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

STATE OF TEXAS,	§	
	§	
***Plaintiff*,**	§	
	§	Civil Action No.: 5:23-cv-00312-C
v.	§	
	§	
PFIZER INC.	§	
	§	
***Defendant*.**	§	
	§	
	§	

REPLY IN SUPPORT OF MOTION TO DISMISS

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INTRODUCTION

Speaking before the National Institutes of Health in 2005, President George W. Bush outlined his administration's strategy for safeguarding the country against a future pandemic. The "cornerstone" of this strategy was "breaking down barriers to vaccine production" to ensure companies like Pfizer could, if necessary, "bring a new vaccine online quickly and manufacture enough to immunize every American." President Bush recognized that, during a pandemic, "American lives depend on rapid advances in vaccine production technology," and he urged Congress to take action:

> I'm [] asking Congress to remove one of the greatest obstacles to domestic vaccine production: the growing burden of litigation. In the past three decades, the number of vaccine manufacturers in America has plummeted, as the industry has been flooded with lawsuits. . . . That leaves our nation vulnerable in the event of a pandemic. . . . Congress must pass liability protection for the makers of life-saving vaccines.[1]

In discussing the "growing burden of litigation" for vaccine manufactures, President Bush did not distinguish between personal injury lawsuits and other types of civil claims. More importantly, Congress never made this distinction in the statutory text when it passed the Public Readiness & Emergency Preparedness Act ("PREP Act") approximately one month later. As the Texas Attorney General ("OAG") acknowledges, the PREP Act must be interpreted according to its "plain text." (Opp. at 19.) Here the text of the statute immunizes the makers of vaccines and other "covered countermeasures" against "*all* claims for loss" whenever the Secretary for the U.S. Department of Health & Human Services ("HHS") has declared a "public health emergency." 42 U.S.C. § 247d-6d (emphasis added). This immunity broadly extends to claims for "*any type* of loss," so long as they are in some way connected to the administration or use of a covered

[1] *President Outlines Pandemic Influenza Preparations & Response*, Nov. 1, 2005, https://tinyurl.com/3htr2vzp.

countermeasure. *Id.* § 247d-6d(a)(1), (2)(A) (emphasis added). PREP Act immunity thus covers claims "sounding in tort or contract, as well as claims for loss relating to compliance with local, state, or federal laws, regulations, or other legal requirements."[2]

With regard to the COVID-19 pandemic, HHS issued its first emergency declaration on March 17, 2020. That declaration triggered the PREP Act's expansive liability protections, which remain in effect. Relying on these protections, Pfizer successfully developed a safe and effective COVID-19 vaccine in record time. The U.S. Food & Drug Administration ("FDA") authorized Pfizer's vaccine for emergency use on December 11, 2020, then fully approved the vaccine on August 23, 2021. The FDA has continued to assess the safety and efficacy of COVID-19 vaccines, and senior FDA officials recently noted, "contrary to a wealth of misinformation available on social media and the internet, data from various studies indicate that since the beginning of the pandemic, tens of millions of lives were saved by vaccination." (Mot., ECF 18, at 1 n.2.)

OAG disagrees with FDA's assessment of Pfizer's vaccine and has sued the company under the Texas Deceptive Trade Practices Act ("DTPA") for its public statements about the vaccine's efficacy. For reasons discussed in Pfizer's motion to dismiss, this lawsuit is precluded by the plain text of the PREP Act, which immunizes Pfizer against OAG's claims, and also expressly preempts any action by a state that is contrary to the PREP Act's broad grant of immunity. In opposition, OAG argues for a narrower reading, but in doing so cherry picks words from the statute while ignoring the complete statutory language. This approach permeates OAG's opposition brief, which misleadingly cites not just the language of the PREP Act, but also the

[2] U.S. Dept. of Health & Human Servs., Advisory Opinion on the [PREP Act], May 19, 2020, https://tinyurl.com/5dfa54e3. HHS itself has recognized the breadth of the PREP Act and, to the extent it would be helpful, the Court may wish to solicit the agency's views regarding this motion.

