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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, INC., a 501C3 Organization; DR. DAVID CALDERWOOD, an individual; JOSEPH MAKOWSKI, an individual; LYLE BLOOM, an individual; ELLEN MILLEN, an individual; JODY SOBCZAK, an individual; MICHAEL NELSON, an individual; and JOSEPH LEAHY, an individual;

Plaintiffs,

vs.

The UNITED STATES OF AMERICA; JOSEPH R. BIDEN, JR., in his official capacity as President of the United States; XAVIER BECERRA, Secretary of the U.S. Department of Health and Human Services, in his official capacity, DR. ANTHONY FAUCI, Director of the National Institute of Allergies and Infectious Diseases, in his official capacity, DR. JANET WOODCOCK, Acting Commissioner of the Food and Drug Administration, in her official capacity, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; the FOOD AND DRUG ADMINISTRATION; the CENTER FOR DISEASE CONTROL AND PREVENTION; the NATIONAL INSTITUTE OF HEALTH; the NATIONAL INSTITUTE OF ALLERGIES AND INFECTIOUS DISEASES; and DOES I-X,

Defendants.

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

AMENDED COMPLAINT

Jury Trial Demanded

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INTRODUCTION

1. Plaintiffs are either individuals facing a COVID vaccine mandate, or organizations whose members have received a COVID-19 vaccine mandate. Plaintiffs contend that no emergency exists and thus all EUAs and emergency actions are invalid, the EUAs were issued in bad faith and in violation of the law, the COVID-19 vaccines were misbranded, and any mandate of the COVID-19 vaccines is unconstitutional.

2. This challenge will establish that, illegally and in bad faith, the following are true:

- The COVID vaccine mandates are unlawful and unconstitutional. Further, Plaintiffs assert that the declaration of an emergency, issuance of an EUA, current branding of the COVID-19 vaccines, and mandate of vaccines authorized under said EUA cannot be supported under the following circumstances which will be demonstrated at trial:
- Over 99.8% of all those infected with COVID survive with the number being far higher in a vast majority of the population. Even the highest risk population has approximately a 95% recovery rate which is substantially higher than many other diseases we have lived with for centuries with no emergency measures taken. (Hence *no emergency exists*).
- Merriam Webster defines an emergency as: an unexpected and usually dangerous situation that calls for immediate action.[1] It is undisputed that COVID-19 will remain with us forever and thus this is not an emergency. If we allow emergency measures indefinitely we are constructively amending the Constitution and rewriting legislation through the use of the emergency declaration.
- Those who survive COVID-19 or it's variants ("COVID") obtain robust and durable natural immunity. The natural immunity so obtained is superior to COVID vaccine-induced immunity.
- Adequate alternative treatments exist.
- The COVID vaccines are ineffective against the Delta strain of COVID, which the Center for Disease Control ("CDC") states is the dominant (>99%) strain spreading throughout the United States.
- The CDC Director has acknowledged that the COVID vaccines do not prevent infection or transmission of COVID: "[W]hat the vaccines can't do anymore is prevent transmission."[2] The CDC has also acknowledged that the vaccinated and unvaccinated are equally likely to spread the virus.[3]
- The CDC changed its definition of "vaccine" in August 2021 without following any

[1] https://www.merriam-webster.com/dictionary/emergency. Retrieved 10/29/2021

[2] As the Wuhan vaccine cannot stop transmission of Delta, several studies have proven that the vaccinated are passing the Delta strain amongst each other. For example, as reported by the NEJM, University of San Diego healthcare workers, The New England Journal of Medicine, Resurgence of SARS-CoV-2 Infection in a Highly Vaccinated Health System Workforce (September 30, 2021). https://www.nejm.org/doi/full/10.1056/NEJMc2112981.

[3] https://www.cdc.gov/mmwr/volumes/70/wr/mm7031e2.htm?s_cid=mm7031e2_w

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formal rulemaking process despite the word vaccine carrying important legal implications. Plaintiffs will show this to be a substantive rule change subject to notice and comment under the Administrative Procedures Act ("APA"). This process did not occur prior to these changes.

