UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF TEXAS FORT WORTH DIVISION

PUBLIC HEALTH AND MEDICAL PROFESSIONALS FOR TRANSPARENCY	§	
Plaintiff,	§	**CASE NO. 4:21-CV-01058-P**
v.	§	
FOOD AND DRUG ADMINISTRATION	§	
Defendant.	§	

MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF PFIZER INC.'S MOTION FOR LEAVE TO INTERVENE FOR A LIMITED PURPOSE

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Pfizer Inc. ("Pfizer"), by and through undersigned counsel, hereby submits this Memorandum of Points and Authorities in Support of Pfizer's Motion for Leave to Intervene for a Limited Purpose, pursuant to Rules 24(a) and 24(b) of the Federal Rules of Civil Procedure. Pfizer seeks to intervene in this action brought by Public Health and Medical Professionals for Transparency ("Plaintiff" or "PHMPT") under the Freedom of Information Act, 5 U.S.C. § 552, as amended ("FOIA") for the limited purpose of protecting statutorily-protected confidential information relating to its COVID-19 vaccine.

PRELIMINARY STATEMENT

In this action, Plaintiff seeks to compel the Food and Drug Administration ("FDA" or "Agency") to respond to its FOIA request on an expedited basis and to produce a significant volume of data and information submitted by Pfizer to FDA as part of its application for regulatory approval of the Pfizer-BioNTech COVID-19 vaccine ("the vaccine" or "Comirnaty"). The vaccine received FDA approval, through a BLA, for use in individuals 16 years and older on August 23, 2021. *See* News Release, U.S. Food & Drug Admin., FDA Approves First COVID-19 Vaccine (Aug. 23, 2021), https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine.

Pfizer supports the public disclosure of the vast majority of this information to promote transparency and the public's confidence in the vaccine, and Pfizer seeks to intervene for the limited purpose of ensuring that information that is exempt from disclosure under FOIA is not disclosed inappropriately. Indeed Pfizer, FDA, the Centers for Disease Control and Prevention ("CDC"), and other government agencies already have made public extensive data about the vaccine. By way of example, Pfizer has shared the following information over the course of developing the vaccine:

- **U.S. Food & Drug Admin. Vaccines and Related Biological Products Advisory Committee Briefing Documents and Presentations**, *see, e.g.*, BNT162b2 [COMIRNATY (COVID-19 Vaccine, mRNA)] VRBPAC Briefing Document (Oct. 26, 2021), https://www.fda.gov/media/153409/download; Presentation, BNT162b2 (COVID-19 Vaccine, mRNA) Vaccine – Request for Emergency Use Authorization in Individuals 5 to <12 Years of Age (Oct. 26, 2021), https://www.fda.gov/media/153513/download; BNT162b2 [COMIRNATY (COVID-19 Vaccine, mRNA)] Evaluation of a Booster Dose (Third Dose) VRBPAC Briefing Document (Sept. 17, 2021), https://www.fda.gov/media/152161/download; Presentation, BNT162b2 [COMIRNATY® (COVID-19 Vaccine, mRNA)] Booster (Third) Dose (Sept. 17, 2021), https://www.fda.gov/media/152240/download; Pfizer-BioNTech COVID-19 Vaccine (BNT162, PF-07302048) VRBPAC Briefing Document (Dec. 10, 2020), https://www.fda.gov/media/144246/download; Presentation, BNT162b2 Vaccine Candidate Against COVID-19 (Dec. 10, 2020), https://www.fda.gov/media/144325/download;

- **Pfizer, PF-07302048 (BNT162 RNA-Based COVID-19 Vaccines) Protocol C4591001**, A Phase 1/2/3 Study to Evaluate the Safety, Tolerability, Immunogenicity, and Efficacy of RNA Vaccine Candidates Against COVID-19 in Healthy Individuals (Nov. 2020), https://cdn.pfizer.com/pfizercom/2020-11/C4591001_Clinical_Protocol_Nov2020.pdf;