DTPA and the relevant case law. When these statutes and cases are read in their full context, it becomes clear that the Court should grant Pfizer's motion to dismiss.[3]

ARGUMENT

Pfizer's motion to dismiss turns on a proper reading of three statutes: the PREP Act, the Food, Drug, and Cosmetics Act (the "FDCA"), and the Texas DTPA. Interpretation of these statutes is a pure question of law that can and should be decided on the pleadings. *See Kemp v. G.D. Searle & Co.*, 103 F.3d 405, 407 (5th Cir. 1997). No factual development is necessary to dismiss this case. In determining the meaning of a statute, courts must first and foremost look to the statutory text. *Conn. Nat. Bank v. Germain*, 503 U.S. 249, 253–54 (1992) ("We have stated time and again that courts must presume that a legislature says in a statute what it means and means in a statute what it says there."). "The Court's "duty [is] 'to give effect, if possible, to every clause and word of a statute.'" *United States v. Menasche*, 348 U.S. 528, 538–39 (1955) (quotation omitted). As the Supreme Court has noted, "[i]f judges could add to, remodel, update, or detract from old statutory terms inspired only by extratextual sources and our own imaginations, we would risk amending statutes outside the legislative process reserved for the people's representatives." *Bostock v. Clayton Cnty.*, 590 U.S. 644, 654 (2020).

Although OAG pays lip service to the bedrock rule that "the Court must interpret [statutory] language according to the limitations in the plain text," (Opp. at 19), the opposition brief violates these canons of construction at every turn.

[3] Because the text of the PREP Act does not support OAG's arguments, the State pads its opposition brief with incorrect and unsubstantiated factual allegations about Pfizer's vaccine, including the State's central claim that Pfizer misled the public in claiming the vaccine was 95% effective using a relative risk reduction calculation. (Opp. at 8–9.) The State's allegations can be easily rebutted with a basic understanding of science and statistics. *See* MedCram, Roger Seheult, *Absolute Risk Reduction Verses Relative Risk Reduction: Is One Better For COVID Vaccines?*, Oct. 12, 2022, https://tinyurl.com/yu2ucztn.

A. THE PREP ACT PRECLUDES OAG'S CLAIMS.

1. The PREP Act Immunizes Pfizer Against OAG's Claims.

OAG argues that its DTPA lawsuit is not a "claim for loss" within the meaning of the PREP Act because the statute "defines loss to include specific ailments that equate to the traditional definition of personal injury." (Opp. at 20.) While OAG is correct that a *portion* of the PREP Act's definition of loss refers to "death" and "physical, mental, or emotional injury, illness, disability, or condition," OAG ignores the full definition. *See* 42 U.S.C. § 247d-6d(a)(2)(A). Under the PREP Act, "the term 'loss' means *any type of loss*." *Id.* (emphasis added). This broad language is not limited to personal injuries. In fact, the statute provides "any type of loss" also includes, but is not necessarily limited to, "loss of or damage to property, including business interruption loss." *Id.* § 247d-6d(a)(2)(A)(iv). Read as an integrated whole, the PREP Act's immunity provision extends far beyond "physical or mental loss." (Opp. at 20.)

OAG also counters that the PREP Act cannot apply here because the State "does not need to prove 'loss' at all" to establish a DTPA violation. (Opp. at 20.) However, OAG's complaint explicitly *does* plead a claim for loss. It alleges Pfizer "caused injury, loss, and damage" to the State and its citizens, (Compl. ¶ 8), while at the same time seeking "redress for consumers," including "damages" and "restitution," (*id.* ¶¶ 2, 172–74). OAG conveniently ignores the text of its own complaint in attempting to sidestep PREP Act immunity.

OAG's next argument—that PREP Act immunity "blocks only claims 'from the administration' of a covered product 'to an individual,'" (Opp. at 20)—again contradicts the complete text of the statute. The actual statutory language prohibits claims far beyond those stemming "from the administration of" a covered countermeasure:

> [A] covered person shall be immune from suit and liability under Federal and State law with respect to all claims for loss *caused by, arising out of, relating to, or resulting from* the administration to or the use by an individual of a covered countermeasure.

42 U.S.C. § 247d-6d(a)(1) (emphasis added). The Fifth Circuit has described this language as providing "a broad grant of immunity." *Mitchell v. Advanced HCS, LLC*, 28 F.4th 580, 586 (5th Cir. 2022) (cited Opp. at 19). And the statute clarifies that this "broad grant of immunity" applies:

> to any claim for loss that has a causal relationship with the administration to or use by an individual of a covered countermeasure, including a causal relationship with the design, development, *clinical testing or investigation*, manufacture, labeling, distribution, formulation, packaging, *marketing*, *promotion*, sale, purchase, donation, dispensing, prescribing, administration, licensing, or use of such countermeasure.

