Affidavit

I, **Dr. Jane Ruby**, being duly sworn, depose and state as follows:

1. I make this affidavit in support of the above-referenced MOTION as expert testimony in support thereof. I understand that I am swearing or affirming under oath to the truthfulness of the claims made in this affidavit under penalties of perjury. I have read these statements in this affidavit, these statements are my understanding of the facts and my opinion provided is based upon a reasonable degree of medical and pharmaceutical industry processes certainty. I am providing this affidavit as I have serious, grave concerns for the United States military and the public-at-large.

2. The expert opinions expressed here are my own and arrived at from my personal, professional and educational experiences taken in context, where appropriate, by scientific data, publications, treatises, opinions, documents, reports, and other information relevant to the subject matter.

Experience & Credentials

3. I am competent to testify to the facts and matters set forth herein. A true and accurate copy of my *curriculum vitae* is attached hereto as **Exhibit A**.

4. I have personal knowledge and understanding of these matters and I make this affidavit in support of the truth of the contents contained herein.

5. After receiving a bachelor's degree from Alfred University, I completed my master's degree as a Sigma Theta Tau, cum laude graduate from the University of Rochester, Rochester, NY. I went on to complete my nurse practitioner residency at the University of Rochester, Internal Medicine, with a sub-specialty in Medical and Surgical Cardiology. I have a second master's degree in International Health Economics and Pharmacoeconomics from the Barcelona School of Management of the Universitat Pompeu Fabra, in Barcelona, Spain. I hold two earned doctoral degrees, Doctor of Education (EdD) from the University of Rochester and a PhD in Psychology from Kennedy Western University.

6. I taught undergraduate and graduate nursing curricula at Monroe Community College in Rochester, NY and at Nazareth College of Rochester. I was also on the faculty of the Margaret Warner School of Education and Human Development of the University of Rochester where I taught doctoral research methods. My clinical experiences include being on the staffs of Rochester General Hospital and the University of Rochester Medical Center.

7. I was the managing Director of the Scharf Institute for Neuroscience and Sleep Research in Rochester, New York. In that capacity I managed all personnel including medical doctors, psychologists, medical technicians, polysomnographers, and nurses. My main role was to oversee the execution of multicenter pharmaceutical Phase 2 and Phase 3 human research studies

number of Institutional Review Boards (IRB), some of which were privately based and others that were situated in universities and colleges, both certified by the federal government. I also created and wrote original research protocols and informed consent documents for industry and IRB review and approval, as I am highly trained in the requisite elements of a human study protocol. I am also familiar with human subjects' safety during clinical trials.

8. I have over twenty years of experience in pharmaceutical drug development and medical affairs, including the prior experience described as a principal investigator for multi-center randomized, placebo-controlled trials in the United States and ex-U.S.A. My experience extends to interfacing with FDA guidance documents, regulations, and submission reviews. My experience in the pharmaceutical industry was in medical affairs functions, clinical research operations, regulatory functions, animal and human subjects research study methodology and health economic and patient outcomes research.

Opinion

9. As an experienced research scientist and former healthcare provider, I have been an advocate of good health and health practices and evaluated the health effects of these products that I believe have been authorized and approved illegally. I believe within a reasonable degree of medical certainty that the COVID-19 injections, erroneously referred to as "vaccines" and available and under numerous mandates across the United States are not safe for any human generally; and particularly dangerous for military personnel. It is my belief, based upon a reasonable degree of medical certainty, that the injections could cause serious and permanent injury and the deaths of military personnel in the course of their duties to protect the American people, the American homeland and the U.S. Constitution.

10. I believe within a reasonable degree of medical certainty that the data upon which Department of Defense has based its mandate is flawed and/or inaccurate; and imposing these injections is dangerous and could cause harm to military members, resulting in a risk to our nation's wellbeing and military readiness. My opinion herein has recently been buttressed by the release of the outcomes of these injections in our military members from the Defense Military Epidemiological Database (DMED) showing 300% increase in miscarriages, 269% increase in heart attacks, 393% increase in strokes, 467% increase in pulmonary emboli (blood clots), 300% increase in cancer, and 1052% increase in neurological injuries from January 2021 – November 2021 over the numbers and averages of the preceding five years, correlating with the 2021 roll out of the DOD mandates imposed on military personnel of these prematurely and illegally authorized injections.

