

No. 25-10182

**In the United States Court of Appeals
for the Fifth Circuit**

STATE OF TEXAS,
Plaintiff-Appellant,

v.

PFIZER, INC.,
Defendant-Appellee.

On Appeal from the United States District Court
for the Northern District of Texas, Lubbock Division

APPELLANT'S BRIEF

KEN PAXTON
Attorney General of Texas

BRENT WEBSTER
First Assistant Attorney General

RALPH MOLINA
Deputy First Assistant Attorney General

AUSTIN KINGHORN
Deputy Attorney General for Civil Litigation

JOHNATHAN STONE
Chief, Consumer Protection Division

ABIGAIL E. SMITH
Assistant Attorney General
Texas Bar No. 24141756
Abby.Smith@oag.texas.gov

Office of the Texas Attorney General
Consumer Protection Division
12221 Merit Drive, Suite 650
Dallas, Texas 75251
Phone: 214-290-8830
Fax: (214) 969-7615

Counsel for Plaintiff-Appellant

CERTIFICATE OF INTERESTED PERSONS

No. 25-10182

STATE OF TEXAS,
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Under the fourth sentence of Fifth Circuit Rule 28.2.1, Appellant, as a governmental party, need not furnish a certificate of interested persons.

/s/ Abigail E. Smith
ABIGAIL E. SMITH
Assistant Attorney General
Counsel for Plaintiff-Appellant

STATEMENT REGARDING ORAL ARGUMENT

Appellant requests oral argument. After declining to hold a hearing, the district court issued a one-page order ruling without explanation that the State's DTPA claims against Pfizer, Inc. ("Pfizer") were preempted, barred by immunity, and not adequately pled. This ruling ran counter to several established precedents, including from this Court, and if allowed to stand would bar the Attorney General from protecting Texas consumers from extremely misleading statements. Appellant believes that oral argument will assist the Court in resolving these legal issues.

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INTRODUCTION

Capitalizing on Americans’ fear of the unknown in the early days of the COVID-19 pandemic, Pfizer in 2021 touted its new vaccine as a miracle cure. The U.S. Food and Drug Administration (FDA) had just granted Pfizer an emergency use authorization for its vaccine in December 2020—a regulatory action the State of Texas does not challenge. But when FDA granted that authorization, it did so with several important caveats. First, at the time, it was “not possible” to know how effective the vaccine was beyond two months, because Pfizer had only two months of clinical data on infection rates after vaccination. ROA.56 ¶ 49.A (State’s Original Pet’n). Second, FDA made clear that Pfizer “needed” additional evidence to prove its vaccine protected against “virus shedding and transmission” of COVID-19 to others. *Id.* ¶ 49.C. Lastly, Pfizer’s clinical trial assessed its vaccine’s efficacy against the original strain of the virus only, not against mutations such as the more potent Delta strain. *Id.* ¶ 84.

Yet within weeks, Pfizer’s CEO, Albert Bourla, went on major news networks promoting that the company’s vaccine possessed the very qualities FDA told Pfizer it had not shown. Texans heard that “at 6 months, the protection [of the Pfizer vaccine] is robust”—despite Pfizer only having 2 months of data. *Id.* ¶ 76. Texans heard that getting the Pfizer vaccine prevented transmission and that vaccination was necessary to protect “the people you love most”—despite Pfizer lacking any data on the subject. *Id.* ¶ 67. And Texans heard Pfizer’s CEO publicly insist that the company’s vaccine was “very, very, very effective against Delta”—despite Pfizer having little to no clinical data on the Delta variant. *Id.* ¶ 88.D.

Perhaps worst of all, though, was Pfizer's trademark marketing line: That its vaccine was "95% effective." That claim was highly misleading from the jump. It represented a calculation of so-called "relative risk reduction" for vaccinated individuals in Pfizer's then-unfinished two-month clinical trial. But FDA finds that statistic misleading and prefers drug manufacturers to advertise *absolute* risk reduction: The *actual decrease* in risk between getting a treatment or not. Pfizer's clinical trial showed *absolute* risk reduction of only 0.85%. ROA.55 ¶ 45. In other words, the Pfizer vaccine reduced a person's risk of getting COVID-19 by less than one percent. All of Pfizer's many misrepresentations to the public failed to mention this.

It is now beyond cavil that Pfizer's unsubstantiated claims turned out to be false. Countless vaccine recipients contracted COVID, many died, and at least some data shows that some vaccinated individuals experienced worse outcomes. *Id.* ¶ 114–15. But when scientists, including a former FDA chief, tried to push back, Pfizer engaged in a scheme to censor those individuals—all to gain and maintain market share for a vaccine that earned it tens of billions of dollars in profit. This misrepresentation and censorship scheme was misleading and deceptive, and harmed Texans. Such deceptive actions are bread-and-butter violations of the Texas Deceptive Trade Practices Act (DTPA) and not subject to dismissal on the pleadings.

Nonetheless, Pfizer filed a motion to dismiss that portrayed the State's lawsuit as something that it is not, namely: A challenge to FDA's regulatory decision to approve Pfizer's vaccine. Yet the State's complaint raises no objection to FDA's approval of Pfizer's vaccine, and in fact *agrees* with the agency's official stance in several important respects, such as the deceptive nature of Pfizer's relative risk

reduction statistic and Pfizer's lack of clinical evidence for many of its public statements. Pfizer also argued that the Public Readiness and Emergency Preparedness (PREP) Act and Federal Food, Drug, and Cosmetic Act (FDCA) preempt the State's claims. But that argument also rests on the false premise that Texas challenges the FDA's approval decision, rather than Pfizer's false public claims.

