes medicine on a daily basis. She has researched the Vaccines and is aware that to take them would be to inject herself with an unknown agent that is largely unstudied, but which carries risk to anyone with an autoimmune disease. She fears deeply for her own health and the health of her children, ages 9 and 12. The type of disease she has can be hereditary and nobody knows how it might interact with her children's health, whereas COVID-19 itself poses no risk of death to her children whatsoever.

121. Jennifer has two cousins who did allow themselves to be injected with the Vaccines. They were both healthy prior to the injection. They became extremely ill after being injected and spent weeks on the brink of death in the ICU. They are now out of the ICU but neither of them can walk and they require care from their children. This type of Vaccine related injury constitutes irreparable harm. Her cousins were in good health and now they are unable to walk even though they survived the initial onslaught of the vaccine related sickness. Jennifer's health is not strong and her children may have inherited her autoimmune disorder. If they are pressured or mandated to take the Vaccine and experience reactions similar to Jennifer's cousins' reactions, she and her children might not survive. For a mother of two small children, it is a stark and terrifying concern to think that they may be killed or paralyzed or that she may be rendered unable to care for them or worse. None of the adverse information that this Plaintiff has discovered

about the Vaccines, and none of the information about alternatives, was supplied by the Defendants or as a result of their efforts.

122. STEVEN M. ROTH, MD, of Alabama, has been a practicing emergency medicine physician for 13 years. As part of his practice, Dr. Roth sees patients of all ages. He is aware of the risks and benefits of these investigational agents as well as the current vaccine schedule for other diseases. Based on the most recent numbers from the CDC from May 5, 2021, anyone under the age of 18 has statistically no risk of dying of Covid-19.

123. Dr. Roth has not seen a COVID-19 patient in many months, but he is currently seeing many patients come to the emergency department as post-COVID-19 Vaccine patients. All of said patients came in with COVID-19 like symptoms that occurred within 48 hours of the Vaccine. All said patients required hospital admission. Several of said patients progressed to death, caused by the Vaccine.

124. Dr. Roth's concern is that based upon what he is seeing in the community, and because of the schools asking that students take the experimental COVID-19 Vaccines and putting obstacles around those who do not take it, young people are being pressured to take an experimental Vaccine, and many are succumbing to that pressure. This is deeply disturbing to Dr. Roth, because it is universally known that children statistically do not die from COVID-19 and given that children have a very strong immune system, they are more likely than adults to have an over-reaction to the Vaccine. This means that there is not only no benefit, but also an increased risk for children who receive the Vaccine. Also, with all prior viruses and vaccines, it has been accepted in the medical community that natural immunity is superior to vaccination, and there is no basis

to believe that would be different with SARS-CoV-2. Because of these factors, it is not preferable to give the Vaccine even if it was definitely safe, which these are not.

125. In addition, Dr. Roth is extraordinarily concerned that there have been no animal studies, nor long-term studies, of the COVID-19 Vaccines, especially since prior coronavirus vaccines all caused death in the animals subjected to them.

126. Dr. Roth is aware of many thousands of physicians who agree with him, but who are under great pressure to say nothing. Dr. Roth has chosen to speak out now, at great personal cost to himself, because the alternative is unbearable. Dr. Roth could not live with himself if he stood by and allowed these experimental Vaccines to be inflicted upon children universally, resulting in death and destruction over the years. He considers it immoral and unconscionable that this experimental therapy will be given to children. Not only are children not at risk of death from COVID-19, but they are also not mini-adults. Their organs are still forming, and they are even more vulnerable than adults to developing auto-immune disease in this situation.

127. Dr. Roth would be deeply and directly affected by a change in FDA guidelines regarding Vaccines for young people, and as a result he is imploring this Court to grant the relief requested herein, and to prevent the use of these Vaccines in children. In addition to the direct threat of irreparable harm posed to Dr. Roth's young patients, an additional unwelcome consequence of using coercion to mandate or pressure the participation of healthy young people who are statistically at no risk, is the risk of sharply reducing the public trust in all vaccines. This would also create what can only be described as irreparable harm to the public generally. None of the adverse information

that this Plaintiff has discovered about the Vaccines, and none of the information about alternatives, was supplied by the Defendants or as a result of their efforts.

128. MATT SCHWEDER, of Lexington, Kentucky, is the father of one minor daughter, age 15, and an adult son, age 25. Matt's son is in the Advanced Nurse Practitioner Program at Vanderbilt University. Matt's daughter is an active student and plays soccer for her high school. Matt has, until recently, coached girls select soccer for a number of years and he is very aware of the extraordinary power of peer pressure in the life of young adolescents. Matt's daughter is subjected to a barrage of peer pressure regarding vaccinating, which is a constant source of conversation for her friends, who have been taught to fear that which should hold no fear.

129. In addition, her school system bombards her with weekly emails, pressuring and shaming her and her family into allowing themselves to be experimented on with the experimental Vaccines. The pressure is so intense that one of Matt's daughter's friends was forced to take the Vaccine by his own mother, against his will, at the age of 16, and Matt's daughter had to undergo the trauma of knowing that her friend had become part of this dangerous human experiment even though he was adamantly opposed to doing so. Matt has conducted his own research into COVID-19, and he is well aware that children under the age of 18 have a 0% chance statistically of dying from COVID-19. Matt knows that safe and effective treatments for COVID-19 are available and he fiercely opposes the suppression of these treatments in favor of using untested and potentially life-threatening agents against children who are not at risk. As a father, Matt has witnessed the growing concern his son has, that his school or potential employer might decide to make the experimental agents mandatory, which would put his education

to waste. None of the adverse information that this Plaintiff has discovered about the Vaccines, and none of the information about alternatives, was supplied by the Defendants or as a result of their efforts.

Defendants

130. Defendants are federal agencies, sub-agencies and federal officials.

131. Defendant XAVIER BECERRA ("Secretary Becerra") is the current Secretary of Defendant the U.S. Department of Health and Human Services. He is being sued in his official and personal capacities.

132. Defendant DR. ANTHONY FAUCI ("Dr. Fauci") is the current Director of Defendant National Institute of Allergies and Infectious Diseases, a federal sub-agency of the Department of Health and Human Services. He is being sued in his official and personal capacities.

133. Defendant DR. JANET WOODCOCK ("Dr. Woodcock") is the current Acting Commissioner of the Food and Drug Administration, a federal sub-agency of the Department of Health and Human Services. She is being sued in her official and personal capacities.

134. Defendant U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES ("DHHS") is a federal agency.

135. Defendant FOOD AND DRUG ADMINISTRATION ("FDA") is a federal sub-agency of DHHS.

136. Defendant CENTER FOR DISEASE CONTROL AND PREVENTION ("CDC") is a federal sub-agency of DHHS.

137. Defendant NATIONAL INSTITUTE OF HEALTH ("NIH") is a federal sub-agency of DHHS.

138. Defendant NATIONAL INSTITUTE OF ALLERGIES AND INFECTIOUS DISEASES ("NIAID") is a federal sub-agency of DHHS.

139. JOHN AND JANE DOES I - V, are as yet unknown agencies and individuals who violated the law and harmed Plaintiffs.

140. The Defendants have coordinated, collaborated, planned and conspired, each with the others, and aided and abetted, the unlawful actions described herein.

III. JURISDICTION, VENUE, STANDING

141. This Court exercises subject matter jurisdiction under 28 U.S.C. § 1331, which confers original jurisdiction on federal district courts to hear suits arising under the laws and Constitution of the United States.

142. This Court also exercises subject matter jurisdiction in accordance with 28 U.S.C. § 1361, which grants to district courts original jurisdiction "of any action to compel an officer or employee of the United States or any agency thereof to perform a duty owed to the plaintiff." Defendants owe a duty to Plaintiffs to comply faithfully with § 360bbb-3 and 45 CFR Part 46, the provisions of which are intended to protect them.

143. This Court has the authority to the requested declaratory relief under 28 U.S.C. § 2201, and the requested injunctive relief under 28 U.S.C. § 1343(a).

144. This Court is the appropriate venue for this litigation pursuant to 28 U.S.C. § 1391(e)(1) since the Defendants are officers or employees of the United States acting in an official capacity or under color of legal authority, and agencies of the United States, at least one Plaintiff resides in this District, and real property is not involved.

145. The Administrative Procedures Act ("APA") provides: "A person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of the relevant statute, is entitled to judicial review thereof." 5 U.S.C. § 702. Further:

> *[t]he reviewing court shall -*
>
> > *(2) hold unlawful and set aside agency action, findings, and conclusions found to be -*
> >
> > > *(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;*
> > > *(B) contrary to constitutional right, power, privilege, or immunity;*
> > > *(C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right*

5 U.S.C. § 706.

146. Plaintiffs satisfy the "case-or-controversy" requirement of Article III of the Constitution and have standing to sue because they:

> *[have] suffered an "injury in fact" that is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical; (2) the injury is fairly traceable to the challenged action of the defendant; and (3) it is likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision.*

Sproule v. United States FDA, 2018 U.S. Dist. LEXIS 62507 at *7 (S.D.Fl. 2018) (quoting Fla. Wildlife Fed'n, Inc. v. S. Fla. Water Mgmt. Dist., 647 F.3d 1296, 1302 (11th Cir. 2011)).

IV. STATEMENT OF FACTS

A. The Emergency Use Authorization Framework

Basis for DHHS Secretary's Declaration of Emergency

147. § 360bbb–3(b) authorizes the DHHS Secretary to declare a "public health emergency" justifying the emergency use of unapproved medical products, in relevant part as follows (emphasis added):

> *(b) Declaration of emergency or threat justifying emergency authorized use*
>
> *(1) In General. The Secretary may make a declaration that the circumstances exist justifying the authorization under this subsection for a product on the basis of—*
>
> *[ ]*
>
> *(C) a determination by the Secretary that there is a public health emergency, or a significant potential for a public health emergency, **that affects, or has a significant potential to affect, national security** or the health and security of United States citizens living abroad, and that involves a biological, chemical, radiological, or nuclear agent or agents, or a disease or condition that may be attributable to such agent or agents;*

148. The DHHS Secretary declared a "public health emergency" pursuant to § 360bbb–3(b)(1)(C) on February 4, 2020, after making the relevant finding. Plaintiffs contend and the facts set forth below demonstrate that the finding was made in error, without any real justification, since there is no bona fide underlying public health emergency, and as such the EUAs for the Vaccines are unlawful.

Criteria for Issuance of Emergency Use Authorization

149. Once the DHHS Secretary has declared a public health emergency, § 360bbb–3(c) authorizes him to issue EUAs "only if" certain criteria are met, in relevant part as follows (emphasis added):

> *(c) Criteria for issuance of authorization. The Secretary may issue an authorization under this section with respect to the emergency use of a product **only if**, [ ] the Secretary concludes -*
>
> *(1) that an agent referred to in a declaration under subsection (b) can cause **a serious or life threatening disease or condition**,*
>
> *(2) that, based on the totality of scientific evidence available to the Secretary, including **data from adequate and well-controlled clinical trials**, if available, **it is reasonable to believe that**—*

> *(A) **the product may be effective** in diagnosing, treating, or preventing—*
>
> *(i) such disease or condition; or*
>
> *(ii) a serious or life-threatening disease or condition caused by a product authorized under this section, approved or cleared under this chapter, or licensed under section 351 of the Public Health Service Act [42 U.S.C. 262], for diagnosing, treating, or preventing such a disease or condition caused by such an agent; and*
>
> *(B) **the known and potential benefits of the product**, when used to diagnose, prevent, or treat such disease or condition, **outweigh the known and potential risks of the product**, taking into consideration the material threat posed by the agent or agents identified in a declaration under subsection (b)(1)(D), if applicable;*
>
> *(3) that there is **no adequate, approved, and available alternative** to the product for diagnosing, preventing, or treating such disease or condition;*

150. Plaintiffs contend and the facts set forth below demonstrate that the Secretary has not met and cannot meet the criteria for issuing EUAs for the Vaccines.

Conditions of Authorization

151. Once an EUA has been issued, § 360bbb–3(e) obligates the Secretary to establish such conditions on an authorization as are necessary to ensure that both healthcare professionals and consumers receive certain minimum required information, in relevant part as follows (emphasis added):

> *(e) Conditions of authorization*
>
> *(1) Unapproved Product*
>
> *(A) **Required** conditions. With respect to the emergency use of an unapproved product, the Secretary [ ] **shall** [ ] establish [ ]:*
>
> *(i) Appropriate conditions **designed to ensure** that health care professionals administering the product are informed -*
>
> *(I) that the Secretary has authorized the **emergency use** of the product;*
>
> *(II) of the **significant known and potential benefits and risks** of the emergency use of*

> *the product, and of the extent to which such benefits and risks are known; and*
> *(III) of the **alternatives** to the product that are available, and of their benefits and risks.*
> *(ii) Appropriate conditions designed to ensure that individuals to whom the product is administered are informed -*
> *(I) that the Secretary has authorized the **emergency use** of the product;*
> *(II) of the **significant known and potential benefits and risks** of the emergency use of the product, and of the extent to which such benefits and risks are known; and*
> *(III) of the **option to accept or refuse** administration of the product, of the consequences, if any, of refusing administration of the product, and of the **alternatives** to the product that are available, and of their benefits and risks.*
> *(iii) Appropriate conditions for the **monitoring and reporting of adverse events** associated with the emergency use of the product.*

152. Plaintiffs contend and the facts set forth below demonstrate that the Secretary has failed to satisfy the conditions for authorization, because he has not ensured that healthcare professionals and Vaccine subjects are properly informed.

B. The Vaccine EUAs are Unlawful - There is No Underlying Emergency

153. In approximately January of 2020, the media began creating and circulating news stories that seemed designed to generate panic, regarding a new and deadly disease that could kill us all. This was odd given that the estimated fatality rate at the time was between 2-4%. By contrast, tuberculosis has a fatality rate of approximately 10%, the original SARS virus had a fatality rate of approximately 9%, and the MERS virus had a fatality rate of approximately 30% - all had similar rates of spread.

154. The actual COVID-19 statistics present a vastly different picture than the one painted by the media - a fatality rate of 0.2% globally, which drops to 0.03% for

persons under age 70, which is comparable to the yearly flu. Further, statistically, the fatality risk is limited to the elderly population. The Defendants' own data published through publicly accessible government portals[7] establishes that there is no public health emergency due to SARS-CoV-2 and COVOD-19:

United States Totals	
COVID-19 Emergency Room Visits	1.2% are due to COVID-19 (In 26 states, COVID-19 accounts for less than 1% of ER visits. The highest percentage is 3.1%).
COVID-19 Inpatients	4% of all inpatients are due to COVID-19
COVID-19 ICU Patients	9% of all ICU are due to COVID-19
COVID-19 Hospitalizations	15 per 100,000 or less in 46 states, and 20 per 100,000 or less in 49 states
COVID-19 "Cases"	9 per 100,000 per day

155. The actual COVID-19 fatality numbers are vastly lower than those reported. On March 24, 2020, the DHHS changed the rules applicable to coroners and others responsible for producing death certificates and making "cause of death" determinations - **exclusively for COVID-19**. The rule change states that "COVID-19 should be reported on the death certificate for all decedents where the disease caused *or is assumed to have caused or contributed* to death." Many doctors have attested that permitting such imprecision on a legal document (death certificate) has never happened before in modern medicine. This results in reporting of deaths as caused by COVID-19, even when in fact deaths were imminent and inevitable for other pre-existing reasons and caused by co-morbidities. In other words, people dying **with** COVID-9 are being reported as dying **from** COVID-19. DHHS statistics are now showing that 95% of

[7] See, e.g., https://healthdata.gov and https://healthdata.gov/Health/COVID-19-Community-Profile-Report/gqxm-d9w9

deaths classed as "COVID-19 deaths" involve an average of four additional co-morbidities.

156. Substantial government subsidies paid for reported COVID-19 deaths undoubtedly fuel this misattribution of the cause of death. Former CDC Director Robert Redfield acknowledged this perverse financial incentive in sworn Congressional testimony on COVID-19: "I think you're correct in that we've seen this in other disease processes too, really in the HIV epidemic, somebody may have a heart attack, but also have HIV – the hospital would prefer the classification for HIV because there's greater reimbursement."

157. Dr. Genevieve Briand of John Hopkins University published a study demonstrating that the overall death rate in the United States has remained the same, despite the deaths attributed to COVID-19. Dr. Briand analyzed federal CDC data for 2018 and 2020 and found that nationwide deaths from causes other than COVID-19, decreased by the same amount that COVID-19 deaths increased, raising the presumption that deaths from these other causes have been characterized as COVID-19 deaths. There are no excess deaths due to COVID-19.

158. Similarly, the actual number of COVID-19 "cases" is far lower than the reported number. The signs, symptoms and other diagnostic criteria for COVID-19 are laughably broad. Applying the criteria, countless ailments can be classed as COVID-19, especially the common cold or ordinary seasonal flu. Compounding the problem, the DHHS authorized the use of the polymerase chain reaction ("PCR") test as a diagnostic tool for COVID-19, with disastrous consequences. The PCR tests are themselves experimental products, authorized by the FDA under separate EUAs. Test manufacturers

use disclaimers like this in their product manuals: "[t]he FDA has not determined that the test is safe or effective for the detection of SARS-Co-V-2."

159. A PCR test can only test for the presence of a fragment of the RNA of the SARS-CoV-2 virus, and literally, by itself, cannot be used to diagnose the COVID-19 disease. The RNA fragment detected may not be intact and may be dead, in which case it cannot cause the disease COVID-19. This is analogous to finding a car part, but not a whole car that can be driven. Manufacturer inserts furnished with PCR test products include disclaimers stating that the PCR tests should NOT be used to diagnose COVID-19. This is consistent with the warning issued by the Nobel Prize winning inventor of the PCR test that such tests are not appropriate for diagnosing disease.

160. Further, the way in which the PCR tests are administered guaranties an unacceptably high number of false positive results. Cycle Threshold Value ("CT value") is essentially the number of times that a sample (usually from a nasal swab) is magnified or amplified before a fragment of viral RNA is detected. The CT Value is exponential, and so a 40-cycle threshold means that the sample is magnified around a trillion times. The higher the CT Value, the less likely the detected fragment of viral RNA is intact, alive and infectious.

