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*.**	§	
	§	
	§	

BRIEF IN SUPPORT OF MOTION TO DISMISS

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INTRODUCTION

A national emergency requires a national response. The COVID-19 pandemic was no exception. This once-in-a-century public health crisis claimed more than one million American lives and, at its peak, brought economic activity across the United States to a near stand-still. The centerpiece of the federal government's strategy for combatting the virus and reopening the economy was Operation Warp Speed, a public-private partnership with $10 billion in funding from Congress to enable faster development and approval of a COVID-19 vaccine. Nearly four years have elapsed since President Donald Trump announced the launch of Operation Warp Speed in May 2020, along with the goal of having a safe and effective vaccine available by January 2021.

By any measure, Operation Warp Speed was a massive success. The U.S. Food and Drug Administration ("FDA") authorized not just one, but three COVID-19 vaccines within a year of the pandemic's onset. The first was developed by Pfizer and its partner BioNTech. At the time, President Trump praised Pfizer's vaccine as a "medical miracle" and predicted it would "save millions of lives."[1] History has proven him right. In a recent editorial in the Journal of the American Medical Association, two senior FDA officials highlighted "data from various studies" showing that "since the beginning of the COVID-19 pandemic tens of millions of lives were saved by vaccination."[2]

Two federal statutes were indispensable to this achievement: the Public Readiness and Emergency Preparedness Act ("PREP Act") and the Food, Drug, and Cosmetic Act ("FDCA"). These laws empower the Secretary for the U.S. Department of Health and Human Services

[1] Tal Axelrod, *Trump Hails FDA Approval of COVID-19 Vaccine as Historic Accomplishment*, THE HILL, Dec. 11, 2020, https://tinyurl.com/yc682ubd.

[2] Robert Califf, MD and Peter Marks, MD, Ph.D., *Is Vaccination Approaching a Dangerous Tipping Point?*, J.A.M.A., Jan. 5, 2024, https://tinyurl.com/yfvts5ah.

("HHS") to take emergency actions when the public health is under threat. The PREP Act, for example, allows the Secretary to limit legal liability for the makers of "medical countermeasures" to spur innovation during a national emergency. And the FDCA permits the Secretary to authorize "emergency use" of safe and effective products, on an expedited basis, when there are no adequate and approved alternatives. The Secretary exercised these emergency powers in response to COVID-19 and, as a result, Pfizer's vaccine was widely available in record time.

The Texas Attorney General's Office ("OAG") takes issue with the overwhelming consensus of FDA and other global public health experts. In OAG's words, "COVID-19 vaccines are the miracle that wasn't." (Compl., pg. 1.) OAG believes FDA's authorization of the vaccine was "artificial and flawed," (Compl. ¶ 144), and accuses Pfizer of making "serial misrepresentations" about the vaccine's efficacy, and conspiring to "censor the vaccine's critics," to "confuse and mislead the public" and "achieve widespread adoption of its vaccine," (Compl., pp. 4–5.) And OAG has attempted to fit its opinions about the vaccine into a state-law legal theory by filing this case against Pfizer under the Texas Deceptive Trade Practices Act ("DTPA"). The complaint claims that "[h]ad the public known the truth" about Pfizer's vaccine, many people would have "opted for an alternative or foregone inoculation altogether." (Compl. ¶ 144.)

However, on this matter of national importance, OAG has no legal right to insert itself between FDA and the American people. Congress has tasked FDA, not state officials, with deciding whether Pfizer's vaccine is sufficiently safe and effective, and federal law presents several insurmountable barriers to this lawsuit. Not only does Pfizer have statutory immunity under the PREP Act, but OAG's claims are preempted twice over. Regardless, the complaint cannot state a claim under the DTPA because the so-called "consumers" in this case received their vaccines from the federal government for free. The Court should dismiss this action.

FACTUAL & PROCEDURAL BACKGROUND

A. THE COVID-19 PANDEMIC

The U.S. Centers for Disease Control & Prevention ("CDC") issued its first publication concerning SARS-CoV-2, the novel coronavirus that causes the infectious disease now known as COVID-19, on January 10, 2020. Due to the rapid spread of this deadly, previously unknown virus, the World Health Organization declared COVID-19 a "pandemic" on March 11, 2020. Two days later, President Donald Trump declared COVID-19 a "national emergency." Then, on March 17, 2020, HHS issued an emergency declaration under the PREP Act.

Back in 2005, President George W. Bush signed the PREP Act into law. The statute provides "covered persons" with broad immunity from lawsuits relating to "covered countermeasures" whenever the HHS Secretary issues a declaration "that a disease . . . constitutes a public health emergency" and identifies the specific countermeasures and persons with immunity. 42 U.S.C. § 247d-6d(a), (b)(1). The purpose of the statute is to ensure that Americans have broad access to medical countermeasures when there is an emergency need. Since 2005, HHS has issued declarations relating to numerous public health emergencies aside from COVID-19, including Anthrax, Ebola, Monkeypox, and Zika Virus.[3, 4]

The Secretary's original declaration in this case identified the "COVID-19 outbreak" as a "public health emergency" requiring a "sustained, coordinated proactive response by the

[3] U.S. Dept. of Health & Human Servs., Admin. for Strategic Preparedness and Response, Public Readiness and Emergency Preparedness (PREP) Act, https://tinyurl.com/hzd2nhjw.

[4] Courts routinely take judicial notice of Government websites and other public pronouncements from federal agencies, and it is appropriate for this Court to do so here. *See, e.g., Swindol v. Aurora Flight Sciences Corp.,* 805 F.3d 516, 519 (5th Cir. 2015) (taking judicial notice of "public records" on Government websites because their "accuracy . . . cannot reasonably be questioned"); *Norris v. Hearst Tr.,* 500 F.3d 454, 461 n.9 (5th Cir. 2007) ("[I]t is clearly proper in deciding a 12(b)(6) motion to take judicial notice of matters of public record.").

[g]overnment in order to contain and mitigate the spread of COVID-19." *See* 85 F.R. 15,198, 15,201 (Mar. 17, 2020). The Secretary further noted "any vaccine used to . . . prevent or mitigate COVID-19" qualifies as a "covered countermeasure," and any "manufacturer" of the vaccine is a "covered person." *Id.* at 15,201–202. The Secretary has renewed and amended this declaration numerous times, and its core provisions remain in effect. *See* 88 F.R. 30,769 (May 12, 2023).