After letting Pfizer's motion to dismiss sit on its docket for over nine months, however, the district court dismissed the State's case in a one-page order, essentially without explanation or comment. That order was wrong. The PREP Act preempts only state laws "different from, or in conflict with" federal law, and federal law explicitly "made it illegal 'for any[one] to engage in a deceptive act or practice in or affecting commerce . . . associated with the treatment, cure, prevention, mitigation, or diagnosis of covid-19.'" *FTC v. Romero*, 2022 WL 4095424, at *4 (M.D. Fla. June 29, 2022) (citation omitted). Far from being "different from, or in conflict with" federal law, the State's DTPA claims *mirror* federal law. Similarly, Pfizer's argument that the FDCA preempts the DTPA claims fails because Congress intentionally crafted the FDCA to *not* preempt deception claims against drug manufacturers. *See, e.g., Wyeth v. Levine*, 555 U.S. 555, 574 (2009) (Congress "determined that widely available state rights of action provided appropriate relief for" drug manufacturers' wrongdoings). Pfizer's view that the PREP Act provides immunity against State DTPA claims is also misplaced, because the PREP Act's "immunity" provision extends only to personal injury "claims for loss" based on vaccine administration, not deceptive marketing *parens patriae* claims brought by a sovereign. The Court thus should reverse and remand for further proceedings.

STATEMENT OF JURISDICTION

This Court has jurisdiction under 28 U.S.C. § 1291 because this is an appeal from a final decision of the district court. ROA.842–43. The district court exercised jurisdiction under 28 U.S.C. §§ 1331, 1441, and 1442(a)(1), and issued a final judgment on December 20, 2024. ROA.10. The State timely appealed on January 8, 2025.

ISSUES PRESENTED

1. Whether the Public Readiness and Emergency Preparedness (PREP) Act and Federal Food, Drug, and Cosmetic Act (FDCA) preempt the State’s Texas Deceptive Trade Act (DTPA) claims for misleading and deceptive marketing claims regarding Pfizer’s COVID-19 vaccine;
2. Whether the PREP Act grants Pfizer immunity for DTPA claims based on misleading and deceptive marketing regarding Pfizer’s COVID-19 vaccine;
3. Whether the State adequately pled its DTPA claims.

STATEMENT OF THE CASE

A. The Texas Deceptive Trade Practices Act (DTPA)

The DTPA protects Texas consumers by prohibiting “[f]alse, misleading, or deceptive acts or practices in the conduct of any trade or commerce.” Tex. Bus. & Com. Code § 17.46(a) (hereinafter DTPA § 17.46(a)). Deceptive trade practices are defined broadly to include, among other things, “representing that goods or services have . . . uses, [or] benefits” “which they do not have,” *id.* § 17.46(b)(5); inducing consumers to enter transactions by “failing to disclose information concerning goods or services which was known at the time of the transaction,” *id.* § 17.46(b)(24); and “representing that goods or services are of a particular standard, [or] quality” if they

are not of such standard or quality, *id.* § 17.46(b)(7). By statute, these categories “shall be liberally construed.” *Id.* § 17.44(a); *accord Weitzel v. Barnes*, 691 S.W.2d 598, 600 (Tex. 1985) (the DTPA’s “broad guidelines” must be “liberally construed to protect consumers from deceptive business practices”).

The Texas Attorney General—through the Consumer Protection Division—has *parens patriae* authority to enforce the DTPA whenever it “has reason to believe” unlawful conduct is occurring. DTPA § 17.47(a). The Division can seek injunctive relief, *id.* § 17.47(a); civil penalties up to “\$10,000 per violation,” *id.* § 17.47(c); and restitution and disgorgement, *id.* § 17.47(d). When the Division brings an enforcement action, it “acts in the name of the State and does not” represent any individual injured person(s). *Id.* § 17.47(h).

B. The Federal Regulatory Framework for Drugs and Biologics

FDA must approve any new drug prior to that product’s commercialization. 21 U.S.C. § 355 (drugs); 42 U.S.C. § 262 (biologics); *accord* ROA.44 ¶ 10 n.1 (defining biologics). FDA also has authority to issue an “Emergency Use Authorization” (EUA), which is not a formal approval, but which nevertheless allows a drug product to come to market if the Secretary of Health and Human Services declares an emergency. 21 U.S.C. § 360bbb-3.

Approval Standards: Ordinarily, FDA “shall” deny approval if “there is a lack of substantial evidence that the drug *will have* the effect it purports or is represented to have.” 21 U.S.C. § 355(d)(5) (emphasis added). But the EUA process is laxer. For EUAs, FDA may grant authorization if the product “*may* be effective.” *Id.* § 360bbb-3(c)(2)(A) (emphasis added). In FDA’s own words, the EUA process “provides for

a lower level of evidence” of “effectiveness,” ROA.45 ¶ 13. (quoting FDA published guidance), and the agency recognizes it grants EUAs based on incomplete information. *Id.* ¶¶ 13–19.

Clinical testing: Generally, after obtaining preliminary sign-off from FDA, drug manufacturers initiate lengthy “clinical testing” “for safety and effectiveness.” *Abigail All. for Better Access to Developmental Drugs v. von Eschenbach*, 495 F.3d 695, 698 (D.C. Cir. 2007) (en banc). In a nutshell, this consists of phased testing on humans in order to measure a drug’s safety and effectiveness. *See id.*; ROA.46 ¶ 16 (describing phases in detail). This is an arduous, time-consuming process—at least one study showed new drug development takes on average over eight years to complete. *Id.* ¶ 17. By contrast, FDA subjects EUAs to materially different standards. For example, the agency does not require “adequate and well-controlled clinical trials”; rather, as part of FDA’s overall more *ad hoc* and less formalized process, clinical data need only be submitted “if available,” 21 U.S.C. § 360bbb-3(c)(2).