161. Virtually all scientists, including Dr. Fauci, agree that any PCR test run at a CT value of 35-cycles or greater is useless. Dr. Fauci has stated:

> ***What is now evolving into a bit of a standard is that if you get a cycle threshold of 35 or more that the chances of it being replication competent are miniscule****…We have patients, and it is very frustrating for the patients as well as for the physicians…somebody comes in and they repeat their PCR and it's like 37 cycle threshold…you can almost never culture virus from a 37 threshold cycle. So I think if somebody does come in with 37, 38, even 36, you gotta say, you know, it's dead nucleotides, period." In other words, it is not a COVID-19 infection.*

A study funded by the French government showed that even at 35-cycles, the false positivity rate is as high as 97%. Despite this, a majority of the PCR tests for COVID-19 deployed under EUAs in the United States are run at cycles seemingly guaranteed to produce false positive results. Under the EUAs issued by the FDA, there is no flexibility to depart from the manufacturer's instructions and change the way in which the test is administered or interpreted. The chart below shows that all major PCR tests in use in the United States are run at cycles of 35 or higher.

Manufacturer	Manufacturer's Recommended Cycle Threshold
Xiamen Zeesan SARS-CoV-2 Test Kit (Real-time PCR)	45 cycles
Opti Sars CoV-2 RT-PCR Test	45 cycles
Quest SARS-CoV-2rRT-PCR Test	40 cycles
CDC 2019-Novel Coronavirus Real Time (RT-PCR Diagnostic Panel) Test	40 cycles
Wren Labs COVID-19 PCR Test	38 cycles
LabCorp COVID-19 RT-PCR Test	35 cycles

162. There is, however, one GLARING exception to this standard. THE CDC HAS STATED THAT ONCE A PERSON HAS BEEN VACCINATED, AND THEN AFTER VACCINATION THAT PERSON TESTS POSITIVE FOR COVID-19 USING A PCR TEST, THE CDC WILL ONLY "COUNT" THE POSITIVE RESULT AT 28 CYCLES OR LESS! Why the difference? More recently, the CDC has announced it will no longer compile and report data showing the total number of vaccinated who subsequently contract COVID-19: "[We are] transitioning to reporting only patients with COVID-19 vaccine breakthrough infection that were hospitalized or died to help

maximize the quality of the data collected."[8] There appears to be an agenda to protect the myths about the vaccine, rather than to protect the public.

163. The Defendants and their counterparts in state governments used the specter of "asymptomatic spread" - the notion that fundamentally healthy people could cause COVID-19 in others - to justify the purported emergency. But there is *no credible scientific evidence* that demonstrates that the phenomenon of "asymptomatic spread" is real. On the contrary, on June 7, 2020, Dr. Maria Von Kerkhov, head of the WHO's Emerging Diseases and Zoonosis Unit, told a press conference that from the known research, asymptomatic spread was "very rare." "From the data we have, it still seems to be rare that an asymptomatic person actually transmits onward to a secondary individual." She added for emphasis: "it's very rare." Researchers from Southern Medical University in Guangzhou, China, published a study in August 2020 concluding that asymptomatic transmission of COVID-19 is *almost non-existent*. "Asymptomatic cases were least likely to infect their close contacts," the researchers found. A more recent study involving nearly 10 million residents of Wuhan, China found that there were no - zero - positive COVID-19 tests amongst 1,174 *close contacts* of asymptomatic cases, *indicating the complete absence of asymptomatic transmission*.

164. On September 9, 2020, Dr. Fauci was forced to admit in an official press conference:

> *[E]ven if there is some asymptomatic transmission, in all the history of respiratory borne viruses of any type, asymptomatic transmission has never been the driver of outbreaks. The driver of outbreaks is always a symptomatic person, even if there is a rare asymptomatic person that might transmit, an epidemic is not driven by asymptomatic carriers.*

[8] https://www.cdc.gov/vaccines/covid-19/health-departments/breakthrough-cases.html

165. Ultimately, there is simply no objective evidence to support the Secretary's finding - the necessary legal predicate for unleashing dangerous experimental medical interventions on the American public - that a true public health emergency exists. On a national level, Plaintiffs are unaware of any inter-country requests for aid, or legitimately overwhelmed community health resources or hospitals. The Cambridge dictionary defines the word "emergency" to mean "something dangerous or serious, such as an accident, that happens suddenly or unexpectedly and needs fast action in order to avoid harmful results." COVID-19 has been with us for well over a year, and we know far more about the disease than we did at the outset. Most importantly, we can identify with precision the discrete age segment of the population that is at potential risk. In particular, children under 18 statistically have a zero percent chance of death from COVID-19. If there is no emergency, then the EUAs should be invalidated entirely.

C. The Vaccine EUAs are Unlawful - The Vaccines are Not Effective in Diagnosing, Treating or Preventing SARS-CoV-2 or COVID-19

166. Some countries with the highest rates of Vaccine injection are facing a surge of COVID-19 deaths and infections. Uruguay endured the highest COVID-19 death rate in the world per capita for weeks, even though it had one of the world's most successful vaccination drives. Other highly vaccinated countries like Bahrain, Maldives, Chile and Seychelles, experienced the same surge.

167. CDC data shows that deaths and hospitalizations for COVID-19 infection have tripled among those who have already received the full recommended dosage of the Vaccines in the United States in the past month. Deaths from COVID-19 in those who have received the recommended dosages of the Vaccines increased from 160 as of April 30, 2021 to 535 as of June 1, 2021.

168. CDC data shows that a total of 10,262 SARS-CoV-2 "breakthrough infections" of those who have already received the full recommended dosage of the Vaccines were reported to the CDC from 46 states and territories between January 1, 2021 and April 30, 2021. Meanwhile, a study published by the renowned Cleveland Clinic in Ohio indicates that natural immunity acquired through prior infection with COVID-19 is stronger than any benefit conferred by a Vaccine, rendering vaccination unnecessary for those previously infected.

169. In studying the effectiveness of a medical intervention in randomized controlled trials (often called the gold standard of study design), the most useful way to present results is in terms of Absolute Risk Reduction ("ARR"). ARR compares the impact of treatment by comparing the outcomes of the treated group and the untreated group. In other words, if 20 out of 100 untreated individuals had a negative outcome, and 10 out of 100 treated individuals had a negative outcome, the ARR would be 10% (20 - 10 = 10). **According to a study published by the NIH, the ARR for the Pfizer Vaccine is a mere 0.7%, and the ARR for the Moderna Vaccine is only 1.1%.**

170. From the ARR, one can calculate the Number Needed to Vaccinate ("NNV"), which signifies the number of people that must be injected before even one person benefits from the vaccine. The NVV for the Pfizer Vaccine is 119, meaning that 119 people must be injected in order to observe the reduction of a COVID-19 case in one person. The reputed journal the *Lancet* reports data indicating that the NVV may be as high as 217. The NVV to avoid hospitalization exceeds 4,000. The NVV to avoid death exceeds 25,000.

171. There are several factors that reduce any purported benefit of the COVID-19 Vaccines. First, it is important to note that the Vaccines were only shown to reduce symptoms – not block transmission. For over a year now, these Defendants and state-level public health authorities have told the American public that SARS-CoV-2 can be spread by people who have none of the symptoms of COVID-19, therefore Americans must mask themselves, and submit to innumerable lockdowns and restrictions, even though they are not manifestly sick. If that is the case, and these officials were not lying to the public, and asymptomatic spread is real, then what is the benefit of a vaccine that merely reduces symptoms? There isn't any.

172. Secondly, it appears that these Defendants either did lie about asymptomatic spread or were simply wrong about the science. The theory of asymptomatic transmission - used as the justification for the lockdown and masking of the healthy - was based *solely* upon mathematical modeling. This theory had no actual study participants, and no peer review. The authors made the unfounded assumption that asymptomatic persons were "75% as infectious" as symptomatic persons. But in the real world, healthy false positives turned out to be merely healthy, and were never shown to be "asymptomatic" carriers of anything. Studies have shown that PCR test-positive asymptomatic individuals do not induce clinical COVID-19 disease, not even in a family member with whom they share a home and extended proximity. An enormous study of nearly ten million people in Wuhan, China showed that asymptomatic individuals testing positive for COVID-19 **never** infected others. Since asymptomatic individuals do not spread COVID-19, they do not need to be vaccinated.

D. The Vaccine EUAs are Unlawful - The Known and Potential Risks of the Vaccines Outweigh the Known and Potential Benefits

The "Pfizer-BioNTech COVID-19 Vaccine" and the "Moderna COVID-19 Vaccine" are Novel Gene Therapy Technology, Not Vaccines

173. The CDC defines a "vaccine" as: "A product that stimulates a person's immune system to produce immunity to a specific disease, protecting the person from that disease. Vaccines are usually administered through needle injections but can also be administered by mouth or sprayed into the nose."[9] The CDC defines "immunity" as: "Protection from an infectious disease. If you are immune to a disease, you can be exposed to it without becoming infected."[10]

174. However, the "Pfizer-BioNTech COVID-19 Vaccine" and the "Moderna COVID-19 Vaccine" do not meet the CDC's own definitions. They do not stimulate the body to produce immunity from a disease. They are a synthetic fragment of nucleic acid embedded in a fat carrier that is introduced into human cells, not for the purpose of inducing immunity from infection with the SARS-CoV-2 virus, and not to block further transmission of the virus, but in order to lessen the symptoms of COVID-19. No published, peer-reviewed studies prove that the "Pfizer-BioNTech COVID-19 Vaccine" and the "Moderna COVID-19 Vaccine" confer immunity or stop transmission.

175. Further, the "Pfizer-BioNTech COVID-19 Vaccine" and the "Moderna COVID-19 Vaccine" are not "vaccines" within the common, lay understanding of the public. Since vaccines were first discovered in 1796 by Dr. Edward Jenner, who used cowpox to inoculate humans against smallpox, and called the process "vaccination" (from the Latin term *vaca* for cow), the public has had an entrenched understanding that a vaccine is a microorganism, either alive but weakened, or dead, that is introduced into the

[9] https://www.cdc.gov/vaccines/vac-gen/imz-basics.htm. Retrieved 4/9/2021 at 11:00 AM
[10] https://www.cdc.gov/vaccines/vac-gen/imz-basics.htm. Retrieved 4/9/2021 at 11:00 AM

human body in order to trigger the production of antibodies that confer immunity from the targeted disease, and also prevent its transmission to others. The public are accustomed to these traditional vaccines and understand them.

176. The public are fundamentally uninformed about the gene therapy technology behind the "Pfizer-BioNTech COVID-19 Vaccine" and the "Moderna COVID-19 Vaccine." No dead or attenuated virus is used. Rather, instructions, via a piece of genetic code ("mRNA") are injected into your body that tell your body how to make a certain "spike protein" that is purportedly useful in attacking the SARS-CoV-2 virus.

177. By referring to the "Pfizer-BioNTech COVID-19 Vaccine" and the "Moderna COVID-19 Vaccine" as "vaccines," and by allowing others to do the same, the Defendants knowingly seduce and mislead the public, short-circuit independent, critical evaluation and decision-making by the consumers of these products, and vitiate their informed consent. Meanwhile, this novel technology is being deployed in the unsuspecting human population for the first time in history.

Inadequate Testing

178. The typical vaccine development process takes between 10 and 15 years and consists of the following sequential stages - research and discovery (2 to 10 years), pre-clinical animal studies (1 to 5 years), clinical human trials in four phases (typically 5 years). Phase 1 of the clinical human trials consists of healthy individuals and is focused on safety. Phase 2 consists of additional safety and dose-ranging in healthy volunteers, with the addition of a control group. Phase 3 evaluates efficacy, safety and immune response in a larger volunteer group, and requires two sequential randomized controlled

trials. Phase 4 is a larger scale investigation into longer-term safety. Vaccine developers must follow this process in order to be able to generate the data the FDA needs in order to assess the safety and effectiveness of a vaccine candidate.

179. This 10–15-year testing process has been abandoned for purposes of the Vaccines. The first human-to-human transmission of the SARS-CoV-2 virus was not confirmed until January 20, 2020, and less than a year later both mRNA Vaccines had EUAs and for the first time in history this novel mRNA technology was being injected into millions of human beings. As of June 7, 2021, 138 million Americans, representing 42% of the population, have been fully vaccinated.

180. All of the stages of testing have been compressed in time, abbreviated in substance, and are overlapping, which dramatically increases the risks of the Vaccines. Plaintiffs' investigation indicates that Moderna and Pfizer designed their Vaccines in only two days. It appears that pharmaceutical companies did not independently verify the genome sequence that China released on January 11, 2020. It appears that the Vaccines were studied for only 56 days in macaques, and 28 days in mice, and then animal studies were halted. It appears that the pharmaceutical companies discarded their control groups receiving placebos, squandering the opportunity to learn about the rate of long-term complications, how long protection against the disease lasts and how well the Vaccines inhibit transmission. A number of studies were deemed unnecessary and not performed prior to administration in human subjects, including single dose toxicity, toxicokinetic, genotoxicity, carcinogenicity, prenatal and postnatal development, offspring, local tolerance, teratogenic and postnatal toxicity and fertility. The American public has not

been properly informed of these dramatic departures from the standard testing process, and the risks they generate.

181. AFLDS medico-legal researchers have analyzed the accumulated COVID-19 Vaccine risk data, and report as follows:

Migration of the SARS-CoV-2 "Spike Protein" in the Body

182. The SARS-CoV-2 has a spike protein on its surface. The spike protein is what allows the virus to infect other bodies. It is clear that the spike protein is not a simple, passive structure. The spike protein is a "pathogenic protein" and a toxin that causes damage. The spike protein is itself biologically active, even without the virus. It is "fusogenic" and consequently binds more tightly to our cells, causing harm. If the purified spike protein is injected into the blood of research animals, it causes profound damage to their cardiovascular system, and crosses the blood-brain barrier to cause neurological damage. If the Vaccines were like traditional *bona fide* vaccines, and did not leave the immediate site of vaccination, typically the shoulder muscle, beyond the local draining lymph node, then the damage that the spike protein could cause might be limited.

183. However, the Vaccines were authorized without any studies demonstrating where the spike proteins traveled in the body following vaccination, how long they remain active and what effect they have. A group of international scientists has recently obtained the "biodistribution study" for the mRNA Vaccines from Japanese regulators. The study reveals that unlike traditional vaccines, this spike protein enters the bloodstream and circulates throughout the body over several days post-vaccination. It accumulates in a number of tissues, such as the spleen, bone marrow, liver, adrenal

glands and ovaries. It fuses with receptors on our blood platelets, and also with cells lining our blood vessels. It can cause platelets to clump leading to clotting, bleeding and heart inflammation. It can also cross the blood-brain barrier and cause brain damage. It can be transferred to infants through breast milk. The VAERS system includes reports of infants suckling from vaccinated mothers experiencing bleeding disorders in the gastrointestinal tract.

184. These risks have not been adequately studied in trials, or properly disclosed to healthcare professionals or Vaccine subjects.

Increased Risk of Death from Vaccines

185. The government operated VAERS database is intended to function as an "early warning" system for potential health risks caused by vaccines. It is broadcasting a red alert. Of the 262,000 total accumulated reports in VAERS, only 1772 are not related to COVID-19. The database indicates that the total reported vaccine deaths in the first quarter of 2021 represents a 12,000% to 25,000% increase in vaccine deaths, year-on-year. In ten years (2009-2019) there were 1529 vaccine deaths, whereas in the first quarter of 2021 there have been over 4,000. Further, 99% of all reported vaccine deaths in 2021 are caused by the COVID-19 Vaccines, only 1% being caused by the numerous other vaccines reported in the system. It is estimated that VAERS only captures 1% to 10% of all vaccine adverse events.

186. These risks have not been adequately studied in trials, or properly disclosed to healthcare professionals or Vaccine subjects.

Reproductive Health

187. The mRNA Vaccines induce our cells to manufacture (virus-free) "spike proteins." The "spike proteins" are in the same family as the naturally occurring syncytin-1 and syncytin-2 reproductive proteins in sperm, ova and placenta. Antibodies raised against the spike protein might interact with the naturally occurring syncytin proteins, adversely affecting multiple steps in human reproduction. The manufacturers did not provide data on this subject despite knowing about the spike protein's similarity to syncytin proteins for more than one year. There are now a remarkably high number of pregnancy losses in VAERS, and worldwide reports of irregular vaginal bleeding without clear explanation. Scientists are concerned that the Vaccines pose a substantial risk to a woman's reproductive system. This increased risk of sterility stems from an increased concentration of the spike proteins in various parts of the reproductive system after vaccination. Not enough is known to determine the risk of sterility, but it is beyond question that the risk is increased.

188. Since Plaintiffs filed their Motion for Temporary Restraining Order in this case, new evidence has emerged that further confirms the risk. A leaked Pfizer document (below) exposes that Pfizer Vaccine nanoparticles accumulate in the ovaries at an extraordinarily high rate, in concentrations orders of magnitude higher than in other tissues. Billions of aggressive spike proteins are accumulating in very delicate ovarian tissues, the one place in the human body where females carry a finite number of fertile eggs.