42 U.S.C. § 247d-6d(a)(2)(B) (emphasis added).

The claims in the complaint unquestionably "arise out of" and "relate to" the administration of Pfizer's vaccine; on the very first page, the complaint alleges "hundreds of millions of Americans lined up to receive the [Pfizer] vaccine" based on the company's allegedly misleading efficacy claims. (Compl. at 1; *id.* ¶ 144 ("Had the public known the truth about the efficacy of Pfizer's COVID-19 vaccine, a substantial portion would likely have opted for an alternative or foregone inoculation altogether").) Courts have rejected as "nonsensical" the argument that consumer protection claims lack a sufficient nexus to the "administration" of a covered countermeasure, explaining that "claims for withholding or misrepresenting information… relate to how th[e] covered countermeasure was administered and are thus covered under the [PREP] Act." *M.T. ex rel. M.K. v. Walmart Stores, Inc.*, 528 P.3d 1067, 1079 (Kan. App. 2023).

OAG's final argument against PREP Act immunity—that applying immunity here would "lead to numerous absurdities," (Opp. at 21)— is again belied by the statutory text. OAG claims, for example, that Pfizer's reading of the PREP Act would prevent "even the federal government"

from bringing an enforcement action. (*Id.*) This is simply false. The actual text of the PREP Act contains specific exemptions for enforcement actions by the United States and its agencies. *See*, *e.g.*, 42 U.S.C. § 247d-6d(f) ("Nothing in this section shall be construed to abrogate or limit any right, remedy, or authority that the United States or any agency thereof may possess under any other provision of law."). Thus, the statute "does not provide immunity against *federal* enforcement actions brought by the *federal* government."[4] The explicit carve-out for federal enforcement actions—but not state enforcement actions—strongly indicates Congress intended to immunize covered persons against state actions like this one. *See Bartenwerfer v. Buckley,* 598 U.S. 69, 78 (2023) ("[W]hen Congress includes particular language in one section of a statute but omits it in another section of the same Act, [courts] generally take the choice to be deliberate.").

OAG's slippery-slope argument that Pfizer could claim with impunity that the vaccine cures cancer, (Opp. at 21), entirely misses the point. The statute only provides immunity when the vaccine or other covered countermeasure "was administered or used for the category or categories of diseases, health conditions, or threats to health specified in the declaration." 42 U.S.C. § 247d-6d(a)(3)(B). Here, HHS's emergency declarations related only to the COVID-19 pandemic; any claim regarding the vaccine that is unrelated to COVID-19 would fall outside the PREP Act.

2. The PREP Act Preempts OAG's Claims.

Even if the Court were to adopt the State's (incorrect) reading that PREP Act *immunity* extends only to personal injury claims, the statute's *preemption* clause would still bar OAG's lawsuit. The preemption clause provides "no State . . . may establish, *enforce*, or continue in effect with respect to a covered countermeasure any provision of law or legal requirement that . . . is different from, or in conflict with, any requirement applicable under this section." 42 U.S.C.

[4] *Supra* n.2 at 2 (emphasis added).

§ 247d-6d(b)(8) (emphasis added). In other words, the statute expressly preempts any state effort to "enforce" a law that is inconsistent with Section 247-6d's broad liability protections.

OAG's claims are in direct conflict with Section 247-6d. The complaint's entire premise is that Pfizer's statements about the vaccine misled individuals, thus "harm[ing] Texas and its citizens." (Opp. at 9.) Even OAG agrees that such claims, if brought by *individuals*, would be barred by the PREP Act. (Opp. at 20–22 & n.8.) OAG asserts, however, that *the state* may bring the same claim "on behalf of the public interest of its citizens" acting as "*parens patriae*." (Opp. at 21.) This cannot be correct; the preemption clause would be meaningless if states could bring the very claims the statute bars individuals from bringing. At a minimum, OAG's interpretation would read the word "enforce" out of the preemption clause entirely. *See* 42 U.S.C. § 247d-6d(b)(8). That is something courts must never do. *A.D.T., LLC v. Richmond*, 18 F.4th 149, 156 (5th Cir. 2021) ("Wherever possible, we must read statutes to give effect to their every word.").