For these reasons and more, Congress has understood that EUAs will have inferior guarantees of safety and efficacy compared to formally approved drugs. ROA.45 ¶ 14. Accordingly, Congress mandated that FDA directly inform health care providers of any “significant known and potential benefits and risks” of EUA products. 21 U.S.C. § 360bbb-3(e)(1)(A)(II). Similarly, and unlike with formal approvals, Congress directed FDA to provide individuals receiving an EUA product the same information. *Id.* § 360bbb-3(e)(1)(A)(II).

Prohibitions on Misleading Marketing: Federal law contains several prohibitions on misleading marketing that apply to drug products. For example, it prohibits

“misbrand[ing],” *id.* § 331(c), which includes misleading labeling, as well as misleading “advertising,” *id.* § 331(n). The determination of whether a representation is misleading must take account of whether the manufacturer “fails to reveal material in light of representations” expressly made. *Id.* Additionally, the Federal Trade Commission (FTC) Act prohibits deceptive behavior in commerce generally. 15 U.S.C. § 45. And, critically here, the federal Covid-19 Consumer Protection Act expressly made the FTC Act’s ban on deceptive conduct applicable to *any* representations “associated with the treatment, cure, prevention, mitigation, or diagnosis of covid-19.” Public Law 116-260, 134 Stat. 1182, Title XIV, Section 1401(b)(1). Texas law functionally mirrors these prohibitions on misleading marketing. *See* ROA.48 ¶ 24. Indeed, Texas’s statutory bar on deceptive conduct specifically incorporates the FTC Act. DTPA § 17.46(a).

C. Pfizer’s Limited Emergency Use Authorization

On November 20, 2020, Pfizer submitted an EUA request for its COVID-19 vaccine. ROA.52–53 ¶ 38.¹ That application relied principally on “safety and efficacy data from an ongoing” Phase 3 clinical trial. *Id.* As alleged in the complaint, the specifics of that trial are germane to this proceeding because Pfizer went on to misrepresent its vaccine’s efficacy in ways contrary to the trial’s findings. *Id.* ¶¶ 38–39.

Pfizer’s Study Design & Protocol: Pfizer’s clinical trial enrolled over 40,000 people randomly divided into similarly sized placebo and treatment groups, with

¹ The Complaint below relied on and incorporated by reference FDA’s Pfizer EUA. *See* FDA, *Emergency Use Authorization (EUA) for an Unapproved Product Review Memorandum* (Dec. 11, 2020), <https://www.fda.gov/media/144416/download>.

participants receiving “2 doses of either [the vaccine] or placebo, 21 days apart.” ROA.53 ¶ 39. The study was designed to test for “primary efficacy endpoints.” *Id.* ¶ 40. As relevant here, the first primary efficacy endpoint sought to measure the number of COVID-19 infections seven days after the second dose, among participants who had *not* been infected previously. *Id.* The trial’s definition of a COVID-19 case was not intuitive: If someone tested positive for COVID-19, that alone was *not* considered a COVID-19 case. *Id.* ¶ 42. Instead, to be considered a COVID-19 case, the positive test had to be accompanied by specific symptoms of infection. *Id.* (discussing study’s criteria for a “Defined COVID-19 Case”).

Pfizer’s Initial Results: In its EUA application, Pfizer submitted clinical trial data through November 14, 2020. *Id.* ¶ 44. At that point, Pfizer’s data was highly time limited—only 43.9% of vaccine recipients had completed even two months of post-vaccination follow-up. *Id.* ¶ 43. The data showed that of 17,411 participants who received the vaccine and did not have evidence of a prior infection, 8 people (0.04%) met the study’s criteria for a COVID-19 infection. *Id.* ¶¶ 42, 44. On the other hand, out of the 17,511 participants who received the placebo and who lacked evidence of a prior infection, 162 participants (0.9%) met the relevant study criteria. *Id.* This is the genesis of Pfizer’s “95% effective” statistic—the difference in likelihood of a Defined COVID-19 Case based on 8 occurrences versus 162. *Id.* As explained *infra* at 10–12, this was a *caveat-laden* statistic, and one that did not support what Pfizer was telling the public. ROA.54–56 ¶¶ 44–48.

FDA’s Explicitly Limited Findings: On December 11, 2020, FDA concluded that Pfizer’s data was adequate to support an EUA grant. *Id.* ¶ 48. FDA, however,

also expressly concluded that Pfizer’s results *did not* support making statements on several important efficacy dimensions relevant to Pfizer’s subsequent misrepresentations. First, FDA stated that based on the study’s results, “it is *not possible* to assess sustained efficacy [for Pfizer’s vaccine] over a period longer than 2 months.” *Id.* ¶ 49(A). And second, “[a]dditional evaluations . . . will be needed to assess the effect of the vaccine in preventing virus shedding and transmission,” in particular “the effect . . . against asymptomatic infection” on account of “limited” data. *Id.* ¶ 49(B)–(C). FDA recognized that Pfizer’s results were peculiar in other ways too. *See id.* ¶ 47 (noting how, between the first and second dose, more *vaccinated* persons contracted COVID-19 than unvaccinated persons).