11. It is my opinion that the processes undertaken to grant all Emergency Use

Authorizations and specifically for the recent FDA approval of the Pfizer's injection, Comirnaty, (including the Pfizer-BioNTech Covid 19 Vaccine injections deemed by both the FDA and the Pfizer Inc., to be "the same formulation" and "interchangeable," – please see https://www.fda.gov/vaccines-blood-biologics/qa-comirnaty-covid-19-vaccine-mrna and https://www.pfizer.ca/COMIRNATY-Now-Health-Canada-Approved) and Moderna's injection referred to as Spikevax, as well as the authorizations for AstraZeneca and Johnson & Johnson (Janssen) covid injections are incomplete, based upon inappropriate study designs, insufficient safety and efficacy data yielded from those faulty studies, because they were all authorized and/or approved against FDA Guidance to Industry standards and requirements, thereby yielding results insufficient and inappropriate to be able to establish safety and efficacy, a high and specific threshold for human drug/entity/device use. The studies used to authorize and approve what I believe are dangerous to human beings, are missing key standard study data, FDA required data to establish safety and efficacy, and all safety surveillance and pharmacovigilance processes. Furthermore, these studies show no proof of proper review and legal approval by a human subjects review authority as required by FDA regulations prior to testing in human beings. Also referred to as an institutional review board, these independent bodies are charged with oversight for safety in human research emanating from the Nuremburg Code/Trials. This alone should render these trials null and void and presumed to be dangerous to humans.

COVID-19 Vaccine Research and Development – Inherent Dangers and Omission of Standard Safety Structures for Investigational Trials

12. In the Pfizer COMIRNATY and Pfizer-BioNTech Covid 19 Vaccination Series package insert, (See Exhibit B), the label states that on December 11, 2020, during the randomized, placebo-controlled pivotal trial (the research design required for FDA approval), "participants were "unblinded to offer placebo participants COMIRNATY," which in my expert opinion, immediately transformed the study (as the company itself indicated in its registry on ClinicalTrials.gov, NCT04368728) from a randomized, placebo-controlled, double blind study, the gold standard for human pivotal study data generation to determine the official designations of safety and efficacy, into **a modified-open label, observational, variable dose trial with no informed consent** as to the status change, the exact dosage, or full disclosure of ingredients or their known risks, and completely compromised the required, standard, Good Clinical Practices data for license application. It is my expert opinion, these deviations and the abandonment of standards, previously required of all pharmaceutical drug testing, should render the study data insufficient and inappropriate to file for or to be considered for review for FDA approval of any entity designated for administration to any human being. What resulted was the distribution of an incomplete and deceptive marketing label out to the general public. In my expert opinion this is an egregious and fraudulent misrepresentation of the **Safe and Effective** statements made to the public and is the basis for illegality of all emergency use authorizations and/or FDA approvals.

13. The COVID-19 genetic modification injections (Pfizer, Moderna, J&J) failed to test for standard parameters in *human studies*. The areas missing critical study results include, pharmacokinetics, pharmacodynamics including but not limited to genotoxicity, mutagenicity, teratogenicity, and oncogenicity. In other words, it is not certain if these products will permanently change human genetic material, cause birth defects, reduce fertility, or cause cancer. Pfizer and Moderna claim to use similar mRNA technology and Moderna has stated that the mRNA does indeed intermingle and modify the recipient's genetic code, characterizing it as the patient's "operating system," (see https://www.modernatx.com/mrna-technology/mrna-platform-enabling-drug-discovery-development). Of concern, the manufacturer publicly declares on their website that the mechanism of action of their mRNA is as follows: "[g]enerally, the only thing that changes from one potential mRNA medicine to another is the coding region – the actual genetic code that instructs ribosomes to make protein. Utilizing these instruction sets gives our investigational mRNA medicines a software-like quality. We also have the ability to combine different mRNA sequences encoding for different proteins in a single mRNA investigational medicine." (Source: https://www.modernatx.com/mrna-technology/mrna-platform-enabling-drug-discovery-development). To my knowledge, there is no informed consent, nor anything stamped with the approval of a human subjects' review board, to the public advising that they are submitting to a permanent change in their native genetic sequencing or any of their natural genetic material.

