UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA

NAVY SEAL 1, et al.,	)	
	)	
Plaintiffs,	)	
v.	)	
	)	Case No. 8:21-cv-02429-SDM-TGW
JOSEPH R. BIDEN, et al.,	)	
	)	
Defendants.	)	
	)	

DECLARATION OF ROBERT MALONE, MD, MS, IN SUPPORT OF PLAINTIFFS' MOTION FOR A TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION

Dr. Robert Malone declares under penalty of perjury:

1. I am over the age of eighteen years, have personal knowledge and exposure to the matters set forth in this Declaration, and if called to testify to them, I would and could do so competently.

2. I am an original inventor of core mRNA and DNA vaccination technology; have been involved in developing, designing, and providing oversight of approximately forty phase 1 clinical trials and twenty phase 2 clinical trials, as well as five phase 3 clinical trials; have been involved in infectious disease pathogen advanced development oversight of HIV, Influenza, Plague, Anthrax, VEE/EEE/WEE, Tularemia, Tuberculosis, Ebola, Zika, Ricin toxin, and Engineered pathogens; and, since January 2020, have been leading a large team focused on clinical research design, drug development, computer modeling, and mechanisms of action of repurposed drugs for COVID-19 treatment.

3. I submit this declaration in support of Plaintiffs' arguments that (a) the Pfizer-BioNTech COVID-19 Vaccine and COMIRNATY COVID-19 Vaccine are legally distinct; and (b) there are

no licensed SARS-CoV-2 vaccines currently available in the US. Rather, all currently available doses of SARS-CoV-2 vaccines are experimental medical products made available under the Emergency Use Statutes and Authorizations (EUA).

Education and Professional Experience

4. I graduated from the University of California, Davis with a Bachelor of Science degree in Biochemistry in 1984. I graduated from the University of California, San Diego with a Master's degree in Biology in 1989. I graduated from Northwestern University Medical School, Feinburg School of Medicine, in 1991.

5. I received one year of pathology residence training at University of California, Davis Sacramento Medical Center. I completed a Masters' Degree in Biology from University of California, San Diego in 1989 for work performed primarily at the Salk Institute in the Molecular Biology and Virology Laboratories and Laboratory of Dr. Inder Verma. This and subsequent work at the San Diego corporation "Vical" resulted in nine issued domestic US patents describing mRNA and DNA vaccine platform technology.

6. I completed a Giannini post-doctoral research fellowship at University of California, Davis Department of Pathology in 1992. I completed a Harvard Medical School Global Clinical Research Scholars fellowship in 2016. This fellowship included an emphasis on regulatory affairs, clinical development, bioethics, epidemiology and biostatistics.

7. I am currently licensed to practice medicine in the State of Maryland.

8. I have been extensively and repeatedly trained in clinical research bioethics over many years at a variety of institutions including intensive training by Dr. Adil Shamoo of the University of Maryland, Baltimore.

9. I served as Assistant and Associate Professor of Surgery and/or Pathology at University of California, Davis School of Medicine, University of Maryland School of Medicine, and the Uniformed University of the Health Sciences between 1992 and 2001. During this period, I was awarded numerous peer-reviewed and industrial grants and contracts relating to gene delivery technology, genetic vaccine development, the chemistry and formulation of gene delivery reagents such as those used for mRNA vaccines, mucosal genetic vaccine development and other related topics. This work resulted in numerous additional granted US Patents in these fields and the incorporation of biotechnology companies based on these discoveries including Inovio vaccines.

10. I served as Associate Director, Clinical Research at Dynport Vaccine Company LLC from 2002-2003, supporting the prime systems US DoD contract for all biodefense products under advanced development by the Department of Defense. I also served as Director, Business Development and Program Management for the Bill and Melinda Gates funded Aeras Global TB Vaccine Foundation from 2004-2005; Senior Medical Director, Summit Drug Development Services (a Regulatory Affairs and Clinical Research specialty contract research organization) from 2005-2006; Director, Clinical Development & Medical Affairs, Influenza for Solvay Pharmaceuticals (currently Abbvie) from 2006-2008; and Medical Director, Vaccines for the Beardsworth Consulting Group from 2010 – 2013.

11. I currently serve as CEO and Principal Consultant for RW Malone MD LLC, primarily supporting the US Department of Defense, Defense Threat Reduction Agency (via contracts held by Leidos and MIT-Lincoln Lab). I have been leading or serving as a principal consultant for teams developing both repurposed drugs or vaccines since January 4, 2020, resulting in multiple novel findings, published and pending manuscripts, three clinical trials involving repurposed drugs

(two in USA under DoD funding, one in India under funding from Reliance Healthcare) and one Phase 1 clinical trial for a novel SARS-CoV-2 vaccine.

