IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS

DEFENDING THE REPUBLIC,	§	
	§	
Plaintiff,	§	
	§	
vs.	§	Civil Action No. _____
	§	
FOOD AND DRUG ADMINISTRATION,	§	
	§	
Defendant.	§	

ORIGINAL COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiff, Defending the Republic, brings this action against the U.S. Food and Drug Administration ("FDA") to compel compliance with the Freedom of Information Act, 5 U.S.C. § 552 ("FOIA"), and alleges as follows:

Introduction

1. On February 3, 2022, Defending the Republic filed a FOIA request seeking the expedited production of records relating to the FDA's approval of the Moderna COVID-19 vaccine. The FDA refused that request. Defending the Republic appealed, pleading that the public deserved to know the requested information when making life-altering decisions including whether and when to vaccinate, and which vaccine—if any—to take, considering facts such as vaccine mandates affecting millions of Americans and the waning effectiveness of the Moderna vaccine. The FDA declined the appeal, leaving Defending the Republic with no choice but to file this action seeking a court order requiring the FDA produce the requested records on an expedited schedule—just as those who obtained a court order for the expedited production of records relating to the FDA approved Pfizer-BioNTech vaccine. See *Pub. Health & Med. Pros. for Transparency v. Food & Drug Admin.*, No. 4:21-CV-1058-P, 2022 WL 90237, at *2 (N.D. Tex. Jan. 6, 2022).

Parties

2. Plaintiff, Defending the Republic, is a Texas 501(c)(4) non-profit organization located in Dallas County, Texas. Defending the Republic is a public interest group committed to the rule of law and the principles on which this country was founded. It defends victims of unlawful governmental actions, informs Americans on matters of public concern, and works tirelessly on behalf of those who are subject to unlawful government actions and mandates.

3. Defendant, FDA, is a federal agency under the U.S. Department of Health & Human Services ("HHS"). Its responsibilities include the regulation of clinical investigations of drugs and biological products. The FDA is an agency subject to 5 U.S.C. § 552(f).

Jurisdiction and Venue

4. This Court has jurisdiction under 5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. § 1331. Venue is proper in this district under 5 U.S.C. § 552(a)(4)(B) and 28 U.S. Code § 1391.

Factual Background

A. The COVID-19 pandemic.

5. The United States has suffered from the COVID-19 pandemic and the government's response to it for over two years. There is no doubt that COVID-19 has affected the lives of all Americans. According to the latest statistics, there have been nearly 85 million COVID-19 cases in the United States and 1,005,153 deaths caused by COVID-19.[1] Approximately 258.7 million people have received at least one dose of a COVID-19 vaccine and 221.4 million people

[1] NEW YORK TIMES, Coronavirus in the U.S.: Latest Map and Case Count, updated June 6, 2022, https://www.nytimes.com/interactive/2021/us/covid-cases.html.

have been fully vaccinated.[2] Public parks were shut down, workplaces were shuttered, schools were closed, and children were orphaned.[3]

6. Near the start of the pandemic, on April 1, 2020, the HHS Secretary issued notice that COVID-19 had a "significant potential to affect national security or the health and security of United States Citizens" and further stated "circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID-19 pandemic." 85 Fed. Reg. 18,250 (April 1, 2020). This led to the Emergency Use Authorization ("EUA") of the Pfizer-BioNTech COVID-19 vaccine ("Pfizer Vaccine") on December 11, 2020, soon followed by the granting of an EUA to the Moderna COVID-19 vaccine ("Moderna Vaccine") on December 18, 2020.[4]

7. The Pfizer Vaccine was approved by the FDA under the marketed name Comirnaty on August 23, 2021.[5] Acting FDA Commissioner Janet Woodcock would brag that the authorization of Comirnaty was done on "an unprecedented timeline."[6]

B. The approval of Moderna's Spikevax and waning vaccine effectiveness.

[2] NEW YORK TIMES, See How Vaccinations Are Going in Your County and State, updated June 3, 2022, https://www.nytimes.com/interactive/2020/us/covid-19-vaccine-doses.html.