SARS-CoV-2 mRNA Vaccine (BNT162, PF-07302048)
2.6.5 薬物動態試験の概要表

2.6.5.5B. PHARMACOKINETICS: ORGAN DISTRIBUTION CONTINUED **Test Article: [**

Sample	Total Lipid concentration (µg lipid equivalent/g [or mL]) (males and females combined)							%
	0.25 h	1 h	2 h	4 h	8 h	24 h	48 h	0.25 h
Lymph node (mandibular)	0.064	0.189	0.290	0.408	0.534	0.554	0.727	--
Lymph node (mesenteric)	0.050	0.146	0.530	0.489	0.689	0.985	1.37	--
Muscle	0.021	0.061	0.084	0.103	0.096	0.095	0.192	--
Ovaries (females)	0.104	1.34	1.64	2.34	3.09	5.24	12.3	0.001
Pancreas	0.081	0.207	0.414	0.380	0.294	0.358	0.599	0.003
Pituitary gland	0.339	0.645	0.868	0.854	0.405	0.478	0.694	0.000
Prostate (males)	0.061	0.091	0.128	0.157	0.150	0.183	0.170	0.001
Salivary glands	0.084	0.193	0.255	0.220	0.135	0.170	0.264	0.003
Skin	0.013	0.208	0.159	0.145	0.119	0.157	0.253	--
Small intestine	0.030	0.221	0.476	0.879	1.28	1.30	1.47	0.024
Spinal cord	0.043	0.097	0.169	0.250	0.106	0.085	0.112	0.001
Spleen	0.334	2.47	7.73	10.3	22.1	20.1	23.4	0.013
Stomach	0.017	0.065	0.115	0.144	0.268	0.152	0.215	0.006
Testes (males)	0.031	0.042	0.079	0.129	0.146	0.304	0.320	0.007
Thymus	0.088	0.243	0.340	0.335	0.196	0.207	0.331	0.004
Thyroid	0.155	0.536	0.842	0.851	0.544	0.578	1.00	0.000
Uterus (females)	0.043	0.203	0.305	0.140	0.287	0.289	0.456	0.002
Whole blood	1.97	4.37	5.40	3.05	1.31	0.909	0.420	--
Plasma	3.97	8.13	8.90	6.50	2.36	1.78	0.805	--
Blood:Plasma ratio[a]	0.815	0.515	0.550	0.510	0.555	0.530	0.540	--

PFIZER CONFIDENTIAL
Page 7

189. Each baby girl is born with the total number of eggs she will ever have in her entire life. Those eggs are stored in the ovaries, and one egg is released each month of a normal menstrual cycle. When there are no more eggs, a woman stops menstruating. The reproductive system is arguably the most delicate hormonal and organ balance of all our systems. The slightest deviation in any direction and infertility results. Even in 2021, doctors and scientists do not know all the variables that cause infertility.

190. There is evidence to support that the vaccine could cause permanent autoimmune rejection of the placenta. Placental inflammation resulting in stillbirths mid-pregnancy (second trimester) is seen with COVID-19 and with other similar coronaviruses. There is a case report of a woman with a normally developing pregnancy

who lost the otherwise healthy baby at five months during acute COVID-19. The mother's side of the placenta was very inflamed. This "infection of the maternal side of the placenta inducing acute or chronic placental insufficiency resulting in miscarriage or fetal growth restriction was observed in 40% of pregnant women with similar coronaviruses." The mRNA Vaccines may instigate a similar reaction as the SARS-CoV-2 virus. There is a component in the vaccine that could cause the same autoimmune rejection of the placenta, but indefinitely. Getting COVID-19 has been associated with a high risk of mid mid-pregnancy miscarriage because the placenta fails. The mRNA Vaccines may have precisely the same effect, however, not for just the few weeks of being sick, but forever. Repeated pregnancies would keep failing - mid-pregnancy.

191. On December 1, 2020, a former Pfizer Vice President and allergy and respiratory researcher, Dr. Michael Yeadon, filed an application with the European Medicines Agency, responsible for approving drugs in the European Union, seeking the immediate suspension of all SARS-CoV-2 Vaccines, citing *inter alia* the risk to pregnancies. As of April 26, 2021, the VAERS database contains over 3,000 reports of failed pregnancies associated with the Vaccines.

192. These risks have not been adequately studied in trials, or properly disclosed to healthcare professionals or Vaccine subjects.

Vascular Disease

193. Salk Institute for Biological Studies researchers in collaboration with the University of San Diego, published in the journal *Circulation Research* that the spike proteins themselves damage vascular cells, causing strokes and many other vascular problems. All the vaccines are causing clotting disorders (coagulopathy) in all ages. The

spike proteins are known to cause clotting that the body cannot fix, such as brain thrombosis and thrombocytopenia.

194. These risks have not been adequately studied in trials, or properly disclosed to healthcare professionals or Vaccine subjects.

Autoimmune Disease

195. The spike proteins are perceived to be foreign by the human immune system, initiating an immune response to fight them. While that is the intended therapeutic principle, it is also the case that any cell expressing spike proteins becomes a target for destruction by our own immune system. This is an autoimmune disorder and can affect virtually any organ in the body. It is likely that some proportion of spike protein will become permanently fused to long-lived human proteins and this will prime the body for prolonged autoimmune diseases. Autoimmune diseases can take years to show symptoms and many scientists are alarmed at giving young people such a trigger for possible autoimmune disease.

196. These risks have not been adequately studied in trials, or properly disclosed to healthcare professionals or Vaccine subjects.

Neurological Damage

197. The brain is completely unique in structure and function, and therefore it requires an environment that is insulated against the rest of the body's functioning. The blood-brain-barrier exists so the brain can function without disruption from the rest of the body. This is a complex, multi-layered system, using several mechanisms that keeps nearly all bodily functions away from the brain. Three such systems include: very tight junctions between the cells lining the blood vessels, very specific proteins that go

between, and unique enzymes that alter substances that do go through the cells. Working together, the blood-brain-barrier prevents almost everything from getting in. Breaching it is generally incompatible with life.

198. Most unfortunately, the COVID-19 Vaccines - unlike any other vaccine ever deployed - are able to breach this barrier through various routes, including through the nerve structure in the nasal passages and through the blood vessel walls. The resulting damage begins in the arterial wall, extends to the supporting tissue outside the arteries in the brain, and from there to the actual brain nerve cells inside. The Vaccines are programmed to produce the S1 subunit of the spike protein in every cell in every Vaccine recipient, but it is this subunit that causes the brain damage and neurologic symptoms. Elderly persons are at increased risk for this brain damage.

199. COVID-19 patients typically have neurological symptoms including headache and loss of smell and taste, as well as brain fog, impaired consciousness, and stroke. Researchers have published a paper in the *Journal of Neurological Sciences* correlating the severity of the pulmonary distress in COVID-19 with viral spread to the brain stem, suggesting direct brain damage, not just a secondary cytokine effect. It has been shown recently by Dr. William Banks, professor of Internal Medicine at University of Washington School of Medicine, that the S1 subunit of the spike protein - the part of the SARS-CoV-2 virus that produces the COVID-19 disease and is in the Vaccines - can cross the blood brain barrier. This is even more concerning, given the high number of ACE2 receptors in the brain (the ACE2 receptor is that portion of the cell that allows the spike protein to connect to human tissue). Mice injected with the S1 subunit of the spike protein developed direct damage to the perivascular tissue. In humans, viral spike protein

was detected in the brain tissues of COVID-19 patients, but not in the brain tissues of the controls. Spike protein produces endothelial damage.

200. There are an excessive number of brain hemorrhages associated with COVID-19, and the mechanism suggests that it is the spike protein that is responsible. The federal government's VAERS database shows a dramatic increase in adverse event reporting of neurological damage following injection with the Vaccine.

Year	**Dementia** (Reports following injection with Vaccine)	**Brain Bleeding** (Reports following injection with Vaccine)
2000	4	7
2010	0	17
2015	0	17
2018	21	31
2019	11	17
2020	12 → (43)	4 → (11)
2021	17 → (251)	0 → (258)

201. While the full impact of these Vaccines crossing the blood-brain barrier is unknown, they clearly put vaccinated individuals at a substantially increased risk of hemorrhage, neurological damage, and brain damage as demonstrated by the increased instances of such reporting in the VAERS system.

202. These risks have not been adequately studied in trials, or properly disclosed to healthcare professionals or Vaccine subjects.

Effect on the Young

203. The Vaccines are more deadly or harmful to the young than the virus, and that is excluding the unknown future effects on fertility, clotting, and autoimmune disease. Those under the age of 18 face statistically zero chance of death from SARS-CoV-2 according to data published by the CDC, but there are reports of heart

inflammation - both myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) - in young men, and at least one documented fatal heart attack of a healthy 15-year-old boy in Colorado two days after receiving the Pfizer Vaccine. The CDC has admitted that "[s]ince April 2021, increased cases of myocarditis and pericarditis have been reported in the United States after the mRNA COVID-19 vaccination (Pfizer-BioNTech and Moderna), particularly in adolescents and young adults."

204. The Vaccines induce the cells of the recipient to manufacture trillions of spike proteins for an undetermined amount of time with the pathology described above, whereas naturally occurring COVID-19 comes and goes. The spike protein is the same. The increased risk comes from reprogramming the cells to permanently create the spike protein at potentially high levels. Because immune responses in the young and healthy are more vigorous than those in the old, paradoxically, the vaccines may thereby induce, in the very people least in need of assistance, a very strong immune response, including those which can damage their own cells and tissues, including by stimulating blood coagulation.

205. These risks have not been adequately studied in trials, or properly disclosed to healthcare professionals or Vaccine subjects.

Chronic Disease

206. Healthy children whose birthright is decades of healthy life will instead face premature death or decades of chronic disease. We cannot say what percentage will be affected with antibody dependent enhancement, neurological disorders, autoimmune disease and reproductive problems, but it is a virtual certainty that this will occur.

207. These risks have not been adequately studied in trials, or properly disclosed to healthcare professionals or Vaccine subjects.

Antibody Dependent Enhancement

208. Antibody Dependent Enhancement ("ADE") occurs when SARS-CoV-2 antibodies, created by a Vaccine, instead of protecting the vaccinated person, cause a more severe or lethal case of the COVID-19 disease when the person is later exposed to SARS-CoV-2 in the wild. The Vaccine *amplifies* the infection rather than *preventing* damage. It may only be seen after months or years of use in populations around the world.

209. This paradoxical reaction has been seen in other vaccines and animal trials. One well-documented example is with the Dengue fever vaccine, which resulted in avoidable deaths. Dengue fever has caused 100-400 million infections, 500,000 hospitalizations, and a 2.5% fatality rate annually worldwide. It is a leading cause of death in children in Asian and Latin American countries. Despite over 50 years of active research, a Dengue vaccine still has not gained widespread approval in large part due to the phenomenon of ADE. Vaccine manufacturer Sanofi Pharmaceutical spent 20 years and nearly $2 billion to develop the Dengue vaccine and published their results in the *New England Journal of Medicine*, which was quickly endorsed by the World Health Organization. Vigilant scientists clearly warned about the danger from ADE, which the Philippines ignored when it administered the vaccine to hundreds of thousands of children in 2016. Later, when these children were exposed in the wild, many became severely ill and 600 children died. The former head of the Dengue department of the Research Institute for Tropical Medicine (RITM) was indicted in 2019 by the Philippines

Department of Justice for "reckless imprudence resulting [in] homicide," because he "facilitated, with undue haste," Dengvaxia's approval and its rollout among Philippine schoolchildren.

210. ADE has been observed in the coronavirus setting. The original SARS-CoV-1 caused an epidemic in 2003. This virus is a coronavirus that is reported to be 78% similar to the current SARS-CoV-2 virus which causes the disease COVID-19. Scientists attempted to create a vaccine. Of approximately 35 vaccine candidates, the best four were trialed in ferrets. The vaccines appeared to work in the ferrets. However, when those vaccinated ferrets were challenged by SARS-CoV-1 in the wild, they became extremely ill and died due to what we would term a sudden severe cytokine storm. The reputed journals *Science*, *Nature* and *Journal of Infectious Diseases* have all documented ADE risks in relation to the development of experimental COVID-19 vaccines. The application filed by Dr. Yeadon with the European Medicines Agency on December 1, 2020 also cites to the risk from ADE. ADE is discovered during long-term animal studies, to which the Vaccines have not been subjected.

211. These risks have not been adequately studied in trials, or properly disclosed to healthcare professionals or Vaccine subjects.

Vaccine-Driven Disease Enhancement in the Previously Infected

212. Scientists have noted an immediately higher death rate worldwide upon receiving a Vaccine. This is generally attributed to persons having recently been infected with COVID-19. The FDA states that many persons receiving a Vaccine have COVID-19. A person who previously had SARS-CoV-2, and then receives a Vaccine, mounts an antibody response to the Vaccine that is between 10 and 20 times stronger than the

response of a previously uninfected person. The antibody response is far too strong and overwhelms the Vaccine subject. With a typical vaccine, the body trains itself how to respond to a disease because of exposure to a dead or weakened version of the pathogen. The Vaccines by contrast actually reprogram the body and, in doing so, can escalate the individual's response to levels that place them at risk. Medical studies show severe Vaccine side effects in persons previously infected with COVID-19. Groups of scientists are demanding improved pre-assessment due to vaccine-driven disease enhancement in the previously infected.

213. These risks have not been adequately studied in trials, or properly disclosed to healthcare professionals or Vaccine subjects.

More Virulent Strains

214. Scientists are concerned that universal inoculation may create more virulent strains. This has been observed with Marek's Disease in chickens. A large number of chickens not at risk of death were vaccinated, and now all chickens must be vaccinated or they will die from a virus that was nonlethal prior to widespread vaccination. The current policy to pursue universal vaccination regardless of risk may exert the same evolutionary pressure toward more highly virulent strains.

215. These risks have not been adequately studied in trials, or properly disclosed to healthcare professionals or Vaccine subjects.

Blood Supply

216. Presently, the vaccinated are permitted to donate their spike protein laden blood into the blood supply, which projects all of the risks discussed *supra* onto the general population of unvaccinated blood donees.

217. Scientists and healthcare professionals all over the world are sounding the alarm and frantically appealing to the FDA to halt the vaccines. They have made innumerable public statements. 57 top scientists and doctors from Central and South America are calling for an immediate end to all vaccine COVID-19 programs. Other physician-scientist groups have made similar calls, among them: Canadian Physicians, Israeli People's Committee, Frontline COVID-19 Critical Care Alliance, World Doctors Alliance, Doctors 4 Covid Ethics, and Plaintiff America's Frontline Doctors. These are healthcare professionals in the field who are seeing the catastrophic and deadly results of the rushed vaccines, and reputed professors of science and medicine, including the physician with the greatest number of COVID-19 scientific citations worldwide. They accuse the government of deviating from long-standing policy to protect the public. In the past, government has halted vaccine trials based on a tiny fraction – far less than 1% - of the number of unexplained deaths already recorded. The scientists all agree that the spike protein (produced by the vaccines) *causes disease even without the virus*, which has motivated them to lend their imprimatur to, and risk their reputation and standing on, these public objections.

218. Notwithstanding all of these risks and uncertainties, the federal government is orchestrating a nationwide media campaign, funded with $1 billion, to promote the Vaccines. The President has lent his voice to the campaign: "The bottom line is this: I promise you they are safe. They are safe. And even more importantly, they are extremely effective. If you are vaccinated, you are protected."

E. The Vaccine EUAs are Unlawful - There are Adequate, Approved and Available Alternatives

219. Despite the misinformation being disseminated in the press – and, at times, by the Defendants – there are numerous alternative safe and effective treatments for COVID-19.

220. These alternatives are supported by over 300 studies, including randomized controlled studies. Tens of thousands of physicians have publicly attested, and many have testified under oath, as to the safety and efficacy of the alternatives. Globally and in the United States, treatments such as Ivermectin, Budesonide, Dexamethasone, convalescent plasma and monoclonal antibodies, Vitamin D, Zinc, Azithromycin, Hydroxychloroquine, Colchicine and Remdesivir are being used to great effect, and they are safer than the COVID-19 Vaccines.[11]

221. Doctors from the Smith Center for Infectious Diseases and Urban Health and the Saint Barnabas Medical Center have published an *Observational Study on 255 Mechanically Ventilated COVID Patients at the Beginning of the USA Pandemic*, which states: "Causal modeling establishes that weight-adjusted HCQ [Hydroxychloroquine] and AZM [Azithromycin] therapy improves survival by over 100%."

222. Observational studies in Delhi and Mexico City show dramatic reductions in COVID-19 case and death counts following the mass distribution of Ivermectin. These results align with those of a study in Argentina, in which 800 healthcare professionals received Ivermectin, while another 400 did not. Of the 800, not a single person contracted COVID-19, while more than half of the control group did contract it. Dr. Pierre Kory, a lung specialist who has treated more COVID-19 patients than most doctors, representing a group of some of the most highly published physicians in the world, with over 2,000

[11] Numerous studies can be reviewed here: https://c19early.com (last visited June 7, 2021).

peer reviewed publications among them, testified before the U.S. Senate in December 2020. He testified that based on 9 months of review of scientific data from 30 studies, Ivermectin obliterates transmission of the SARS-CoV-2 virus and is a powerful prophylactic (if you take it, you will not contract COVID-19). Four large randomized controlled trials totaling over 1500 patients demonstrate that Ivermectin is safe and effective as a prophylactic. In early outpatient treatment, three randomized controlled trials and multiple observational studies show that Ivermectin reduces the need for hospitalization and death in statistically significant numbers. In inpatient treatment, four randomized controlled trials show that Ivermectin prevents death in a statistically significant, large magnitude. Ivermectin won the Nobel Prize in Medicine in 2015 for its impacts on global health.

223. Inexplicably, the Defendants never formed or assigned a task force to research and review existing alternatives for preventing and treating COVID-19. Instead, the Defendants and others set about censoring both concerns about the Vaccines, and information about safe and effective alternatives.

F. The Vaccine EUAs are Unlawful - Information is Being Suppressed, and Healthcare Professionals and Vaccine Subjects are Not Properly Informed

224. The Associated Press, Agence France Press, British Broadcasting Corporation, CBC/Radio-Canada, European Broadcasting Union (EBU), Facebook, Financial Times, First Draft, Google/YouTube, The Hindu Times, Microsoft, Reuters, Reuters Institute for the Study of Journalism, Twitter, The Washington Post and The New York Times all participate in the "Trusted News Initiative" which has agreed to not allow any news critical of the Vaccines.

225. Individual physicians are being censored on social media platforms (e.g., Twitter, Facebook, Instagram, TikTok), the modern day "public square." Plaintiff AFLDS has recorded innumerable instances of social media deleting scientific content posted by AFLDS members that runs counter to the prevailing Vaccine narrative, and then banning them from the platform altogether as users. Facebook has blocked the streaming of entire events at which AFLDS Founder Dr. Simone Gold has been an invited guest, prior to her uttering a word. Other doctors have been banned for posting or tweeting screenshots of government database VAERS. YouTube censored the testimony of undersigned counsel Thomas Renz, Esq. before the Ohio legislature.

226. The censorship also extends to medical journals. In an unprecedented move, the four founding topic editors for the *Frontiers in Pharmacology* journal all resigned together due to their collective inability to publish peer reviewed scientific data on various drugs for prophylaxis and treatment of COVID-19.