- **Preprints of safety and efficacy data as they became available,** *see, e.g.*, Stephen Thomas et al., Six Month Safety and Efficacy of the BNT162b2 mRNA COVID-19 Vaccine, medRxiv 2021.07.28.21261159 (July 28, 2021), https://www.medrxiv.org/content/10.1101/2021.07.28.21261159v1.full.pdf; Xuping Xie et al., Neutralization of SARS-CoV-2 spike 69/70 deletion, E484K, and N501Y variants by BNT162b2 vaccine-elicited sera, bioRxiv 2021.01.27.427998 (Jan. 27, 2021), https://www.biorxiv.org/content/10.1101/2021.01.27.427998v1.full.pdf; Alexander Muik et al., Neutralization of SARS-CoV-2 lineage B.1.1.7 pseudovirus by BNT162b2 vaccine-elicited human sera, bioRxiv 2021.01.18.426984 (Jan. 18, 2021), https://www.biorxiv.org/content/10.1101/2021.01.18.426984v1.full.pdf; Xuping Xie et al., Neutralization of N501Y mutant SARS-CoV-2 by BNT162b2 vaccine-elicited sera, bioRxiv 2021.01.07.425740 (Jan. 7, 2021), https://www.biorxiv.org/content/10.1101/2021.01.07.425740v1.full.pdf; Ugur Sahin et al., BNT162b2 induces SARS-CoV-2-neutralising antibodies and T cells in humans, medRxiv 2020.12.09.20245175 (Dec. 9, 2020), https://www.medrxiv.org/content/10.1101/2020.12.09.20245175v1.full.pdf; Edward Walsh et al., RNA-Based COVID-19 Vaccine BNT162b2 Selected for a Pivotal Efficacy Study, medRxiv 2020.08.17.20176651 (Aug. 17, 2020), https://www.medrxiv.org/content/10.1101/2020.08.17.20176651v1.full.pdf; Ugur Sahin et al., Concurrent human antibody and TH1 type T-cell responses elicited by a COVID-19 RNA vaccine, medRxiv 2020.07.17.20140533 (July 17, 2020), https://www.medrxiv.org/content/10.1101/2020.07.17.20140533v1.full.pdf; Mark Mulligan et al., Phase 1/2 Study to Describe the Safety and Immunogenicity of a COVID-19 RNA Vaccine Candidate (BNT162b1) in Adults 18 to 55 Years of Age: Interim Report, medRxiv 2020.06.30.20142570 (June 30, 2020), https://www.medrxiv.org/content/10.1101/2020.06.30.20142570v1.full.pdf; and

- **Publications presenting safety and efficacy data,** *see, e.g.*, Emmanuel Walter et al., Evaluation of the BNT162b2 Covid-19 Vaccine in Children 5 to 11 Years of Age, NEW ENG. J. MED. 386, 35–46 (2022), https://www.nejm.org/doi/full/10.1056/NEJMoa2116298; Yang Liu et al., Letter to the Editor: Neutralizing Activity of BNT162b2-Elicited Serum, NEW ENG. J. MED. 384, 1466–68 (2021), https://www.nejm.org/doi/full/10.1056/NEJMc2102017; Jianying Liu et al., BNT162b2-elicited neutralization of B.1.617 and other SARS-CoV-2 variants, NATURE 596, 273–75 (2021), https://www.nature.com/articles/s41586-021-03693-y; Xuping Xie et al., Neutralization of SARS-CoV-2 spike 69/70 deletion, E484K and N501Y variants by BNT162b2 vaccine-elicited sera, NATURE MED. 27, 620–21 (2021), https://www.nature.com/articles/s41591-021-01270-4; Alexander Muik et al., Neutralization of SARS-CoV-2 lineage B.1.1.7 pseudovirus by BNT162b2 vaccine–elicited human sera, SCIENCE 371, 1152–53 (2021), https://www.science.org/doi/10.1126/science.abg6105; Stephen Thomas et al., Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine through 6 Months, NEW ENG. J. MED. 385, 1761–73 (2021), https://www.nejm.org/doi/full/10.1056/NEJMoa2110345; Fernando Polack et al., Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine, NEW ENG. J. MED. 383, 2603–15 (2020), https://www.nejm.org/doi/full/10.1056/NEJMoa2034577; Edward Walsh et al., Safety and Immunogenicity of Two RNA-Based Covid-19 Vaccine Candidates, NEW ENG. J. MED. 383, 2439–50 (2020), https://www.nejm.org/doi/full/10.1056/NEJMoa2027906.

FACTUAL BACKGROUND

Plaintiff submitted its FOIA request for this information to FDA on August 27, 2021. Compl., Ex. A.1, ECF No. 1-1 (the "FOIA Request"). In the FOIA request, Plaintiff seeks, pursuant to 21 C.F.R. § 601.51(e), data and information contained in the biologics license application ("BLA") for the vaccine, including *inter alia*, test protocols, safety and effectiveness data, correspondence and written summaries of discussions relating to the biological product file, adverse event reports, lot testing records, and other data, "with the exception of publicly available reports on the Vaccine Adverse Events Reporting System." *See* FOIA Request 2. While Pfizer supports the public review of much of this information which will help build trust and confidence in the vaccine, the records Plaintiff has requested also contain information exempt from production under FOIA, including the personal privacy information of individuals who participated in clinical trials and confidential business and trade secret information of Pfizer, such as its proprietary manufacturing processes. *See* 5 U.S.C. § 552(b)(4), (b)(6).