[3] CDC, The Hidden U.S. COVID-19 Pandemic: Orphaned Children – More than 140,000 U.S. Children Lost a Primary or Secondary Caregiver Due to the COVID-19 Pandemic, Oct. 7, 2021, www.cdc.gov/media/releases/2021/p1007-covid-19-orphaned-children.html.

[4] Berkeley Lovelace, Jr., CNBC, FDA approves second COVID vaccine for emergency use as it clears Moderna's for U.S. distribution, Dec. 18, 2020, www.cnbc.com/2020/12/18/moderna-covid-vaccine-approved-fda-for-emergency-use.html.

[5] FDA, FDA Approves First COVID-19 Vaccine, Aug. 23, 2021, https://www.fda.gov/newsevents/press-announcements/fda-approves-first-covid-19-vaccine.

[6] Justine Coleman, THE HILL, FDA grants full approval to Pfizer's COVID-19 vaccine, Aug, 23, 2021, https://thehill.com/policy/healthcare/568980-fda-grants-full-approval-to-pfizers-covid-19-vaccine/.

8. On January 31, 2022, the FDA approved the Moderna Vaccine to be marketed as Spikevax.[7] The FDA promised the public that "Spikevax meets the FDA's rigorous standards for safety, effectiveness and manufacturing quality required for approval."[8] According to Dr. Peter Marks, the director of the FDA's Center for Biologics Evaluation and Research:

> "The FDA's medical and scientific experts conducted a thorough evaluation of the scientific data and information included in the application pertaining to the safety, effectiveness, and manufacturing quality of Spikevax. This includes the agency's independent verification of analyses submitted by the company, our own analyses of the data, along with a detailed assessment of the manufacturing processes, test methods and manufacturing facilities."[9]

9. Despite the FDA's promises, a closer inspection of the Spikevax approval reveal there may be glaring issues in the approval process. The Spikevax package insert concedes "[a]vailable data on SPIKEVAX administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy."[10] And while the FDA publicly pronounced that the "data demonstrated that Spikevax was 93% effective in preventing COVID-19,"[11] the Spikevax fact sheet for recipients and caregivers provides important context omitted by the public officials: "The [Spikevax] duration of protection against COVID19 is currently unknown.[12]

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[7] FDA, Coronavirus (COVID-19) Update: FDA Takes Key Action by Approving Second COVID-19 Vaccine, Jan. 31, 2022, www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-key-action-approving-second-covid-19-vaccine.

[8] *Id*.

[9] *Id*.

[10] Spikevax package insert, revised 1/2022, last visited June 6, 2022, https://www.fda.gov/media/155675/download.

[11] *Id*.

[12] Spikevax Vaccine Information Fact Sheet for Recipients and Caregivers, revised March 29, 2022, last visited June 6, 2022, https://www.fda.gov/media/144638/download.

10. This promise of Spikevax's effectiveness is reminiscent of the FDA's claims about the data produced by Pfizer-BioNTech that led to the approval of Comirnaty: "the vaccine [Comirnaty] was 91% effective in preventing COVID-19 disease."[13]

11. Despite these assurances of effectiveness, COVID-19 cases among the fully vaccinated continue to rise. According to the New York Department of Health, there have been nearly 1.5 million "laboratory-confirmed breakthrough cases of COVID-19 among fully-vaccinated people in New York State."[14] In Washington State, there have been approximately 485,000 COVID-19 breakthrough cases from January 17, 2021 through May 21, 2022, where "0.5% died of COVID-related illness."[15]

12. These numbers are consistent with studies published by the Centers for Disease Control and Prevention ("CDC"), which show that "[b]ooster shots of the Pfizer-BioNTech and Moderna vaccines lose substantial effectiveness after about four months."[16] Even Dr. Anthony Fauci, the White House chief medical advisor and National Institute of Allergy and Infectious Diseases Director, admitted – before the Spikevax approval – that the COVID-19 vaccines have "waning immunity."[17] This lessening effectiveness coincides with a surge in COVID-19 deaths of

[13] FDA, FDA Approves First COVID-19 Vaccine, Aug. 23, 2021, https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine.