B. OPERATION WARP SPEED

In the early months of the pandemic, there was no vaccine to protect against COVID-19. To address this urgent and unmet need, the Trump Administration launched Operation Warp Speed on May 15, 2020. Because large numbers of people were getting sick and dying from COVID-19, the federal government "refused to accept business-as-usual timelines for vaccines and other essential tools" and pledged, in collaboration with private industry, to "squeeze every last inefficiency out of the process and pour every resource" into an unprecedented effort to produce, among other things, hundreds of millions of doses of COVID-19 vaccines by January 2021.[5] This was an audacious, but necessary, goal; at the time, potential vaccine candidates, including Pfizer's, were still in the early phases of clinical development, and their prospects were uncertain.

FDA issued guidance to industry in June 2020 concerning the agency's rigorous expectations before it would consider licensing any COVID-19 vaccine candidate, including for Emergency Use Authorization ("EUA").[6] "Under an EUA, FDA may allow the use of unapproved medical products. . . in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions when certain statutory criteria have been met, including that there are no

[5] U.S. Dept. of Defense, Immediate Release: Trump Administration Announces Framework and Leadership for 'Operation Warp Speed,' May 15, 2020, https://tinyurl.com/3yajcvnd.

[6] U.S. Dept. of Health & Human Servs., Food & Drug Admin., Development and Licensure of Vaccines to Prevent COVID-19: Guidance for Industry, June 2020, https://tinyurl.com/mtz5nyfz.

adequate, approved, and available alternatives."[7] These "statutory criteria" also include that, based on FDA's assessment of the "totality of scientific evidence" including "data from adequate and well-controlled clinical trials, if available," the "known and potential benefits of the product . . . outweigh the known and potential risks of the product." 21 U.S.C. § 360bbb-3(c).

As part of Operation Warp Speed, Pfizer entered into an agreement to sell its vaccine to the U.S. Department of Defense ("DoD") while the product was still in development. (Compl. ¶ 27.) The key terms of this agreement are found in two instruments: (1) a Base Agreement executed on July 20, 2020; and (2) a Statement of Work ("SOW") executed on July 21, 2020. The SOW provides that DoD would pay $1.95 billion—or $19.50 per dose—for 100 million doses of the vaccine, contingent on Pfizer first securing FDA approval or an EUA. (Compl. ¶¶ 53–54.) These agreements were negotiated and signed *before* Pfizer commenced the placebo-controlled clinical trial of the vaccine, now known as the "landmark study." (Compl. ¶ 39.)

C. THE LANDMARK STUDY & FDA APPROVAL

On July 27, 2020—six days after finalizing the government purchase agreement—Pfizer and BioNTech launched the landmark study. (Compl. ¶ 39.) The landmark study was a placebo-controlled, randomized, observer-blind study to evaluate the safety, tolerability, immunogenicity, and efficacy of the Pfizer-BioNTech vaccine against COVID-19 in healthy individuals. (Compl. ¶¶ 39–40.)[8] Approximately 40,000 participants were enrolled in the study at 153 clinical research

[7] U.S. Dept. of Health & Human Servs., Food & Drug Admin., Emergency Use Authorization for Vaccines Explained, Nov. 20, 2020, https://tinyurl.com/46esw485.

[8] A "placebo-controlled" trial is one in which there are at least two groups—one gets the active treatment, the other gets the placebo, and everything else is held the same between the groups, so that any difference in their outcome can be attributed to the active treatment. A "randomized" trial is one in which the participants are divided by chance into separate groups that compare different treatments or other interventions. An "observer-blind" study is one in which those charged with measuring, recording, and assessing changes in research participants do not know which of the participants have received the active treatment and which have received the placebo.

sites. (Compl. ¶ 43.) Under Pfizer's clinical trial protocol, about half of the participants received two doses of the vaccine, with 21 days between each dose, and the remaining participants received placebo injections on the same schedule. (Compl. ¶¶ 43–44.)

Pfizer and BioNTech announced initial results from the landmark study, which showed a two-dose regimen of the vaccine conferred 95 percent protection against COVID-19 in persons 16 years of age and older, in November 2020. (Compl. ¶¶ 43–44.) Based on these results, Pfizer and BioNTech asked FDA to authorize the vaccine for emergency use in this age group, and FDA, then under the Trump Administration, issued the EUA on December 11, 2020. (Compl. ¶ 48.) In FDA's press release announcing the EUA, the agency touted the vaccine's 95 percent efficacy expressed in terms of relative risk reduction: "Among [trial] participants, 18,198 received the vaccine and 18,325 received placebo. *The vaccine was 95% effective in preventing COVID-19 disease among these clinical trial participants* with eight COVID-19 cases in the vaccine group and 162 in the placebo group."[9]

Immediately after receiving the EUA, Pfizer started shipping the first batches of its vaccine to DoD.[10] The government opted to provide the vaccine to the public for free, and the first doses of the vaccine were administered in the U.S. outside of the clinical trial setting on December 14, 2020. (Compl. ¶¶ 146–51.)[11]

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[9] U.S. Food & Drug Admin., *FDA Takes Key Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for First COVID-19 Vaccine*, Dec. 11, 2020, http://tinyurl.com/uz84ppkh (emphasis added).

[10] Ben Guarino et al., *'The Weapon That Will End The War': First Coronavirus Vaccine Shots Given Outside Trials In U.S.*, THE WASHINGTON POST, Dec. 14, 2020, https://tinyurl.com/4na9kyby.

[11] Centers for Medicare & Medicaid Servs., *Trump Administration Acts to Ensure Coverage of Life-Saving COVID-19 Vaccines & Therapeutics*, Nov. 13, 2020, http://tinyurl.com/3w9btrdr.

FDA has since issued additional EUAs for use of Pfizer's vaccine in different age groups and for booster doses, and FDA fully approved the vaccine, now known by the brand name "Comirnaty," on August 23, 2021.[12] These authorizations and approvals remain in place. *See*, *e.g.*, *United States ex rel. Jackson v. Ventavia Rsch. Grp., LLC*, 667 F. Supp. 3d 332, 361 (E.D. Tex. 2023) (noting "[t]he [g]overnment's unbroken chain of authorization and payments" for the vaccine and remarking "[t]o this day, the FDA has not revoked its approval of Pfizer's vaccine").