OAG also argues its DTPA claims are not preempted because they "mirror available federal ones." (Opp. at 13–14.) This is irrelevant. OAG ignores the plain text of the PREP Act, which preempts state enforcement actions that are "different from, or in conflict with, any requirement applicable under *this section.*" 42 U.S.C. § 247d-6d(b)(8) (emphasis added). In context, "this section" refers to the PREP Act itself, *i.e.*, Section 247d-6 of Title 42, which exists for the sole purpose of extending *liability protections* to covered persons during a public health crisis. OAG's complaint does just the opposite—it seeks to *impose liability* on a vaccine maker for actions taken in response to a national emergency. If the preemption clause doesn't apply here, it is truly a dead letter.

B. THE FDCA ALSO PREEMPTS OAG'S CLAIMS.

The FDCA provides a second, independent basis for preemption. OAG disputes this by citing inapposite cases arising in the failure-to-warn context, where state-law claims against drug

and medical device makers are sometimes permitted depending on the similarity between the FDA-approved label and state-law requirements. (Opp. at 15–16.) But this case does not involve a dispute over labeling or failure-to-warn claims. Rather, as outlined in Pfizer's moving brief, OAG's claims are preempted because the State is attempting to substitute its unscientific views about Pfizer's vaccine for the expert judgment of FDA, essentially alleging that an FDA-approved product failed to meet FDA's own requirements. *See Exela Pharma Scis., LLC v. Sandoz, Inc.*, 486 F. Supp. 3d 1001, 1015 (W.D.N.C. 2020) ("For the [p]laintiff to now second guess the FDA's decision in a civil action based on state law would render the FDA's authority to be a nullity."). Tellingly, OAG does not even attempt to distinguish the line of cases cited in Pfizer's motion.

Instead of grappling with the applicable law, OAG asserts it is not disputing FDA's regulatory and policy decisions, but rather championing FDA's position on the vaccine. (Opp. at 17.) Nothing could be further from the truth. (*See*, *e.g.*, Compl. at 3 (challenging FDA's finding that Pfizer's vaccine is safe and effective by claiming it has "negative vaccine efficacy" meaning "a greater percentage of persons contracted, and even died from, COVID-19 than unvaccinated"), ¶¶ 11–15 (denigrating FDA's rigorous EUA process), ¶¶ 100–01 (contesting FDA's conclusion that Pfizer's vaccine is safe), ¶¶ 119–23 (questioning FDA's approval of the vaccine as a booster and claiming FDA only granted approval "under political pressure from the White House").) These statements and others are entirely at odds with FDA's unwavering support for Pfizer's product; they are exactly the type of anti-vaccination rhetoric that FDA has decried as "contributing to the continued death and serious illness toll of COVID-19."[5]

C. OAG'S CLAIMS FAIL UNDER THE DTPA.

The DTPA's stated purpose is to "protect *consumers* against false, misleading, and

[5] U.S. Food & Drug Admin., *FDA Letter to Florida Department of Health Regarding COVID-19 Vaccine Safety*, Dec. 14, 2023, https://tinyurl.com/2jsuvu7y.

deceptive *business practices*, unconscionable actions, and breaches of warranty." Tex. Bus. & Com. Code § 17.44 (emphasis added). Texas courts have consistently interpreted the DTPA as applying to "protect consumers in consumer transactions." *Amstadt v. U.S. Brass Corp.*, 919 S.W.2d 644, 649 (Tex. 1996). Here, there is no consumer transaction connected to trade or commerce that can be regulated under the Act. The DTPA simply cannot be read to apply to the federal government's public health initiative to provide *free* COVID-19 vaccines to all Americans. (*See* Mot. at 18–24.)

OAG does not meaningfully address the DTPA's statutory text. Instead, OAG asserts that the State's DTPA enforcement actions need not involve a specific consumer. (Opp. at 25.) But the cases cited in the opposition merely say that OAG need not be a "consumer" itself to have standing to bring a claim; these cases do not dispute that the statute's stated goal is to "protect consumers" from deceptive "business practices." Tex. Bus. & Com. Code § 17.44.

Citing *Mother & Unborn Baby Care of N. Texas, Inc. v. State*, 749 S.W.2d 533 (Tex. App. 1988), OAG claims there need not be an actual purchase to trigger DTPA liability. (Opp. at 23.) But the *Mother* court held there was "no doubt" that the challenged conduct affected trade and commerce; although no purchase actually occurred, the defendant falsely advertised commercial services, and the women who responded to those advertisements were "consumers" as they sought "to purchase a service upon which this complaint is based." *Id.* at 538. By contrast, the Texans who received Pfizer's vaccine in 2020 and 2021 did not "seek[] or acquire[]" the product "by purchase or lease," nor did Pfizer "advertise" its vaccine—that is, "promote its sale"—to Texas residents. (*See* Mot. at 20–23 (explaining the definition of "consumer" under Texas law).)