After FDA denied Plaintiff's request for expedited processing of the FOIA request, Plaintiff commenced this action on September 16, 2021. *See* Compl. ¶¶ 41–53.

This Court held a Scheduling Conference in this matter on December 14, 2021. In briefing submitted to this Court in advance of that Conference, counsel for FDA emphasized that the Agency supports Plaintiff's general right to the information sought in its FOIA request, subject to standard exemptions under FOIA for sensitive business and confidential personal information. *See, e.g.*, First Joint Report 6 (Nov. 5, 2021), ECF No. 18 ("FDA is committed to transparency, in general, and in particular with respect to records related to the Biological License Application ('BLA') for the Comirnaty vaccine"). FDA expressed concern, however, about its ability to adequately review the volume of requested information in the timeframe that Plaintiff proposed in order to protect against the inadvertent disclosure of trade secrets, sensitive commercial and financial information, and confidential personal information about clinical trial test subjects. *See, e.g.*, First Joint Report 7 ("To ensure protection of this information, and other information subject to withholding under the FOIA exemptions, FDA must carefully review and, if necessary, redact exempt information on a line-by-line basis. . . . [I]t is not feasible for FDA to review and produce the substantial volume of records that Plaintiff seeks to obtain on a short timeframe."); Second Joint Report 5 (Nov. 15, 2021), ECF No. 20 ("This type of review for more than 329,000 pages will necessarily require time if the agency is going to be able to perform the careful analysis necessary to protect sensitive information."). At the Scheduling Conference, the Court suggested that intervention by Pfizer would be advisable given these concerns. Pfizer was not aware of Plaintiff's FOIA request or this litigation prior to reading news reports about this Scheduling Conference in December 2021.

On January 6, 2022, the Court issued an Order requiring disclosure of more than 12,000 pages of information responsive to Plaintiff's FOIA request by January 31, 2022, and subsequently at a rate of 55,000 pages every 30 days, including production of redacted versions of any documents for which FDA claims a privilege, exemption, or exclusion. *See* Order, ECF No. 35.

In light of FDA's statements regarding its capacity to review the requested information at an increased pace, and this Court's order to produce this information on an expedited basis, Pfizer seeks leave to intervene in this action for the limited purpose of ensuring that information exempt from disclosure under FOIA is adequately protected as FDA complies with this Court's order.

ARGUMENT

I. PFIZER IS ENTITLED TO INTERVENE AS A MATTER OF RIGHT UNDER RULE 24(A)

Rule 24(a) of the Federal Rules of Civil Procedure sets forth the requirements for intervention as a matter of right. *See* Fed. R. Civ. P. 24(a)(2); *Entergy Gulf States Louisiana, L.L.C. v. U.S. EPA*, 817 F.3d 198, 203 (5th Cir. 2016). To intervene pursuant to Rule 24(a), an applicant must satisfy four requirements:

> (1) the application for intervention must be timely; (2) the applicant must have an interest relating to the property or transaction which is the subject of the action; (3) the applicant must be so situated that the disposition of the action may, as a practical matter, impair or impede his ability to protect that interest; (4) the applicant's interest must be inadequately represented by the existing parties to the suit.

Entergy, 817 F.3d at 203 (quoting *Haspel & Davis Milling & Planting Co. v. Bd. of Levee Comm'rs of the Orleans Levee Dist.*, 493 F.3d 570, 578 (5th Cir. 2007)); *see also In re Lease Oil Antitrust Litig.*, 570 F.3d 244, 247 (5th Cir. 2009) (same).

Courts in the Fifth Circuit liberally construe Rule 24. *Adam Joseph Res. v. CNA Metals Ltd.*, 919 F.3d 856, 864 (5th Cir. 2019) ("Although the movant bears the burden of establishing its right to intervene, Rule 24 is to be liberally construed.") (internal quotation marks omitted)

(quoting *Brumfield v. Dodd*, 749 F.3d 339, 341 (5th Cir. 2014)); *Wal–Mart Stores, Inc. v. Texas Alcoholic Beverage Comm'n*, 834 F.3d 562, 565 (5th Cir. 2016) (same). Intervention should be allowed "where no one would be hurt and the greater justice could be attained." *John Doe No. 1 v. Glickman*, 256 F.3d 371, 375 (5th Cir. 2001); *see also Wal–Mart Stores, Inc.*, 834 F.3d at 565 (same). As set forth below, the requirements for intervention as of right are satisfied here.