227. Dr. Philippe Douste-Blazy, a cardiology physician, former France Health Minister, 2017 candidate for Director of the WHO and former Under-Secretary-General of the United Nations, described the censorship in chilling detail:

> *The Lancet* boss said "Now we are not going to be able to, basically, if this continues, publish any more clinical research data, because the pharmaceutical companies are so financially powerful today and are able to use such methodologies, as to have us accept papers which are apparently, methodologically perfect but in reality, which manage to conclude what they want to conclude." … one of the greatest subjects never anyone could have believed … I have been doing research for 20 years in my life. I never thought the boss of *The Lancet* could say that. And the boss of the *New England Journal of Medicine* too. He even said it was "criminal" - the word was used by him. That is, if you will, when there is an outbreak like the COVID-19, in reality, there are people … us, we see "mortality" when you are a doctor or yourself, you see "suffering." And there are people who see "dollars" - that's it.

228. In many instances, highly publicized attacks on early treatment alternatives seem to be done in bad faith. For example, one study on Hydroxychloroquine overdosed study participants by administering a multiple of the standard prescribed dose, and then reported the resulting deaths as though they were not a result of the overdose. The 27 physician-scientist authors of the study were civilly indicted and criminally investigated, and still the Journal of the American Medical Association has not retracted the article.

G. The Vaccine EUAs are Unlawful - Inadequate System for Monitoring and Reporting Vaccine Adverse Events

229. VAERS was established in 1986 in order to facilitate public access to information regarding adverse events potentially caused by vaccines. Uniquely for COVID-19, the CDC has developed a parallel system called "V-Safe." V-Safe is an app on a smart phone which people can use to report adverse events. Plaintiffs' investigation indicates that vaccine subjects who are provided with written information are given the V-Safe contact information. Plaintiffs cannot access V-Safe data, since it is controlled exclusively by the CDC. Plaintiffs are concerned that the information in V-Safe exceeds that in VAERS, in terms of volume and kind, defying Congressional intent in creating VAERS.

H. Non-Consensual Human Experimentation and Informed Consent

Customary International Law Ban on Non-Consensual Human Experimentation

230. Customary international law applies directly to the United States and its agencies and instrumentalities. It is well established that customary international law includes a norm that prohibits non-consensual human medical experimentation. Abdullahi v. Pfizer, 562 F.3d 163, 174-188 (2nd Cir. 2009).

231. In August 1947, an International Military Tribunal ("IMT") sitting in Nuremberg, Germany convicted 15 Nazi doctors for crimes against humanity for conducting medical experiments without the consent of their subjects. "Among the nonconsensual experiments that the tribunal cited as a basis for their convictions were **the testing of drugs for immunization against malaria, epidemic jaundice, typhus, smallpox and cholera**." Id. at 178 (quoting United States v. Brandt, 2 Trials of War Criminals Before the Nuremberg Military Tribunals Under Control Council Law No. 10, 181-182 (1949) (emphasis added). The Nuremberg Code was created as part of the IMT's judgment, and it helps to define the contours of the customary international law norm. Its first Principle is that **"[t]he voluntary consent of the human subject is absolutely essential.**" Id. at 179 (emphasis added). The Code elaborates on the Principle as follows:

> *This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision.*

232. The Nuremberg Code contains other principles relevant here, for example that "[t]he experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random or unnecessary" (Principle 2), and "[t]he experiment should be [ ] designed and based on the results of animal experimentation" (Principle 3), and "[t]he degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem" (Principle 6).

233. The Nuremberg Code has been adopted and amplified by numerous international declarations and agreements, including the World Medical Association's Declaration of Helsinki, the guidelines authored by the Council for International Organizations of Medical Services, Art. 7 of the International Covenant on Civil and Political Rights, the International Covenant on Human Rights, the Universal Declaration on Bioethics and Human Rights, and others.

234. "The history of the norm in United States law demonstrates it has been firmly embedded for more than 45 years and [ ] its validity has never been seriously questioned by any court." Id. at 182.

Federal Regulations and the Requirement of Voluntary, Informed Consent

235. Federal Regulations relating to the protection and informed consent of human subjects further implement aspects of this norm and are binding legal obligations. In 1979, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research issued the Belmont Report, which addressed the issue of informed consent in human experimentation. The Report identified respect for self-determination by "autonomous persons" as the first of three "basic ethical principles" which "demands that subjects enter into the research voluntarily and with adequate information." Ultimately, the principles of the Belmont Report, which itself was guided by the Nuremberg Code and the Declaration of Helsinki, were adopted by the DHHS and FDA in their regulations requiring the informed consent of human subjects in medical research.

236. 45 CFR § 46.401 *et seq.*, applies to "all research involving children as subjects, conducted or supported by [DHHS]." § 46.405 states:

> *HHS will conduct or fund research in which the IRB finds that more than minimal risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is likely to contribute to the subject's well-being, only if the IRB finds that:*
>
> *(a) The risk is justified by the anticipated benefit to the subjects;*
>
> *(b) The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and*
>
> *(c) Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in § 46.408.*

U.S. Public Health Authorities' Involvement in Unlawful Human Experimentation

237. It is entirely reasonable to posit that the U.S. public health establishment would in fact design, fund, supervise and implement a non-consensual human medical experiment involving the Vaccines, in conjunction with private sector actors, given its historical track record. On October 1, 2010, President Obama apologized to the Guatemalan government and people for a program of non-consensual human experimentation that had been funded and approved by the U.S. Public Health Service ("PHS") and implemented on the ground by a PHS doctor employed for this purpose by private institutions but reporting to supervisors including PHS doctors. The evidence was suppressed and remained buried until discovered by a private researcher in 2010. A presidential commission investigated and found that in fact thousands of Guatemalans, including orphans, insane asylum patients, prisoners and military conscripts, had been intentionally exposed to syphilis, gonorrhea and other pathogens in furtherance of experiments on the use of penicillin as a prophylaxis.

238. On May 16, 1997, President Clinton apologized to the African American community for the so-called "Tuskegee Study of Untreated Syphilis in the Negro Male", a non-consensual human medical experiment funded, organized and implemented by the PHS, again with important private sector participation. This was the longest non-therapeutic, non-consensual experiment on human beings in the history of public health, run by the PHS, spanning 40 years from 1932 until its exposure by a whistleblower in 1972. The purpose of the study was to observe the effects of untreated syphilis in black men and their family members. There are numerous other examples, too many for inclusion here.

Targeting Children Who Are Intrinsically Unable to Consent

239. Within days of the FDA extending the Pfizer EUA to children ages 12 to 15, local governments commenced hastily passing laws eliminating the requirement for parental consent, and even parental knowledge, of medical treatments administered to children as young as 12. This is intended to pave the way for children to receive the Vaccines at school, without parental knowledge or consent.

240. However, children in the 12 to 18 age group are not developmentally capable of giving voluntary, informed consent to the Vaccines. Their brains are rapidly changing and developing, and their actions are guided more by the emotional and reactive amygdala and less by the thoughtful, logical frontal cortex. Hormonal and body changes add to their emotional instability and erratic judgment. Children also have a well-known and scientifically studied vulnerability to pressure from peers and adults. This age group is particularly susceptible to pressure to do what others see as the right thing to do - in this case, to be injected with the Vaccine "for the sake of other people and society."

241. That the American population, and children in particular, are being used as experimental test subjects (guinea pigs) in medical experimentation using the Vaccines is undeniable. The Texas State Senate heard sworn testimony on May 6, 2021 from Dr. Angelina Farella, a pediatrician who has given tens of thousands of vaccinations in her office. She testified:

> Dr. Farella: "I have given tens of thousands of vaccinations in my career. I am very pro-vax actually except when it comes to this covid vaccine … We are currently allowing children 16, 17 years old to get this vaccine, and they were never studied in this trial… Never before in history have we given medications that were not FDA approved to people who were not initially studied in the trial. There were no trial patients under the age of 18… They're extrapolating the data from adults down to children and adolescents. This is not acceptable. Children are not little adults. … Children have 99.997% survivability from the Covid. Let me repeat that for you all to understand: 99.997%."
>
> Senator Hall: "Has there been another vaccine that had the high incidents of serious hospitalizations and deaths that this vaccine is now showing?
>
> Dr. Farella: "Not to this extent. Not even close."
>
> Sen. Hall: "Any other vaccine would have been pulled from the market?"
>
> Dr. Farella: "Absolutely."
>
> Sen. Hall: "Have you seen any other vaccine that was put out for the public that skipped the animal tests?"
>
> Dr. Farella: "Never before. Especially for children."
>
> Sen. Hall: "…Folks I think that's important to understand here, that what we're talking about is the American people … **this is the test program**."

Self-Disseminating Vaccines

242. The phenomenon of "self-disseminating vaccines" adds a new dimension to the problem of the lack of informed consent. These vaccines spread automatically from the vaccinated to the unvaccinated, without the knowledge or consent of the unvaccinated. They are not a science fiction concept, rather they have been a research subject for years if not decades.

243. Page 67 of the Pfizer EUA application describes the possibility of **the passive "vaccination" of the unvaccinated through proximity to the vaccinated**, including inhalation or skin contact. Pursuant to the referenced document, each person getting the Pfizer Vaccine had to consent to the possibility of exposing pregnant women through inhalation or skin contact (note that pharmaceutical companies can only disclose actual, not purely speculative, risks). According to the document, an "exposure during pregnancy" event that must be reported to Pfizer within 24 hours occurs if:

> *A male participant who is receiving or has discontinued study intervention exposes a female partner prior to or around the time of conception.*
> *A female is found to be pregnant while being exposed or having been exposed to study intervention due to environmental exposure. Below are examples of environmental exposure during pregnancy:*
>
> > *A female family member or healthcare provider reports that she is pregnant after having been exposed to the study intervention by inhalation or skin contact.*

Further, an "exposure during breastfeeding" event occurs if "[a] female participant is found to be breastfeeding while receiving or after discontinuing study intervention."

244. There are worldwide reports of irregular and often very heavy vaginal bleeding in the unvaccinated who are near those who have been injected with the Vaccines, even in post-menopausal women. These public reports are scrubbed from the Internet rapidly, however Plaintiff AFLDS has also received innumerable emails from

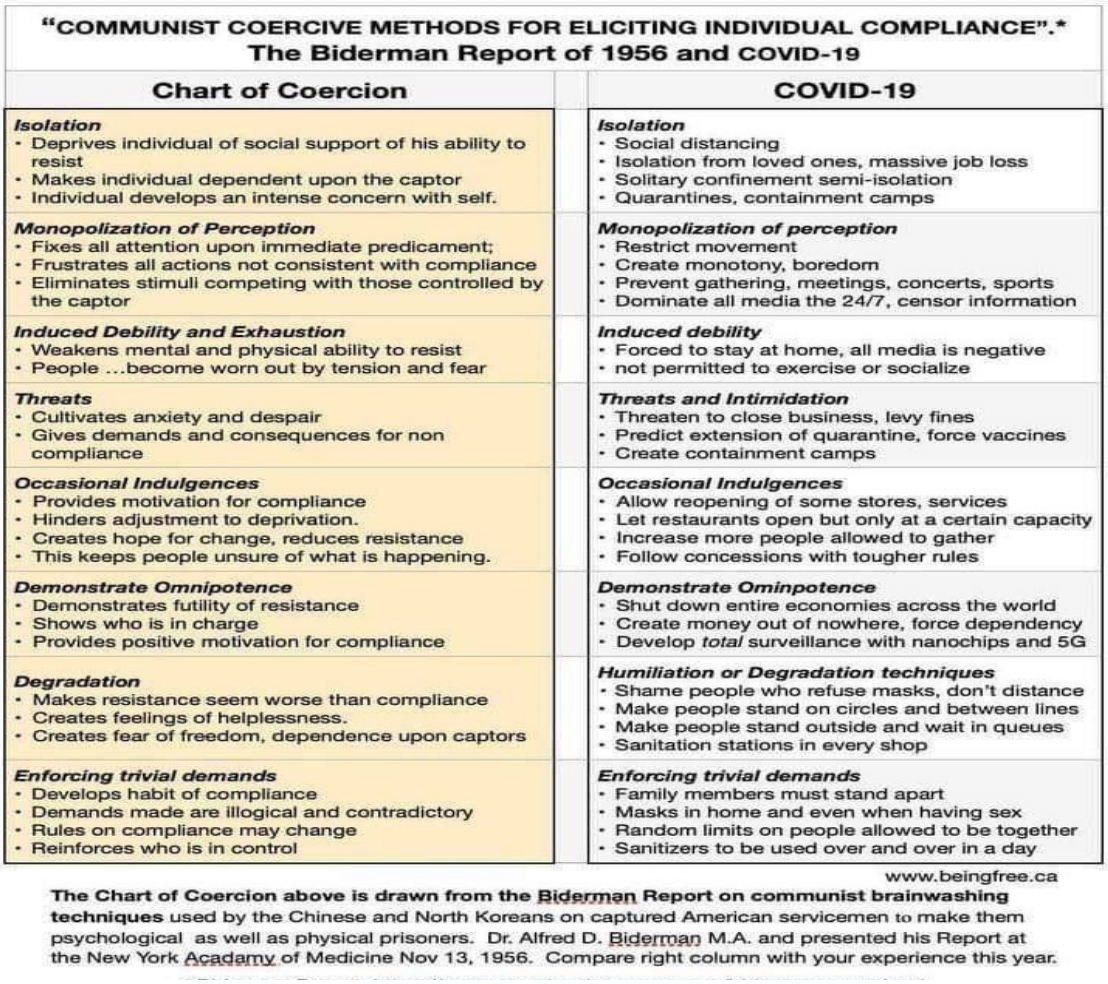
around the world with the same reports. It is well documented that the vaccinated have excessive bleeding and clotting disorders including vaginal bleeding, miscarriages, gastrointestinal bleeding and immune thrombocytopenia.

Psychological Manipulation

245. The idea of using fear to manipulate the public is not new, and is a strategy frequently deployed in public health. In June, 2020, three American public health professionals, concerned about the psychological effects of the continued use of fear-based appeals to the public in order to motivate compliance with extreme COVID-19 countermeasures, authored a piece for the journal *Health Education and Behavior* calling for an end to the fearmongering. In doing so, they acknowledged that fear has become an accepted public health strategy, and that it is being deployed aggressively in the United States in response to COVID-19:

> "… behavior change can result by increasing people's perceived severity and perceived susceptibility of a health issue through heightened risk appraisal coupled by raising their self-efficacy and response-efficacy about a behavioral solution. In this model, fear is used as the trigger to increase perceived susceptibility and severity."

246. In 1956, Dr. Alfred Biderman, a research social psychologist employed by the U.S. Air Force, published his study on techniques employed by communist captors to induce individual compliance from Air Force prisoners of war during the Korean War. The study was at the time and to some extent remains the core source for capture resistance training for the armed forces. The chart below compares the techniques used by North Korean communists with the fear-based messaging and COVID-19 countermeasures to which the American population has been subjected over the last year.



"COMMUNIST COERCIVE METHODS FOR ELICITING INDIVIDUAL COMPLIANCE".*
The Biderman Report of 1956 and COVID-19

Chart of Coercion	COVID-19
Isolation • Deprives individual of social support of his ability to resist • Makes individual dependent upon the captor • Individual develops an intense concern with self.	***Isolation*** • Social distancing • Isolation from loved ones, massive job loss • Solitary confinement semi-isolation • Quarantines, containment camps
Monopolization of Perception • Fixes all attention upon immediate predicament; • Frustrates all actions not consistent with compliance • Eliminates stimuli competing with those controlled by the captor	***Monopolization of perception*** • Restrict movement • Create monotony, boredom • Prevent gathering, meetings, concerts, sports • Dominate all media the 24/7, censor information
Induced Debility and Exhaustion • Weakens mental and physical ability to resist • People …become worn out by tension and fear	***Induced debility*** • Forced to stay at home, all media is negative • not permitted to exercise or socialize
Threats • Cultivates anxiety and despair • Gives demands and consequences for non compliance	***Threats and Intimidation*** • Threaten to close business, levy fines • Predict extension of quarantine, force vaccines • Create containment camps
Occasional Indulgences • Provides motivation for compliance • Hinders adjustment to deprivation. • Creates hope for change, reduces resistance • This keeps people unsure of what is happening.	***Occasional Indulgences*** • Allow reopening of some stores, services • Let restaurants open but only at a certain capacity • Increase more people allowed to gather • Follow concessions with tougher rules
Demonstrate Omnipotence • Demonstrates futility of resistance • Shows who is in charge • Provides positive motivation for compliance	***Demonstrate Ominpotence*** • Shut down entire economies across the world • Create money out of nowhere, force dependency • Develop *total* surveillance with nanochips and 5G
Degradation • Makes resistance seem worse than compliance • Creates feelings of helplessness. • Creates fear of freedom, dependence upon captors	***Humiliation or Degradation techniques*** • Shame people who refuse masks, don't distance • Make people stand on circles and between lines • Make people stand outside and wait in queues • Sanitation stations in every shop
Enforcing trivial demands • Develops habit of compliance • Demands made are illogical and contradictory • Rules on compliance may change • Reinforces who is in control	***Enforcing trivial demands*** • Family members must stand apart • Masks in home and even when having sex • Random limits on people allowed to be together • Sanitizers to be used over and over in a day

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The Chart of Coercion above is drawn from the Biderman Report on communist brainwashing techniques used by the Chinese and North Koreans on captured American servicemen to make them psychological as well as physical prisoners. Dr. Alfred D. Biderman M.A. and presented his Report at the New York Academy of Medicine Nov 13, 1956. Compare right column with your experience this year.

After a year of sustained psychological manipulation, the population is now weakened, frightened, desperate for a return of their freedoms, prosperity and normal lives, and especially vulnerable to pressure to take the Vaccine. The lockdowns and shutdowns, the myriad rules and regulations, the confusing and self-contradictory controls, the enforced docility, and the consequent demoralization, anxiety and helplessness are typical of authoritarian and totalitarian conditions. This degree of systemic and purposeful coercion means that Americans cannot give truly free and voluntary informed consent to the Vaccines.