FDA has continued to express confidence in the safety and efficacy of Pfizer's vaccine in the face of politically motivated attacks.[13] For example, FDA issued multiple letters to the Florida Department of Health, most recently stating: "We stand firmly behind our regulatory decision making with the authorizations and approvals of the COVID-19 vaccines, which have a highly favorable safety profile, and which have saved, and continue to save, many lives."[14] FDA cautioned that "the challenge we continue to face is the ongoing proliferation of misinformation and disinformation about these vaccines which results in vaccine hesitancy," "lowers vaccine uptake," and "contribut[es] to the continued death and serious illness toll of COVID-19."

On a similar note, last month the Director of FDA's Center for Biologics Evaluation & Research testified before Congress that "COVID-19 vaccines have been shown to be safe.

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[12] U.S. Food & Drug Admin., *FDA Approves First COVID-19 Vaccine*, Aug. 23, 2021, http://tinyurl.com/3wefvyy4; U.S. Food & Drug Admin., *FDA Authorizes Booster Dose of Pfizer-BioNTech COVID-19 Vaccine for Certain Populations* Sept. 22, 2021, http://tinyurl.com/ky76zvm5; U.S. Food & Drug Admin., *FDA Authorizes Bivalent Pfizer-BioNTech COVID-19 Vaccine as Booster Dose for Certain Children 6 Months through 4 Years of Age*, Mar. 14, 2023, http://tinyurl.com/2p9uyj64.

[13] *See*, *e.g.*, *Governor Ron DeSantis Petitions Florida Supreme Court for Statewide Grand Jury on COVID-19 Vaccines & Announces Creation of the Public Health Integrity Committee*, Dec. 13, 2022, http://tinyurl.com/kkax9236.

[14] U.S. Food & Drug Admin., *FDA Letter to Florida Department of Health Regarding COVID-19 Vaccine Safety*, Dec. 14, 2023, http://tinyurl.com/3upwfz6k.

COVID-19 vaccines have been shown to be effective. They are supported by the best available scientific data; they underwent FDA's rigorous regulatory authorization and approval processes; and their safety over time is closely monitored."[15]

D. PROCEDURAL HISTORY

On May 1, 2023, OAG issued a Civil Investigative Demand ("CID") to Pfizer seeking information concerning Pfizer's development and marketing of the COVID-19 vaccine. Pfizer fully cooperated with the CID, producing over 70,000 documents, yet OAG—without providing the required notice to Pfizer, *see* Tex. Bus. & Com. Code § 17.505—filed this complaint on November 30, 2023.

Contrary to FDA's position under both Republican and Democratic administrations, OAG takes the view that Pfizer's COVID-19 vaccine is ineffective and dangerous. OAG claims, for example, that Pfizer's vaccine is "merely 0.85% effective" and, indeed, has "negative efficacy" in some communities, meaning "a greater percentage of vaccinated persons contracted, and even died from COVID-19 than unvaccinated." (Compl., pp. 1–3.) The complaint takes direct aim at FDA's competency and integrity, suggesting the agency's process for evaluating new vaccines is inadequate and claiming FDA only approved Pfizer's vaccine as a booster "under political pressure from the White House." (Compl. ¶¶ 11–15, 123.)

OAG claims Pfizer violated the DTPA when it truthfully stated, based on then-existing data, that the vaccine showed 95% efficacy in the landmark study; getting vaccinated can protect the health of individuals and their families; vaccine efficacy remained strong six months after vaccination; and the vaccine worked against variants, including the Delta variant. (Compl. ¶¶ 56–

[15] Assessing America's Vaccine Safety Systems, Part 1: Hearing Before Committee On Oversight And Accountability (Testimony of Dr. Peter Marks), Feb. 15, 2024, https://tinyurl.com/muf9aahk.

91.) Many of the Pfizer statements that OAG challenges are identical to statements FDA itself has made about the vaccine.[16] In fact, OAG is in the very unusual position of contradicting numerous public statements from the Texas Department of State Health Services, the expert agency the Texas Legislature has entrusted with protecting public health within the state's borders.[17]

The Texas Attorney General has made numerous media appearances in which he discusses this case. In those interviews, he makes his views crystal clear: he disagrees with the federal government's pandemic response, including its decisions to authorize and purchase Pfizer's vaccine, and he is seeking to challenge those federal policy decisions under state law. Noting his view that both Pfizer and the federal government have "punished" people who criticize the vaccine, the Attorney General has explained his lawsuit seeks to reveal "a media effort, [and] a government effort, despite the facts, to force people to take this vaccine."[18] He describes Pfizer as working hand-in-hand with the federal government to encourage Americans to get vaccinated, and, in his view, Pfizer only did so "because Congress gave them immunity from liability."

The Attorney General's allegations are baseless and unsupported, but there's one thing he gets right: in order to ensure broad access to the lifesaving COVID-19 vaccine, Congress has

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[16] *See supra* n.9 (statement from FDA that "[t]he vaccine was 95% effective in preventing COVID-19"); U.S. Food & Drug Admin, *Joint Statement from HHS Public Health and Medical Experts on COVID-19 Booster Shots*, Aug. 18, 2021 ("The COVID-19 vaccines authorized in the United States continue to be remarkably effective in reducing risk of severe disease, hospitalization, and death, even against the widely circulating Delta variant.").

[17] *See*, *e.g.*, Tex. Dept. of State Health Servs., *COVID-19 Deaths by Vaccination Status Dashboard*, Apr. 28, 2023, http://tinyurl.com/6zww4je5 ("In the most recent 28 days with available data, compared to Texans vaccinated with the updated bivalent booster, unvaccinated Texans were 11x more likely to die of a COVID-19 associated illness."); Tex. Dept. of State Health Servs., *Texas Data Shows Unvaccinated People 20 Times More Likely to Die from COVID-19*, Feb. 10, 2022, http://tinyurl.com/4xjtxbr4.

[18] *Just the News, No Noise With GOP Rep. Briggs, AG Paxton*, Feb. 7, 2024, at 27:17–28:13, http://tinyurl.com/4kzs8749.

immunized companies like Pfizer against lawsuits like this one. For this reason and many others discussed below, the Court should dismiss this frivolous case.