- Plaintiffs contend that the vaccines are not actually vaccines.
- On October 22, 2020, during a web-conference/meeting of the Vaccines and Related Biological Products Advisory Committee of the FDA, a slide was shown to the attendees disclosing likely known adverse consequences of the vaccines. Despite this disclosure the COVID vaccines have been relentlessly misbranded, without limitation, as both "vaccines" and as "safe and effective".
- Mandating COVID vaccines violates the fundamental right of bodily integrity protected by United States Constitution as stated in *Planned Parenthood v. Casey,* 505 U.S. 833 (1992), which cited and largely overturned *Jacobson v Massachusetts,* 197 U.S. 11 (1905).
- The COVID vaccines cause a significantly higher incidence of injuries, adverse reactions, and deaths than any prior vaccines that have been allowed to remain on the market and pose a significant health risk to recipients.
- As COVID vaccines do not prevent the infection or transmission of COVID but do result in a significant number of adverse events and deaths, Plaintiffs allege that the authorization alone is an illegal abuse of discretion, and the mandate of these vaccines is an unconscionable act done in bad faith.

THE PARTIES

PLAINTIFFS

3. **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.

4. 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

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published Ethics Opinion in the AMA Code of Medical Ethics as opinion 8.7, "Routine Universal Immunization of Physicians."

5. 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 vaccines, but they also have an ethical duty to encourage their patients to do likewise. 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.

6. "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."

7. The ethical opinion adopted by the AMA House of Delegates declares 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.*

8. 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.

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9. A great number of AFLDS member physicians and medical workers are currently facing COVID vaccine mandates at threat of their "job".

10. 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.

11. 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."

12. The gross imbalance of equities between an individual physician and the various large institutions and pharmaceutical companies which exert tremendous sway over their professional calling has many physicians fearful of pushing back against COVID vaccine mandates.

13. AFLDS may assert and protect the rights of its members as an association. (*see* Doe v. Stincer, 175 F.3d 879 (11th Cir. 1999). *See also* Pa. Psychiatric Society v. Green Spring Health Servs., Inc., 280 F.3d 278 (3d Cir.2002); Association of American Physicians & Surgeons, Inc. v. Texas Medical Board, 627 F.3d 547 (5th Cir. 2010); Retired Chi. Police Ass'n v. City of Chicago, 7 F.3d 584, 601-02, 608 (7th Cir. 1993). Cf., *and* Ass'n of Am. Physicians & Surgeons v. United States FDA, No. 20-1784, 2021 U.S. App. LEXIS 27157 (6th Cir. Sep. 9, 2021)).

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14. **DR. DAVID CALDERWOOD ("Dr. Calderwood")** is a physician licensed to practice medicine in the State of Alabama. He lives and works in Huntsville, Madison County, Alabama, and one of his patients is Plaintiff JOSEPH MAKOWSKI. Dr. Calderwood has advised Makowski to not take any of the vaccines at issue in this complaint due to his health condition(s). Dr. Calderwood is entitled to assert the rights of his patient. (*See* Craig v. Boren, 429 U.S. 190 (1976); June Medical Services, LLC v. Russo, 140 S.Ct. 2103, 2118-19 (2020); *and* Robinson v. Attorney Gen., 957 F.3d 1171, 1177 (11th Cir. 2020)).

15. **JOSEPH MAKOWSKI ("Makowski")** lives and works in Huntsville, Alabama. Makowski works for a federal contractor that provides services on a federal installation in Madison County. Makowski's employer has issued a mandate declaring that he must be vaccinated no later than November 8, 2021. However, Makowski's physician, Dr. Calderwood, has advised that because of his medical problems, he should not take any Vaccine.

16. **ELLEN MILLEN ("Millen")** is a resident of Huntsville, Alabama and a systems engineer at Raytheon, a federal contractor. She has been employed there for 25 years. As a result of Defendant Biden's Executive Order applicable to contractor employees, Millen confronts the vaccine mandate in November, 2021.

17. **LYLE BLOOM ("Bloom")** is a resident of Huntsville, Alabama and a Program Director for Cummings Aerospace, a federal contractor. As a result of Defendant Biden's Executive Order applicable to contractor employees, Bloom confronts the vaccine mandate in November, 2021.

18. **JODY SOBCZAK ("Sobczak")** is a resident of Huntsville, Alabama and an employee of Boeing. As a result of Defendant Biden's Executive Order applicable to contractor employees, he confront the vaccine mandate in November, 2021.

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19. **MICHAEL NELSON ("Nelson")** and **JOSEPH LEAHY (Leahy")** are citizens and residents of Madison County, Alabama, and both are employed at the Marshall Space Flight Center in Huntsville. As a result of Defendant Biden's Executive Order applicable to federal government employees, both confront the vaccine mandate in November, 2021.