247. At the same time, the population is being subjected to an aggressive, coordinated media campaign promoting the Vaccines funded by the federal government

with $1 billion. The media campaign is reinforced by a system of coercive rewards and penalties designed to induce vaccination. The federal government is offering a range of its own incentives, including free childcare. The Ohio Governor rewarded those Ohio residents accepting the Vaccines by allowing them to enter into the "Vaxamillion" lottery with a total $5 million prize and the chance to win a fully funded college education, while barring entry for residents who decline the Vaccines. In New York, metro stations offer free passes to those receiving the Vaccine in the station. West Virginia is running a lottery exclusively for the vaccinated with free custom guns, trucks and lifetime hunting and fishing licenses, a free college education, and cash payments of $1.5 million and $600,000 as the prizes. Previously, the state offered a $100 savings bond for each injection with a Vaccine. New Mexican residents accepting the Vaccines will be entered into weekly drawings to take home a $250,000 prize, and those fully vaccinated by early August could win the grand prize of $5 million. In Oregon, the vaccinated can win $1 million, or one of 36 separate $10,000 prizes through the state's "Take Your Shot" campaign. Other state and local governments are partnering with fast food chains to offer free pizza, ice cream, hamburgers and other foods to the vaccinated. Many people are desperate following the last year of economic destruction and deprivation of basic freedoms, and they are especially vulnerable to this coercion.

248. The penalties take many forms, among them:

- Using guilt and shame to make unvaccinated children and adults feel badly about themselves for refusing the Vaccines
- Threatening the unvaccinated with false fears and anxieties about COVID-19, especially children who are at no risk statistically
- Removing the rights of those who are unvaccinated:
    - Being prohibited from working
    - Being prohibited from attending school or college

- Being limited in the ability to travel in buses, trains and planes
- Being prohibited from traveling outside the United States
- Being excluded from public and private events, such as performing arts venues.

249. The combined effect of (i) the suppression and censorship of information regarding the risks of the Vaccines, (ii) the failure to inform the public regarding the novel and experimental nature of the mRNA Vaccines, (iii) the suppression and censorship of information regarding alternative treatments, (iv) the failure to inform and properly educate the public that the Vaccines are not in fact "approved" by the FDA, (v) the failure to inform and properly educate the public that the DHHS Secretary has *not* determined that the Vaccines are "safe and effective" and on the contrary has merely determined that "**it is reasonable to believe**" that the Vaccines "**may be effective**" and that the benefits outweigh the risks, (vi) the sustained psychological manipulation of the public through official fear-based messaging regarding COVID-19, draconian countermeasures and a system of rewards and penalties, is to remove any possibility that Vaccine recipients are giving voluntary informed consent to the Vaccines. They are participants in a large scale, ongoing non-consensual human experiment.

I. Conflicts-of-Interest

250. While Plaintiffs make no allegations regarding the legality or illegality of the potential conflicts-of-interest identified herein, they are numerous, now well publicized, and may create an incentive to suppress alternative treatments while promoting and profiting from the experimental COVID-19 Vaccines.

251. NIAID scientists developed the Moderna COVID-19 Vaccine in collaboration with biotechnology company Moderna, Inc. NIAID Director Dr. Fauci referred to the Moderna COVID-19 Vaccine when he said: "Finding a safe and effective

vaccine to prevent infection with SARS-CoV-2 is an urgent public health priority. This Phase 1 study, launched in record speed, is an important first step toward achieving that goal." NIAID scientists submitted an Employee Invention Report to the NIH Office of Technology Transfer in order to receive a share in the profits from the sale of the Moderna COVID-19 Vaccine. Each inventor stands to receive a personal payment of up to $150,000 annually from sales of the Moderna COVID-19 Vaccine. NIAID stands to earn millions of dollars in revenue from the sale of the Moderna COVID-19 Vaccine.

252. The NIH Director stated the following in May 2020: "We do have some particular stake in the intellectual property behind Moderna's coronavirus vaccine." In fact, NIH and Moderna signed a contract in December 2019 that states "mRNA coronavirus vaccine candidates are developed and jointly owned by the two parties." Moderna, Inc. is currently valued at $25 billion despite having no federally approved drugs on the market.

253. The DHHS awarded $483 million in grants to Moderna, Inc. to accelerate the development of the Moderna COVID-19 Vaccine. Dr. Fauci could have focused on treatments, including treatments he previously advised were beneficial in countering SARS-CoV-1. Instead, Dr. Fauci directed the NIAID, NIH, Congress and the White House to develop the Vaccines, where he has financial and professional ties.

254. Further, on May 11, 2021, Senator Rand Paul asked Dr. Anthony Fauci under oath about the origins of SARS CoV-2 and the NIH and NIAID funding for Gain-of-Function research, and Dr. Fauci stated to the Senator and to all of Congress and to the American people stating that the NIH and NIAID did not fund Gain-of-Function (making viruses more lethal) research when in fact, he provided at least $60 million funding. The

Defendants obfuscate and profit financially, personally and professionally while the American people suffer.

255. Plaintiffs' investigation has revealed additional conflicts-of-interest among members of the Vaccines and Related Biological Products Advisory Committee ("VRBPAC"), which is an FDA sub-agency that reviews and evaluates data concerning the safety, effectiveness, and appropriate use of vaccines and related biological products. VRBPAC makes recommendations to the FDA regarding whether or not to grant EUAs. The FDA is not bound to follow the VRBPAC's recommendations, but should VRBPAC advise against approval, especially over safety concerns, it would make it harder for the FDA to move forward.

256. The University of Florida Conflicts of Interest Program and the Project on Government Oversight report that numerous members of the VRBPAC have conflicts-of-interest:

- Dr. Hana el-Sahly, the VRBPAC Chair, was working with Moderna, as one of the three lead investigators for the company's 30,000 person trial of its Vaccine in July 2020. Plaintififs cannot locate information related to payments made to Dr. el-Sahly by the company.

- The Acting Chair Dr. Arnold Monto received $54,114 from 2013 to 2019 from vaccine contenders Pfizer, GlaxoSmithKline and Shionogi. He also received $10,657 from Novartis, which has a contract to manufacture Vaccines. Dr. Monto received a total of $194,254 from pharmaceutical companies, the largest contributor being Seqirus, a company developing COVID-19 vaccine in Australia.

- In 2019, Dr. Archana Chaterjee received $23,904 from Pfizer, $11,738 from Merck and $11,480 from Sanofi, each of which was racing to develop a COVID-19 vaccine. Since 2013, she has received more than $200,000 in consulting fees, travel, lodging and other payments from those companies and others working on COVID-19 vaccines. She is also a professor of epidemiology at the University of Michigan, which is partnering with AstraZeneca on a clinical trial of a potential COVID-19 vaccine.

- Dr. Myron Levine is Associate Dean of Global Health, Vaccinology and Infectious Diseases at the University of Maryland School of Medicine, which is participating in a clinical trial of the Moderna COVID-19 Vaccine. Since 2013, Dr. Levine has received general payments of $41,635 and research funding of $2.3 million. His 2019 funding was approximately six times the mean of similar physicians. His largest source of funding is from Sanofi Pasteur, which is developing a COVID-19 vaccine.

- Dr. Cody Meissner is the head of all clinical trials for all of Tufts Children's Hospital. Since 2013, Tufts University has been paid $13.2 million in general payments, and $34.2 million in research payments, by companies like Pfizer and Janssen.

- Dr. Paul Offit is Director of Vaccine Education Center and an attending physician in the Division of Infectious Diseases at Children's Hospital of Philadelphia. Since 2013, the Hospital has received $4.6 million in general payments, and $32 million in research payments, from companies like Pfizer and Novartis.

- Dr. Steven Pergam is Associate Professor, Vaccine and Infectious Disease Division, and Clinical Research Division, Fred Hutchinson Cancer Research Center. Since 2013, Dr. Pergam has received $4,167 in general payments, and $140,311in research funding from companies like Merck, which has been developing a COVID-19 vaccine. He is participating in clinical trials of the Sanofi-Aventis COVID-19 vaccine and has participated in research with Merck.

- Dr. Andrea Shane is professor of pediatrics at Emory University School of Medicine. Since 2013, Emory University Hospital has received $44.1 million in general payments, and $170.7 million in research funding, with Pfizer being a primary donor. Since 2013, the Wesley Woods Center of Emory University has received $41,205 in general payments, and $3.4 million in research payments, with Janssen being a primary donor.

- Dr. Paul Spearman is Director of the Division of Infectious Diseases at Cincinnati Children's Hospital and a Professor in the Department of Pediatrics at the University of Cincinnati School of Medicine. Dr. Spearman received $39,459 in research funding from GlaxoSmithKline and AstraZeneca, both of which have developed COVID-19 vaccines. Plaintiffs cannot locate payment data for the years 2016-2019. The University of Cincinnati Medical Center has received $2.2 million in general payments and $4.3 million in research

funding since 2013, with Pfizer topping the list of donors. Cincinnati Children's Hospital is a COVID-19 vaccine clinical trial site.

- Dr. Geeta K. Swamy is a Senior Associate Dean in the Department of Obstetrics and Gynecology, and Associate Vice President for Research, Duke University School of Medicine. Duke is a clinical trial site for the Pfizer-BioNTech COVID-19 Vaccine and the AstraZeneca vaccine. Since 2013, Dr. Swamy has received general payments of $63,000 largely from Pfizer, Sanofi and GlaxoSmithKline, all COVID-19 vaccine manufacturers, and $206,000 in research funding from GlaxoSmithKline, approximately three times the mean funding of similar physicicians. Since 2013, Duke University Hospital has received $7.6 million in general payments ($866,000 from Pfizer) and $40.6 million in research funding ($2.7 million from Pfizer) from pharmaceutical companies.

V. COUNTS

COUNT I

DECLARATORY JUDGMENT

§ 360bbb–3(b) - Cessation of Public Health Emergency; APA (All Defendants)

257. Plaintiffs adopt all of the preceding paragraphs and incorporate them by reference, as if fully set forth herein.

258. The DHHS Secretary declared a "public health emergency" pursuant to 21 U.S.C. § 360bbb-3(b)(1)(C) on February 4, 2020, after finding that "there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19."[12]

259. It is clearly not the intention of the statute that the DHHS Secretary should be able to renew his declaration of a "public health emergency" in perpetuity when the basis for the emergency no longer exists. Further, the DHHS Secretary cannot continue

[12] *See* https://www.fda.gov/media/147737/download (last visited June 7, 2021).

renewing his emergency declaration as a pretense for dodging the licensing requirements for vaccines and other drugs all to the benefit of well-funded political partners.

260. Further, in Home Building and Loan Association v. Blaisdell, 290 U.S. 398 (1934), the U.S. Supreme Court stated: "Whether an emergency exists upon which the continued operation of the law depends is always open to judicial inquiry." 290 U.S. at 442, citing Chastleton Corp. v. Sinclair, 264 U.S. 543 (1924).

261. In Sinclair, the Supreme Court stated: "A law depending upon the existence of emergency or other certain state of facts to uphold it may cease to operate if the emergency ceases or the facts change." 264 U.S. at 547.

262. Both Blaisdell and Sinclair are clear authority that an emergency and the rules promulgated thereunder must end when the facts of the situation no longer support the continuation of the emergency.

263. They also forbid this Court to merely assume the existence of a "public health emergency" based on the pronouncements of the Defendants. They are clear authority that it is the duty of the court of first instance to grapple with this question and conduct an inquiry. "[A] Court is not at liberty to shut its eyes to an obvious mistake when the validity of the law depends upon the truth of what of what is declared." Id. The Sinclair court instructed lower courts to inquire into the factual predicate underlying a declaration of emergency, where there appears to have been a change of circumstances: "the facts should be gathered and weighed by the court of first instance and the evidence preserved for consideration by this Court if necessary." 264 U.S. at 549.

264. Whereas one can make allowances for an initial, precautionary declaration of a "public health emergency" in the absence of reliable information and experience of

SARS-CoV-2 and COVID-19 (though we do not concede this), over time that justification has worn thin and it is no longer valid. We are no longer in the nascent stage. There is a wealth of data. The Defendants' own data demonstrates an undeniable change in circumstances, and that the exigencies underlying the "public health emergency" no longer exist, if they ever did. Plaintiffs have accumulated and will present expert medical and scientific evidence further supporting this contention. If the exigencies no longer exist, then the "public health emergency" must end. Plaintiffs therefore seek a Declaratory Judgment terminating the "public health emergency" declared by DHHS Secretary Azar and extended by DHHS Secretary Becerra, and the EUAs which are legally predicated upon that "public health emergency."

265. Plaintiffs therefore seek a Declaratory Judgment that: the actions of the Defendants are unlawful and arbitrary, capricious, not in accordance with § 360bbb-3, contrary to constitutional rights, powers, privileges and immunities, and in excess of statutory jurisdiction, authority or limitations; that the exigencies underlying the "public health emergency" no longer exist, if they ever did; that the "public health emergency" has ended; and that in the absence of a "public health emergency" the Defendants lack any reason to continue to authorize the emergency use by the American public of the dangerous, experimental Vaccines, thereby nullifying all Vaccine EUAs as unlawful.

COUNT II

DECLARATORY JUDGMENT

§ 360bbb–3(c) - Failure to Meet Criteria for Issuance of Vaccine EUAs; APA (All Defendants)

266. Plaintiffs adopt all of the preceding paragraphs and incorporate them by reference, as if fully set forth herein.

267. Under § 360bbb–3(c), the DHHS Secretary and his delegee, the Commissioner of the FDA, are authorized to issue and sustain the Vaccine EUAs "only if" they can satisfy certain criteria. As Plaintiffs have alleged and for the reasons set forth herein, the Defendants have failed to do so:

a. SARS-CoV-2 and COVID-19 are not "a serious or life-threatening disease or condition" for 99% of the population;

b. the scientific evidence and data available to the DHHS Secretary are not derived from "adequate and well-controlled" clinical trials, since the Vaccine trials are compressed, overlapping, incomplete and in many cases run by the Vaccine manufacturers themselves;

c. it is *not* "reasonable to believe" that the Vaccines "may be effective" in treating or preventing SARS-CoV-2 and COVID-19;

d. it is *not* "reasonable to believe" that "the known and potential benefits of the [Vaccines]" in preventing or treating SARS-CoV-2 and COVID-19 "outweigh the known and potential risks of the product"; and

e. there are "adequate, approved, and available alternative[s] to the [Vaccines]" for preventing or treating SARS-CoV-2 and COVID-19, including *inter alia* Ivermectin and Hydroxychloroquine which are prescribed by doctors worldwide with great effect and are approved by physicians as meeting the standard of care among similarly situated medical professionals.

268. Plaintiffs therefore seek a Declaratory Judgment that: the actions of the Defendants are unlawful and arbitrary, capricious, not in accordance with § 360bbb-3, contrary to constitutional rights, powers, privileges and immunities, and in excess of statutory jurisdiction, authority or limitations; and that the Vaccine EUAs are unlawful, since the DHHS Secretary and his delegee the FDA Commissioner cannot meet the criteria for their issuance, thereby nullifying all Vaccine EUAs.

COUNT III

DECLARATORY JUDGMENT

§ 360bbb–3(e) - Failure to Establish Conditions for Vaccine EUAs; APA

(All Defendants)

269. Plaintiffs adopt all of the preceding paragraphs and incorporate them by reference, as if fully set forth herein.

270. § 360bbb–3(e) provides that the DHHS Secretary, as a condition to ongoing validity of the Vaccine EUAs, "shall [ ] establish" certain "[r]equired conditions" "designed to ensure" that both healthcare professionals and Vaccine recipients are duly informed of certain critical information. As Plaintiffs have alleged and for the reasons set forth herein, the Defendants have failed to do so:

a. neither healthcare professionals nor Vaccine recipients are being informed by the Defendants, and conditions do not exist ensuring that others will inform them, that the DHHS Secretary "has authorized the emergency use of the [Vaccines]" since they are not being informed of the true meaning of the EUAs, specifically, that the Secretary has *not* determined that the Vaccines are "safe and effective" (notwithstanding the President's widely publicized statements to the contrary, which are amplified daily by countless other governmental and private sector statements that the Vaccines are "safe and effective"), and that instead the DHHS Secretary has only determined that he has "reason to believe" that the Vaccines "may be effective" in treating or preventing SARS-CoV-2 and COVID-19, based on trials of the Vaccines that are not being conducted like any previous trials and are compressed, overlapping, incomplete and in many instances conducted by the Vaccine manufacturers themselves;

b. neither healthcare professionals nor Vaccine recipients are being informed by the Defendants, and conditions do not exist ensuring that others will inform them, of "the significant known and potential [ ] risks" of the Vaccines, since there is a coordinated campaign funded with $1 billion to extol the virtues of the Vaccines, and a simultaneous effort to censor information about the inefficacy of the Vaccines in preventing or treating SARS-CoV-2 and COVID-19, Vaccine risks, and injuries and deaths caused by the Vaccine;

c. Vaccine recipients are not being informed by the Defendants, who have a financial stake in the intellectual property underlying at least one Vaccine, and who have other financial conflicts of interest, and conditions do not exist ensuring that others will inform them, that there are alternatives to the Vaccines and of their benefits;

d. Vaccine recipients are not being informed by the Defendants, and conditions do not exist ensuring that others will inform them, of their "option to accept or refuse" the Vaccines, since they have been saturated with unjustified fear-messaging regarding SARS-CoV-2 and COVID-19, psychologically manipulated, and coerced by a system of rewards and penalties that render the "option to [ ] refuse" meaningless; and

e. Appropriate conditions do not exist for "the monitoring and reporting of adverse events" since only a fraction (as low as 1%) of adverse events are reported to VAERS by physicians fearing liability, and the Defendants have established a parallel reporting system for COVID-19 that is not accessible by Plaintiffs or the rest of the public.

271. Plaintiffs therefore seek a Declaratory Judgment that: the actions of the Defendants are unlawful and arbitrary, capricious, not in accordance with § 360bbb-3, contrary to constitutional rights, powers, privileges and immunities, and in excess of statutory jurisdiction, authority or limitations; and that the Vaccine EUAs are unlawful, since the DHHS Secretary has not established and maintained the required conditions, thereby nullifying all Vaccine EUAs.

COUNT IV

DECLARATORY JUDGMENT

Customary International Law - Non-Consensual Human Experimentation (All Defendants)

272. Plaintiffs adopt all of the preceding paragraphs and incorporate them by reference, as if fully set forth herein.

273. All of the Vaccines are experimental, in that they have not completed the usual 10–15-year course of clinical trials that are still ongoing and are not approved by the FDA. The trials that are underway do not test all applications and risks of the Vaccines, including long-term risks. Further, the mRNA Vaccines are a novel gene therapy technology that has never before been used in the American population. Vaccine

recipients are provided with a V-Safe application for their smart phones, unique to COVID-19 Vaccines, which assists the Defendants to collect data on the ongoing Vaccine experiment in the general population, even as the general population is excluded from this information.