14. When compared to other, standard package inserts/labeling of FDA approved drugs, biologics, and medical devices, there is also an absence of a description of the molecular structure of the biologic. This is a further failure to disclose to medical prescribers, the formula and molecular weight. These disclosures are critical because they determines the fate of a compound regarding molecular interactions in the body generally and in the presence of concomitant medication therapy.

15. Two FDA Guidance for Industry documents, Considerations for the Design of Early-Phase Clinical Trials of Cellular and Gene Therapy Products, (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/considerations-design-early-phase-clinical-trials-cellular-and-gene-therapy-products), Human Gene Therapy Products Incorporating Human Genome Editing (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/human-gene-therapy-products-incorporating-human-genome-editing) illustrate FDA's *known* concerns of the never-before-tested in humans mRNA gene editing therapies including but not limited to

a. Prolonged bioactivity in the body
b. "Significant risks and uncertain benefits"
c. Persistence in the body

d. Gene integration and gene alteration with potential migration from target site, ectopic tissue formation, clonal outgrowths, abnormal cell activity, viral, all of unknow duration.
e. "The possibility of shedding, i.e. excretion/secretion of viral particles or bacteria that could be transmitted to other individuals." (Source: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/considerations-design-early-phase-clinical-trials-cellular-and-gene-therapy-products), page 5;
f. "expression of a delivered gene may be uncontrolled and interfere with normal function of a critical enzyme, hormone, or biological process in the recipient. Some GT products are designed to integrate into the DNA of the recipient's cells to allow for long-term expression of the integrated genes. This genomic alteration could cause activation or inactivation of neighboring genes and give rise to benign or malignant tumors" page 4; (Source: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/considerations-design-early-phase-clinical-trials-cellular-and-gene-therapy-products).

16. In the human trial for Comirnaty / Pfizer-BioNTech Covid-19, the protocol lists a significant number of exclusions whereby subpopulations of people and those with certain medical comorbidity or conditions could not enter the trial; this results in the absence of controlled trial data for both safety and efficacy. In my expert opinion, this should render any mandates for those populations as **contraindications.** These populations or conditions are missing from the final Approval label (See **Exhibit B**). Taken from the Pfizer protocol for Comirnaty / Pfizer-BioNTech Covid Vaccine protocol (Clinicaltrials.gov, see Study NCT04368728) are as follows:

a. Medical or psychiatric condition including recent (within the past year) or active suicidal ideation/behavior or laboratory abnormality that may increase the risk of study participation or, in the investigator's judgment, make the participant inappropriate for the study.
b. Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV).
c. History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (e.g., anaphylaxis) to any component of the study intervention(s).
d. Receipt of medications intended to prevent COVID 19.
e. Previous clinical (based on COVID-19 symptoms/signs alone, if a SARS-CoV-2 NAAT result was not available) or microbiological (based on COVID-19 symptoms/signs and a positive SARS-CoV-2 NAAT result) diagnosis of COVID 19.

f. Individuals at high risk for severe COVID-19, including those with any of the following risk factors:
    i. Hypertension
    ii. Diabetes mellitus
    iii. Chronic pulmonary disease
    iv. Asthma
    v. Current vaping or smoking
    vi. History of chronic smoking within the prior year
    vii. BMI >30 kg/m2
g. Anticipating the need for immunosuppressive treatment within the next 6 months.
h. Individuals currently working in occupations with high risk of exposure to SARS-CoV-2 (e.g., healthcare worker, emergency response personnel).
i. Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination.
j. Individuals with a history of autoimmune disease or an active autoimmune disease requiring therapeutic intervention.
k. Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection.
l. **Women who are pregnant or breastfeeding**.
m. Previous vaccination with any coronavirus vaccine. *(These did not exist at the time).*
n. Individuals who receive treatment with immunosuppressive therapy, including cytotoxic agents or systemic corticosteroids, e.g., for cancer or an autoimmune disease, or planned receipt throughout the study.
o. Regular receipt of inhaled/nebulized corticosteroids.
p. Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study.
q. Participation in other studies involving study intervention within 28 days prior to study entry through and including 6 months after the last dose of study intervention, with the exception of non-Pfizer interventional studies for prevention of COVID 19, which are prohibited throughout study participation.
r. Previous participation in other studies involving study intervention containing lipid nanoparticles.
s. Positive serological test for SARS-CoV-2 IgM and/or IgG antibodies at the screening visit.
t. Any screening hematology and/or blood chemistry laboratory value that meets the definition of a ≥ Grade 1 abnormality.