ARGUMENT

A. THE STATE'S CLAIMS ARE PRECLUDED UNDER FEDERAL LAW.

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

As the Attorney General has acknowledged, federal law provides Pfizer with broad immunity from claims related to the COVID-19 vaccine, including the claims raised in this lawsuit. Because Congress, though the PREP Act, has granted companies like Pfizer immunity from claims like those advanced by OAG, that office cannot state a claim upon which relief could be granted. *See* Fed. R. Civ. P 12(b)(6); *see Gibson v. Johnson & Johnson*, No. 22-04383, 2023 WL 4851413, at *2 (E.D. Pa. July 28, 2023) (granting 12(b)(6) motion to dismiss claims relating to the COVID-19 vaccine based on PREP Act immunity); *Cowen v. Walgreen Co.*, No. 22-cv-157, 2022 WL 17640208, at *3 (N.D. Okla. Dec. 13, 2022) (same).

The PREP Act provides broad immunity from suit to private companies aiding the government in response to a public health emergency:

> Subject to the other provisions of this section, 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 if a declaration under subsection (b) has been issued with respect to such countermeasure.

42 U.S.C. § 247d-6d(a)(1) (emphasis added).

This provision applies to Pfizer; HHS's March 17, 2020 Declaration identified COVID-19 vaccine manufactures as "covered persons" and their vaccines as "covered countermeasures" under the statute. *See* 85 F.R. 15,198, 15,201–202; *see also T.C. ex rel. Cabaniss v. Pfizer Inc.*, No. 22-cv-01242, 2022 WL 17578871, at *2 (S.D. Cal. Nov. 9, 2022) (holding Pfizer "is facially

immune from suit in this Court under the PREP Act" and dismissing claims relating to the use of Pfizer's COVID-19 vaccine), *aff'd* No. 23-55297, 2024 WL 511872 (9th Cir. Feb. 9, 2024).

It is also clear that OAG has brought a "claim for loss" subject to the statute's immunity provision. The PREP Act defines "loss" broadly, stating "the term 'loss' means *any* type of loss," including but not limited to "(i) death; (ii) physical mental, or emotional injury, illness, disability, or condition; (iii) fear of physical, mental, or emotional injury, illness, disability, or condition, including the need for medical monitoring; and (iv) loss of or damage to property, including business interruption loss." 42 U.S.C. § 247d-6d(a)(2)(A) (emphasis added).

Under this expansive definition, the statute provides immunity from claims for "any type of loss" related to the administration or use of Pfizer's vaccine. *See Kehler v. Hood*, No. 4:11-cv-1416, 2012 WL 1945952, at *3 (E.D. Mo. May 30, 2012) ("Novartis, the alleged manufacturer of the H1N1 vaccine at issue here, is protected by the PREP Act and is absolutely immune from liability for any type of loss caused by the vaccine."); *Cowen*, 2022 WL 17640208, at *3 ("In the PREP Act, Congress plainly provided immunity under both 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." (emphasis in original)).

The claims here fall squarely within this broad definition of "loss." According to OAG's own complaint, Pfizer's alleged "unlawful acts or practices" "caused injury, loss, and damage to [the State], as well as caused adverse effects to the lawful conduct of trade and commerce, thereby directly or indirectly affecting the people of this State." (Compl. ¶ 8.) The complaint further requests damages and restitution, which are only recoverable when the State or its citizens have suffered a "loss." (*Id.* ¶¶ 172–74.)

Other courts have agreed that similar claims fall within the PREP Act's grant of immunity. In *Gibson v. Johnson & Johnson*, for example, the plaintiff alleged Johnson & Johnson "violated the False Claims Act in marketing the [COVID-19] vaccine and providing 'intentionally misleading information.'" 2023 WL 4851413, at *2. The plaintiff claimed he suffered "serious physical and psychiatric adverse effects, injury, and risk of death along with financial distress" as a result of inoculation and a "lethal combination of false information, misrepresentation, inadequate clinical testing, gross negligence and recklessness, and inadequate medical health care." *Id*. The court dismissed plaintiff's claims, agreeing that the defendants, as manufacturers of the vaccine, are immune under the PREP Act. *Id.* at *3; *see also M.T. ex rel. M.K. v. Walmart Stores, Inc*., 528 P.3d 1067, 1078–79 (Kan. Ct. App. 2023) (holding PREP Act immunity applied to "claims of withholding or misrepresenting information" about the COVID-19 vaccine).

The complaint in this case asserts state-law claims for "losses" "caused by, arising out of, relating to, or resulting from the administration to and use by" individuals of Pfizer's vaccine, a covered countermeasure. Accordingly, the PREP Act immunizes Pfizer against this lawsuit.

2. The PREP Act Preempts The State's Claims.

OAG's claims are expressly preempted under the PREP Act as well. Ordinary preemption, sometimes called "defensive preemption," is an affirmative defense that "may arise either by express statutory term or by a direct conflict between the operation of federal and state law." *Johnson v. Baylor Univ.*, 214 F.3d 630, 632 (5th Cir. 2000); *Mitchell v. Advanced HCS, LLC*, 28 F.4th 580, 585 n.2 (5th Cir. 2022) ("[D]efensive preemption is an affirmative defense that a defendant can invoke to defeat a plaintiff's state-law claim on the merits by asserting the supremacy of federal law." (quotation omitted)). Where a plaintiff's state-law claims are preempted, he or she cannot state a claim upon which relief can be granted, and the court should dismiss them under Rule 12(b)(6). *See Hernandez v. Metro. Life Ins. Co.*, No. 5:19-cv-37, 2019

WL 2563836, at *5 (W.D. Tex. Apr. 11, 2019) (granting motion to dismiss DTPA claims based on ERISA preemption); *St. Pierre v. Ward*, 542 F. Supp. 3d 549, 554 (W.D. Tex. 2021) (granting motion to dismiss DTPA claims based on defensive preemption).

Congressional intent is the touchstone of any preemption analysis, and "Congress' intent may be explicitly stated in the statute's language or implicitly contained in its structure and purpose." *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 516 (1992). "When a federal law contains an express preemption clause, [courts] 'focus on the plain wording of the clause, which necessarily contains the best evidence of Congress' preemptive intent.'" *Chamber of Com. Of U.S. v. Whiting*, 563 U.S. 582, 594 (2011) (quoting *CSX Transp., Inc. v. Easterwood,* 507 U.S. 658, 664 (1993)).