A. Pfizer's Motion to Intervene is Timely

First, Pfizer's motion to intervene is timely. Pfizer first learned of this litigation just one month ago. Rule 24 does not provide a specific deadline by which parties should move to intervene, but courts routinely treat motions filed within several months after an intervenor learns of its stake in an action as timely. *See, e.g.*, *John Doe No. 1*, 256 F.3d at 377–78 (finding intervenor's motion to intervene timely when filed a month after it became aware of its stake in the lawsuit); *Wal–Mart Stores, Inc.*, 834 F.3d at 565–66 (holding motion to intervene was timely when filed three months after defendant filed its answer following denial of motion to dismiss).

Moreover, the Fifth Circuit consistently emphasizes that courts "should discourage premature intervention because it wastes judicial resources." *John Doe No. 1*, 256 F.3d at 376 (quoting *Sierra Club v. Espy*, 18 F.3d 1202, 1206 (5th Cir. 1994) (internal quotation marks and alterations omitted)). "Thus, the timeliness clock runs either from the time the applicant knew or reasonably should have known of his stake in the case into which he seeks to intervene or from the time he became aware that his stake would no longer be protected by the existing parties to the lawsuit." *Id.* (internal quotation marks and citations omitted). Here, Pfizer learned of this action from news reports in connection with the December 14, 2021 Scheduling Conference, and reviewed FDA's statements raising concerns about its ability to review the BLA adequately for FOIA-exempt material under the Court's timeline shortly thereafter. In light of the above, Pfizer filed its limited motion to intervene on January 21, 2022. Accordingly, Pfizer's motion is timely.

B. Pfizer Has a Direct Interest Relating to the Action

Pfizer satisfies Rule 24(a)'s second element, which requires that it have a "direct, substantial, [and] legally protectable" interest in the property or transaction that forms the basis of the controversy." *Espy*, 18 F.3d at 1207. Pfizer's interest in protecting its proprietary trade secret and confidential commercial information meets this standard. A "property interest . . . is the most elementary type of right that Rule 24(a) is designed to protect." *Texas v. United States,* 805 F.3d 653, 658 (5th Cir. 2015) (internal quotation marks and citation omitted). Courts routinely grant motions to intervene in FOIA cases involving FDA where a manufacturer seeks to protect its confidential business information. *See, e.g.*, *Pub. Citizen Health Rsch. Grp. v. FDA*, 185 F.3d 898, 900 (D.C. Cir. 1999) (noting that a drug manufacturer intervened to protect confidential information from disclosure under FOIA); *Appleton v. FDA*, 310 F. Supp. 2d 194, 196–97 (D.D.C. 2004) (permitting New Drug Application ("NDA") holders to intervene as a matter of right in FOIA lawsuit seeking release of materials from the FDA's review of NDAs).

C. Disposition of this Action May Impair Pfizer's Ability to Protect Its Interests

Based on FDA's recent statements about its ability to review the BLA adequately for Pfizer's confidential information under the required timeline, there is a risk that this matter could result in inadvertent disclosure of FOIA-protected material. Pfizer's ability to protect its interests would be directly impaired if its trade secrets and other proprietary information were disclosed as a result of this action. *See, e.g.*, *Appleton*, 310 F. Supp. 2d at 197 ("[D]isclosure[] resulting from the disposition of this action could impair the applicants' ability to protect their trade secrets or confidential information."). While much of the information sought by Plaintiff relates to the safety and efficacy of the vaccine, and Pfizer supports the disclosure of that information to promote confidence in the vaccine, certain other information in the BLA reflects Pfizer's trade secrets and

confidential commercial information, the disclosure of which would cause substantial harm to Pfizer's business interests. As such, Pfizer satisfies Rule 24(a)'s third element.

D. Pfizer's Interests Are Not Adequately Represented by Existing Parties

The final requirement for intervention under Rule 24(a) is that the "applicant's interest must be inadequately represented by the existing parties to the suit." *Entergy*, 817 F.3d at 203. "The applicant has the burden of demonstrating inadequate representation, but this burden is 'minimal.'" *Id.* (quoting *Brumfield*, 749 F.3d at 345); *see also Trbovich v. United Mine Workers*, 404 U.S. 528, 538 n.10 (1972) (same). Courts in the Fifth Circuit have held that the mere possibility that representation may be inadequate satisfies this requirement for intervention. *Entergy*, 817 F.3d at 203 (The applicant need only "show[] that representation . . . 'may be' inadequate.") (quoting *Haspel*, 493 F.3d at 578); *see also Espy*, 18 F.3d at 1207 (same); *see also Trbovich*, 404 U.S. at 538 n.10 (same).