D. The Complaint’s Factual Allegations About Pfizer’s Serial Misrepresentations Concerning its COVID-19 Vaccine

Notwithstanding the limited nature of Pfizer’s clinical trial data and scope of FDA’s EUA, Pfizer rapidly began making material misrepresentations about the vaccine in an attempt to gain market share and earn profits that would justify the enormous financial and reputational risk Pfizer took in developing a COVID-19 vaccine. ROA.58–68 ¶¶ 54–91. The State’s complaint alleges in great detail how Pfizer made four different types of misrepresentations in a successful attempt to mislead the public about the efficacy of its vaccine, in violation of DTPA sections 17.46(b)(5) (representing a product has a use or benefit that it lacks), (7) (representing a product is of a particularly quality when it is not), and (24) (failing to disclose material information known at the time of a transaction). The complaint additionally pleads a fifth claim that Pfizer engaged in a scheme to conceal its vaccine’s underperformance by

censoring critics, in violation of DTPA section 17.46(b)(8) (disparaging another by false or misleading representation of facts).

“95% effective”: From at least December 2020 and throughout 2021, Pfizer repeatedly issued press and other public statements touting the vaccine’s alleged “95%” efficacy. ROA.58–60 ¶¶ 56–62. The media mimicked these representations, disseminating Pfizer’s falsehoods over the globe. *Id.* ¶¶ 63–65. As is now well-known, the 95% efficacy statistic bore no resemblance to reality. *Id.* ¶¶ 94, 105–09. And, as alleged in detail in the State’s complaint, these representations were false, misleading, or deceptive *when made* in at least two ways.

First, Pfizer’s 95% efficacy representation was misleading because it relied on a flawed method of expressing a drug’s efficacy known as “relative risk reduction.” *Id.* ¶¶ 44, 25–34 (explaining that experts consider relative risk reduction statistics “meaningless and misleading”). FDA itself has explained in public guidance to industry that the statistic is often misleading because “[w]hen information is presented” in a “relative risk format,” the ostensible “reduction *seems* large and treatments are viewed more favorably” than warranted. *Id.* ¶¶ 25–31.² For example, if a drug changes risk from two deaths per 100 people to one death per 100 people, the drug’s relative risk reduction is 50% (half as many deaths), but the *actual* risk reduction is just 1% (one fewer person will die out of one hundred). Stadel et al., *Misleading*

² FDA, *Communicating Risks and Benefits: An Evidence-Based User’s Guide* 56 (2011), <https://www.fda.gov/about-fda/reports/communicating-risks-and-benefits-evidence-based-users-guide> (FDA Risk Guidance).

use of risk ratios, 365 *The Lancet* 1306–07 (Apr. 9, 2005) (incorporated into the complaint by reference at ¶ 31).

A host of scientific literature corroborates the propensity for the statistic to be “misused” by manufacturers to “exaggerate” a drug’s benefits. ROA.50–51 ¶¶ 31, 34. And the overwhelming majority of pharmaceutical companies heed that advice, unlike Pfizer. A study by Yale Law and Medicine researchers found that in a sample size of 97 consumer advertisements for prescription drugs, *only one* presented “relative risk reduction” alone to convey efficacy.³

For these reasons, FDA’s official guidance instructs drug manufacturers and industry participants to “[p]rovide *absolute* risks, not just relative risks.” when describing efficacy. ROA.51 ¶ 31 (FDA Guidance at 56) (emphasis added)). Pfizer’s own data showed that the *absolute* risk reduction from its vaccine was *less than one percent*, *id.* ¶ 45, and that it was necessary to treat 119 people to prevent a single Defined COVID-19 Case, *id.* ¶ 46. Central to understanding these enormous discrepancies and their significance is the fact that very few participants in *either* the placebo *or* treatment groups actually contracted COVID-19 (as defined by the study). *Id.* ¶ 45. But Pfizer never said a word about absolute risk reduction to the public.

Second, Pfizer’s representations about 95% efficacy were deceptive because Pfizer presented them to the public in a manner materially different from how it

³ See Kristina Klara et al., *Direct-to-Consumer Broadcast Advertisements for Pharmaceuticals: Off-Label Promotion and Adherence to FDA Guidelines*, J. GEN. INTERN. MED. 651 (May 2018), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5910340/>.

measured efficacy in the clinical trial. For example, in public Pfizer touted the vaccine as “more than 90% effective in *preventing* COVID-19 in participants.” ROA.58–59 ¶ 56 (emphasis added). However, that is not what the trial measured. *Supra* at 8. Rather, Pfizer’s study was designed to count only participants who tested positive *and* showed certain symptoms. ROA.54 ¶ 42.

Transmission: Pfizer also used deceptive and misleading tactics to create a public culture of fear and shame by convincing people that their own vaccination status would “affect the lives of others,” including “people you love the most.” ROA.61 ¶ 67; *see also id.* ¶¶ 66–72. Specifically, Pfizer represented to the public that “[w]idespread vaccination is a critical tool to help stop transmission.” *Id.* ¶ 69. But Pfizer’s clinical trial did not support this representation. After all, FDA recognized that “[a]dditional evaluations” would “be needed to assess the effect of the vaccine in preventing virus shedding and transmission.” *Id.* ¶ 49.D. Pfizer’s clinical trial simply was not designed to test for protection against transmission (or asymptomatic illness). *Id.* ¶ 42. Indeed, even when Pfizer obtained its formal vaccine approval in August 2021, FDA recognized that there were *still* no reliable indicators that the vaccine protected against “asymptomatic infection and transmissibility of the virus.” *Id.* ¶ 96. Moreover, significant public studies suggested that the vaccine did not protect against transmission at all. *Id.* ¶¶ 103–04.