DEFENDANTS

20. Defendants are the United States of America, the President of the United States, appointed officials of the United States government, and United States governmental agencies responsible for the issuance and implementation of the challenged actions.

21. **JOSEPH R. BIDEN, JR. ("President Biden")** issued the challenged executive orders of September 9, 2021. See 86 Fed. Reg. 50985, and 86 Fed. Reg. 50989.

22. **XAVIER BECERRA ("Secretary Becerra")** is the current Secretary of the U.S. Department of Health and Human Services. He is being sued in his official capacity.

23. **DR. ANTHONY FAUCI ("Dr. Fauci")** is the 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 capacity.

24. **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 capacity.

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

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

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

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

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

30. **DOES I - X**, are as yet unknown agencies and/or individuals who violated the law and harmed Plaintiffs.

31. The Federal Defendants have coordinated, collaborated, planned and conspired, each with the others, and aided and abetted each other to implement and undertake the unlawful actions described herein.

32. Those Plaintiffs working for federal contractors or the federal government confront COVID vaccine mandates that threaten their employment, and/or their employers have issued unlawful denials of religious accommodation exemptions.

III. JURISDICTION, VENUE, STANDING

33. 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.

34. 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 21 U.S.C. § 360bbb-3, the provisions of which are intended to protect them.

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

36. This Court has Jurisdiction under the Constitution of the United States and Authority under its own equitable powers.

37. 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, and at least one Plaintiff resides in this District, and real property is not involved.

38. This Court has authority under Administrative Procedures Act ("APA"), which 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, et seq.). 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).

39. 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. (*Fla Wildlife Fed'n, Inc. v. S. Fla. Water Mgmt. Dist., 647 F.3d 1296, 1302 (11th Cir. 2011)).

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40. 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)).

41. 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).

42. 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.)

43. 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).

I. NO EMERGENCY EXISTS

The Emergency Use Authorization Framework

Basis for DHHS Secretary's Declaration of Emergency

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44. 21 U.S.C. § 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;*

45. 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

46. 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*

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> *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;*

47. 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

48. 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 —*

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> *(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.*

49. 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, and because he has actively suppressed and/or mischaracterized information relating to the Vaccines without which informed consent cannot be provided and without which the conditions for authorization cannot be and have never been met.

The Vaccine EUAs are Unlawful — There is No Underlying Emergency

50. 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.

51. The actual COVID-19 statistics present a vastly different picture than the one painted by the media — a fatality rate of 0.2% globally, dropping to 0.03% for persons under age 70, which is comparable to the yearly flu. Further, statistically, the fatality risk is limited to the

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elderly population. The Defendants' own data published through publicly accessible government portals[4] 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

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

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

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53. 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."

54. 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.

55. 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"

56. 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

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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.

57. 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.

58. 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.*

59. 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.

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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

60. 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."[5] There appears to be an agenda to protect the myths about the vaccine, rather than to protect the public.

61. 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

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

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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*.

62. 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.*[6]

63. 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 over a year

[6] See, starting at minute 44:
Error! Main Document Only.https://www.youtube.com/watch?v=w6koHkBCoNQ&t=2638s (visited Oct. 19, 2021)

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and a half, 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. For example, children under 18 statistically have a zero percent chance of death from COVID-19. Even if this were not the case, absent an emergency, the EUAs must be invalidated entirely.

III. EMERGENCY USE AUTHORIZATION WAS GRANTED IN VIOLATION OF LAW

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

64. 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.

65. 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 May of this year. 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.

66. 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

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acquired through prior infection with COVID-19 is stronger than any benefit conferred by a Vaccine, rendering vaccination unnecessary for those previously infected.

67. 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%.**[7]

68. 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.

69. 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

[7] See: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7996517/ (Visited Oct. 19, 2021)

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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.

70. 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.[8] Since asymptomatic individuals do not spread COVID-19, they do not need to be vaccinated.

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

71. 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

[8] See: https://www.sciencedaily.com/releases/2020/11/201130131511.htm (visited Oct. 19, 2021)

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]

72. 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.

73. 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 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.

74. 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

[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

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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.

75. 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

76. 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.

77. 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.

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78. 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.

79. 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

80. 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-

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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.

81. 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.

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

Increased Risk of Death from Vaccines

83. 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,

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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.

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

Reproductive Health

85. 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.

