FILED
2021 Sep-16 AM 11:09
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. XAVIER BECERRA, *et al.*, Defendants.	CIVIL ACTION NO. 2:21-CV-702-CLM

DECLARATION OF SUZANN BURK

I, Suzann Burk, make the following declaration under oath pursuant to 28 U.S.C. § 1746. I am aware that this declaration will be filed with the United States District Court for the Northern District of Alabama in the case referenced above, and that it is the legal equivalent of a statement under oath, made under penalty of perjury.

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 ("ALFOI") 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 and Opposition to Plaintiffs' Motion for a Preliminary Injunction in the above-captioned case. 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**
1	Pfizer-BioNTech	Fact Sheet for Recipients and Caregivers	May 10, 2021 (revised)
2	Pfizer-BioNTech	Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers)	May 19, 2021 (revised)
3	Pfizer-BioNTech	Letter of Authorization from Denise M. Hinton, Chief Scientist, FDA, to Pfizer Inc.	May 10, 2021
4	Pfizer-BioNTech	COVID-19 Vaccine Emergency Use Authorization Review Memorandum	Dec. 11, 2020

5	Pfizer-BioNTech	COVID-19 Vaccine EUA Amendment Review Memorandum	May 10, 2021
6	Moderna	Fact Sheet for Recipients and Caregivers	Mar. 26, 2021 (revised)
7	Moderna	Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers)	Mar. 31, 2021 (revised)
8	Moderna	Letter of Authorization from Denise M. Hinton, Chief Scientist, FDA, to ModernaTX, Inc.	Feb. 25, 2021
9	Moderna	COVID-19 Vaccine Emergency Use Authorization Review Memorandum	Dec. 18, 2020
10	Janssen	Fact Sheet for Recipients and Caregivers	Apr. 23, 2021 (revised)
11	Janssen	Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers)	Apr. 23, 2021 (revised)
12	Janssen	Letter of Authorization from Denise M. Hinton, Chief Scientist, FDA, to Janssen Biotech, Inc.	June 10, 2021
13	Janssen	COVID-19 Vaccine Emergency Use Authorization Review Memorandum	Feb. 27, 2021

6. I certify that each document listed in Paragraph 5 was the current effective version as of June 10, 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 1–13 and the facts contained in this declaration are true and correct pursuant to 28 U.S.C. § 1746.

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 September 16, 2021

CERTIFICATE OF SERVICE

I hereby certify that on September 16, 2021, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to counsel of record.

/s/ James W. Harlow
JAMES W. HARLOW
Senior Trial Attorney