12. I have a history of over a decade of service to the NIAID as either reviewer or study section chairperson for evaluating large contract bids for development of Biodefense and other Medical Countermeasures against emerging infectious diseases and biothreat agents.

13. I currently sit on the NIH/FNIH ACTIV COVID-19 Drug development panel.

14. I co-authored a book entitled "NOVEL CORONAVIRUS: A Practical Guide for Preparation and Protection (originally published Feb 2020).

15. I played a key role in the discovery and clinical development of the repurposed drugs Famotidine and Famotidine + Celecoxib as treatment for both outpatient and inpatient COVID-19 disease, and have academic publications relating to this work. This work has yielded FDA and Indian health authority approved INDs for clinically testing these agents in outpatient and inpatient randomized controlled trials.

16. I supported the Indian corporation Reliance in development of a second-generation SARS-CoV-2 vaccine that is now IND approved by the Indian health authority for initiation of clinical trials which are anticipated for Q4 2021.

17. I have previously served as an expert witness in cases relating to vaccine development, COVID-19, and related topics.

18. Together with Dr. Peter Navarro, I developed and published (lay press, Washington times) public policy recommendations involving targeting SARS-CoV-2 vaccine deployment to high risk groups (elderly, morbidly obese, immunodeficient and others), providing early COVID-19 treatment options (including antibody therapies), home diagnostic tests, and computational algorithms enabling individual assessment of COVID-19 risks.

19. Attached as **Exhibit A** is a true and correct copy of my curriculum vitae.

BioNTech's COMIRNATY Vaccine is distinct from the Pfizer-BioNTech Vaccine

20. Defendants' argument that the Pfizer-BioNTech vaccine is fully interchangeable with BioNTech's COMIRNATY is incorrect. Even if the vaccines might be produced at the same facilities or with the "same formulation," as defendants assert, does not mean they are fully interchangeable. The Pfizer-BioNTech vaccine is only authorized under the Emergency Use Authorization provision while the BioNTech vaccine received FDA approval. However, as will be addressed below, there is no FDA approved SARS-CoV-2 vaccine available. That is to say, the FDA approved BioNTech COMIRNATY vaccine is not available.

21. Although the FDA has stated that the two vaccines have the "same formulation . . . and can be used interchangeably to provide the vaccination series without presenting any safety or effectiveness concerns," that does not mean they are the same vaccine. In fact, the FDA has explained that the two "products are legally distinct" but "with certain differences that do not impact safety or effectiveness." *See* Letter United States Food and Drug Administration to Pfizer at 3, n. 10 (Sept. 22, 2021) (A true and correct copy of the letter is attached as **Exhibit B**); Letter United States Food and Drug Administration to Pfizer at 3, n. 11 (Oct. 20, 2021) (A true and correct copy of the letter is attached as **Exhibit C**); Letter United States Food and Drug Administration to Pfizer at 3 (A true and correct copy of the letter is attached as **Exhibit D**); CDC COVID-19 Vaccine Related Codes at 4 (A true and correct copy of the document is attached as **Exhibit E**).

22. The notion that the two legally distinct products are wholly interchangeable appears to be based on an incorrect understanding that a regulated product authorized for marketing by the FDA consists only of the active drug substance as delivered into a vial or other container in the case of

an injectable vaccine. However, the Pfizer-BioNTech vaccine and BioNTech COMIRNATY vaccine are legally distinct products, as described by the FDA documents available at https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/comirnaty-and-pfizer-biontech-covid-19-vaccine. These vaccines and any other FDA regulated medicinal product consists of the entirety of the data supporting the safe and effective use of the product, as well as the quality systems, production methods and processes, laboratory assays (including in-process and release assays), materials, facilities & equipment, and packaging & labeling of the product. Packaging and labeling specifically includes a package insert summarizing the data supporting the intended safe and effective use, and also describing the risks associated with the medical product.

23. These packaging and labeling aspects for the Pfizer-BioNTech vaccine and BioNTech's COMIRNATY, which are intrinsic aspects of the regulated product, are explicitly not identical between these two legally distinct products. For example, BioNTech's COMIRNATY includes FDA approved labeling and a package insert designed to inform the recipient of the (incomplete, as recognized by the FDA) list of risks and benefits of the product, whereas the Pfizer-BioNTech vaccine does not. Therefore, the Pfizer-BioNTech vaccine and BioNTech's COMIRNATY are neither identical legally nor functionally.