u. Positive test for HIV, hepatitis B surface antigen (HBsAg), hepatitis B core antibodies (HBc Abs), or hepatitis C virus antibodies (HCV Abs) at the screening visit.
v. SARS-CoV-2 NAAT-positive nasal swab within 24 hours before receipt of study intervention.
w. Less than 12 years of age. *this is particularly significant because Pfizer-BioNTech companies have requested EUA for <12 years of age, including 2-11 year olds with no randomized, controlled study data and no proof of Human Subjects Review Board evaluation and approval.*

17. The COVID-19 genetic modification vaccines (Pfizer, Moderna, J&J) failed to disclose or conduct and/or include any study results for standard pre-licensing safety that would adequately and at a minimum, inform prescribers and patients of serious considerations. These findings are, by good standard practices, included in the Prescriber's Information / Package Insert, commonly referred to as the Label. The missing studies and results include key information such as:

a. Pharmacokinetics – studies on the fate of the drug after administration:
    i. Drug Half Life
    ii. Drug-Drug Interactions (against standard metric drugs)
    iii. Absorption
    iv. Elimination
    v. Receptor Affinity
    vi. Tissue and Body Fluid Mass and Volume
    vii. Drug Metabolism
    viii. Maximum Drug Concentration
    ix. Time to Concentration
    x. CYP450 Isoenzyme Impact on Liver and Drug: Identification of the microsomes in this system that are affected by this biologic and how that may interfere with or enhance effect on liver function. Interaction with this human enzyme system of concern can increase or decrease the mechanism of action of other medications or endogenous hormones and enzymes.
b. Pharmacodynamics – the entity's actions on the body
    i. Receptor Binding – a critical component for drug-drug interactions and safety issues related to mechanism of action.
    ii. Drug Effect at Receptor Binding, *particularly Angiotensin Converting Enzyme-2 Receptors, the key receptor for the resulting Subunit 1 pathogen, the Spike Protein resulting from the Pfizer, Moderna, and J&J self-proclaimed mechanism of action (MOA).*

iii. Concentration of the Drug at the Receptor Sites

18. The There are four phases to human trials in drug development and Phase 3 is most critical as it comprises the last phase of testing to be completed before the drug's details and clinical trial results are submitted to the regulatory authorities for approval of the drug's release on the open market. See Exhibit C, Phases of Human Trials). While Phase 1 focuses on tolerability and safety in a small number of healthy subjects and Phase 2 establishes efficacy and optimal dosing regimen, Phase 3 should demonstrate and confirm the preliminary evidence gathered in the previous trials that the entity is, a safe, beneficial and effective treatment for the intended indication. The absence of findings from this part of the study as well as from the missing elements enumerated in Sections 15 and 16 violate FDA Guidance Expectations for proper review submission and approval.

19. The COVID-19 genetic vaccines (Pfizer, Moderna, J&J) are currently conducting Phases 1, 2 & 3 simultaneously which is dangerous and unprecedented in drug development. My expert position is that this departure from standard human trial phases conduct whereby FDA is allowing Phases 1/2/3 of human trials to run consecutively, (without Subjects' Informed Consent), is a serious departure from standard human trial phases, which should run ***consecutively,*** because each Phase must incorporate the results in order to inform the subsequent Phase on next steps for safety and efficacy. See Exhibit C, Phases of Clinical Drug Trials)

20. The COVID-19 genetic vaccines (Pfizer, Moderna, J&J) failed to study the following standard good practice subpopulations for the effects enumerated in the exclusion criteria sufficiently with a placebo control arm:
    a. Age
    b. Gender
    c. Race
    d. Liver Impairment
    e. Kidney/Renal Impairment

