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

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

AMERICA'S FRONTLINE DOCTORS, *et al.*, Plaintiffs, v. UNITED STATES OF AMERICA, *et al.*, Defendants.	CIVIL ACTION NO. 2:21-CV-702-CLM

DECLARATION OF SUZANN BURK

I, Suzann Burk, declare as follows:

1. I am the Director of the Division of Disclosure and Oversight Management ("DDOM"), Office of Communication Outreach and Development, Center for Biologics Evaluation and Research ("CBER"), United States Food and Drug Administration ("FDA"), in Silver Spring, Maryland.

2. As the Director of DDOM, I have overall responsibility for the disclosure of documents officially maintained by CBER, the center in FDA that regulates biologic products such as blood, vaccines, gene therapy, and human cells, tissues, and cellular and tissue-based products. I have been the Director of DDOM since June 24, 2018. Prior to that date, I was the Team Lead of the Electronic Disclosure Team in DDOM for approximately nine and one-half years. Prior to that, I was a member of the Congressional and Oversight Branch in DDOM for two years

and a member of the Access Litigation and Freedom of Information Branch in DDOM for four years.

3. In my capacity as Director of DDOM I have access to official CBER documents. I am responsible for disclosing documents in litigation on behalf of CBER.

4. I submit this declaration in support of Defendants' Motion to Dismiss Plaintiffs' Amended Complaint and in opposition to Plaintiffs' Motion for a Preliminary Injunction. The statements made in this declaration are based on my personal knowledge and official records available to me in my official capacity.

5. Attached hereto are copies of the following documents:

Exhibit	**Vaccine Manufacturer**	**Document**	**Date**
Exhibit 1	Pfizer-BioNTech	Fact Sheet for Recipients and Caregivers 12 years of age and older	Oct. 29, 2021
Exhibit 2	Pfizer-BioNTech	Fact Sheet for Recipients and Caregivers 5–11 years of age	Oct. 29, 2021
Exhibit 3	Pfizer-BioNTech	Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers), 12 years of age and older, purple cap	Oct. 29, 2021
Exhibit 4	Pfizer-BioNTech	Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers), 12 years of age and older, gray cap	Oct. 29, 2021
Exhibit 5	Pfizer-BioNTech	Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers), 5–11 years of age, orange cap	Oct. 29, 2021

Exhibit 6	Pfizer-BioNTech	Letter of Authorization from Jacqueline A. O'Shaughnessy, Acting Chief Scientist, FDA, to Pfizer Inc.	Oct. 29, 2021 (revised)
Exhibit 7	Pfizer-BioNTech	COVID-19 Vaccine Emergency Use Authorization Review Memorandum	Dec. 11, 2020
Exhibit 8	Pfizer-BioNTech	COVID-19 Vaccine EUA Amendment Review Memorandum	May 10, 2021
Exhibit 9	Pfizer-BioNTech	COVID-19 Vaccine EUA Amendment Review Memorandum	Aug. 12, 2021
Exhibit 10	Pfizer-BioNTech	COVID-19 Vaccine EUA Amendment Review Memorandum	Sept. 24, 2021
Exhibit 11	Pfizer-BioNTech	COVID-19 Vaccine EUA Amendment Review Memorandum	Oct. 20, 2021
Exhibit 12	Moderna	Fact Sheet for Recipients and Caregivers	Oct. 20, 2021 (revised)
Exhibit 13	Moderna	Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers)	Oct. 20, 2021 (revised)
Exhibit 14	Moderna	Letter of Authorization from Jacqueline A. O'Shaughnessy, Acting Chief Scientist, FDA, to ModernaTX, Inc.	Oct. 20, 2021 (reissued)
Exhibit 15	Moderna	COVID-19 Vaccine Emergency Use Authorization Review Memorandum	Dec. 18, 2020
Exhibit 16	Moderna	COVID-19 Vaccine EUA Amendment Review Memorandum	Aug. 12, 2021
Exhibit 17	Moderna	COVID-19 Vaccine EUA Amendment Review Memorandum	Oct. 20, 2021
Exhibit 18	Janssen	Fact Sheet for Recipients and Caregivers	Oct. 20, 2021 (revised)

Exhibit 19	Janssen	Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers)	Oct. 20, 2021 (revised)
Exhibit 20	Janssen	Letter of Authorization from Jacqueline A. O'Shaughnessy, Acting Chief Scientist, FDA, to Janssen Biotech, Inc.	Oct. 20, 2021 (reissued)
Exhibit 21	Janssen	COVID-19 Vaccine Emergency Use Authorization Review Memorandum	Feb. 27, 2021
Exhibit 22	Janssen	COVID-19 Vaccine EUA Amendment Review Memorandum	Oct. 20, 2021

6. I certify that each document listed in Paragraph 5 was the current effective version as of November 5, 2021, and was publicly available on FDA's website, https://www.fda.gov, as of that date.

7. I declare under penalty of perjury that the foregoing Exhibits 1–22 and the facts contained in this declaration are true and correct pursuant to 28 U.S.C. § 1746.

Suzann H. Burk -S

Digitally signed by Suzann H. Burk -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Suzann H. Burk -S, 0.9.2342.19200300.100.1.1=1300129983
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SUZANN BURK
Division Director
Office of Communication,
Division of Disclosure and Oversight
Management, Outreach and Development
Center for Biologics Evaluation and Research
Food and Drug Administration
U.S. Department of Health and Human Services

Executed on December 16, 2021