[14] New York State Department of Health, COVID-19 Breakthrough Data, last visited June 6, 2022, https://coronavirus.health.ny.gov/covid-19-breakthrough-data.

[15] Washington State Department of Health, SARS-CoV-2 Vaccine Breakthrough Surveillance and Case Information Resource, June 1, 2022, https://doh.wa.gov/sites/default/files/2022-02/420-339-VaccineBreakthroughReport.pdf.

[16] Lena H. Sun, THE WASHINGTON POST, Booster effectiveness wanes after 4 months, but showed sturdy protection against hospitalization, CDC study shows, Feb. 11, 2022, www.washingtonpost.com/health/2022/02/11/covid-boosters-omicron-protection/.

[17] Sasha Pezenik, ABC NEWS, Fauci says 3-shot vaccine should be 'standard,' warns of winter 'double whammy', Nov. 16, 2021, https://abcnews.go.com/Health/fauci-shot-vaccine-standard-warns-winter-double-whammy/story?id=81213958.

the vaccinated. In January and February of 2022, "more than 40% of Covid-19 deaths were among the vaccinated."[18]

13. Moderna recognizes the waning effectiveness of its vaccines. On March 17, 2022, it asked the FDA "to authorize a fourth shot of its Covid-19 vaccine as a booster dose for all adults."[19] On March 29, 2022, the FDA authorized a fourth Moderna dose "for everyone age 50 and older, as well as a fifth dose for certain younger people with compromised immune systems."[20] All this was done less than two months after the FDA's approval of Spikevax, casting serious doubts on the FDA's approval of the Moderna vaccine and the representations of Spikevax's effectiveness.

C. Defending the Republic's FOIA request.

14. On February 3, 2022, Defending the Republic made a FOIA request for all documents, data, and records submitted by Moderna to the FDA concerning the approval of Spikevax. Defending the Republic asked for expedited processing for this request. The request was made consistent with, and in furtherance of, Defending the Republic's mission to ensure public access to essential information relating to COVID-19. The FOIA request stated:

> "Please provide all data and information submitted by Moderna relating to the FDA review and approval of Spikevax. This includes, but is not limited to, all safety and effectiveness data and information; all data and information in the biological product file; and all ingredients."

[18] Diedre McPhillips, CNN, Growing share of Covid-19 deaths are among vaccinated people, but booster shots substantially lower the risk, May 11, 2022, https://www.cnn.com/2022/05/11/health/unvaccinated-covid-deaths-growing/index.html.

[19] NBC NEWS, Moderna Asks FDA to authorize second booster for adults, March 17, 2022, www.nbcnews.com/news/us-news/moderna-asks-fda-authorize-second-booster-adults-rcna20558.

[20] Spencer Kimball, CNBC, CDC recommends fourth Pfizer and Moderna Covid vaccine doses for people age 50 and older, March 29, 2022, www.cnbc.com/2022/03/29/fda-authorizes-fourth-pfizer-covid-vaccine-dose-for-people-age-50-and-older-.html.

15. On February 9, 2022, the FDA denied Defending the Republic's request for expedited processing, stating:

> "I have determined that your request for expedited processing does not meet the criteria under the FOIA. You have not demonstrated a compelling need that involves an imminent threat to the life or physical safety of an individual. Neither have you demonstrated that there exists an urgency to inform the public concerning actual or alleged Federal Government activity. Therefore, I am denying your request for expedited processing."[21]

16. Defending the Republic appealed this denial on February 9, 2022, explaining in detail why there was a compelling need to produce the records on an expedited basis.[22]

17. The FDA denied Defending the Republic's appeal on June 6, 2022: "After conducting a thorough review of your appeal, we have determined that you have not demonstrated a compelling need for expedited processing. Therefore, we have decided to uphold the FDA's decision to deny the request for expedited processing."[23] Defending the Republic was informed that its request was placed "in the complex queue" and was provided an estimate that there should be a response "within approximately 18-24 months."[24] The information requested—just like the data the FDA reviewed to approve Comirnaty—is information the American people need to know now. It is an urgent matter of public health.