274. Vaccine recipients are not being informed of the risks of the Vaccines, and therefore cannot give informed consent.

275. Vaccine recipients have been subjected, for over a year, to sustained psychological manipulation regarding SARS-CoV-2 and COVID-19 through fear-based public messaging designed to induce their compliance with draconian countermeasures of questionable constitutionality. The COVID-19 countermeasures have inflicted incalculable psychological, emotional and economic loss. In these dire circumstances, the public are now instructed to take the Vaccine in order to regain their freedoms and some semblance of normalcy in their daily lives. At the same time, they are presented with substantial incentives and rewards for accepting the Vaccines, and penalties such as job loss, suspension or termination from school, and denial of access to performance venues, planes, trains and buses, should they exercise their "option" to refuse the Vaccines. This is systemic, state-organized coercion of the kind ordinarily reserved to communist and other dictatorial regimes, and it vitiates voluntary consent.

276. Defendants' acts described herein constitute medical experimentation on non-consenting human subjects in violation of the law of nations. The customary international law prohibition against non-consensual human experimentation is expressed and defined international treaties and declarations, international judicial decisions, and in the domestic legislation of numerous countries throughout the world, including the

United States. It is widely accepted that experimentation on unknowing human subjects is morally and legally unacceptable.

277. The deployment of the Vaccines in the foregoing circumstances violates the customary international law norm prohibiting non-consensual human experimentation.

278. Plaintiffs therefore seek a Declaratory Judgment that the Vaccine EUAs are unlawful, since they violate the customary international law norm prohibiting non-consensual human experimentation, thereby nullifying all Vaccine EUAs.

COUNT V

DECLARATORY JUDGMENT

45 CFR Part 46 - Protection of Human Subjects; APA (All Defendants)

279. Plaintiffs adopt all of the preceding paragraphs and incorporate them by reference, as if fully set forth herein.

280. For all of the foregoing reasons, the deployment of the Vaccines into the general population constitutes an ongoing human experiment, or "clinical trial" for purposes of 45 CFR Part 46, and triggers the mandatory protections of human experiment subjects mandated by this extensive regulation. The Defendants have failed to implement those protections.

281. For instance, 45 CFR § 46.405 states that DHHS will conduct or fund research involving children that presents "more than minimal risk" to the children "only if" an Institutional Review Board ("IRB") reviews the proposed experiment and makes certain mandatory findings. One of those findings is that "[t]he risk is justified by the anticipated benefit to the subjects." The very real and substantial risks of the Vaccines

can *never* be justified when they are administered *en masse* to children under the age of 18, since they have statistically no risk from SARS-CoV-2 and COVID-19.

282. Plaintiffs therefore seek a Declaratory Judgment that: the actions of the Defendants are unlawful and arbitrary, capricious, not in accordance with § 360bbb-3, contrary to constitutional rights, powers, privileges and immunities, and in excess of statutory jurisdiction, authority or limitations; and that the Vaccine EUAs are unlawful, since they violate 45 CFR Part 46, thereby nullifying all Vaccine EUAs.

COUNT VI

MANDAMUS

28 U.S.C. § 1361
(Individual Federal Defendants)

283. The individual federal defendants have a clear duty to act to ensure the faithful implementation of § 360bbb-3 and 45 CFR Part 46, the provisions of which are mandatory and intended to protect Plaintiffs.

284. There is "'practically no other remedy.'" Collin v. Berryhill, 2017 U.S. Dist. LEXIS 78222 at *9, quoting Helstoski v. Meanor, 442 U.S. 500, 505 (1979). Courts have held that the perceived medical urgencies created by COVID-19 itself, and also those created by the decisions, orders and actions of authorities responding to COVID-19, can make it impractical and inappropriate to force a plaintiff seeking mandamus to wait for alternative processes to run their course:

> *Moreover, given the broader context of the COVID-19 pandemic, we agree with the Fifth Circuit that '[i]n mill-run cases, it might be a sufficient remedy to simply wait for the expiration of the TRO, and then appeal an adverse preliminary injunction. In other cases, a surety bond may ensure that a party wrongfully enjoined can be compensated for any injury caused. Those methods would be woefully inadequate here.'*

In re Rutledge, 956 F.3d 1018, (8th Cir. 2020), quoting In re Abbott, 2020 U.S. App. LEXIS 10893 at *14.[13]

285. Plaintiffs therefore seek mandamus, compelling the individual federal defendants to perform the duties owed to them pursuant to § 360bbb-3 and 45 CFR Part 46.

COUNT VII

CIVIL MONEY DAMAGES

Bivens - Fifth Amendment, Personal Autonomy and Bodily Integrity (Individual Federal Defendants in their Personal Capacity)

286. Plaintiffs adopt all of the preceding paragraphs and incorporate them by reference, as if fully set forth herein.

287. The Supreme Court has reminded us:

> *No man in this country is so high that he is above the law. . . . All the officers of the government, from the highest to the lowest, are creatures of the law, and are bound to obey it. . . . [And the] Courts of justice are established, not only to decide upon the controverted rights of the citizens against each other, but also upon rights in controversy between them and the government.*

United States v. Lee, 106 U.S. 196, 220 (1882).

288. Plaintiffs Joel Wood, Brittany Galvin, Aubrey Boone, Snow Mills, Angelia Deselle, Kristi Simmonds, Vidiella A/K/A Shawn Skelton and the Estate of Dovi Sanders Kennedy assert constitutional claims under the Fifth Amendment against the individual federal defendants pursuant to Bivens v. Six Unknown Named Agents of Federal Bureau of Narcotics, 403 U.S. 388 (1971). "Bivens established that a citizen

[13] The Supreme Court subsequently vacated the judgment in In re Abbott, and remanded to the Fifth Circuit with instructions to dismiss the case as moot, following the Texas Governor's relaxation of his order restricting abortion as a non-essential surgical procedure, however the decision did not turn on an analysis of mandamus. *See*, Planned Parenthood Ctr. for Choice v. Abbott, 2021 U.S. LEXIS 647.

suffering a compensable injury to a constitutionally protected interest [can] invoke the general federal question jurisdiction of the district courts to obtain an award of monetary damages against the responsible federal official." Butz v. Economou, 438 U.S. 478, 504 (1978).

Personal Autonomy and Bodily Integrity

289. In Planned Parenthood v. Casey, 505 U.S. 833, 857 (1992), the U.S. Supreme Court stated:

> *Roe, however, may be seen not only as an exemplar of Griswold liberty, but as a rule (whether or not mistaken) of personal autonomy and bodily integrity, with doctrinal affinity to cases recognizing limits on governmental power to mandate medical treatment or to bar its rejection. If so, our cases since Roe accord with Roe's view that a State's interest in the protection of life falls short of justifying any plenary override of individual liberty claims. Cruzan v. Director, Mo. Dept. of Health, 497 U.S. 261, 278, 111 L. Ed. 2d 224, 110 S. Ct. 2841 (1990); cf., e. g., Riggins v. Nevada, 504 U.S. 127, 135, 118 L. Ed. 2d 479, 112 S. Ct. 1810 (1992); Washington v. Harper, 494 U.S. 210, 108 L. Ed. 2d 178, 110 S. Ct. 1028 (1990); see also, e. g., Rochin v. California, 342 U.S. 165, 96 L. Ed. 183, 72 S. Ct. 205 (1952); Jacobson v. Massachusetts, 197 U.S. 11, 24-30, 49 L. Ed. 643, 25 S. Ct. 358 (1905).*

To reiterate: "a State's interest in the protection of life falls short of justifying any plenary override of individual liberty claims."

290. The Defendants' purported interest in the protection of lives through mass injection of the Vaccines falls short of justifying "any plenary override" of Plaintiffs' "individual liberty claims."

291. The Supreme Court has stated that the protected liberty claims inherent in personal autonomy and bodily integrity include both the right *to be free from* unwanted medical intervention, and the right *to obtain* medical intervention:

> *As the joint opinion acknowledges, ante, 505 U.S. at 857, this Court has recognized the vital liberty interest of persons in refusing unwanted medical*

> *treatment. Cruzan v. Director, Mo. Dept. of Health, 497 U.S. 261, 111 L. Ed. 2d 224, 110 S. Ct. 2841 (1990). Just as the Due Process Clause protects the deeply personal decision of the individual to refuse medical treatment, it also must protect the deeply personal decision to obtain medical treatment, including a woman's decision to terminate a pregnancy.*

Id. at 927.

292. The Vaccine-injured Plaintiffs were told and believed that they were allowing a "safe and effective" and FDA-approved vaccine, when in fact they were participating in a medical experiment involving an untested, unapproved, new intervention based on genetic manipulation. "This notion of bodily integrity has been embodied in the requirement that informed consent is generally required for medical treatment. [ ] The logical corollary of the doctrine of informed consent is that the patient generally possesses the right not to consent, that is, to refuse treatment." Cruzan, 497 U.S. at 269.

293. Defendants are liable for the alleged conduct in that Defendants, acting under color of law and authority as United States officials, personally and through their own actions, with deliberate indifference, set the conditions for, committed, directed, ordered, confirmed, ratified, acquiesced, had command responsibility for, aided and abetted, conspired to, and/or otherwise directly or indirectly caused or facilitated, medical experimentation on Plaintiffs Brittany Galvin, Aubrey Boone, Snow Mills, Angelia Deselle, Kristi Simmonds, Vidiella A/K/A Shawn Skelton and the Estate of Dovi Sanders Kennedy without their informed consent, depriving them of their clearly established, constitutionally protected liberty interest in personal autonomy and bodily integrity, including their right to refuse medical treatment, of which a reasonable person would

have known, thereby injuring them physically, emotionally and psychologically, and in the case of Plaintiff Kennedy causing her death.

Right to Work, Liberty Interest to Engage in Business Activity

294. The 14th Amendment guarantees a citizen's right to work for a living and support herself by pursuing a chosen occupation. Board of Regents v. Roth, 408 U.S. 564, 572 (1972); Truax v. Raich, 239 U.S. 33, 41 (1915) ("It requires no argument to show that the right to work for a living in the common occupations of the community is of the very essence of the personal freedom and opportunity that it was the purpose of the [14th] Amendment to secure.").

295. Without the right to work in a profession of our own choosing, rather than being directed into a profession by state bureaucrats or being directed not to work and placed on state subsidies, we are slaves.

296. Defendants are liable for the alleged conduct in that Defendants, acting under color of law and authority as United States officials, personally and through their own actions, with deliberate indifference, set the conditions for, committed, directed, ordered, confirmed, ratified, acquiesced, had command responsibility for, aided and abetted, conspired to, and/or otherwise directly or indirectly caused or facilitated, the violations of law set forth herein, which have deprived Plaintiff Wood of his clearly established, constitutionally protected liberty interest in working in the profession of his own choosing, of which a reasonable person would have known, thereby injuring him economically, emotionally and psychologically.

VI. PRAYER FOR RELIEF

WHERFORE, and for the foregoing reasons, Plaintiffs request that this Court:

(A) Declare that the exigencies underlying the DHHS Secretary's declaration of a "public health emergency" under § 360bbb-3(b) never existed, or if they ever did exist, have since ceased to exist, and in the absence of those exigencies, the declaration of the "public health emergency", the extensions thereof and the Vaccine EUAs are unlawful, null, void and terminated;

(B) Declare that the DHHS Secretary and his delegee the Acting Commissioner of the FDA have failed to meet the criteria for issuing the Vaccine EUAs under § 360bbb-3(c), and therefore the Vaccine EUAs are unlawful, null, void and terminated;

(C) Declare that the DHHS Secretary has failed to meet the conditions of authorization under § 360bbb-3(e), and therefore the Vaccine EUAs are unlawful, null, void and terminated;

(D) Declare that the Defendants are engaged in non-consensual human experimentation in violation of the law of nations;

(E) Declare that the Defendants have failed to meet the requirements of 45 CFR Part 46 for the protection of human subjects in medical experimentation;

(F) Enjoin the enforcement of the challenged declaration of a "public health emergency" and further renewals thereof, the enforcement of the Vaccine EUAs, and further extensions of the Vaccine EUAs to children under the age of 16;

(G) Award to the Plaintiffs named in Count VII, under Bivens, compensatory damages, including both economic and non-economic damages, against the individual federal Defendants; and

(H) Award Plaintiffs such other and additional relief as the Court deems fit.

VII. JURY DEMAND

Plaintiffs request a jury trial on all issues so triable, including without limitation the quantum of damages.

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Dated: June 10, 2021.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this date, June 10, 2021, I electronically transmitted this pleading to the Clerk of the Court using the CM/ECF system for filing, which will send notification of such filing to the following counsel for the Defendants:

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Lowell H. Becraft, Jr.

Thomas Renz

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

Civil Action No. 21-CV-2228

DAN ROBERT, SSGT, U.S. ARMY,
HOLLIE MULVIHILL, SSGT, USMC, and
OTHER SIMILARLY SITUATED
INDIVIDUALS,

Plaintiffs,

v.

LLOYD AUSTIN, in his official capacity as Secretary of Defense, U.S. Department of Defense,

XAVIER BECERRA, in his official capacity as Secretary of the U.S. Department of Health and Human Services,

JANET WOODCOCK, in her official capacity as Acting Commissioner of the U.S. Food & Drug Administration

Defendants.

COMPLAINT

Plaintiffs Staff Sergeant Daniel Robert, U.S. Army, and Staff Sergeant Holli Mulvihill, USMC, individually and on behalf of all other similarly situated active duty, National Guard, and Reserve servicemembers, as documented survivors of COVID-19, file this action against the Department of Defense ("DoD"), seeking a declaratory judgment that the DoD cannot force them to take a COVID-19 vaccination under existing military regulations, federal regulations, federal law, and the U.S. Constitution. The Secretary of Defense, Lloyd Austin (the "SECDEF") has

publicly notified Plaintiffs, via Memo, that he will seek authorization from the President of the United States of America (the "President"), to mandate the COVID-19 vaccine on or about September 15, 2021. Upon information and belief, the DoD is already vaccinating military members in flagrant violation of its legal obligations and the rights of servicemembers under federal law and the Constitution. Army Regulation 40-562 ("AR 40-562") provides documented survivors of an infection, a presumptive medical exemption from vaccination because of the natural immunity acquired as a result of having survived the infection. "General examples of medical exemptions include the following… Evidence of immunity based on serologic tests, documented infection, or similar circumstances." AR 40-562, ¶2-6a.(1)(b). Plaintiffs also seek a declaratory judgment on the separate basis that the Emergency Use Authorization ("EUA") DoD COVID-19 Vaccine mandate, which they have been notified is imminent, cannot be issued in violation of 10 U.S.C. §1107 and its implementing regulations, including DoD Directive 6200.2, the FDA regulation of biologics at 21 C.F.R. § 50 *et seq.*, as well as the law regarding informed consent 50 U.S.C. 1520 ("The Nuremburg Code").

Neither the President, nor the SECDEF, nor the Secretary of the Department of Health and Human Services, nor the Secretary of the Food and Drug Administration have complied with the requirements of those controlling pieces of federal law. Therefore, any forced vaccination of Plaintiffs would be/are being administered in blatant violation of federal law, the attendant regulations, and the U.S Constitution, denying Plaintiffs due process of law and violating their bodies. Plaintiffs seek this relief pursuant to the Administrative Procedures Act, 5 U.S.C. §702, et seq., the Federal Declaratory Judgment Act, 28 U.S.C. § 2201, and the All Writs Act, 28 U.S.C. §1651. Plaintiff also seek temporary and permanent injunctive relief preventing their forced

vaccination attendant to their claims for declaratory judgment.

PARTIES

1. Staff Sergeant Daniel Robert, U.S. Army, is a Drill Sargent and infantryman currently on active duty stationed at Fort Bragg, North Carolina.

2. Staff Sergeant Holli Mulvihill, USMC, is an air traffic controller currently on active duty stationed at MCAS New River, North Carolina.

3. Defendant, U.S. Department of Defense ("DoD"), is an agency of the United States Government. It is led by SECDEF who has publicly stated that the Department will seek authorization of the President to begin mandating the vaccination of the force on or about September 15, 2021.

4. Defendant, Department of Health and Human Services ("HHS"), is an agency of the United States Government. It is led by Secretary Xavier Becerra.

5. Defendant, Food and Drug Administration ("FDA"), is an agency of the United States Government. It is led by acting Secretary Janet Woodcock.

CLASS ACTION ALLEGATIONS

6. This action is brought by the Plaintiffs on their own behalf and on behalf of the class of all other military members similarly situated, under the provisions of FED. R. CIV. P. 23(a) and (b).

7. The class so represented by the Plaintiffs consists of (at least) active duty and reserve component members of the United States Armed Forces and National Guard members who have already caught and recovered from COVID-19, documented and reported it to superiors and have been or will be ordered to take any COVID-19 vaccine for this public health mandate.

8. The exact number of members of the class described above is not precisely known, but there are currently in excess of 1.8 million members of the active-duty component of the Armed Forces. The class is so numerous that joinder of individual members is impracticable, if not impossible.

9. The relief sought is common to the entire class and there are common questions of law and fact that relate to and affect the rights of each class member. These common questions include the exact legal status under 21 U.S.C. §355 of any of the vaccines against COVID-19 that the military is using on members now and will use in the future; whether the vaccines are being used under a Presidential waiver pursuant to a specific request from the SECDEF, under 10 U.S.C. §1107; or pursuant to the Emergency Use Authorization under 10 U.S.C. §1107a; whether the proper findings and requests have been made regarding the nature and duration of the military exigency that requires a waiver of informed consent under DoD Instruction ("DoDI") 6200.02.

10. Plaintiffs' claims are typical of the claims all members of the class could make depending upon the exact nature of the vaccines and each Defendant's actions with regard to their legal obligations. There is no conflict between Plaintiffs and other members of the class with respect to this action or with respect to the claims for relief made herein. Indeed, Plaintiffs' claims would also apply to any military member who meets the requirements for medical exemption under AR 40-562, ¶2-6a(1)(a) or (1)(b).

11. The Plaintiffs are representative parties for the class and are able to fairly and adequately protect the interests of the class. The attorneys for the Plaintiffs are experienced and capable in litigating the claims at issue and have engaged in substantial litigation on similar issues to these in previous litigation. Attorneys Todd Callender, Colton Boyles, David Willson, and Dale

Saran will actively conduct and be responsible for the conduct of the action on behalf of the plaintiff class.