21. The COVID-19 genetic vaccines (Pfizer) claim in the labeling (See **Exhibit B,** page 6, section 6.1) that "because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a vaccine cannot be directly compared to rates in the clinical trials of another vaccine and may not reflect the rates observed in practice." The manufacturer uses this unorthodox proclamation to justify failure to conduct safety evaluation that it had planned to do in the manufacturer's own protocol and in its Pharmacovigilance Plan, both submitted to the FDA and that currently sits on ClinicalTrials.gov, the U.S. government

website repository for trial registration. (https://clinicaltrials.gov/ct2/show/NCT04368728?cond=NCT04368728&draw=2&rank=1).

a. Prior to COMIRNATY's full FDA approval, the FDA issued a Warning regarding the rates of heart inflammation and heart failure in teenagers; but that Warning did not translate equally to the product labeling, no Black Box Warning transferred to the Label, and in fact did not even translate to Contraindications Section for these products.
b. It is good standard practice to include studies for any entity administered concomitantly with monoamine oxidase inhibitors (MAOIs) and/or include a contraindication for simultaneous use.
c. Prescribers and medical providers are not only not discouraged, but they are affirmatively encouraged, to proceed with injecting this series into populations that were either excluded in the study or who subsequently reported serious life-threatening adverse events as reported by the federal government's tracking sites Vaccine Adverse Reporting System (VAERS) and V-Safe.
d. In direct contradiction to the FDA/CDC Safety meeting in October 2020, prior to the vaccination roll out program, there are no warning or precautions included in the Label relative to the FDA's known and prior warnings.
e. The Serious Adverse Event Section in the Label is devoid of data already known to the public through the VAERS and V-SAFE reporting systems, both the only sources for the public to be informed of risks. This raises the question as to why the reported rates of cardiac injury, sudden cardiac death, blood clot caused strokes, teen heart attacks, paralysis and serious permanent motor impairment and blood dyscrasias (as demonstrated by numerous scientists including UK physician Dr. Philipe VanWelbergen, Dr. Barbel Ghitalla, and Dr. Robert Young among others) are absent from the Label. Dr. Robert Young has provided recent evidence that vials of Pfizer, Moderna, Johnson & Johnson, & AstraZeneca properly constituted for individual use per the manufacturers' instructions yielded visual microscopy evidence of lethal parasites, stainless steel aggregations, graphene oxide, and "nanoparticles of bismuth, titanium, vanadium, iron, copper, silicon, aluminum embedded in Pfizer vials."
(See **Exhibit D**, Blood smears, Dr. VWB & Dr. BG); Source: https://www.drrobertyoung.com/post/transmission-electron-microscopy-reveals-graphene-oxide-in-cov-19-vaccines
f. Teratogenicity is a primary concern in all experimental medical interventions and drugs under review, and unless it is studied (after human subjects' review board approval), it is a de facto contraindication to give, much less mandate, any medical intervention to a woman of child bearing years, a pregnant woman, or newborn baby. In fact, the reason there is no guidance in the Label for use in pregnant women is because pregnant women were not studied. Women of child-

bearing age were also excluded; therefore, no safety data is included in the Label and the Label only indicates that "Available data on COMIRNATY administered to pregnant women is insufficient to inform vaccine-associated risks in pregnancy." If the data is insufficient by the Companies' and the P-B Label, then it should be contraindicated in that population.

i. Similarly, the Label states, "It is not known whether COMIRNATY is excreted in human milk." Pursuant to good and standard clinical research practices this would constitute a de facto contraindication.

g. There is no information or data to guide prescribers on whether to use this and what the degree of safety would be for use in those with concomitant illnesses, otherwise known as medical comorbidity.

h. There is no information on how to consider dose adjustment for special populations and those already medically compromised.

i. The Label is missing data and guidance information on Carcinogenesis, Mutagenesis, and Impairment on Fertility – despite the disclosure by Pfizer that researchers during the trial were warned to avoid contact between people of child-bearing age and those who have gotten this entity. (See **Exhibit E**, Pfizer Protocol, page 132).