OAG also argues that the DTPA's plain language does not govern because one of Pfizer's many cited cases was vacated on other grounds by the Fifth Circuit. (Opp. at 23 (citing *Word of*

Faith Outreach Ctr. Church, Inc. v. Morales, 986 F.2d 962, 969 (5th Cir. 1993).) The Fifth Circuit's ruling on other grounds did not undermine the district court's accurate statement that, in enacting the DTPA, "the Texas Legislature was concerned with 'business,' not gratuitous transactions." *Word of Faith World Outreach Ctr. Church, Inc. v. Morales*, 787 F. Supp. 689, 697 (W.D. Tex. 1992), *vacated on other grounds* 986 F.2d 962 (5th Cir. 1993).[6] This is still the law. *See, e.g.*, *Bass v. Hendrix*, 931 F. Supp. 523, 535 (S.D. Tex. 1996) ("A gratuitous act is not a purchase under the DTPA.").[7] The State's argument has no merit.[8]

CONCLUSION

For all of these reasons, the Court should dismiss OAG's lawsuit with prejudice.

[6] Although it had no substantive impact, we apologize to the Court for the incorrect citation, which should have included the Fifth Circuit's subsequent treatment of the case.

[7] OAG's citation to *Flenniken v. Longview Bank & Tr. Co.*, 661 S.W.2d 705, 707 (Tex. 1983), which addressed the DTPA's "unconscionable acts" provision, is not relevant here as the complaint does not allege claims under that provision. (Opp. at 24.)

[8] OAG's claims also fail because they are not plausible. (*See* Mot. at 25.) OAG's central claim is that Pfizer's claim that the vaccine was 95% effective using relative risk reduction was misleading. *See supra* n.3. But FDA's own efficacy criteria for the EUA was 50%, expressed in terms of relative risk reduction. *See* Food & Drug Admin., Emergency Use Authorization for Vaccines Explained, Nov. 20, 2020, https://tinyurl.com/46esw485. And when FDA announced the EUA, it stated the vaccine's "efficacy in preventing confirmed COVID-19 . . . was 95.0%," again using relative risk reduction. Food & Drug Admin., *Emergency Use Authorization for an Unapproved Product Review Memorandum*, Dec. 11, 2020, https://tinyurl.com/2mm9apa2; (*see also* Opp. at 6 n.1 (noting the complaint "relies upon and incorporates by reference" the EUA).)

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Respectfully submitted,

DLA PIPER LLP (US)

/s/ Meagan D. Self
Meagan D. Self
TX Bar No. 24078453
Meagan.Self@dlapiper.com
1900 North Pearl Street
Suite 2200
Dallas, TX 75201
Telephone: (214) 743-4500

Carlton E. Wessel
Admitted *pro hac vice*
Carlton.Wessel@dlapiper.com
500 Eighth Street, NW
Washington, D.C. 20004
Telephone: 202.799.4000

Andrew J. Hoffman II
Admitted *pro hac vice*
Andrew.Hoffman@dlapiper.com
2000 Avenue of the Stars
Suite 400, North Tower
Los Angeles, CA 90067
Telephone: 310.595.3000

Lianna Bash
Admitted *pro hac vice*
lianna.bash@dlapiper.com
701 Fifth Avenue, Suite 6900
Seattle, WA 98104
Telephone: (206) 839-4800

FOLEY & LARDNER LLP

/s/ Edward D. Burbach
Edward D. Burbach
TX Bar No. 03355250
eburbach@foley.com
Robert F. Johnson, III
TX Bar No. 10786400
rjohnson@foley.com
600 Congress Ave., Suite 2900
Austin, TX 78701
Telephone: (512) 542-7070

FARGASON, BOOTH, ST. CLAIR RICHARDS & WILKINS LLP

/s/ Robert. W. St. Clair
Robert W. St. Clair, P.C.
TX Bar No. 18985300
rstclair@lbklawyers.com
James F. Perrin
TX Bar No. 24027611
jperrin@lbklawyers.com
4716 4th St., Suite 200
Lubbock, Texas 79416
Telephone: (806) 744-1100

Attorneys for Pfizer Inc.

CERTIFICATE OF SERVICE

I certify that on May 9, 2024 a copy of the foregoing document was served via the Court's electronic filing system on all counsel of record.

/s/ Meagan D. Self
Meagan D. Self