12. This action is properly maintained as a class action because the prosecution of separate actions by individual members of the class would create a risk of individual adjudications to class members that would, as a practical matter, be dispositive of the interests of others not party to the litigation or would substantially impair or impede their ability to protect their interests.

13. This action is properly maintained as a class action because the mixed questions of law and fact common to the members of the class predominate over any questions affecting only individual members and a class action is superior to other available methods of fair and efficient adjudication of the controversy.

JURISDICTION AND VENUE

14. There is a legitimate controversy because the Plaintiffs in this case are already or about to be ordered to take an "Investigational New Drugs", as defined in 21 CFR 56.104(c) ("IND"), or drug unapproved for its applied use, or EUA (experimental) vaccine for a virus from which they already have the maximum possible systemic immunity by virtue of their immune systems having already defeated it; and for which they, therefore, have no need. This case implicates the most fundamental of all human rights, the right of a person to bodily integrity and to make their own choices about what will be put into their body. Upon information and belief, the DoD has already begun vaccinating members in violation of its legal obligations.

15. Jurisdiction is proper in this Court under the Administrative Procedures Act, 5 U.S.C. §702, the Declaratory Judgment Act, 28 U.S.C. §2201, and under 28 U.S.C. §§1331, 1346, and 1361.

16. Venue is proper in this Court pursuant to 28 U.S.C. §1402 where members of the Plaintiff class are present in the district and directly impacted by the proposed order as members, leadership, and the physically located military reservations of the Defendant DoD in this Court's jurisdiction.

FACTUAL BACKGROUND

17. Army Regulation 40-562, "Immunization and Chemoprophylaxis for the Prevention of Infectious Diseases"[1] presumptively exempts from any vaccination requirement a service member that the military knows has had a documented previous infection.

18. Plaintiffs, individually and as a class, have all previously suffered and recovered from COVID-19 infections with the development of natural immunity as demonstrated to or documented by the military.

19. AR 40-562 was signed on Oct. 7, 2013, went into effect on Nov. 7, 2013, and remains in effect today. It applies to all branches of the military. The Regulation also applies whether the proposed COVID-19 vaccines it seeks to administer to Plaintiffs and the class are IND, as an IND under EUA, 21 USC Sec. 360bbb-3, or as a fully approved FDA vaccine.

20. Plaintiffs and the proposed Plaintiff class of documented COVID-19 survivors file this lawsuit now upon information and belief that service members across the services have already been given a COVID-19 vaccine by the military without any of the proper political officials having complied with their legally mandated obligations under federal law, specifically 10 U.S.C. §1107

[1] This document is an all-service publication and has an equivalent name for each of the applicable services. We have chosen to use the Army designation throughout for ease, but these arguments apply equally under AFI 48-110, BUMEDINST 6230.15B, COMDETINST M6230.4G. *See*, AR 40-562, ¶2-6a.(1)(b).

and its implementing instructions.

21. Long established precepts of virology demonstrate that the immunity provided by recovery from actual infection is at least as pronounced and effective, if not many times more so, than any immunity conferred by a vaccine. This is no less true of COVID-19. See **Exhibit 1** with attached CV, Expert Medical opinion of Dr. Peter A. McCullough, M.D., M.P.H. "Following the science" as it relates to COVID-19 validates and reaffirms the wisdom of maintaining long-established virology protocol, most recently codified in AR 40-562 in 2013.

22. Service members that have natural immunity, developed from surviving the virus, should be granted a medical exception from compulsory vaccination because the DoD Instruction policy reflects the well-established understanding that prior infection provides the immune system's best possible response to the virus. "COVID-19 did not occur in anyone over the five months of the study among 2,579 individuals previously infected with COVID-19, including 1,359 who did not take the vaccine." See, e.g., **Exhibit 2**, *Necessity of COVID-19 vaccination in previously infected individuals*, Shrestha, Burke, *et al*., Cleveland Clinic.[2]

23. Plaintiffs and the Plaintiff class should be exempted from compulsory vaccination regardless of the legal status of the vaccines with the FDA because the requirements to vitiate a military service member's right to informed consent have not been met and cannot be met by the Defendants.

24. Federal law only allows the forced vaccination of service members with an IND *after* the SECDEF has complied with all of the legal requirements of 10 U.S.C. §1107 or §1107a,

[2] Plaintiffs have included a small sample of studies demonstrating the superiority of naturally acquired immunity over novel mRNA vaccines with no established safety history and unknown side-effects. See, e.g., **Exhibits 3-8**.

depending upon the status of the vaccine.

25. DoD Instruction 6202.02 ("DoDI") states (in part) that:

> The Heads of DoD Components:
> …Shall, when requesting approval to use a medical product under an EUA or IND application, develop, in coordination with the Secretary of the Army, medical protocols, compliant with this Instruction, for use of the product and, if the request is approved, execute such protocols in strict compliance with their requirements…
> Shall, when using medical products under a force health protection program pursuant to an EUA, comply with Enclosure 3, Federal Food Drug and Cosmetic Act section 564 (Reference (d)), section 1107a of Reference (e) and applicable FDA requirements.
> Shall, when using medical products under a force health protection program pursuant to an IND application, comply with Enclosure 4, section 1107 10 U.S.C., and applicable provisions of References (e) through (g). Requirements applicable to the use of medical products under an IND application do not apply to the use of medical products under an EUA within the scope of the EUA.

26. One of the (many) obligations that the SECDEF has with respect to use of either an IND/drug unapproved for its applied use (under §1107) or an EUA (under §1107a) is to provide detailed, written notice to the servicemember that includes information regarding (1) the drug's status as an IND, unapproved for its applied use, or EUA; (2) "[t]he reasons why the investigational new drug or drug unapproved for its applied use is being administered[;]" and (3) "the possible side effects of the investigational new drug or drug unapproved for its applied use, including any known side effects possible as a result of the interaction of such drug with other drugs or treatments being administered to the members receiving such drug."

27. Federal law requires that the SECDEF requests to the President for a written authorization to waive a servicemember's right to informed consent include the certification that such vaccination is required as to a particular member's participation in a *specified military operation* that contains the following additional criteria:

(i) The extent and strength of evidence of the safety and effectiveness of the Investigational

New Drug in relation to the medical risk that could be encountered during the military operation, supports the drug's administration under an IND; and

(ii) The specified military operation presents a substantial risk that military personnel may be subject to a chemical, biological, nuclear, or other exposure *likely to produce death or serious or life-threatening injury or illness*; and

(iii) *That there is no available satisfactory alternative therapeutic or preventive treatment in relation to the intended use of the investigational new drug*; and

(iv) that conditioning the use of the investigational new drug upon voluntary participation of each member could significantly risk the safety and health of any individual member who would decline its use, the safety of other military personnel, and the accomplishment of the military mission[,] which remains undefined at this time (emphasis added).

28. The relevant Defendants have not complied with these requirements and upon information and belief have been engaged in an ongoing pattern of intentional vaccination of servicemembers in knowing violation of these obligations and servicemembers' rights.

29. The applicable section of the Federal Food, Drug, and Cosmetic Act (Title 21, Chapter 9) regarding EUA of biologics for the military is found at 21 U.S.C. §360bbb-3. It contains a lengthy list of requirements for either the Secretary of the Department of Homeland Security, the Secretary of Defense, the Secretary of the FDA, including detailed findings regarding the exact military contingency that the Secretary of Defense has used to go to the President in order to override servicemembers' right of informed consent before the administration of any EUA drug or device.

30. The Defendants have not complied and cannot comply with their respective

requirements to support the DoD's actions in vitiating the informed consent rights of servicemembers regarding these unapproved biologics because:

(a) these drugs are not being used in response to any specific military threat in a theater of operations, but rather are a naked attempt to leverage the Plaintiffs' military status against them in order to move forward with an unnecessary public health mandate;

(b) there is near zero risk to healthy, fit, young men and women of the U.S. Armed Services, and

(c) there are numerous safe, long-standing, proven alternative treatments (such as ivermectin, "anti-infective oral and nasal sprays and washes, oral medications, and outpatient monoclonal antibodies, which are 'approved' drugs by the Food and Drug Administration and highly effective in preventing and treating COVID-19")[3] and the existence of such treatments is a legal bar to the use of an EUA or IND without informed consent.

FIRST CAUSE OF ACTION
(VIOLATION OF ADMINISTRATIVE PROCEDURE ACT)

31. Plaintiffs reallege the facts in Paragraphs 1 through 30 as if fully set forth in this Count.

32. The United States Government, acting through the DoD, violated its own regulations, DoDI 6200.02 and AR 40-562, by ignoring the Plaintiffs right to informed consent and vaccinating members of the armed forces without complying with applicable federal law and implementing regulations.

33. Defendants' failure to follow federal law and regulations creates a legal wrong

[3] See **Exhibit 1**, Expert Medical Opinion of Dr. Peter McCullough.

against Plaintiffs.

34. As a result of Defendants' unlawful actions, Plaintiffs have suffered damages, including being required to take an unnecessary drug of unknown long-term safety profile; being subject to or threatened with disciplinary action under the Uniform Code of Military Justice ("UCMJ"), to include adverse administrative action; enduring differential treatment, including being segregated from eating with one's fellow service members in the military dining facilities and subject to ridicule; being denied leave and/or freedom of movement, among others, as a result of Defendants' illegal scheme and actions.

SECOND CAUSE OF ACTION
(VIOLATION OF 10 U.S.C. §1107)

35. Plaintiffs reallege the facts in Paragraphs 1 through 30 as if fully set forth in this Count.

36. This case involves an actual controversy surrounding the legality of any orders or actions the DoD has taken with regard to vaccinating service members against COVID-19 in the absence of the Secretaries and DoD's moral and statutory obligations.

37. The United States Government, acting through the DoD, violated a federal statute, namely 10 U.S.C. §1107, as well as DoDI 6200.02, when it illegally required or stated it would require or mandate members of the class of Plaintiffs who have already had the virus to submit to COVID-19 vaccinations in an IND or "unapproved for their applied use" status.

38. As a result of Defendants' unlawful actions, Plaintiffs have suffered damages, including being required to take an unnecessary drug of unknown long-term safety profile; being subject to or threatened with disciplinary action under UCMJ, to include adverse administrative action; enduring differential treatment, including being segregated from eating with one's fellow

service members in the military dining facilities and subject to ridicule; being denied leave and/or freedom of movement, among others, as a result of the Defendants' illegal scheme and actions.

THIRD CAUSE OF ACTION
(VIOLATION OF 10 U.S.C. §1107a)

39. Plaintiffs reallege the facts in Paragraphs 1 through 30 as if fully set forth in this Count.

40. This case involves an actual controversy surrounding the legality of any orders or actions the DoD has taken with regard to vaccinating service members against COVID-19 in the absence of the Secretaries and DoD's moral and statutory obligations.

41. The United States Government, acting through the DoD, HHS, and FDA, violated a federal statute, namely 10 U.S.C. §1107a, as well as 21 U.S.C. §355, DoDI 6200.02, when it illegally required or threatened to mandate members of the class of Plaintiffs who have already had the virus, to submit to COVID-19 vaccinations in an EUA status. Even though not currently lawfully mandated by SECDEF and other Defendants, many Plaintiffs, e.g., service members, have been ordered, or coerced by virtue of military structure and rank, to submit to taking the vaccine.

42. As a result of Defendants' unlawful actions, the Plaintiffs have suffered damages, including being required to take an unnecessary drug of unknown long-term safety profile; being subject to or threatened with disciplinary action under the UCMJ, to include adverse administrative action; enduring differential treatment, including being segregated from eating with one's fellow service members in the military dining facilities and subject to ridicule; being denied leave and/or freedom of movement, among others, as a result of the Defendants' illegal scheme and actions.

FOURTH CAUSE OF ACTION
(VIOLATION OF 50 U.S.C. §1520)

43. Plaintiffs reallege the facts in Paragraphs 1 through 30 as if fully set forth in this Count.

44. This case involves an actual controversy surrounding the legality of any orders or actions the DoD has taken with regard to vaccinating service members against COVID-19 in the absence of the Secretaries and DoD's moral and statutory obligations.

45. The United States Government, acting through the DoD, HHS, and FDA, violated a federal statute, namely 50 U.S.C. §1520, when it illegally required members of the class of Plaintiffs who have already had the virus to submit to COVID-19 vaccinations in any FDA status. The right of informed consent is one of the sacrosanct principles that came out of the Nazi Doctor Tribunals conducted at Nuremburg. The overriding legal principle was that no State, not even the United States, may force its citizens to undergo unwanted medical procedures merely by declaring an emergency.[4]

46. As a result of Defendants' unlawful actions, the Plaintiffs have suffered damages, including being required to take an unnecessary drug of unknown long-term safety profile; being subject to or threatened with disciplinary action under the UCMJ, to include adverse administrative action; enduring differential treatment, including being segregated from eating with one's fellow service members in the military dining facilities and subject to ridicule; being denied leave and/or freedom of movement, among others, as a result of the Defendants' illegal scheme and actions.

WHEREFORE, Plaintiffs respectfully ask this Court to:

[4] If this were the correct legal principle, then the Nazi doctors were wrongly tried and convicted as Germany was in a declared state of emergency at the time of the Nazi medical experiments.

A. Find that the use of investigational new drugs or drugs unapproved for their applied use is illegal until and unless the Secretary of Defense complies with his statutory requirements in requesting a waiver of informed consent and until the President makes the requisite finding under 10 U.S.C. §1107; and

B. Find that all members of the Plaintiffs' class are still entitled to a medical exemption from vaccination even after the Defendants have complied with their legal obligations under the implementing DoDI 6200.02;

Alternatively, if applicable,

C. Find that the use of vaccines under an EUA is illegal until and unless all of the Defendants comply with their statutory obligations in requesting a waiver of informed consent under 10 U.S.C. §1107a and the implementing regulations and laws;

D. Find that all members of the Plaintiffs' class are still entitled to a medical exemption from vaccination even after the Defendants have complied with their legal obligations under DoDI 6200.02;

Plaintiffs also ask this Honorable Court to:

E. Find and declare that any order issued by DoD requiring the Plaintiffs to receive inoculation with COVID-19 vaccines are patently unlawful;

F. Enjoin the DoD from vaccinating any service members until this action has completed and the status of any vaccine has been determined and the requirements for taking away Plaintiffs' rights of informed consent have been met; and

G. Award Plaintiffs their costs and attorneys' fees and any other relief this Court may

find appropriate.

Date: August 17, 2021

Respectfully submitted,

s/ Todd Callender
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STATE OF FLORIDA

OFFICE OF THE GOVERNOR
EXECUTIVE ORDER NUMBER 21-81

(Prohibiting COVID-19 Vaccine Passports)

WHEREAS, on March 9, 2020, I issued Executive Order 20-52, subsequently extended, declaring a state of emergency for the entire State of Florida as a result of COVID-19; and

WHEREAS, on December 23, 2020, I issued Executive Order 20-315, as subsequently extended by Executive Orders 21-46, 21-47, 21-62, 21-67, and 21-79, directing Florida's initial phase of vaccine distribution and prioritizing seniors first; and

WHEREAS, the State of Florida is leading the effort to distribute the vaccine to elderly and vulnerable populations of the State and has successfully provided vaccines to nearly 3.5 million seniors; and

WHEREAS, many Floridians have not yet had the opportunity to obtain a COVID-19 vaccination, some have infection-acquired immunity, and others may be unable to obtain a COVID-19 vaccination due to health, religious, or other reasons; and

WHEREAS, Florida seeks to ensure that every Floridian who desires a COVID-19 vaccine can obtain one, but such vaccines will not be mandated; and

WHEREAS, no COVID-19 vaccine is required by law; and

WHEREAS, individual COVID-19 vaccination records are private health information which should not be shared by mandate; and

WHEREAS, so-called COVID-19 vaccine passports reduce individual freedom and will harm patient privacy; and

WHEREAS, requiring so-called COVID-19 vaccine passports for taking part in everyday life—such as attending a sporting event, patronizing a restaurant, or going to a movie theater—would create two classes of citizens based on vaccination; and

WHEREAS, it is necessary to protect the fundamental rights and privacies of Floridians and the free flow of commerce within the state.

NOW, THEREFORE, I, RON DESANTIS, as Governor of Florida, by virtue of the authority vested in me by Article IV, Section 1(a) of the Florida Constitution and by the Florida Emergency Management Act, as amended, and all other applicable laws, promulgate the following Executive Order:

Section 1. No Florida government entity, or its subdivisions, agents, or assigns, shall be permitted to issue vaccine passports, vaccine passes, or other standardized documentation for the purpose of certifying an individual's COVID-19 vaccination status to a third party, or otherwise publish or share any individual's COVID-19 vaccination record or similar health information.

Section 2. Businesses in Florida are prohibited from requiring patrons or customers to provide any documentation certifying COVID-19 vaccination or post-transmission recovery to gain access to, entry upon, or service from the business.

Section 3. All executive agencies under my direction shall work to ensure businesses comply with this order. Any provision of Florida Statutes is hereby suspended solely to the extent it restricts a Florida agency from requiring compliance with this order as a condition for a license, permit, or other state authorization necessary for conducting business in Florida.

Section 4. All businesses must comply with this order to be eligible for grants or contracts funded through state revenue.

Section 5. The requirements in this order do not otherwise restrict businesses from instituting COVID-19 screening protocols in accordance with state and federal law to protect

public health, and nothing herein shall be construed to interfere with individuals' rights to access their own personal health information under federal law.

Section 6. This order is effective immediately and shall remain in effect for the duration of Executive Order 20-52, as extended.

IN TESTIMONY WHEREOF, I have hereunto set my hand and caused the Great Seal of the State of Florida to be affixed, at Tallahassee, this 2nd day of April, 2021.

RON DESANTIS, GOVERNOR

ATTEST:

SECRETARY OF STATE

FILED
2021 APR -2 PM 12:25
DEPARTMENT OF STATE
TALLAHASSEE, FL

HRSA
Health Resources & Services Administration

Data & Statistics

The United States has the safest, most effective vaccine supply in history. In the majority of cases, vaccines cause no side effects, however they can occur, as with any medication—but most are mild. Very rarely, people experience more serious side effects, like allergic reactions.
In those instances, the National Vaccine Injury Compensation Program (VICP) allows individuals to file a petition for compensation.