FDA's general interest in avoiding the disclosure of proprietary and private information does not ensure that FDA will adequately protect Pfizer's business interests. Indeed, it is well-established in this Circuit that Government entities generally cannot adequately represent the interests of aspiring intervenors, especially where the government "must represent the broad public interest," while the intervenor seeks to protect specific concerns, such as an individual company's proprietary or economic rights. *Espy*, 18 F.3d at 1208 ("Given the minimal burden on the movants to satisfy this requirement, we conclude that the government's representation of the intervenors' interest is inadequate."); *see also John Doe No. 1*, 256 F.3d at 381 (same). Likewise, although Pfizer and Plaintiff share an interest in transparency regarding the vaccine, that commonality does not extend to Pfizer's trade secrets or confidential commercial information. Moreover, Pfizer is uniquely positioned to evaluate the potential commercial sensitivities associated with the production of its regulatory submissions and identify trade secrets and other protected confidential

information. Thus, while Pfizer shares some interests with the existing Parties, Pfizer ultimately must intervene to protect its unique business interests and is best positioned to do so.

E. Pfizer Has Standing in This Action

The Supreme Court has held that "an intervenor of right must have Article III standing in order to pursue relief that is different from that which is sought by a party with standing." *See DeOtte v. Azar*, 332 F.R.D. 173, 179 (N.D. Tex. 2019) (citing *Town of Chester, N.Y. v. Laroe Ests., Inc.*, 137 S. Ct. 1645, 1648 (2017)). This Court has found, however, that this standing requirement is limited to instances where a plaintiff-intervenor is affirmatively seeking relief. *See Franciscan All., Inc. v. Azar*, 414 F. Supp. 3d 928, 938 n.3 (N.D. Tex. 2019) (concluding when defendant-intervenors did not "seek relief" and "as long as they do not also intend to add an affirmative claim for relief during the district court proceedings, Putative Intervenors need not establish standing to intervene."). Because Pfizer is not seeking affirmative relief and is intervening for the limited purpose of protecting its business interest by ensuring compliance with FOIA's statutory exemptions, the standing requirement should not apply here.

Nonetheless, to the extent the standing requirement applies, Pfizer has standing to intervene. To establish standing under Article III, a prospective intervenor must show: (1) injury-in-fact, (2) causation, and (3) redressability. *DeOtte*, 332 F.R.D. at 179 (citing *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992)). Here, Pfizer's injury-in-fact is the potential disclosure of its trade secrets and confidential commercial information and the associated economic harm to Pfizer. As to causation, the relief requested by Plaintiff could deprive Pfizer of its intellectual property rights if Pfizer is not afforded the opportunity to advocate for protection of certain confidential commercial information within the larger set of information to be disclosed. Redressability, likewise, is satisfied, as the risk of injury to Pfizer likely will be minimized by its intervention and

the implementation of a production protocol that safeguards against the disclosure of trade secrets and other confidential commercial information.

Because it satisfies the requirements for intervention under Rule 24(a), Pfizer respectfully asks that this Court permit it to intervene in this action as a matter of right.

II. IN THE ALTERNATIVE, THIS COURT SHOULD PERMIT PFIZER TO INTERVENE UNDER RULE 24(B)

Alternatively, if the Court finds that Pfizer does not have the right to intervene under Rule 24(a), Pfizer respectfully requests that this Court grant it permission to intervene under Rule 24(b). Courts have discretion to permit intervention where the movant "has a claim or defense that shares with the main action a common question of law or fact." Fed. R. Civ. P. 24(b)(1)(B). In considering a motion for permissive intervention, the Court considers whether the motion is timely and whether the proposed intervention will "unduly delay or prejudice the adjudication of the rights of the original parties." Fed. R. Civ. P. 24(b)(3); *see also United States v. Colvin*, 203 B.R. 930, 941 (N.D. Tex. 1996).

Pfizer's interest in protecting its trade secrets and confidential commercial information shares questions of both law and fact in common with the present case. As shown above, Pfizer's motion also is timely. Moreover, Pfizer's intervention will not prejudice the Parties because Pfizer does not dispute that Plaintiff is entitled to non-exempt information from the BLA under its FOIA request and Pfizer does not seek any delay in the production of that information. Rather, Pfizer's intervention will facilitate production of the information Plaintiff seeks since Pfizer can assist the Parties in efficiently segregating and redacting any data and information that are subject to FOIA statutory exemptions.

CONCLUSION

For the foregoing reasons, Pfizer respectfully requests that this Court grant its Motion for Leave to Intervene.

Dated: January 21, 2022

Respectfully submitted,

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