Durability: Pfizer also made a series of misrepresentations about the vaccine’s durability of protection. ROA.62–65 ¶¶ 73–82. For example, in February 2021, Pfizer claimed that “at 6 months [from vaccination,] the protection is robust.” *Id.* ¶ 76. This was false. In February 2021, Pfizer did not even *have* 6 months of post-

vaccination trial data. *Id.* ¶ 43 (mid-November 2020, Pfizer barely had two months of follow-up data). And FDA told Pfizer that “it [wa]s *not possible*” based on Pfizer’s then-existing data “to assess sustained efficacy over a period longer than 2 months.” *Id.* ¶ 49. Then, in March 2021, Pfizer’s own ongoing trial results revealed substantial waning efficacy. *Id.* ¶¶ 80, 94. But Pfizer withheld these results from the public until late July 2021. *Id.* ¶ 80. Global studies also revealed that the vaccine rapidly lost efficacy within mere months of the second shot. *Id.* ¶¶ 105–09. Nevertheless—and despite having actual knowledge of waning efficacy—Pfizer issued a series of deceptive statements to create the impression that durability was long-lasting, *id.* ¶¶ 77–79; and the press repeated these statements, *id.* ¶¶ 81–82.

Protection against variants: Pfizer also made a host of misrepresentations about whether its vaccine would protect against COVID variants. ROA.65–68 ¶¶ 83–91. Pfizer’s clinical trial did not evaluate efficacy against any variants. *Id.* ¶ 95 (FDA recognizing this). But that was a major problem for Pfizer because, shortly after its EUA grant, multiple variants—including the notorious Delta variant—quickly overtook the original virus as the predominant cause of COVID. *Id.* ¶ 83. Instead of admitting that it did not, and could not, know whether its vaccine was effective against Delta, Pfizer told the public in spring and summer 2021 that its vaccine was “very effective, around 90%” against Delta, and that it was “very, very, very effective against Delta.” *Id.* ¶ 88.

These misrepresentations were particularly egregious in light of the actual facts. Pfizer’s entire clinical trial was conducted prior to Delta’s emergence. *Id.* ¶ 95. For that reason, FDA recognized there was no telling whether Pfizer’s vaccine possessed

“effectiveness against SARS-CoV-2 variants” like Delta. *Id.* Indeed, even as late as September 2021, Pfizer’s data about Delta was limited to an “exploratory” data set of only twenty-three people that FDA characterized as “very limited.” *Id.* ¶ 121. Meanwhile, public studies suggested that the vaccine had little to *negative* effect against the Delta variants. *Id.* ¶¶ 110–16. Data from the U.K. and Scotland, for example, showed that during Delta a greater percentage of vaccinated were dying from COVID than unvaccinated. *Id.* ¶¶ 114–16.

Censorship: Finally, Pfizer engaged in a coordinated campaign to censor and intimidate critics of its vaccine. ROA.78–82 ¶¶ 125–38. Pfizer had unique access to prominent social media companies, and used that access to demand that the companies censor prominent scientists and other stakeholders who raised reasonable and fact-based questions about its vaccine’s efficacy. For example, Pfizer feared that former FDA Director Brett Giroir’s belief in natural immunity would “driv[e] news coverage” and be “corrosive” to the public confidence in Pfizer’s vaccine. *Id.* ¶¶ 132–33.

Pfizer thus encouraged social media companies to censor Giroir and others. *Id.* ¶ 133. For example, Dr. Scott Gottlieb, the leader of Pfizer’s regulatory and compliance committee, leveraged his contacts at Twitter to flag Giroir’s tweets as “misleading.” *Id.* ¶¶ 133–34. Gottlieb also persuaded Twitter to suspend the account of Alex Berenson, a journalist with hundreds of thousands of followers, by claiming he was a “conspiracy theorist”—despite many of Berenson’s claims being true at the time they were made and corroborated by subsequent data and analysis. *Id.* ¶ 125–31.

E. Procedural History

On November 30, 2023, the State filed its Original Petition against Pfizer in the 99th District Court – Lubbock County, alleging violations of the DTPA. ROA.38. On December 28, 2023, Pfizer removed the case to the Northern District of Texas, Lubbock Division. ROA.10. On March 25, 2024, Pfizer filed its motion to dismiss under Rule 12(b)(6), making three arguments: first, that Pfizer had PREP Act immunity against any claims based on its vaccine; second, that the PREP Act and the FDCA preempted the State’s claims; and third, that the State failed to plead a DTPA claim. ¶ROA.250.

After sitting on the motion for over nine months, on December 20, 2024, the district court issued a two-page order granting Pfizer’s motion to dismiss. ROA.842. The order ruled for Pfizer on all grounds, stating that Pfizer was “entitled to immunity” under the PREP Act, that the PREP Act and FDCA preempted the State’s claims, and that the State failed to adequately plead a DTPA claim. *Id.* The State timely appealed.

SUMMARY OF ARGUMENT

I. The State’s DTPA claims against Pfizer are not preempted. The PREP Act’s preemption provision applies only to state laws that are “different from, or in conflict with, any requirement applicable” under that statute. 42 U.S.C. § 247d-6d(b)(8)(A). But the relevant PREP Act provision was modeled after section 5(a) of the FTC Act (FTCA). *FTC v. Romero*, 2022 WL 4095424, at *4 (M.D. Fla. June 29, 2022). The DTPA likewise expressly references FTCA section 5 and directs courts to construe the DTPA and FTCA harmoniously. DTPA § 17.46(c)(1). The DTPA

thus “mirrors federal law” in this regard, *Zyla Life Scis., L.L.C. v. Wells Pharma of Houston, L.L.C.*, No. 23-20533, 2025 WL 1076889, at *4 (5th Cir. Apr. 10, 2025). (quoting *Asbell v. Kansas*, 209 U.S. 251, 258 (1908)), and is not “different from, or in conflict with” the PREP Act.