22. The COMIRNATY product that has been deemed (https://www.pfizer.com/news/press-release/press-release-detail/pfizer-biontech-covid-19-vaccine-COMIRNATYr-receives-full) to "have the same formulation [as the Pfizer-BioNTech Covid-19 Vaccine] and can be used interchangeably to provide the Covid-19 vaccination series," was granted full FDA approval, licensed, and labeled with the Indication "to prevent Covid-19 in individuals 16 years of age and older." This is in contrast to the a priori primary endpoint in the study protocol (See **Exhibit E**). The primary endpoint is the measure used to validate the entity's separation from placebo which indicates the degree of efficacy and if the entity statistically separates from placebo, this constitutes the basis for the FDA approved indication or otherwise known as the legal marketing authorization. In the Pfizer protocol NCT04368728 on Clinicaltrials.gov, the primary endpoint was less severe symptoms and lower rates of hospitalizations. Upon FDA approval on August 23, 2021, both the company and the FDA announced the approval of Comirnaty/ Pfizer-BioNTech Covid 19 Vaccine for the indication "to prevent Covid 19." See Label Exhibit B)

23. The companies declare that the COMIRNATY product, while the same formulation, is currently "unavailable," in direct contradiction to Pfizer's statement that COMIRNATY was used in over 20,000 people in 2021. (See **Exhibit B**, Pfizer Package Insert).

24. The FDA approval letter for COMIRNATY, dated August 23, 2021, from RADM Denise Hinton to Pfizer that has been used by the Department of Defense to claim that there is now a "fully licensed vaccine", constitutes a "deceptive or misleading statement" about a product

as that term is used in regards to marketing or labeling a drug or vaccine. Until a vaccine has shown the requisite safety, efficacy, and potency requirements by rigorous scientific studies designed according to FDA's established standard criteria, the vaccine, in my expert opinion has not been shown to meet the FDA's own standards for FDA approval.

25. The FDA's approval letter clearly states that a different vaccine, manufactured by BioNTech Manufacturing GmbH in Germany and known as COMIRNATY, is being approved as a fully licensed vaccine. In this same letter, RADM Hinton also extends the Emergency Use Authorization for the Pfizer BioNtech vaccine. Later in the same letter, RADM Hinton states that the BioNtech vaccine is the equivalent to the COMIRNATY vaccine, while they are "legally distinct", that no safety or efficacy concerns are present, and that because of the lack of availability of the COMIRNATY vaccine that the Pfizer BioNtech is allowed to be substituted in place of the approved COMIRNATY vaccine. This is all done without any evidence as to how the BioNtech vaccine can be declared safe or effective when it has not even completed a successful Phase III trial. (See Exhibit F for FDA Guidance Document on requirements for Phase 3 trials: https://www.fda.gov/media/87621/download. Furthermore, in the Pfizer protocol (See Exhibit E) three formulations are enumerated, with no disclosures on the distinctions:

a. BNT 162b1
b. BNT 162b2
c. BNT 162SA
d. The protocol indicates that the injected will randomly be injected with any one of at least 8 doses including one dose 100mcg, which is essentially >3 times the approved dose, 30 mcg in Comirnaty.

26. The COVID-19 genetic vaccine companies (Pfizer, Moderna, J&J) have not provided complete FDA or the public disclosure on their vaccine boxes, package inserts or labels for all of the ingredients within these injection vials. Vis a vis fundamental human rights, governed by International Law and the Nuremberg Code of 1947, the vaccine-specific ingredient information is critical, required and necessary to know so that any human can make an informed decision whether to consent to inoculation.

27. The Pfizer, Moderna, and J&J vaccines are considered "genetic vaccines", or vaccines produced from gene therapy molecular platforms which, according to US FDA regulatory guidance, are classified as gene delivery therapies and should be under a **fifteen-year** regulatory cycle with annual visits for safety evaluation by the research sponsors. (*Long Term Follow-up After Administration of Human Gene Therapy Products. Guidance for Industry*. FDA-2018-D-2173. 2020. Accessed July 13, 2021, at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/long-term-follow-after-administration-human-gene-therapy-products.

28. The FDA has "advised sponsors to observe subjects for delayed adverse events for as long as fifteen years following exposure to the investigational gene therapy product, specifying

that the long-term follow-up observation should include a minimum of five years of annual examinations, followed by ten years of annual queries of study subjects, either in person or by questionnaire." (emphasis added). Thus, the administration of the Moderna, Pfizer, and J&J vaccines should not be undertaken without the proper consent and arrangements for long-term follow-up which are currently not offered in the US. (See, EUA briefing documents for commitments as to follow up: Moderna, Pfizer, J&J).