The PREP Act expressly preempts state-law claims, like the ones here, that attempt to impose liability related to covered countermeasures:

> During the effective period of a declaration under subsection (b), or at any time with respect to conduct undertaken in accordance with such declaration, no State . . . may establish, enforce, or continue in effect with respect to a covered countermeasure any provision of law or legal requirement that—
>
> (a) is different from, or is in conflict with, any requirement applicable under this section; and
>
> (b) relates to the design, development, clinical testing or investigation, formulation, manufacture, distribution, sale, donation, purchase, marketing, promotion, packaging, labeling, licensing, use, any other aspect of safety or efficacy, or the prescribing, dispensing, or administration by qualified persons of the covered countermeasure, or to any matter included in a requirement applicable to the covered countermeasure under this section or any other provision of this chapter, or under the Federal Food, Drug, and Cosmetic Act.

42 U.S.C. § 247d-6d(b)(8). The phrase "relates to" in subsection (b) expresses a "broad pre-emptive purpose." *Gonzalez v. Blue Cross Blue Shield Ass'n*, 62 F.4th 891, 903 (5th Cir. 2023) ("Congress characteristically employs the phrase ['relates to'] to reach any subject that has a connection with, or reference to, the topics the statute enumerates." (quotations omitted)).

Congress enacted the PREP Act to incentivize private companies to assist the federal government in providing potentially lifesaving countermeasures during a public health emergency without fear of later being sued for actions taken in a time of crisis. *See* 42 U.S.C. § 247d-6d(a)(1). In offering immunity to the manufacturers of COVID-19 vaccines, HHS emphasized the serious public health emergency caused by the pandemic and the need for "a sustained, coordinated proactive response by the [g]overnment in order to contain and mitigate the spread" of the virus. 85 F.R. 15,198, 15,201–202. Pfizer answered the federal government's call. Despite this, OAG seeks to hold the company liable under state law for actions "relating to," among other things, the "design," "development," "clinical testing," and "safety and efficacy" of the COVID-19 vaccine. *See* 42 U.S.C. § 247d-6d(b)(8)(1). This lawsuit, which is in direct conflict with important federal prerogatives, is tailor made for dismissal under the PREP Act.[19]

3. The FDCA Also Preempts The State's Claims.

Congress granted FDA—not state attorneys general—the authority to ensure the safety, purity, and potency of vaccines administered in the United States. 42 U.S.C. § 262(a)(1)(C). Under federal law, FDA must make public health decisions based on evidence and scientific expertise, 21 U.S.C. § 355, and follow statutory criteria when granting EUAs and other vaccine approvals, 42 U.S.C. § 262 (biologics licensing criteria); 21 U.S.C. § 360bbb-3 (biologics EUA criteria). If a vaccine is marketed or sold without appropriate FDA authorization or approval, the agency has the exclusive right to bring an enforcement action. *See* 21 U.S.C. § 337 (requiring all

[19] Some courts have held the PREP Act is not a *complete* preemption statute. *See, e.g.*, *Mitchell*, 28 F.4th at 588–89. These cases, which analyze whether the PREP Act provides a stand-alone basis for *removal* of state-law claims to federal court, are not applicable here because they consider only complete preemption, not defensive preemption. The Fifth Circuit has noted the PREP Act's express preemption clause is "defensive," and thus can be raised as a defense to liability, even if the statute does not provide a separate basis for federal removal. *Id.* at 585 n.2, 589.

proceedings enforcing the FDCA "shall be by and in the name of the United States"). The statute gives FDA "complete discretion" to "decide how and when [its enforcement authority] should be exercised." *Heckler v. Chaney*, 470 U.S. 821, 835 (1985). FDA's actions pursuant to its emergency powers are similarly "committed to agency discretion." 21 U.S.C. § 360bbb-3(i).

This statutory framework reflects Congress's determination that FDA is "appropriately the arm of [g]overnment to make" the scientific and medical judgments needed to ensure vaccine safety and efficacy. *CIBA Corp. v. Weinberger*, 412 U.S. 640, 643-44 (1973). To fulfill this congressional mandate, FDA uses teams of scientists to evaluate applications for new vaccines. This team of experts reviews the available scientific data to assess "the safety and efficacy of the vaccine" and whether "manufacturing and facility information assure product quality and consistency." In some cases (including this one), FDA also seeks input from a committee of independent scientists and technical experts, known as the Vaccines and Related Biological Products Advisory Committee ("VRBPAC"), which provides its assessment of the scientific data and their public health significance. FDA then makes a decision "based on its analysis of the benefits and risks for the intended population who will receive a vaccine."[20]

Pfizer's COVID-19 vaccine underwent FDA's rigorous authorization and approval process, and the agency has determined, in its expert judgment, that the vaccine's benefits outweigh its risks. Nevertheless, OAG asserts that it reviewed the regulatory framework for EUAs and licensing of vaccines, (Compl. ¶¶ 1–34), as well as Pfizer's clinical trial data and real-world evidence, (Compl. ¶¶ 35–124), and came to a very different conclusion: "Even by EUA standards, Pfizer's data was [sic] remarkably weak." (Compl. ¶ 119). In OAG's judgment, FDA "engage[ed]

[20] U.S. Dept. of Health & Human Servs., Food & Drug Admin., Vaccine Development – 101, Dec. 14, 2020, http://tinyurl.com/yc5jerkk.

in an artificial and flawed consideration and balance of Pfizer's vaccine's benefits and risks." (Compl. ¶ 144.) Put differently, this action is a thinly veiled attempt by a state attorney general office to usurp FDA's rightful statutory authority under federal law. This is improper.

Under the Supremacy Clause of the Constitution, "state laws that conflict with federal law are 'without effect.'" *Atria Grp., Inc. v. Good*, 555 U.S. 70, 76 (2008). OAG's lawsuit runs headlong into the doctrine of "conflict preemption," which applies when "there is an actual conflict between state and federal law," and the "state law 'stands as an obstacle to the accomplishment and execution of the full purpose and objectives of Congress.'" *Hillsborough Cnty., Fla. v. Automated Med. Lab'ys, Inc.*, 471 U.S. 707, 713 (1985). A state-law claim conflicts with the FDCA and is preempted if it would disturb "the federal statutory scheme . . . used by the [FDA] to achieve a somewhat delicate balance of statutory objectives." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001).