The FDCA also does not preempt the State’s DTPA claims—indeed, the Supreme Court has held that there is “no merit” to the “argument” that the FDCA generally preempts state law claims. *Wyeth v. Levine*, 555 U.S. 555, 573 (2009). Contrary to Pfizer’s arguments below, the State’s DTPA claims do not second-guess or question the FDA’s authority to grant limited EUA approval to Pfizer’s COVID-19 vaccine—rather, the State’s claims allege that Pfizer made gross misrepresentations to the public about specific aspects of its vaccine’s performance, and those are not preempted. *Louisiana v. Pfizer, Inc.*, No. 3:13-CV-00727-BAJ-RL, 2014 WL 3541057, at *7 n.3 (M.D. La. July 17, 2014).

II. The PREP Act does not immunize Pfizer from the State’s DTPA claims because the PREP Act immunity provision applies only to claims for “loss” (physical harm or mental anguish) resulting from the “administration . . . of a covered countermeasure” (such as injection of a vaccine) to an “individual.” 47 U.S.C. § 247d-6d(a)(1). But the State’s DTPA claims satisfy none of those three requirements for immunity. The State’s claims are not for specific ailments or physical harm, because under the DTPA the State does not need to prove “loss” at all; it must merely prove that Pfizer engaged in any false, misleading, or deceptive conduct in trade or commerce, and that suing Pfizer “would be in the public interest.” DTPA § 17.47(a). The State’s claims are also not based on harm suffered by an individual from

receiving the vaccine—rather, the State is acting in its *parens patriae* capacity to enforce its consumer protection statutes on behalf of the public interest of Texans. *Hood ex rel. Mississippi v. JP Morgan Chase*, 737 F.3d 78, 81 (5th Cir. 2013). Furthermore, if this Court adopts Pfizer’s interpretation, it would lead to absurd results, such as barring even the FDA from suing Pfizer for making demonstrably false claims, such as that its COVID-19 vaccine cured cancer.

III. The State adequately pled its DTPA claims. Pfizer’s misrepresentations impacted “trade or commerce,” regardless of whether they were provided for free, because Texas courts have held that “transfer of valuable consideration is not necessary” for the State to plead a DTPA claim. *Mother & Unborn Baby Care of N. Texas, Inc. v. State*, 749 S.W.2d 533, 538 (Tex. App. 1988), *writ denied* (Nov. 16, 1988). Nor does it matter that Pfizer sold its vaccine to the U.S. government, instead of directly to consumers; the Texas Supreme Court has held that “[p]rivacy between the plaintiff and defendant is not a consideration” in DTPA lawsuit. *Flenniken v. Longview Bank & Tr. Co.*, 661 S.W.2d 705, 707 (Tex. 1983). It is also irrelevant whether Pfizer’s misrepresentations were related to a “consumer transaction,” because that DTPA requirement applies only to suits brought by individuals—it does not apply to Attorney General lawsuits brought in the public interest. *Household Retail Servs., Inc. v. State*, No. 04-00-00734-CV, 2001 WL 984779, at *3 n.4 (Tex. App. Aug. 29, 2001) (emphasis added) (comparing DTPA § 17.50 (consumer lawsuits) to DTPA §§ 17.46(a), 17.47(a) (Attorney General lawsuits)).

STANDARD OF REVIEW

The dismissal of a case for failure to state a claim under Rule 12(b)(6) is reviewed *de novo*. *McKay v. LaCroix*, 117 F.4th 741, 746 (5th Cir. 2024). In determining whether to grant a motion to dismiss, the court must “accept as true all well-pleaded facts and construe the complaint in the light most favorable to the plaintiff.” *Sw. Airlines Pilots Ass’n v. Sw. Airlines Co.*, 120 F.4th 474, 482 (5th Cir. 2024) (citation omitted).

ARGUMENT

I. The State’s Claims Are Not Preempted.

It is well-established that in pharmaceutical regulation, “Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness,” *Merck Sharp & Dohme Corp. v. Albright*, 587 U.S. 299, 311 (2019), and that “Congress has repeatedly declined to pre-empt state law,” *Wyeth v. Levine*, 555 U.S. 555, 581 (2009). State law commonly provides a valid cause of action against products regardless of whether they are FDA-approved. *See Medtronic v. Lohr*, 518 U.S. 470 (1996). Nothing about the PREP Act or the FDCA changes that here.

A. Congress does not lightly preempt State law.

At the outset, “[i]n all pre-emption cases,” *Wyeth*, 555 U.S. at 565, courts should “start with the assumption that the historic police powers of the States were not to be superseded ... unless that was the clear and manifest purpose of Congress,” *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). The requirement that Congress speak clearly before courts may find preemption, moreover, has special force for regulations of medicine, which is “a field which the States have traditionally

occupied.” *Wyeth*, 555 U.S. at 565 (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996), in turn quoting *Rice*, 331 U.S. at 230)).