86. 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

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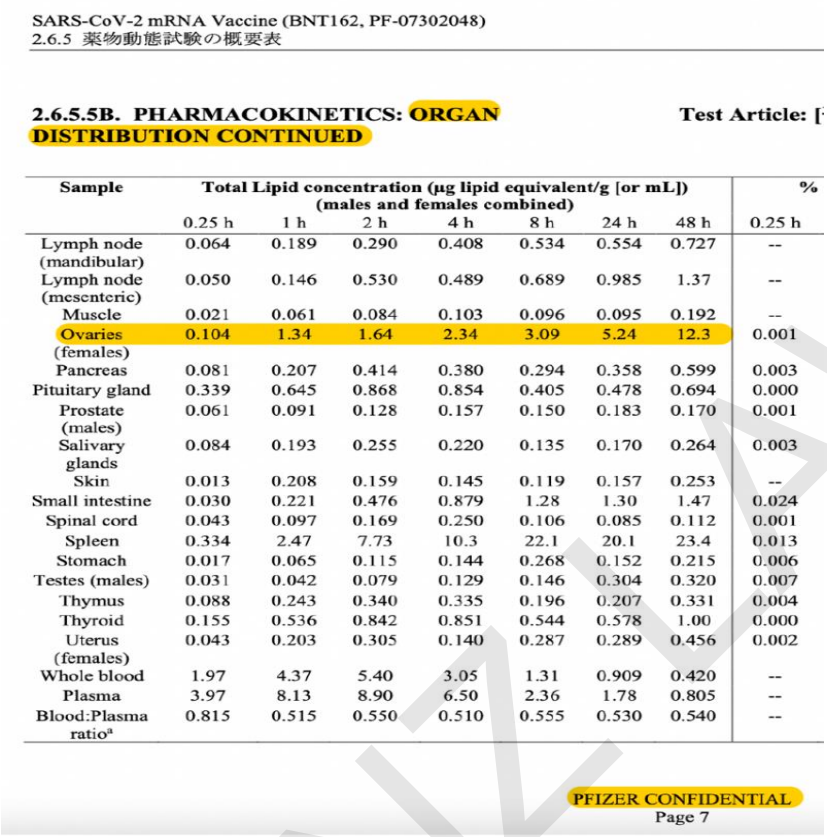
proteins are accumulating in very delicate ovarian tissues, the one place in the human body where females carry a finite number of fertile eggs.



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	--

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87. 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.

88. 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

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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 — mid-pregnancy.

89. 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,[11] 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.

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

Vascular Disease

91. 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.

[11] See: https://2020news.de/en/dr-wodarg-and-dr-yeadon-request-a-stop-of-all-corona-vaccination-studies-and-call-for-co-signing-the-petition/ (visited Oct. 19, 2021)

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

Autoimmune Disease

93. 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.

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

Neurological Damage

95. 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.

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96. 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.

97. 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.

98. 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

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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)

99. 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.

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

Effect on the Young

101. 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

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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."[12]

102. 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.

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

Chronic Disease

104. 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.

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

Antibody Dependent Enhancement

106. Antibody Dependent Enhancement ("ADE") occurs when SARS-CoV-2 antibodies, created by a Vaccine, instead of protecting the vaccinated person, cause a more severe

[12] See: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html (visited Oct. 19, 2021)

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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.

107. 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. [13]

108. 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

[13] See: https://www.science.org/content/article/dengue-vaccine-fiasco-leads-criminal-charges-researcher-philippines (visited Oct. 19, 2021)

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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.

109. 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

110. 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.

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

More Virulent Strains

112. 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.[14] The current policy to pursue universal vaccination regardless of risk may exert the same evolutionary pressure toward more highly virulent strains.

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

Blood Supply

114. 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.

115. 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

[14] See: https://www.pbs.org/newshour/science/tthis-chicken-vaccine-makes-virus-dangerous (visited Oct. 19, 2021)

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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.

116. 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."

The Vaccine EUAs are Unlawful — There are Adequate, Approved and Available Alternatives

117. 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.

118. 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, and Colchicine are being used to great effect, and they are safer than the COVID-19 Vaccines.[15]

[15] Numerous studies can be reviewed here: https://c19early.com (visited Oct. 20, 2021).

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119. 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%."[16]

120. 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. 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).[17] 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.

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[16] See: https://www.medrxiv.org/content/10.1101/2021.05.28.21258012v1 (visited Oct. 20, 2021)
[17] See: https://covid19criticalcare.com/senate-testimony/ (visited Oct. 19, 2021)

121. 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.