Plaintiffs "may not bring a state-law claim against a defendant when the state law claim is in substance (even if not in form) a claim for violating the FDCA." *Loreto v. Proctor & Gamble Co.*, 515 F. App'x 576, 579 (6th Cir. 2013). FDA's exclusive right to enforce the FDCA would be "thwarted if savvy plaintiffs can label as arising under a state law . . . a claim that in substance seeks to enforce the FDCA." *Id.*; *see also PDK Labs, Inc. v. Friedlander*, 103 F.3d 1105, 1113 (2d Cir. 1997) ("There can be no state law cause of action if a plaintiff's true goal" is to "enforce alleged violations of the FDCA."). In particular, state-law claims are preempted if they, in effect, allege an FDA-regulated product fails to meet the FDCA's requirements. *Exela Pharma Sciences, LLC v. Sandoz, Inc.*, 486 F. Supp. 3d 1001 (W.D.N.C. 2020); *see also Utts v. Bristol-Myers Squibb Co.*, 251 F. Supp.3d 644, 678 (S.D.N.Y. 2017) (state law claims that "challenge[] the FDA's approval . . . are preempted").

Exela is illustrative. There FDA permitted the defendant to import a lifesaving drug into the United States to address a critical drug shortage, and the plaintiff sued the defendant because the drug (1) had not satisfied the FDCA's criteria to market a new drug in the United States; and (2) contained, in plaintiff's estimation, unsafe levels of a contaminant. *Exela*, 486 F. Supp. 3d at 1009–10. According to the plaintiff, the importation and sale of defendant's unapproved, unsafe drug was "unfair" and violated North Carolina's Deceptive Trade Practices Act. *Id.* at 1013–14.

In dismissing plaintiff's state-law claim, the court articulated two conflict-preemption grounds that are relevant here. First, the court concluded the plaintiff's claim, in substance, challenged FDA's decision to permit defendant's unapproved drug to remain on the market. *Id.* at 1014. Because FDA has the exclusive authority to enforce the FDCA's requirements, preemption applied. *Id.* Second, the court recognized that FDA's decision "necessarily involved balancing the risks inherent in a drug shortage with the safety risks of allowing the importation and sale of an unapproved product." *Id.* Permitting plaintiff's state DTPA claim to proceed, the court reasoned, would thwart FDA's purpose and "disrupt the delicate and considered balance that the FDA struck." *Id.* at 1014–15. "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." *Id.* at 1015.

The complaint in this case is similar. Right from its opening sentence—"The COVID-19 vaccines are the miracle that wasn't"—the complaint contradicts FDA's conclusion concerning Pfizer's vaccine made after an extremely thorough review of the product. OAG purports to have undertaken an independent review of the available data and concluded they do not warrant an EUA or full approval under federal law. By doing so, OAG has invaded the very heartland of FDA's authority, attempting to substitute the Attorney General's views about the vaccine for the evidence-based determinations of FDA. While OAG may disagree with the agency, that office may not

"stand in the shoes of the FDA to determine whether [the] sale of [Pfizer's vaccine] amounts to the sale of an unapproved drug under the FDCA." *See id*. at 1014 (quotation omitted).

Were there any doubt that the complaint's state-law claims are a pretext for challenging federal regulatory and policy decisions, the complaint's central thesis dispels it. (*See* Compl. at 1–2.) OAG seeks to hold Pfizer liable because, as of November 14, 2020, the company reported that its COVID-19 vaccine showed 95% efficacy in the landmark study. (Compl. ¶¶ 44, 154–156.) OAG says this representation is misleading because it expresses the vaccine's efficacy in terms of relative risk reduction. (*Id*.) In OAG's judgment, absolute risk reduction is a better metric, and it allegedly shows the vaccine is less than 1% effective. (*Id*.) OAG ignores, however, that FDA itself uses the 95% relative risk reduction claim repeatedly when discussing the landmark study, including in the vaccine's licensing memorandum, the fact sheets provided to patients and physicians, and other communications with the public.[21]

Properly understood, OAG's complaint second guesses FDA's decision making with respect to Pfizer's vaccine and thereby serves as "an obstacle to the accomplishment and execution of the full purposes and objectives" of the agency. *See Hillsborough Cnty., Fla.*, 471 U.S. at 713. OAG's clear intrusion into the federal statutory scheme surrounding vaccine approval cries out for preemption of OAG's claims.

B. THE STATE FAILS TO PLEAD A VIOLATION OF TEXAS LAW.

Setting immunity and preemption to the side, the complaint fails for a more basic reason: it does not state a claim under the Texas DTPA. *See* Fed R. Civ. P. 12(b)(6). To establish a DTPA violation, the complaint alleges that Pfizer made "material misrepresentations" about the vaccine's

[21] *See supra* n.8; s*ee also* U.S. Dept. of Health & Human Servs., Food & Drug Admin., Q&A for Comirnaty, Aug. 23, 2021, https://tinyurl.com/byj7wun3 ("The vaccine was 95% effective in preventing COVID-19 disease among these clinical trial participants[.]").

efficacy, including that the product showed "95% efficacy" in the landmark study. According to OAG, Pfizer "ramped up its misleading campaign" after receiving preliminary clinical trial results in November 2020, and continued a "pervasive campaign of misrepresentation"—in media appearances, press releases, and tweets—throughout 2021. (Compl. ¶¶ 56, 146.)

The Court is required, for present purposes, to "assume the veracity" of these unfounded allegations. *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009). Even so, the purported "misrepresentations" in this case are not actionable under the DTPA. The statute prohibits "[f]alse, misleading, or deceptive acts or practices *in the conduct of any trade or commerce*." Tex. Bus. & Com. Code §17.46(a) (emphasis added). The statute further provides that it "shall be liberally construed and applied to promote its underlying purposes," which are to "*protect consumers* against false, misleading, and deceptive *business practices*, unconscionable actions, and breaches of warranty," as well as "provide efficient and economical procedures to secure such protection." *Id*. § 17.44 (emphasis added).