24. There may be other differences between the Pfizer-BioNTech vaccine and BioNTech's COMIRNATY in the totality of the products in terms of quality systems, production methods and processes, laboratory assays (including in-process and release assays), materials, facilities & equipment. The provided FDA communication appears to assert that the materials used and final formulation is essentially identical, but potential differences in addition to the differences in packaging and labeling are not explicitly addressed.

25. On the basis of these facts and observations, it is my expert opinion that the Pfizer-BioNTech vaccine and BioNTech's COMIRNATY are not identical, and that the FDA has appropriately identified them as legally separate and distinct products. The assertions that the Pfizer-BioNTech vaccine and BioNTech's COMIRNATY are identical is not based in regulatory or legal fact.

BioNTech's COMIRNATY Vaccine is not available in the US

26. It is my expert opinion, based on the aforementioned FDA letters dated September 22, 2021 (Exhibit B at 6, n.12), October 20, 2021 (Exhibit C at 7, n. 13) , and October 29, 2021 (Exhibit D at 9, n. 17), as well as the September 13, 2021 National Institutes of Health news release (Exhibit F), and a CDC release of COVID-19 Vaccine Related Codes (Exhibit E), **that the FDA regulated product labeled COMIRNATY is the only FDA licensed SARS-CoV-2 vaccine** (A true and correct copy of the NIH press release is attached hereto as Exhibit F) **but it is not yet available for use in the U.S.** In the FDA letters dates September 22, 2021 and October 20, 2021 (both cited above), the FDA expressly states: "Although COMIRNATY (COVID-19 Vaccine, mRNA) is approved to prevent COVID-19 in individuals 16 years of age and older, **there is not sufficient approved vaccine available for distribution to this population in its entirety at the time of reissuance of this EUA**." (emphasis added).

27. As stated in the CDC COVID-19 Vaccine Related Codes document (Exhibit E), "**COMINARTY products are not orderable at this time. NDCs are listed per FDA Structured Product Label (SPL) document for the BLA licensed product. These codes are not included in CDC Vaccine Code Set files at this time. Pfizer has provided the following statement regarding the COMINARTY branded NDCs and labels:** 'Pfizer received FDA BLA license on 8/23/2021 for its COVID-19 vaccine for use in individuals 16 and older (COMIRNATY). At that

time, the FDA published a BLA package insert that included the approved new COVID-19 vaccine tradename COMIRNATY and listed 2 new NDCs (0069-1000-03, 0069-1000-02) and images of labels with the new tradename. **At present, Pfizer does not plan to produce any product with these new NDCs and labels over the next few months while EUA authorized product is still available and being made available for U.S. distribution. As such, the CDC, AMA, and drug compendia may not publish these new codes until Pfizer has determined when the product will be produced with the BLA labels**.'" (Exhibit E) (first bolding in original, second bolding emphasis added).

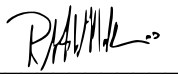
28. On September 13, 2021, the NIH published the identical Pfizer statement: "**At present, Pfizer does not plan to produce any product with these new NDCs and labels over the next few months while EUA authorized product is still available and being made available for U.S. distribution. As such, the CDC, AMA, and drug compendia may not publish these new codes until Pfizer has determined when the product will be produced with the BLA labels**." (Exhibit. F) (emphasis added).

29. Based on all information available to me, it is my expert opinion that **none** of the SARS-CoV-2 vaccines currently available in the U.S. are FDA approved and licensed for use. All doses currently available (Pfizer-BioNTech, Moderna, and Johnson & Johnson) are experimental medical products made available as such by the FDA and the Department of Health and Human Services under the Emergency Use Statutes and Authorizations (EUA). Under the EUA, and the FDA Fact Sheets for Pfizer-BioNTech, Moderna, and Johnson & Johnson, individuals have the "option to accept or refuse" the products.

VERIFICATION

I, Robert Malone, MD, MS, am over the age of eighteen years and a Declarant in this action. The statements and allegations that pertain to me or which I make in this DECLARATION are true and correct, and based upon my personal knowledge (unless otherwise indicated). If called upon to testify to their truthfulness, I would and could do so competently. I declare under penalty of perjury, under the laws of the United States, that the foregoing statements are true and correct to the best of my knowledge.

Dated: November 9, 2021



Robert Malone, MD, MS