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

122. 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.

123. 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.

124. 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.

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125. 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.

126. 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

127. 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

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information in V-Safe exceeds that in VAERS, in terms of volume and kind, defying Congressional intent in creating VAERS.

H. Human Experimentation and the Requirement of Informed Consent

128. "Involuntarily subjecting nonconsenting individuals to foreign substances with no known therapeutic value — often under false pretenses and with deceptive practices hiding the nature of the interference — is a classic example of invading the core of the bodily integrity protection." (Guertin v. Michigan, 912 F.3d 907, 920-21 (6th Cir. 2019)).

Federal Regulations and the Requirement of Voluntary, Informed Consent

129. Federal Regulations relating to the protection and informed consent of human subjects further implement aspects of this norm and are binding legal obligations.

130. In 1962, via § 103 (b), Drug Amendments Act of 1962, Pub. L. 87-781, 76 Stat. 780, at 783,[18] Congress became concerned about subjecting humans to drug experiments without informed consent. Later, 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.

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

[18] Now codified at 21 U.S.C. § 355 (i).

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131. 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.

132. 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.[19]

Targeting Children Who Are Intrinsically Unable to Consent

[19] See: https://en.wikipedia.org/wiki/Unethical_human_experimentation_in_the_United_States (visited Oct. 19, 2021)

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133. 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.

134. 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."

135. 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?

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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 Vaccine

136. 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.

137. 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:*

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> *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."

138. 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

139. 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."

140. 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

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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 relentlessly subjected for more than a year and a half.

"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

www.beingfree.ca

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.

141. After more than 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.

142. 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.

143. The penalties take many forms, among them:

- Using guilt and shame to make unvaccinated adults and children 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

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- 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.

144. 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

145. 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.

146. 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-

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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."[20] 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.

147. 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.

148. 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.

149. 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.

[20] See: https://www.nih.gov/news-events/news-releases/nih-clinical-trial-investigational-vaccine-covid-19-begins (Oct. 19, 2021)

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150. 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.

151. 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.

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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 physicians. Since 2013, Duke University Hospital has received $7.6 million in general payments

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($866,000 from Pfizer) and $40.6 million in research funding ($2.7 million from Pfizer) from pharmaceutical companies.

Note: (potential additional conflicts of interest have come to light since this information was originally obtained. Plaintiffs will supplement this pleading with that additional information as it is confirmed).

IV. THE MANDATES ARE UNLAWFUL

152. On September 9, 2021, President Biden issued Executive Order 14042 (86 Fed. Reg. 50985), the purpose of which was to "decrease the spread of COVID–19, which will decrease worker absence, reduce labor costs, and improve the efficiency of contractors and subcontractors at sites where they are performing work for the Federal Government." To achieve this goal, this Order directed that "new contracts" and similar agreements of the federal government to obtain goods and services from various vendors and manufacturers were to include certain COVID provisions therein.

153. This Order directed the recently created Safer Federal Workforce Task Force to draft and develop a "Task Force Guidance" document by September 24, 2021 and submit the same to the Director of the Office of Management and Budget, and if that Director determines that such Guidance "will promote economy and efficiency in Federal contracting if adhered to by Government contractors and subcontractors", that determination was to be published in the Federal Register.[21]

154. The "Task Force Guidance", as with all such federal agency Guidances, is without force and effect as law because the same has not been promulgated as a "rule" pursuant to the Administrative Procedure Act, 5 U.S.C. § 552, *et seq*., and 41 U.S.C. § 1707 (b).

[21] That determination was so published in the Federal Register of September 28, 2021, 86 Fed.Reg. 53691.

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155. The determination of the Director of the Office of Management and Budget is without force and effect as law because it has not been promulgated as a "rule" pursuant to the Administrative Procedure Act, 5 U.S.C. § 552, *et seq*., and 41 U.S.C. § 1707 (b).

156. The President claimed 3 U.S.C. § 301 as one statutory authority to issue Executive Order 14042. This section provides as follows:

> The President of the United States is authorized to designate and empower the head of any department or agency in the executive branch, or any official thereof who is required to be appointed by and with the advice and consent of the Senate, to perform without approval, ratification, or other action by the President (1) any function which is vested in the President by law, or (2) any function which such officer is required or authorized by law to perform only with or subject to the approval, ratification, or other action of the President: Provided, That nothing contained herein shall relieve the President of his responsibility in office for the acts of any such head or other official designated by him to perform such functions. Such designation and authorization shall be in writing, shall be published in the Federal Register, shall be subject to such terms, conditions, and limitations as the President may deem advisable, and shall be revocable at any time by the President in whole or in part.