Argument

18. "The basic purpose of FOIA is to ensure an informed citizenry, vital to the functioning of a democratic society, needed to check against corruption and to hold the governors accountable to the governed." *N.L.R.B. v. Robbins Tire & Rubber Co.*, 437 U.S. 214, 242, 98 S.

[21] Exhibit 1.

[22] Exhibit 2.

[23] Exhibit 3 at p. 1.

[24] Exhibit 3 at p. 3.

Ct. 2311, 2327, 57 L. Ed. 2d 159 (1978). "Congress has long recognized that 'information is often useful only if it is timely' and that, therefore 'excessive delay by the agency in its response is often tantamount to denial.'" *Open Soc'y Just. Initiative v. CIA*, 399 F. Supp. 3d 161, 164 (S.D.N.Y. 2019) citing H.R. Rep. No. 93-876, at 6271 (1974).

19. FOIA allows for the "expedited processing of request for records" where there is shown to be a "compelling need." 5 U.S.C. § 552(a)(6)(E)(i)(II). The term "compelling need," in the context of Defending the Republic's request, means "with respect to a request made by a person primarily engaged in disseminating information, urgency to inform the public concerning actual or alleged Federal Government activity." 5 U.S.C. § 552(a)(6)(E)(v)(II).

20. In making its final denial, the FDA assumed that Defending the Republic met the "compelling need" criteria that the organization is "'primarily engaged in disseminating information to the general public and not merely to a narrow interest group' and that the subject of the requested records 'specifically concerns identifiable operations or activities of the Federal Government.'"[25] The FDA instead wrongly determined that there is no "urgency to inform the public" about the Moderna records, justifying its denial by claiming there is no "particular urgency" to receive "data and information not already posted to the FDA webpage regarding" Spikevax.[26]

21. Defending the Republic is certainly "primarily engaged in disseminating information to the general public," and the FDA has not argued or determined otherwise. Defending the Republic is dedicated to informing the American public on important matters,

[25] Exhibit 3 at p. 2.

[26] Exhibit 3 at p. 3.

including COVID-19 vaccines and mandates. Its website has a number of videos and articles[27] related to COVID-19, has a newsletter[28] that spreads awareness on COVID-19 issues and other matters, and it is litigating a number of cases involving COVID-19 mandates.[29] As part of its efforts to inform the public, Defending the Republic filed an *amicus* brief to the Supreme Court relating to the Occupational Safety and Health Administration's COVID-19 vaccine mandate, noting that through our litigation the government conceded that the Department of Defense did not have Comirnaty and could not say whether vaccines labeled Comirnaty existed at all.[30]

22. With respect to Defending the Republic's FOIA request, there is definitely an "urgency to inform the public." The determination of the "urgency to inform" focuses "on three factors: (1) whether the request concerns a matter of current exigency to the American public; (2) whether the consequences of delaying a response would compromise a significant recognized interest; and (3) whether the request concerns federal government activity." *Am. C.L. Union v. U.S. Dep't of Just.*, 321 F. Supp. 2d 24, 29 (D.D.C. 2004), (citing *Al-Fayed v. CIA*, 254 F.3d 300, 310 (D.C. Cir. 2001)). The FOIA request meets all three factors.

23. To explain further, COVID-19 and the approval of COVID-19 vaccines is a matter of current exigency to the American public. The request for records relating to the Moderna vaccine, like the FOIA request for data underlying the FDA's approval of Pfizer's Comirnaty, is a matter of "paramount public importance." *Pub. Health & Med. Pros. for Transparency v. Food & Drug Admin.*, No. 4:21-CV-1058-P, 2022 WL 90237, at *1 (N.D. Tex. Jan. 6, 2022). There may

[27] Defending the Republic, COVID Resources, last visited June 6, 2022, https://defendingtherepublic.org/covid/.