The DTPA may be "liberally construed," but it is not limitless, and Pfizer's public statements about the COVID-19 vaccine, one of the crowning achievements of Operation Warp Speed, are not within the DTPA's reach. As the complaint acknowledges, the federal government was the sole U.S. purchaser of the vaccine during 2020 and 2021—when Pfizer allegedly overstated the vaccine's benefits—and until very recently the federal government made the vaccine available, free of charge, to all people living in the United States. (Compl. ¶ 151.) For the reasons discussed below, this large-scale, federal effort to protect Americans during a national emergency by purchasing vaccines and giving them away for free is not "trade" or "commerce," nor are the Texas residents who chose to get vaccinated under these circumstances "consumers" within the meaning of the DTPA.

1. Pfizer's Statements Were Not Connected To Any "Trade Or Commerce."

"When interpreting a Texas statute," federal courts in the Fifth Circuit "use the same methods of statutory interpretation used by the Supreme Court of Texas." *CANarchy Craft Brewery Collective, LLC v. Tex. Alcoholic Beverage Comm'n*, 37 F.4th 1069, 1074 (5th Cir. 2022). Under Texas law, a court's "fundamental goal when reading statutes is to ascertain and give effect to the Legislature's intent." *Id*. In doing so, "the text is the alpha and the omega of the interpretive process." *BankDirect Cap. Fin., LLC v. Plasma Fab, LLC*, 519 S.W.3d 76, 86 (Tex. 2017). "If the text is unambiguous, we must take the Legislature at its word," and "the judge's inquiry is at an end." *Id*. Said another way, "[w]e must rely on the words of the statute, rather than re-write those words to achieve an unstated purpose." *Id*. at 87. "Separation of powers demands that judge-interpreters be sticklers." *Id*. at 86.

OAG has sued Pfizer for public statements that allegedly occurred (1) months after the United States contracted to purchase the company's vaccine, and (2) concurrent with a massive federal effort to provide COVID-19 vaccines to hundreds of millions of Americans at no cost. This federal government vaccination program was not "trade" or "commerce." The DTPA defines these terms, collectively, to mean "the advertising, offering for sale, sale, lease, or distribution of any good or service, of any property, tangible or intangible, real, personal, or mixed, and any other article, commodity, or thing of value, wherever situated[.]" Tex. Bus. & Com. Code § 17.45(6). This definition, read in the context of the DTPA as a whole, "makes it clear that 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) (quoting Tex. Tex. Bus. & Com. Code § 17.44). A free vaccine program is the latter, not the former.

The individual components of "trade or commerce" under the DTPA—"advertising," "sale," "lease," and "distribution"—reinforce that the statute regulates "business" transactions

where goods or services are exchanged for valuable consideration. *See* Tex. Bus. & Com. Code §§ 17.44 and 17.45(6). When faced with undefined statutory terms like these, the Court should apply their "common, ordinary meaning unless a more precise definition is apparent from the statutory context or the plain meaning yields an absurd result." *Camacho v. Ford Motor Co.*, 993 F.3d 308, 311 (5th Cir. 2021). Courts "typically look first to dictionary definitions" when determining the ordinary meaning of an undefined statutory term. *Fort Worth Transp. Auth. v. Rodriguez*, 547 S.W.3d 830, 838 (Tex. 2018).

"Advertising" means "drawing the public's attention to something to promote its *sale*." *Advertising*, Black's Law Dictionary (11th ed. 2019) (emphasis added). "Sale," in turn, means "[t]he transfer of property or title *for a price*." *Sale*, Black's Law Dictionary (11th ed. 2019) (emphasis added). "Lease" is similar; in the context of personal property, this term refers to a "contract by which the possessor . . . conveys the right to use that property *in exchange for consideration*." *Lease*, Black's Law Dictionary (11th ed. 2019) (emphasis added). Finally, "business" means "[a] commercial enterprise carried on *for profit*" or "that by which one earns a livelihood." *Business*, Black's Law Dictionary (11th ed. 2019) (emphasis added).[22]

The ordinary meanings of "trade" and "commerce" incorporate the same concept. "Trade" means "[t]he business of *buying and selling* or bartering goods or services." *Trade*, Black's Law

[22] "Distribution" also appears in the DTPA's definition of "trade or commerce." Tex. Bus. & Com. Code § 17.45(6). The ordinary meaning of this term may be broad enough to apply in both commercial and non-commercial settings. *See Distribution*, Black's Law Dictionary (11th ed. 2019) (defining "distribution" as "the act or process of apportioning or giving out"). Read in context, however, "distribution" carries a narrower meaning. *See Greater Houston Partnership v. Paxton*, 468 S.W.3d 51, 61 (Tex. 2015) ("The canon of statutory construction known as *noscitur a sociis*—'it is known by its associates'—holds that the meaning of a word or phrase, especially one in a list, should be known by the words immediately surrounding it."). Here, "distribution" appears in a list and the "words immediately surrounding it" all refer to commercial activities—advertising, selling, and leasing—meaning "distribution" too should be read as referring to a commercial activity. *See Paxton*, 468 S.W.3d at 61.

Dictionary (11th ed. 2019) (emphasis added). And "commerce" refers to the "*exchange* of good and services, esp. on a large scale involving transportation between cities, states, and countries." *Commerce*, Black's Law Dictionary (11th ed. 2019) (emphasis added).

All of these terms, read as an integrated whole, show the DTPA applies to private business transactions, not charitable endeavors or large-scale government programs to advance the public health. While the complaint identifies various statements that were, in OAG's view, "false, misleading or deceptive," Pfizer did not make these statements in connection with the sale of the vaccine. As previously discussed, the statements in question, which Pfizer allegedly made in 2020 and 2021, characterized the clinical data supporting the vaccine's efficacy. These public statements took place long after Pfizer contracted to provide hundreds of millions of doses to the federal government; the vaccine was not for sale to individual Texans. (Compl. ¶¶ 53, 151.) Because Pfizer's so-called "misrepresentations" in this case were disseminated to the general public—which received the vaccine for free—and not the federal officials who actually authorized and purchased the product, the alleged misstatements did not occur "in the conduct of any trade or commerce" and the complaint fails to state a DTPA claim.