157. The President also claimed provisions of the Federal Property and Administrative Services Act, 40 U.S.C. § 101, *et seq*., as statutory authority to issue Executive Order 14042. This section provides as follows:

> The purpose of this subtitle is to provide the Federal Government with an economical and efficient system for the following activities:
>
> (1) Procuring and supplying property and nonpersonal services, and performing related functions including contracting, inspection, storage, issue, setting specifications, identification and classification, transportation and traffic management, establishment of pools or systems for transportation of Government personnel and property by motor vehicle within specific areas, management of public utility services, repairing and converting, establishment of inventory levels, establishment of forms and procedures, and representation before federal and state regulatory bodies.
>
> (2) Using available property.
>
> (3) Disposing of surplus property.
>
> (4) Records management.

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158. The subsequent provisions of the Federal Property and Administrative Services Act are no broader than the purpose of this Act as set forth in § 101.

159. However, these statutes do not provide the President with authority to impose vaccine mandates, and thus he lacks the statutory as well as constitutional authority to impose these mandates he may believe assist in a speedy resolution of the current COVID-19 crisis. Youngstown Sheet & Tube Co. v. Sawyer, 343 U.S. 579 (1952).[22]

160. On September 9, 2021, President Biden issued Executive Order 14043 (86 Fed.Reg. 50989). The apparent objective of this Order was to mandate COVID-19 vaccinations for federal employees. As authority for this Order, the President relied upon 5 U.S.C. §§ 3301, 3302, and 7301 as permitting him to impose vaccine mandates on federal employees.

5 U.S.C. § 3301 provides as follows:

> The President may—
>
> (1) prescribe such regulations for the admission of individuals into the civil service in the executive branch as will best promote the efficiency of that service;
>
> (2) ascertain the fitness of applicants as to age, health, character, knowledge, and ability for the employment sought; and
>
> (3) appoint and prescribe the duties of individuals to make inquiries for the purpose of this section.

161. The origin of § 3301 is found in § 9 of "An Act Making Appropriations for sundry civil Expenses of the Government for the fiscal Year ending June 30, eighteen hundred and seventy-two, and for other Purposes", 16 Stat. 495, 514, ch. 114. This section was later incorporated into the Revised Statutes of 1873 as § 1753, and thereafter was incorporated into 5 U.S.C. § 631 when the U.S. Code was created in 1926. A part of this § 631 became § 3301 when

[22] See also Schaezlein v. Cabaniss, 135 Cal. 466, 471, 67 P. 755 (1902); State v. Marana Plantations, 75 Ariz. 111, 115, 252 P.2d 87 (1953); and Boreali v. Axelrod, 71 N.Y.2d 1, 6, 517 N.E.2d 1350 (1987).

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this title of the U.S. Code was enacted into positive law in 1966. See Pub.L. 89-554, 80 Stat. 378, at 417.

162. 5 U.S.C. § 3302 provides as follows:

> (a) The President may prescribe rules which shall provide, as nearly as conditions of good administration warrant, for—
>
> (1) open, competitive examinations for testing applicants for appointment in the competitive service which are practical in character and as far as possible relate to matters that fairly test the relative capacity and fitness of the applicants for the appointment sought;
>
> (2) noncompetitive examinations when competent applicants do not compete after notice has been given of the existence of the vacancy; and
>
> (3) authority for agencies to appoint, without regard to the provision of sections 3309 through 3318, candidates directly to positions for which—
>
> (A) public notice has been given; and
>
> (B) the Office of Personnel Management has determined that there exists a severe shortage of candidates (or, with respect to the Department of Veterans Affairs, that there exists a severe shortage of highly qualified candidates) or that there is a critical hiring need.
>
> The Office shall prescribe, by regulation, criteria for identifying such positions and may delegate authority to make determinations under such criteria.
>
> (b) An individual may be appointed in the competitive service only if he has passed an examination or is specifically excepted from examination under section 3302 of this title. This subsection does not take from the President any authority conferred by section 3301 of this title that is consistent with the provisions of this title governing the competitive service.
>
> (c)(1) For the purpose of this subsection, the term "technician" has the meaning given such term by section 8337(h)(1) of this title.
>
> (2) Notwithstanding a contrary provision of this title or of the rules and regulations prescribed under this title for the administration of the competitive service, an individual who served for at least 3 years as a technician acquires a competitive status for transfer to the competitive service if such individual—
>
> (A) is involuntarily separated from service as a technician other than by removal for cause on charges of misconduct or delinquency;
>
> (B) passes a suitable noncompetitive examination; and
>
> (C) transfers to the competitive service within 1 year after separating from service as a technician.
>
> (d) The Office of Personnel Management shall promulgate regulations on the manner and extent that experience of an individual in a position other than the