This bedrock presumption against preemption reflects the reality that both the federal governments and the States are sovereign, and that the Constitution protects State authority. “In our federal system, the National Government possesses only limited powers; the States and the people retain the remainder,” including (as relevant here) the “broad authority to enact legislation for the public good—what [the Supreme Court] ha[s] often called a ‘police power.’” *Bond v. United States*, 572 U.S. 844, 854 (2014). By contrast, the federal government “has no such authority and ‘can exercise only the powers granted to it.’” *Id.* (quoting *McCulloch v. Maryland*, 4 Wheat. 316, 405 (1819)). As the Supreme Court has emphasized, one of the most important things that States use their police powers to do is protect the public in commercial transactions. *See, e.g., Edenfield v. Fane*, 507 U.S. 761, 769 (1993). In fact, “[t]here is no question that” a State’s “interest in ensuring the accuracy of commercial information in the marketplace is substantial.” *Id.*

Accordingly, at least as a rule, “there can by definition be no conflict” between the laws of two sovereigns when they comport with one another. *Chamber of Com. v. Whiting*, 563 U.S. 582, 601–03 (2011). “States may have a legitimate interest in punishing or providing redress for wrongs even if federal law already does so.” *Zyla Life Scis., L.L.C. v. Wells Pharma of Houston, L.L.C.*, No. 23-20533, 2025 WL 1076889, at *5 (5th Cir. Apr. 10, 2025). Indeed, because the federal government “has limited resources . . . , it often welcomes state aid in enforcing shared legal norms.” *Id.*

Furthermore, the Court’s preemption analysis must be limited to the statutory text. This is true because, not only must Congress clearly preempt law that is at the heart of a State’s police powers, but when a statute contains an express preemption provision, the statute’s “pre-emptive scope” is “governed entirely by the express language.” *Cipollone v. Liggett Grp.*, 505 U.S. 504, 517 (1992).

B. The DTPA is not “different from, or in conflict with” federal law.

1. Here, the text of the PREP Act’s preemption provision defeats Pfizer’s argument because it applies only to state laws that are “*different from, or in conflict with, any requirement applicable*” under the PREP Act. § 247d-6d(b)(8)(A) (emphasis added). Nothing about Texas’ consumer protection claims asserted here are “different from, or in conflict with” the scope of the PREP Act, nor with any aspect of federal law altogether. The PREP Act’s single preemption provision provides:

[N]o State or political subdivision of a 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 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, or 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).

Pfizer’s argument—adopted with essentially no explanation by the district court—overlooks that the claims alleged in the State’s complaint mirror available federal ones. The federal “Covid-19 Consumer Protection Act made it illegal ‘for any[one] to engage in a deceptive act or practice in or affecting commerce in violation of section 5(a) of the [FTC] Act (15 U.S.C. § 45(a)) that is associated with the treatment, cure, prevention, mitigation, or diagnosis of covid-19.’” *Romero*, 2022 WL 4095424, at *4. And the State’s first four DTPA claims all concern “deceptive act[s] or practice[s] . . . associated with the treatment” and “prevention” of “covid-19.” *Id.* The fifth DTPA claim pled, regarding censorship, also is not preempted because it has nothing to do with “design, development, clinical testing,” *etc.* 47 U.S.C. § 247d-6d(b)(8)(B).

Furthermore, the DTPA expressly references FTCA section 5 and instructs courts to construe the DTPA and FTCA harmoniously. DTPA § 17.46(c)(1). This case is accordingly a far cry from one that is “different from, or in conflict with” any federal laws. 47 U.S.C. § 247d-6d(b)(8)(A). Where, as here, “state law mirrors federal law, it ‘recognizes the supremacy of the national law’ by ‘conform[ing] to it.’” *Zyla Life Scis.*, 2025 WL 1076889, at *4 (quoting *Asbell v. Kansas*, 209 U.S. 251, 258 (1908)). For this reason alone, Pfizer’s PREP Act preemption argument fails.

2. Below, Pfizer claimed the State’s suit is preempted because it “seeks to hold the company liable under state law for actions ‘relating to’” its vaccine. ROA.269. But the PREP Act’s preemption provision does not preempt *all* actions that relate to vaccines; rather, such actions are preempted only if they *additionally* are “different from, or [are] in conflict with” federal law. 42 U.S.C. § 247d-6d(b)(8)(A). And the

State's actions here are not. Indeed, in many respects the State's claims are premised on Pfizer's complete disregard of FDA's explanation to Pfizer of what its data supported. FDA told Pfizer it did not have adequate data to make several representations that it nevertheless went on to tell the public. *Compare, e.g.*, ROA.56 ¶ 49 (FDA's finding: "[I]t is *not possible* to assess sustained efficacy over a period longer than 2 months."), *with id.* ¶ 76 (Pfizer's misrepresentation: "At 6 months [from vaccination,] the protection is robust."). The State is not preempted from enforcing against those misrepresentations. *See, e.g., Jacob v. Mentor Worldwide*, 40 F.4th 1329, 1338 (11th Cir. 2022) (no preemption of claim where state law claim relies on "violation of federal requirements as evidence that [manufacturer] violated state law"); *accord Wyeth*, 555 U.S. at 581 ("Wyeth has not persuaded us that failure-to-warn claims like Levine's obstruct the federal regulation of drug labeling.").

The PREP Act's preservation of State claims not "different from, or in conflict with" federal law is a well-established concept in the Supreme Court and this Circuit, particularly for federally regulated products. For example, federal law expressly preempts state laws "different from, or in addition to" federal laws for medical devices. 21 U.S.C. § 360k(a). But courts routinely permit state law claims against medical device manufacturers provided the claims do not rely on "conflicting state statutes and regulations." *Medtronic*, 518 U.S. at 489 (state negligence action against manufacturer); *see also, e.g., Borskey v. Medtronics, Inc.*, 105 F.3d 651, 651 (5th Cir. 1996) ("To the extent that the appellants' state law actions set forth violations of federal requirements, they are not preempted."). Similarly, federal law governing pesticides preempts state laws "in addition to or different from" federal

requirements. 7 U.S.C. § 136v(b). But the courts routinely permit State law claims “fully consistent with federal requirements” to go forward against pesticide manufacturers, including claims related to efficacy. *Bates v. Dow Agrosciences*, 544 U.S. 431, 449 (2005) (materially similar, for federal pesticide law). Under these circumstances, the law is clear that Texas is not prohibited from enforcing the DTPA against Pfizer’s misrepresentations. *See, e.g., Jacob*, 40 F.4th at 1338 (no preemption where state law claim relies on a “violation of federal requirements as evidence that [manufacturer] violated state law”).