What does it mean to be awarded compensation?
Being awarded compensation for a petition does not necessarily mean that the vaccine caused the alleged injury. In fact:

- Approximately 60 percent of all compensation awarded by the VICP comes as result of a negotiated settlement between the parties in which HHS has not concluded, based upon review of the evidence, that the alleged vaccine(s) caused the alleged injury.
- Attorneys are eligible for reasonable attorneys' fees, whether or not the petitioner is awarded compensation by the Court, if certain minimal requirements are met. In those circumstances, attorneys are paid by the VICP directly. By statute, attorneys may not charge any other fee, including a contingency fee, for his or her services in representing a petitioner in the VICP.

What reasons might a petition result in a negotiated settlement?

- Consideration of prior U.S. Court of Federal Claims decisions, both parties decide to minimize risk of loss through settlement
- A desire to minimize the time and expense of litigating a case
- The desire to resolve a petition quickly

How many petitions have been awarded compensation?
According to the CDC, from 2006 to 2019 over 4 billion doses of covered vaccines were distributed in the U.S. For petitions filed in this time period, 8,438 petitions were adjudicated by the Court, and of those 5,983 were compensated. This means for every 1 million doses of vaccine that were distributed, approximately 1 individual was compensated.

Since 1988, over 24,335 petitions have been filed with the VICP. Over that 30-year time period, 20,208 petitions have been adjudicated, with 8,278 of those determined to be compensable, while 11,930 were dismissed. Total compensation paid over the life of the program is approximately $4.6 billion.

VICP Adjudication Categories, by Alleged Vaccine for Petitions Filed Since the Inclusion of Influenza as an Eligible Vaccine for Filings 01/01/2006 through 12/31/2019

Name of Vaccine Listed First in a Petition (other vaccines may be alleged or basis for compensation)	Number of Doses Distributed in the U.S., 01/01/2006 through 12/31/2019 (Source: CDC)	Compensable Concession	Compensable Court Decision	Compensable Settlement	Compensable Total	Dismissed/Non-Compensable Total	Grand Total
DT	794,777	1	0	5	6	4	10
DTaP	109,991,074	24	24	115	163	128	291
DTaP-Hep B-IPV	79,798,141	6	7	30	43	63	106
DTaP-HIB	1,135,474	0	1	2	3	2	5
DTaP-IPV	31,439,498	0	0	5	5	4	9
DTap-IPV-HIB	74,403,716	4	4	9	17	39	56
DTP	0	1	1	3	5	3	8
DTP-HIB	0	1	0	2	3	1	4
Hep A-Hep B	17,946,038	3	1	18	22	8	30
Hep B-HIB	4,787,457	1	1	2	4	1	5
Hepatitis A (Hep A)	203,339,060	8	6	47	61	36	97
Hepatitis B (Hep B)	216,772,259	12	12	73	97	94	191
HIB	137,675,315	2	1	11	14	10	24
HPV	132,062,306	18	14	115	147	231	378
Influenza	1,842,400,000	1,195	224	2,865	4,284	744	5,028
IPV	78,237,532	0	1	4	5	5	10
Measles	135,660	0	0	1	1	0	1
Meningococcal	119,054,485	8	5	44	57	20	77
MMR	116,647,585	24	16	93	133	134	267

Name of Vaccine Listed First in a Petition (other vaccines may be alleged or basis for compensation)	Number of Doses Distributed in the U.S., 01/01/2006 through 12/31/2019 (Source: CDC)	Compensable Concession	Compensable Court Decision	Compensable Settlement	Compensable Total	Dismissed/Non-Compensable Total	Grand Total
MMR-Varicella	32,226,723	12	0	14	26	19	45
Mumps	110,749	0	0	0	0	0	0
Nonqualified	0	0	0	3	3	44	47
OPV	0	1	0	0	1	5	6
Pneumococcal Conjugate	269,907,936	38	3	57	98	61	159
Rotavirus	125,787,826	21	4	23	48	19	67
Rubella	422,548	0	1	1	2	0	2
Td	71,408,785	13	6	65	84	28	112
Tdap	294,534,882	149	22	362	533	113	646
Tetanus	3,836,052	15	2	47	64	21	85
Unspecified	0	1	1	4	6	593	599
Varicella	127,901,171	9	7	32	48	25	73
Grand Total	**4,092,757,049**	**1,567**	**364**	**4,052**	**5,983**	**2,455**	**8,438**

Notes on the Adjudication Categories Table

The date range of 01/01/2006 through 12/31/2019 was selected to reflect petitions filed since the inclusion of influenza vaccine in July 2005. Influenza vaccine now is named in the majority of all VICP petitions.

In addition to the first vaccine alleged by a petitioner, which is the vaccine listed in this table, a VICP petition may allege other vaccines, which may form the basis of compensation.

Vaccine doses are self-reported distribution data provided by US-licensed vaccine manufacturers. The data provide an estimate of the annual national distribution and do not represent vaccine administration. In order to maintain confidentiality of an individual manufacturer or brand, the data are presented in an aggregate format by vaccine type. Flu doses are derived from CDC's FluFinder tracking system, which includes data provided to CDC by US-licensed influenza vaccine manufacturers as well as their first line distributors.

"Unspecified" means insufficient information was submitted to make an initial determination. The conceded "unspecified" petition was for multiple unidentified vaccines that caused abscess formation at the vaccination site(s), and the "unspecified" settlements were for multiple vaccines later identified in the Special Masters' decisions

Definitions

Compensable – The injured person who filed a petition was paid money by the VICP. Compensation can be achieved through a concession by the U.S. Department of Health and Human Services (HHS), a decision on the merits of the petition by a special master or a judge of the U.S. Court of Federal Claims (Court), or a settlement between the parties.

- **Concession**: HHS concludes that a petition should be compensated based on a thorough review and analysis of the evidence, including medical records and the scientific and medical literature. The HHS review concludes that the petitioner is entitled to compensation, including a determination either that it is more likely than not that the vaccine caused the injury or the evidence supports fulfillment of the criteria of the Vaccine Injury Table. The Court also determines that the petition should be compensated.
- **Court Decision**: A special master or the court, within the United States Court of Federal Claims, issues a legal decision after weighing the evidence presented by both sides. HHS abides by the ultimate Court decision even if it maintains its position that the petitioner was not entitled to compensation (e.g., that the injury was not caused by the vaccine).
  For injury petitions, compensable court decisions are based in part on one of the following determinations by the court:
  1. The evidence is legally sufficient to show that the vaccine more likely than not caused (or significantly aggravated) the injury; or
  2. The injury is listed on, and meets all of the requirements of, the Vaccine Injury Table, and HHS has not proven that a factor unrelated to the vaccine more likely than not caused or significantly aggravated the injury. An injury listed on the Table and meeting all Table requirements is given the legal presumption of causation. It should be noted that conditions are placed on the Table for both scientific and policy reasons.
- **Settlement**: The petition is resolved via a negotiated settlement between the parties. This settlement is not an admission by the United States or the Secretary of Health and Human Services that the vaccine caused the petitioner's alleged injuries, and, in settled cases, the Court does not determine that the vaccine caused the injury. A settlement therefore cannot be characterized as a decision by HHS or by the Court that the vaccine caused an injury. Petitions may be resolved by settlement for many reasons, including consideration of prior court decisions; a recognition by both parties that there is a risk of loss in proceeding to a decision by the Court making the certainty of settlement more desirable; a desire by both parties to minimize the time and expense associated with litigating a case to conclusion; and a desire by both parties to resolve a case quickly and efficiently.
- **Non-compensable/Dismissed**: The injured person who filed a petition was ultimately not paid money. Non-compensable Court decisions include the following:
  1. The Court determines that the person who filed the petition did not demonstrate that the injury was caused (or significantly aggravated) by a covered vaccine or meet the requirements of the Table (for injuries listed on the Table).
  2. The petition was dismissed for not meeting other statutory requirements (such as not meeting the filing deadline, not receiving a covered vaccine, and not meeting the statute's severity requirement).
  3. The injured person voluntarily withdrew his or her petition.

Petitions Filed, Compensated and Dismissed, by Alleged Vaccine, Since the Beginning of VICP, 10/01/1988 through 09/01/2021

Vaccines	Filed Injury	Filed Death	Filed Grand Total	Compensated	Dismissed
DTaP-IPV	16	0	16	5	4
DT	69	9	78	26	52
DTP	3,288	696	3,984	1,273	2,709
DTP-HIB	20	8	28	7	21
DTaP	478	85	563	244	268
DTaP-Hep B-IPV	97	39	136	44	64
DTaP-HIB	11	1	12	7	4
DTaP-IPV-HIB	49	21	70	17	39
Td	231	3	234	130	79
Tdap	1,039	8	1,047	535	114
Tetanus	172	3	175	87	48
Hepatitis A (Hep A)	132	7	139	62	39
Hepatitis B (Hep B)	737	62	799	288	442
Hep A-Hep B	42	0	42	22	9
Hep B-HIB	8	0	8	5	3
HIB	47	3	50	21	20
HPV	543	17	560	146	248
Influenza	7,839	200	8,039	4,305	780
IPV	269	14	283	9	271
OPV	282	28	310	158	152
Measles	145	19	164	55	107
Meningococcal	114	3	117	58	21
MMR	1,022	62	1,084	415	596
MMR-Varicella	57	2	59	26	19
MR	15	0	15	6	9
Mumps	10	0	10	1	9
Pertussis	4	3	7	2	5
Pneumococcal Conjugate	295	22	317	102	77
Rotavirus	111	6	117	70	30
Rubella	190	4	194	71	123
Varicella	111	10	121	68	37
Nonqualified[1]	112	10	122	3	115
Unspecified[2]	5,426	9	5,435	10	5,416
Grand Total	**22,981**	**1,354**	**24,335**	**8,278**	**11,930**

[1] Nonqualified petitions are those filed for vaccines not covered under the VICP.
[2] Unspecified petitions are those submitted with insufficient information to make a determination.

Petitions Filed

Fiscal Year	Total
FY 1988	24
FY 1989	148
FY 1990	1,492
FY 1991	2,718
FY 1992	189
FY 1993	140
FY 1994	107
FY 1995	180
FY 1996	84
FY 1997	104
FY 1998	120
FY 1999	411
FY 2000	164
FY 2001	215
FY 2002	958
FY 2003	2,592
FY 2004	1,214
FY 2005	735
FY 2006	325
FY 2007	410
FY 2008	417
FY 2009	397
FY 2010	447
FY 2011	386
FY 2012	402
FY 2013	504
FY 2014	633
FY 2015	803
FY 2016	1,120
FY 2017	1,243
FY 2018	1,238
FY 2019	1,282
FY 2020	1,192
FY 2021	1,941
Total	**24,335**

Adjudications

Generally, petitions are not adjudicated in the same fiscal year as filed. On average, it takes 2 to 3 years to adjudicate a petition after it is filed.

Fiscal Year	Compensable	Dismissed	Total
FY 1989	9	12	21
FY 1990	100	33	133
FY 1991	141	447	588
FY 1992	166	487	653
FY 1993	125	588	713
FY 1994	162	446	608
FY 1995	160	575	735
FY 1996	162	408	570
FY 1997	189	198	387
FY 1998	144	181	325
FY 1999	98	139	237
FY 2000	125	104	229
FY 2001	86	88	174
FY 2002	104	104	208
FY 2003	56	100	156
FY 2004	62	247	309
FY 2005	60	229	289
FY 2006	69	193	262
FY 2007	82	136	218
FY 2008	147	151	298
FY 2009	134	257	391
FY 2010	180	330	510
FY 2011	266	1,742	2,008
FY 2012	265	2,533	2,798
FY 2013	369	651	1,020
FY 2014	370	194	564
FY 2015	520	145	665
FY 2016	700	187	887
FY 2017	696	204	900
FY 2018	544	199	743
FY 2019	642	184	826
FY 2020	710	217	927
FY 2021	635	221	856
Total	**8,278**	**11,930**	**20,208**

Awards Paid

Fiscal Year	Number of Compensated Awards	Petitioners' Award Amount	Attorneys' Fees/Costs Payments	Number of Payments to Attorneys (Dismissed Cases)	Attorneys' Fees/Costs Payments (Dismissed Cases)	Number of Payments to Interim Attorneys'	Interim Attorneys' Fees/Costs Payments	Total Outlays
FY 1989	6	$1,317,654.78	$54,107.14	0	$0.00	0	$0.00	$1,371,761.92
FY 1990	88	$53,252,510.46	$1,379,005.79	4	$57,699.48	0	$0.00	$54,689,215.73
FY 1991	114	$95,980,493.16	$2,364,758.91	30	$496,809.21	0	$0.00	$98,842,061.28
FY 1992	130	$94,538,071.30	$3,001,927.97	118	$1,212,677.14	0	$0.00	$98,752,676.41
FY 1993	162	$119,693,267.87	$3,262,453.06	272	$2,447,273.05	0	$0.00	$125,402,993.98
FY 1994	158	$98,151,900.08	$3,571,179.67	335	$3,166,527.38	0	$0.00	$104,889,607.13
FY 1995	169	$104,085,265.72	$3,652,770.57	221	$2,276,136.32	0	$0.00	$110,014,172.61
FY 1996	163	$100,425,325.22	$3,096,231.96	216	$2,364,122.71	0	$0.00	$105,885,679.89
FY 1997	179	$113,620,171.68	$3,898,284.77	142	$1,879,418.14	0	$0.00	$119,397,874.59
FY 1998	165	$127,546,009.19	$4,002,278.55	121	$1,936,065.50	0	$0.00	$133,484,353.24
FY 1999	96	$95,917,680.51	$2,799,910.85	117	$2,306,957.40	0	$0.00	$101,024,548.76
FY 2000	136	$125,945,195.64	$4,112,369.02	80	$1,724,451.08	0	$0.00	$131,782,015.74
FY 2001	97	$105,878,632.57	$3,373,865.88	57	$2,066,224.67	0	$0.00	$111,318,723.12
FY 2002	80	$59,799,604.39	$2,653,598.89	50	$656,244.79	0	$0.00	$63,109,448.07
FY 2003	65	$82,816,240.07	$3,147,755.12	69	$1,545,654.87	0	$0.00	$87,509,650.06
FY 2004	57	$61,933,764.20	$3,079,328.55	69	$1,198,615.96	0	$0.00	$66,211,708.71
FY 2005	64	$55,065,797.01	$2,694,664.03	71	$1,790,587.29	0	$0.00	$59,551,048.33
FY 2006	68	$48,746,162.74	$2,441,199.02	54	$1,353,632.61	0	$0.00	$52,540,994.37
FY 2007	82	$91,449,433.89	$4,034,154.37	61	$1,692,020.25	0	$0.00	$97,175,608.51
FY 2008	141	$75,716,552.06	$5,191,770.83	74	$2,531,394.20	2	$117,265.31	$83,556,982.40
FY 2009	131	$74,142,490.58	$5,404,711.98	36	$1,557,139.53	28	$4,241,362.55	$85,345,704.64
FY 2010	173	$179,387,341.30	$5,961,744.40	59	$1,933,550.09	22	$1,978,803.88	$189,261,439.67
FY 2011	251	$216,319,428.47	$9,572,042.87	403	$5,589,417.19	28	$2,001,770.91	$233,482,659.44
FY 2012	249	$163,491,998.82	$9,241,427.33	1,020	$8,649,676.56	37	$5,420,257.99	$186,803,360.70
FY 2013	375	$254,666,326.70	$13,543,099.70	704	$7,012,615.42	50	$1,454,851.74	$276,676,893.56
FY 2014	365	$202,084,196.12	$12,161,422.64	508	$6,824,566.68	38	$2,493,460.73	$223,563,646.17
FY 2015	508	$204,137,880.22	$14,445,776.29	118	$3,546,785.14	50	$3,089,497.68	$225,219,939.33

Fiscal Year	Number of Compensated Awards	Petitioners' Award Amount	Attorneys' Fees/Costs Payments	Number of Payments to Attorneys (Dismissed Cases)	Attorneys' Fees/Costs Payments (Dismissed Cases)	Number of Payments to Interim Attorneys'	Interim Attorneys' Fees/Costs Payments	Total Outlays
FY 2016	689	$230,140,251.20	$16,298,140.59	99	$2,741,830.10	59	$3,502,709.91	$252,682,931.80
FY 2017	706	$252,245,932.78	$22,045,785.00	131	$4,439,538.57	52	$3,363,464.24	$282,094,720.59
FY 2018	521	$199,588,007.04	$16,658,440.14	112	$5,106,382.65	58	$5,151,148.78	$226,503,978.61
FY 2019	653	$196,217,707.64	$18,991,247.55	102	$4,791,157.52	65	$5,457,545.23	$225,457,657.94
FY 2020	733	$186,860,677.55	$20,188,683.76	113	$5,750,317.99	76	$5,090,482.24	$217,890,161.54
FY 2021	650	$202,580,447.55	$22,628,783.73	130	$6,367,015.98	49	$4,425,985.25	$236,002,232.51
Total	**8,224**	**$4,273,742,418.51**	**$248,952,920.93**	**5,696**	**$97,012,505.47**	**614**	**$47,788,606.44**	**$4,667,496,451.35**

NOTE: Some previous fiscal year data has been updated as a result of the receipt and entry of data from documents issued by the Court and system updates which included petitioners' costs reimbursements in outlay totals,

"Compensated" are petitions that have been paid as a result of a settlement between parties or a decision made by the U.S. Court of Federal Claims (Court). The # of awards is the number of petitioner awards paid, including the attorneys' fees/costs payments, if made during a fiscal year. However, petitioners' awards and attorneys' fees/costs are not necessarily paid in the same fiscal year as when the petitions/petitions are determined compensable. "Dismissed" includes the # of payments to attorneys and the total amount of payments for attorneys' fees/costs per fiscal year. The VICP will pay attorneys' fees/costs related to the petition, whether or not the petition/petition is awarded compensation by the Court, if certain minimal requirements are met. "Total Outlays" are the total amount of funds expended for compensation and attorneys' fees/costs from the Vaccine Injury Compensation Trust Fund by fiscal year.

Since influenza vaccines (vaccines administered to large numbers of adults each year) were added to the VICP in 2005, many adult petitions related to that vaccine have been filed, thus changing the proportion of children to adults receiving compensation.