[28] Defending the Republic Newsletter, last visited June 6, 2022, https://defendingtherepublic.substack.com/.

[29] Defending the Republic, Fighting Mandates, last visited June 6, 2022, https://defendingtherepublic.org/coker-v-austin/.

[30] Defending the Republic, Fighting Mandates, last visited June 6, 2022, https://defendingtherepublic.org/amicus-brief-scotus/.

not be a more important issue at the FDA than the COVID-19 pandemic, "getting every American vaccinated, and making sure that the American public is assured that this was not rushed on behalf of the United States." *Pub. Health & Med. Pros. For Transparency*, 2022 WL 90237, at *1 (cleaned up).

24. As Defending the Republic explained in its February 9, 2022 appeal, "the public and the medical community have an urgent and compelling interest in analyzing the data and information underlying the FDA's approval of Moderna's COVID-19 vaccine."[31] With respect to the urgency of obtaining these records, Defending the Republic pleaded to the FDA that the public needed to be able to review the Moderna data in light of the vaccine's waning effectiveness, the necessity of additional boosters, the lack of public information regarding Spikevax's risks to pregnant women, and the FDA's own determination that there are serious risks of myocarditis and pericarditis after the second dose of Moderna's vaccine.[32]

25. Defending the Republic further argued that the FOIA request should be expedited in light of federal and local vaccine mandates:

> Adding to the urgency are the federal, state, and local government mandates of COVID-19 vaccines. Hundreds of millions of Americans are, or could be, subject to these mandates. Approximately 10 million healthcare workers in an estimated 76,000 facilities are required to receive a COVID-19 vaccine. Many of these providers are hesitant to receive the required vaccines, leading to fears, 'particularly among nursing homes and smaller rural hospitals, that the mandate will exacerbate the existing staffing shortages that have crippled much of the country during this latest surge.' And in New York City, with a population exceeding 8 million people, citizens must show proof of vaccination to go to a restaurant, watch a ballgame, or go to the gym.

[31] Exhibit 2 at p. 1.

[32] Exhibit 2 at p. 1-2.

26. Defending the Republic also reminded the FDA that the federal court for the Northern District of Texas had already ordered the expedited production of records submitted to the FDA regarding the approval of Pfizer's Comirnaty vaccine.[33]

27. Furthermore, and as previously explained in this Complaint, millions are dead and tens of millions have been infected.[34] The federal government – and the FDA – have recognized the exigent circumstances created by the COVID-19 pandemic. Masks were mandated in public for over two years. President Biden promised a "full-scale wartime effort" to combat the pandemic.[35] The White House, recognizing the urgency of a more robust COVID-19 response, said it would "[i]nvest $25 billion in a vaccine manufacturing and distribution plan that will guarantee it gets to every American, cost-free."[36] As part of the National COVID-19 Preparedness Plan, there are tens of thousands of vaccine locations around the country with the "ability to administer more than a combined 125,000 shots a day" (if not more) – with the assistance of thousands of federal personnel and active-duty troops.[37]

28. As Defending the Republic explained to the FDA, its request comes at a time where millions of state and federal workers, including military service members and those employed in

[33] *Id*. at p. 3.

[34] NEW YORK TIMES, Coronavirus in the U.S.: Latest Map and Case Count, updated June 6, 2022, https://www.nytimes.com/interactive/2021/us/covid-cases.html.

[35] Sheryl Gay Stolberg, THE NEW YORK TIMES, Biden rolls out 'full-scale, wartime' coronavirus strategy, including requiring masks on some planes, trains and buses, Jan. 21, 2021, www.nytimes.com/2021/01/21/us/politics/biden-rolls-out-full-scale-wartime-coronavirus-strategy-including-requiring-masks-on-some-planes-trains-and-buses.html.

[36] The White House, COVID-19 Priorities, last visited June 6, 2022, https://www.whitehouse.gov/priorities/covid-19/.