29. Because the US FDA and CDC have offered no methods of risk mitigation or proof of continued safety surveillance for these serious adverse effects which can lead to permanent disability or death, no one should be pressured, coerced, receive the threat or reprisal, or be mandated to receive one of these investigational products against their will.

30. It is never good, nor standard, nor reasonable research practice to perform a large-scale clinical investigation without the necessary structures in place to ensure the safety and protection of human subjects. These structures include a critical event committee, data safety monitoring board and human ethics committee. These groups in large studies work to objectively assess the safety of the investigational product and research integrity. The goal is to mitigate risk and protect human subjects. It is my understanding that the COVID-19 vaccine program sponsored by the CDC and FDA has implemented none of these crucial safety structures which, to my knowledge, have never been omitted from any large-scale clinical investigation, not to mention that the subject clinical investigation is of far greater and unprecedented magnitude and complexity than any of its predecessors. It is my assessment that the COVID-19 clinical investigation has provided no meaningful risk mitigation for subjects (restricting groups, a special assessment of side effects, or follow-up visits) to ensure or improve the safety of the program.

31. According to expert medical opinion, there are emerging trends demonstrating that any Covid-19 vaccine is especially risky for those in the 12 – 29 year-old demographic, with resulting complications in the cardiovascular, neurological, hematologic, and immune systems. *(See*, Rose J, et al). Increasingly, the medical community is acknowledging the possible risks and side effects inclusive of myocarditis, Bell's Palsy, Pulmonary Embolus, Pulmonary Immunopathology and severe allergic reaction causing anaphylactic shock. *See* Chien-Te Tseng, Elena Sbrana, Naoko Iwata-Yoshikawa, Patrick C Newman, Tania Garron, Robert L Atmar, Clarence J Peters, Robert B Couch, *Immunization with SARS coronavirus vaccines leads to pulmonary immunopathology on challenge with the SARS virus*, https://pubmed.ncbi.nlm.nih.gov/22536382/ (last visited June 21, 2021); Centers for Disease Control and Prevention, *Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Pfizer-BioNTech COVID-19 Vaccine*—United States, December 14–23, 2020 (Jan 15, 2021), https://www.cdc.gov/mmwr/volumes/70/wr/mm7002e1.htm (last visited June 26, 2021).

32. The Centers for Disease Control has held emergency meetings on this issue and the medical community is responding to the crisis. It is known that myocarditis causes injury to heart muscle cells and may result in permanent heart damage culminating in heart failure, arrhythmias, and cardiac death. These conditions could call for a lifetime need for multiple medications, implantable cardio defibrillators, and heart transplantation. Heart failure has a five-year 50% survival and would markedly reduce the lifespan of a child or young adult who develops this complication after vaccine-induced myocarditis (McCullough PA, Philbin EF, Spertus JA, Kaatz S, Sandberg KR, Weaver WD; Resource Utilization Among Congestive Heart Failure (REACH) Study. Confirmation of a heart failure epidemic: findings from the Resource Utilization Among Congestive Heart Failure (REACH) study. J Am Coll Cardiol. 2002 Jan 2;39(1):60-9. doi: 10.1016/s0735-1097(01)01700-4.

33. COVID-19 vaccine-induced myocarditis has a predilection for young males below age 30 years, a substantial demographic of the US military. The Centers for Disease Control has held emergency meetings on this issue, the medical community is responding to the crisis, and the US FDA has issued a warning on the Pfizer and Moderna vaccines "Fact Sheet for Patients and Caregivers," the apparent substitute for an official, and comprehensive Informed Consent document, for myocarditis. Given the prevalence of this event in younger males, no individual under age 30 under any set of circumstances should feel obliged to take this risk with the current genetic vaccines, particularly the Pfizer and Moderna products. https://www.fda.gov/news-events/press-announcements/coronavirus-COVID-19-update-june-25-2021.