2. Pfizer's Statements Were Not Connected To Any "Consumer Transaction."

The complaint also fails under Rule 12(b)(6) because OAG's allegations do not involve any Texas "consumers." "Despite [the DTPA's] broad, overlapping prohibitions, we must keep in mind why the Legislature created this simple, nontechnical cause of action: to protect consumers in consumer transactions." *Amstadt v. U.S. Brass Corp.*, 919 S.W.2d 644, 649 (Tex. 1996); *see also Morales*, 787 F. Supp. at 697 ("The purpose of the DTPA is to protect 'consumers' and no other class of persons.") For this reason, "the defendant's deceptive conduct must occur in connection with a consumer transaction" before liability may attach. *Amstadt*, 919 S.W2d at 649.

The DTPA defines "consumer" as "an individual, partnership, corporation, this state, or a subdivision or agency of this state who seeks or acquires *by purchase or lease*, any goods or services." Tex. Bus. & Com. Code § 17.45(4) (emphasis added). This "purchase or lease" requirement is indispensable. *See Morales*, 787 F. Supp. at 698 ("In order to be a consumer, one must purchase or seek to purchase goods or services."); *see also Rutherford v. Whataburger, Inc.*, 601 S.W.2d 441, 444 (Tex. Civ. App.—Dallas 1980, writ ref'd, n.r.e.) (plaintiff who won a contest, but never received his prize, was not a "consumer"). Moreover, when someone receives goods or services that were "provided gratuitously," the recipient is not a "consumer" of those goods and services. *See Rayford v. Maselli*, 73 S.W.3d 410, 411 (Tex. App.—Houston [1st Dist.] 2002, no writ) (inmate receiving free legal services from a government agency was not a "consumer").

In this case, OAG purports to act "in the public interest" because Pfizer allegedly caused "injury, loss, and damage" that "directly or indirectly affect[ed] the people of this State." (Compl. ¶ 8.) Specifically, OAG alleges that Pfizer's conduct "resulted in the public engaging in an artificial and flawed consideration and balancing of [the] vaccine's benefits and risks," and "[h]ad 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." (Compl. ¶ 144.) Pfizer disputes these allegations in the strongest possible terms. Regardless, these claims are not actionable under the DTPA because, during the time frame at issue in the complaint, the "people of this State" were not "consumers" of the vaccine. Texas residents who chose to get vaccinated in 2020 and 2021—the height of the pandemic—received a COVID-19 vaccine for free and often without the ability to choose which manufacturer's vaccine they received. These individuals did not "purchase or lease" Pfizer's vaccine and, accordingly, they were not involved in a "consumer transaction" giving rise to potential liability under Texas law.

Nor was the federal government's purchase of the vaccine a "consumer transaction" subject to the DTPA's "broad, overlapping prohibitions." *See Amstadt*, 919 S.W.2d at 649. The statute defines "consumer" to include "individual[s], partnership[s], corporation[s], this state, or a subdivision or agency of this state," but makes no mention of the United States and its subdivisions or agencies. Tex. Bus. & Com. Code § 17.45(4). OAG is asking this Court to re-write the statute to add a category of consumers that the Texas Legislature omitted, a practice that is clearly not permitted. *See Hogan v. Zoanni*, 627 S.W.3d 163, 169 (Tex. 2021) ("[W]e presume the Legislature chose statutory language deliberately and purposefully, and that it likewise excluded language deliberately and purposefully." (internal citations omitted)).

Finally, the "people of this State" cannot achieve "consumer" status as intended third party beneficiaries of Operation Warp Speed. *Cf. Kennedy v. Sale*, 689 S.W.2d 890, 892 (Tex. 1985) (individual deemed "consumer" under the DTPA where the relevant purchase was specifically "consummated for his benefit" by another consumer). While true "intended beneficiaries" may sometimes qualify as "consumers," the Fifth Circuit has held a mere "incidental beneficiary" of a purchase is "not a consumer under the Act and lacks standing to invoke the DTPA." *Chamrod v. Volvo Cars of North Am.*, 145 F.3d 671, 673 (5th Cir. 1998).

When, as here, a government action is "intended generally to benefit the people of this state," "general beneficence does not create third-party rights." *South Tex. Water Auth. v. Lomas*, 223 S.W.3d 304, 307 (Tex. 2007); *see also Duque v. Wells Fargo. N.A.*, 462 S.W.3d 542, 550 (Tex. App.—Houston [1st Dist.] 2015) (consent judgment negotiated by government entities "no doubt benefits the general public," but individual members of the public remain "incidental beneficiaries" under the settlement); Restatement (Second) of Contracts § 313 cmt. a

("Government contracts often benefit the public, but individual members of the public are treated as incidental beneficiaries unless a different intention is manifested.").

Because Texas residents who received free COVID-19 vaccines in 2020 and 2021 did not "purchase or lease" those vaccines; because the same individuals are, at best, incidental beneficiaries of Operation Warp Speed; and because the Texas Legislature omitted the federal government from the DTPA's definition of "consumer," the complaint fails to identify any "consumer transaction" subject to regulation under the DTPA. Dismissal is required.

3. The State's Allegations Are Implausible.

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Iqbal,* 556 U.S. at 678 (quoting *Bell Atlantic Corp. v. Twombly,* 550 U.S. 555, 570 (2007)). The complaint here comes nowhere close. Its essential allegation is that Pfizer's vaccine was ineffective, (Compl. ¶ 45), and also presented "significant safety concerns," (Compl. ¶ 142). But FDA's unbroken chain of approvals for the vaccine, along with the federal government's numerous public statements endorsing the product's benefit-risk profile, reveal that OAG's allegations do not "raise a right to relief above a speculative level." *See Twombly*, 550 U.S. at 555. Neither does the assertion that Pfizer "intimidated and silenced" vaccine skeptics, (Compl. ¶¶ 125–138), purportedly by alerting social media companies to misinformation on their websites. *See Iqbal*, 556 U.S. at 678–79 (when deciding a motion to dismiss, a court must "draw on its judicial experience and common sense" and need not "accept as true a legal conclusion couched as a factual allegation"). Measured against the *Twombly/Iqbal* standards, OAG's complaint falls short and fails to state a DTPA claim.

CONCLUSION

For all of these reasons, the Court should dismiss the Attorney General's lawsuit, with prejudice, under Federal Rule of Civil Procedure 12(b)(6).

Dated: March 25, 2024

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on March 25, 2024 a copy of the foregoing document was served via the Court's electronic filing system on all counsel of record.

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