[37] The White House, National COVID-19 Preparedness Plan, last visited June 6, 2022, https://www.whitehouse.gov/covidplan/.

health care, are subject to COVID-19 vaccine mandates.[38] The CMS Mandate covers an estimated 10.4 million workers.[39] Over "3.5 million federal executive branch workers" were ordered to undergo mandatory COVID-19 vaccination by President Biden.[40] All 1.4 million military service members[41], and all Department of Defense civilian employees[42], are subject to the Department of Defense COVID-19 vaccine mandate issued by Secretary of Defense Lloyd Austin. Many states and cities have their own vaccine requirements. In New York City, for example, workers "who perform in-person work or interact with the public in the course of business must show proof that they have received a COVID-19 vaccine."[43]

29. Consistent with its mission, Defending the Republic will publicly disseminate information it obtains relating to its FOIA request. Any delayed response to the FOIA request would compromise and otherwise inhibit Defending the Republic's recognized interest to inform the public of the Moderna vaccine. It would also compromise the significant recognized interest

[38] *See* CMS.gov, Statement by CMS Administrator Chiquita Brooks-LaSure On the U.S. Supreme Court's Decision on Vaccine Requirements, Jan. 13, 2022, www.cms.gov/newsroom/press-releases/statement-cms-administrator-chiquita-brooks-lasure-us-supreme-courts-decision-vaccine-requirements#:~:text=CMS'%20vaccine%20rule%20will%20cover,the%20risk%20of%20severe%20disease ("CMS' vaccine rule will cover 10.4 million health care workers at 76,000 medical facilities. Giving patients assurance on the safety of their care is a critical responsibility of CMS and a key to combatting the pandemic.")

[39] *Id*.

[40] Kevin McGill, AP NEWS, May 23, 2022, https://apnews.com/article/biden-covid-health-government-and-politics-23b86b0db8e0770567698fb837c959d3 ("A federal appeals court is being asked to reconsider its decision allowing the Biden administration to require that federal employees get vaccinated against COVID-19.")

[41] Daniel E. Slotnik and Helene Cooper, The New York Times, With F.D.A. approval for a Covid vaccine, the Pentagon and others add vaccine requirements, Aug. 23, 2021, www.nytimes.com/2021/08/23/us/pfizer-vaccine-mandates.html.

[42] U.S. Department of Defense, Mandatory Coronavirus Disease 2019 Vaccination of DoD Civilian Employees, Oct. 4, 2021, www.defense.gov/News/Releases/Release/Article/2799045/Mandatory-Coronavirus-Disease-2019-Vaccination-of-DoD-Civilian-Employees/.

[43] NYC Health, COVID-19: Vaccine, last visited June 6, 2022, https://www1.nyc.gov/site/doh/covid/covid-19-vaccine-workplace-requirement.page#:~:text=Workers%20in%20New%20York%20City,to%20work%20at%20their%20workplace.

of the American public, including parents, physicians, independent experts, and policy makers, in reviewing and analyzing the Moderna data for themselves. Millions of Americans would be subject to vaccine requirements for vaccines they are prevented from fully understanding. Stale information will not serve Defending the Republic or the American public. *See Pub. Health & Med. Pros. for Transparency*, 2022 WL 90237, at *2 (concluding "the expeditious completion of Plaintiff's request is not only practicable, but necessary").

30. Additionally, the information and data sought by Defending the Republic "concerns federal government activity." It relates to the FDA's approval of Spikevax and whether that approval was based on adequate and sufficient data.

31. For these reasons, Defending the Republic seeks immediate relief pursuant to 5 U.S.C. § 552 (a)(6)(E)(iii), which provides that the "denial of a request for expedited processing . . . shall be subject to judicial review[.]"

Relief Requested

Defending the Republic respectfully requests this Court:

A. Order expedited briefing and proceedings in this matter;

B. Order the FDA produce all documents responsive to Defending the Republic's FOIA request on an expedited schedule;

C. Award Plaintiff reasonable attorney fees and other litigation costs reasonably incurred in this action, consistent with 5 U.S.C. § 552 (a)(4)(E)(i); and

D. Award any other relief this Court may deem just and proper.

Dated: June 7, 2022.

Respectfully submitted,

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