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

35. Furthermore, the CDC announced on June 24, 2021, that the vaccine is "likely linked" to myocarditis. "Advisory Board, CDC panel reports 'likely association' of heart inflammation and mRNA COVID-19 vaccines in young people," (June 24, 2021) https://www.advisory.com/daily-briefing/2021/06/24/heart-inflammation.

36. On July 12, 2021, the US FDA sent out an additional warning for Guillain-Barre Syndrome or ascending paralysis for the J&J vaccine, which is not predictable and, when it occurs, can result in ascending paralysis, respiratory failure, the need for critical care and death. Not all cases completely resolve, and some vaccine victims may require long term mechanical ventilation or become quadra- or paraplegics. Prolonged neurological rehabilitation is commonly required, and this will call for time away from school and studies for those children injured from the J&J vaccine with Guillain-Barre Syndrome. https://www.fda.gov/media/150723/download

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

37. There is recent research demonstrating that the COVID-19 vaccine is dangerous for those who have already had COVID-19 and recovered with inferred robust, complete, and durable immunity. These patients were excluded from the FDA-approved clinical trials performed by Pfizer, Moderna, and J&J. From these trials the safety profile was unknown when the products were approved for Emergency Use Authorization in 2020. There has been no study demonstrating clinical benefit with COVID-19 vaccination in those who have well documented or even suspected prior COVID-19 illness.

38. To my knowledge, there are no studies that demonstrate the clinical benefit of COVID-19 vaccination in COVID-19 survivors or those with suspected COVID-19 illness or subclinical disease who have laboratory evidence of prior infection. The CDC has admitted that natural immunity is superior to any level of immunity resulting from pathogen exposure known as artificial vaccination such as these Covid-19 injections.

Conclusion

I have reviewed the Complaint for Declaratory and Injunctive Relief which delineates the significant departures from standard procedures, protocols and safety measures and conclude as follows:

39. It is my expert medical opinion that it is not good, nor standard, nor reasonable professional research or clinical practice to widely utilize these never-before-tested-in-human beings, biologic therapy (mRNA, adenoviral DNA COVID-19 vaccines) in populations where there is no information generated from fully completed, controlled registrational trials with the FDA, specifically COVID-19 survivors, suspected COVID-19-recovered, pregnant or women who could become pregnant at any time after investigational vaccines; and especially our military.

40. In my expert opinion, the risks associated with the investigational COVID-19 vaccines far outweigh any theoretical benefits, are not minor or unserious, and many of those risks are unknown and have not been adequately quantified; nor the duration of their consequences evaluated or shown to be calculable. Therefore, in my expert medical opinion, the Emergency Use Authorization and FDA Approval for the administration of COVID-19 vaccines creates an unethical, unreasonable, clinically unjustified, unsafe, and unnecessary risk to the military of the United States of America.

41. The gross deviations in conducting adequate safety and efficacy studies, the lack of disclosure on product content, the absence of informative trial data in good clinical research practices for basic categories and conditions, the absence of Human Subjects Review (HSRB) oversight, the absence of Good Manufacturing Practices oversight created by the FDA, the lack of a full human subjects review board approval stamped, informed consent for replaced only by an abbreviated patient one-page checklist, and the deviations and omissions from protocol to Label

are of great concern to me. In my expert opinion, the foregoing constitutes a lack of scientific justification for the Approval, all Emergency Use Authorizations, and any mandated administration of both the COMIRNATY and Pfizer-BioNTech vaccine formulations, both of which have been declared by the companies as one and the same.

State of Florida

County of Palm Beach

The undersigned, being duly sworn, deposes and says:

I, Jane Ruby, declare under the penalty of perjury of the laws of the United States of America, and state upon personal knowledge that:

I am an adult of sound mind, over 21years old, and declare that the information herein is true, correct and complete and that I have voluntarily affirmed this affidavit based upon my own personal knowledge, education, and experience, and under the penalty of perjury of the laws of the United States of America.

Dr. Jane Ruby, PhD, EdD, MS, MS Economics

SUBSCRIBED AND SWORN TO BEFORE ME on the 10 day of April 2022 to certify which witness my hand and official seal.

CINDY FURINO
Notary Public-State of Florida
Commission # HH 29352
My Commission Expires
August 16, 2024

Notary Public for the State of Florida

My Commission Expires:
8/16/24