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competitive service, such as the excepted service (as defined under section 2103) in the legislative or judicial branch, or in any private or nonprofit enterprise, may be considered in making appointments to a position in the competitive service (as defined under section 2102). In promulgating such regulations OPM shall not grant any preference based on the fact of service in the legislative or judicial branch. The regulations shall be consistent with the principles of equitable competition and merit based appointments.

(e) Employees at any place outside the District of Columbia where the President or the Office of Personnel Management directs that examinations be held shall allow the reasonable use of public buildings for, and in all proper ways facilitate, holding the examinations.

(f)(1) Preference eligibles or veterans who have been separated from the armed forces under honorable conditions after 3 years or more of active service may not be denied the opportunity to compete for vacant positions for which the agency making the announcement will accept applications from individuals outside its own workforce under merit promotion procedures.

(2) If selected, a preference eligible or veteran described in paragraph (1) shall receive a career or career-conditional appointment, as appropriate.

(3) This subsection shall not be construed to confer an entitlement to veterans' preference that is not otherwise required by law.

(4) The area of consideration for all merit promotion announcements which include consideration of individuals of the Federal workforce shall indicate that preference eligibles and veterans who have been separated from the armed forces under honorable conditions after 3 years or more of active service are eligible to apply. The announcements shall be publicized in accordance with section 3327.

(5) The Office of Personnel Management shall prescribe regulations necessary for the administration of this subsection. The regulations shall ensure that an individual who has completed an initial tour of active duty is not excluded from the application of this subsection because of having been released from such tour of duty shortly before completing 3 years of active service, having been honorably released from such duty.

163. Section 2 of "An act to regulate and improve the civil service of the United States", 22 Stat 403, ch. 27, enacted by Congress on January 16, 1883, is the genesis of § 3302. When the current U.S. Code was created in 1926, parts of this section were incorporated into 5 U.S.C. § 633, and when this title of the U.S. Code was enacted into positive law in 1966, it became § 3302. See Pub.L. 89-554, 80 Stat. 378, at 417.

164. 5 U.S.C. § 7301 provides as follows:

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> The President may prescribe regulations for the conduct of employees in the executive branch.

165. The origin of § 7301 is the same as that for § 3301: § 9 of "An Act Making Appropriations for sundry civil Expenses of the Government for the fiscal Year ending June 30, eighteen hundred and seventy-two, and for other Purposes", 16 Stat. 495, 514, ch. 114. This § 9 was later incorporated into the Revised Statutes of 1873 as § 1753 and was later incorporated into 5 U.S.C. § 631 when the U.S. Code was created in 1926. A single sentence of § 631 became § 7301 when this title of the U.S. Code was enacted into positive law in 1966. See Pub.L. 89-554, 80 Stat. 378, at 417.

166. Sections 3301, 3302 and 7301 have the same meaning now as when they were laws adopted by Congress in 1873 and 1883. At that time, these sections were merely parts of federal civil service laws and the President then (as now) lacked authority to impose vaccine mandates on federal employees, either through these or any other statutes.

167. To the extent that the President contends that Executive Orders 14042 and 14043 authorize the imposition of mandatory vaccines, that construction would be illegal and contrary to the plain language of 21 U.S.C. § 360bbb–3 (e)(1)(A)(ii): recipients of an EUA vaccine must be informed "(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."

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168. Pursuant to the above quoted § 360bbb–3, every American, possessed of the constitutional right to bodily integrity,[23] has the perfect right to refuse an EUA vaccination for any disease, whether COVID-19 or some other disease.

COUNT I

DECLARATORY JUDGMENT

§ 360bbb–3(b) — Cessation of Public Health Emergency; APA
(All Defendants)

169. Plaintiffs adopt all of the preceding paragraphs and incorporate them by reference, as if fully set forth herein.

170. 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."[24]

171. 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 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.

172. 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

[23] Doe v. Moore, 410 F.3d 1337, 1343 (11th Cir. 2005) ("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.'").

[24] *See* https://www.fda.gov/media/147737/download (last visited June 7, 2021).

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).

173. 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.

174. 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.

175. 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.

176. 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

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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."

177. Plaintiffs therefore seek a Declaratory Judgment that: the actions of the Defendants are unlawful and arbitrary, capricious, an abuse of discretion, 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

BODILY INTEGRITY

The Fundamental Right to Bodily Integrity Bars Mandates (All Defendants)

178. Plaintiffs adopt all of the preceding paragraphs and incorporate them by reference, as if fully set forth herein.

179. There exists a fundamental right to bodily integrity in which the Supreme Court has recognized places "limits on governmental power to mandate medical treatment or to bar its rejection." These limits stand so strongly that "a State's interest in the protection of life falls short of justifying any plenary override of individual liberty claims." *Planned Parenthood v. Casey,* 505

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U.S. 833 (1992). This high standard indicates that ANY governmental intrusion on decisions related to bodily integrity should be reviewed under the strictest of scrutiny.

180. *Planned Parenthood v. Casey* upheld rights related to abortion. Abortion results in the death of a child almost 100% of the time. This stands in stark contrast to the COVID-19 vaccines which carry unknown long-term risks (there have been no long-term studies), have the highest risk of side-effects, including death, of any vaccine in history, and are being mandated for a disease that has well over a 99% recovery rate for a vast majority of the population.

181. As such, Plaintiffs request injunctive and declaratory relief against any mandate or action that would lead to the mandate of the COVID-19 vaccines.

COUNT III

DECLARATORY JUDGMENT

§ 360bbb–3(c) — Failure to Meet Criteria for Issuance of Vaccine EUAs; APA
(All Defendants)

182. Plaintiffs adopt all of the preceding paragraphs and incorporate them by reference, as if fully set forth herein.

183. 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:

- SARS-CoV-2 and COVID-19 are not "a serious or life-threatening disease or condition" for 99% of the population;
- 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;
- it is *not* "reasonable to believe" that the Vaccines "may be effective" in treating or preventing SARS-CoV-2 and COVID-19;

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- 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

- 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.

184. 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 an abuse of discretion (as violative of 21 U.S.C. 21 U.S.C. § 352(j)) and unlawful, since the DHHS Secretary and his delegee the FDA Commissioner cannot meet the criteria for their issuance, thereby nullifying all Vaccine EUAs.

COUNT IV

DECLARATORY JUDGMENT

§ 360bbb–3(e) — Failure to Establish Conditions for Vaccine EUAs; APA (All Defendants)

185. Plaintiffs adopt all of the preceding paragraphs and incorporate them by reference, as if fully set forth herein.

186. § 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:

- 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

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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;

- 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.

187. 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 an abuse of discretion (as violative of 21

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U.S.C. 21 U.S.C. § 352(j)), and unlawful, since the DHHS Secretary has not established and maintained the required conditions, thereby nullifying all Vaccine EUAs.

COUNT V

MANDAMUS

28 U.S.C. § 1361
(Individual Federal Defendants)

188. The individual federal defendants have a clear duty to act to ensure the faithful implementation of § 360bbb-3, the provisions of which are mandatory and intended to protect Plaintiffs.

189. 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.)[25]

190. Plaintiffs therefore seek mandamus, compelling the individual federal defendants to perform the duties owed to them pursuant to § 360bbb-3.

COUNT VI

[25] 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.

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DECLARATORY JUDGMENT

191. Plaintiffs adopt all of the preceding paragraphs and incorporate them by reference, as if fully set forth herein.

192. Wherefore, Plaintiffs request the following declarations:

- A declaration that EOs 14042 and 14043 are invalid to authorize compulsory EUA vaccinations of American Citizens;
- A declaration that § 360bbb–3 as well as the constitutional right to bodily integrity permit an American citizen to refuse without adverse consequences any EUA vaccine.

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 their constitutional right to bodily integrity;

(E) Enjoin the enforcement of the challenged declaration of a "public health emergency" and further renewals thereof, the enforcement of the Vaccine EUAs;

(F) Enjoin enforcement of any and all actions by Defendants in violation of the Constitutional right to Bodily Integrity.

(G) Award Plaintiffs such other and additional relief as the Court deems fit.

VII. JURY DEMAND

RELAW

Plaintiffs request a jury trial on all issues so triable.

Dated: November 4, 2021.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this date, November 4, 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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