C. Congress deliberately did not preempt state claims against drug manufacturers.

1. The FDCA likewise does not preempt the State’s claims. Although FDA is charged under the FDCA with approving drug products, *see, e.g.,* 21 U.S.C. § 355, the Supreme Court has held that generally, the FDCA does not preempt state law claims. *See, e.g., Wyeth*, 555 U.S. at 573 (holding there is simply “no merit” to the “argument” that FDA approvals shield manufacturers from “comply[ing] with a state-law duty”).⁴ “Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness”—rather, “all evidence of Congress’ purposes is to the contrary.” *Id.* at 575, 574. In enacting the FDCA, Congress recognized that “state-law remedies further consumer protection by motivating

⁴ Congress added a preemption clause to the FDCA that “applies only to medical devices” and the Supreme Court has recognized that “Congress could have applied the pre-emption clause to the entire FDCA,” but did not do so. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 327 (2008).

manufacturers to produce safe and effective drugs.” *Id.* That is why suits under state law are common against FDA-approved products, including against advertising that is “false and misleading as to efficacy.” *Delarosa v. Boiron, Inc.*, No. 10-1569-JST (CWX), 2011 WL 13130856, at *3 (C.D. Cal. Dec. 29, 2011) (no preemption); *In re Zantac (Ranitidine) Prods. Liab. Litig.*, 546 F.Supp.3d 1284, 1308 (S.D. Fla. 2021) (materially similar).

Before the district court, however, Pfizer protested that “FDA[] [has the] exclusive right to enforce the FDCA.” ROA.271. That is technically true, but irrelevant. It is technically true because no “private right of action exists” under the FDCA. *PDK Labs, Inc. v. Friedlander*, 103 F.3d 1105, 1113 (2d Cir. 1997). But it is irrelevant because the State’s claims arise under *state* law, ROA.87–89 ¶¶ 152–70, and because “Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness,” *Merck Sharp & Dohme Corp. v. Albright*, 587 U.S. 299, 311 (2019). FDCA standards are commonly enforced through *state* law causes of action. *See, e.g., Zyla*, 2025 WL 1076889, at *10 (“*Wyeth* permitted distinct state regulation under the FDCA. If that does not conflict with federal enforcement prerogatives, neither does parallel state regulation.”); *In re MDL 2700 Genentech Herceptin*, 960 F.3d 1210, 1234 (10th Cir. 2020) (no preemption where “federal regulatory standard is precisely the same as the state law standards sought to be imposed by the plaintiffs”).

Pfizer also argued before the district court that the State’s lawsuit is an attack on FDA’s decision to approve its vaccine as safe and effective. ROA.270–73, 259–63. At the outset, Pfizer’s arguments in this regard improperly relied on non-judicially

noticeable documents outside the complaint. *See Linenweber v. Sw Airlines Co.*, 2023 WL 6149106, at *4 (N.D. Tex. 2023). But in any event, those arguments deliberately misunderstand the State’s complaint, which focuses on misleading representations to *the public*, not FDA’s approval decisions. Two examples illustrate the point.

First, Pfizer, citing Paragraph 144 of the complaint, claimed in the district court that the State argues that “FDA ‘engaged in an artificial and flawed consideration and balance of Pfizer’s vaccine’s benefits and risks.’” ROA.270–71. But paragraph 144 actually states: “Pfizer’s misrepresentations resulted in *the public* engaging in an artificial and flawed consideration and balancing of Pfizer’s vaccine’s benefits and risks 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.”

Second, Pfizer also claimed below that the State’s “complaint second guesses FDA’s decision making” and then invokes case law where a plaintiff “in substance, challenged FDA’s decision to permit defendant’s unapproved drug to remain on the market.” ROA.272–73. But the complaint repeatedly endorses FDA’s findings as evidence, including that “FDA went out of its way to expressly state that Pfizer’s results did not support several important vaccine characteristics that are highly relevant to Pfizer’s representations to the public.” ROA.56 ¶ 49.

The bottom line is this: The State takes no issue with FDA’s determination to grant Pfizer an EUA and, later, other approvals. Instead, the State’s complaint contains well-pled factual allegations focusing on Pfizer’s gross misrepresentations to the public about specific aspects of its vaccine’s performance, and that is not

preempted. *See Louisiana v. Pfizer, Inc.*, No. 3:13-CV-00727-BAJ-RL, 2014 WL 3541057, at *7 n.3 (M.D. La. July 17, 2014) (state lawsuit against Pfizer not preempted by FDCA when the State did not challenge the FDA’s approval, but rather sought “damages for Pfizer’s alleged intentionally false, fraudulent, and misleading conduct”). Indeed, many of Pfizer’s representations contradicted *precisely* what FDA found in its formal EUA memorandum. *See supra* at 9–12. It would be little different than if Pfizer represented that its vaccine cured cancer. And that is surely something that the State can enforce against.

2. Below, Pfizer further claimed the “95% efficacy” claim shows the State is “challenging federal regulatory and policy decisions.” ROA.273 Pfizer contended that “FDA itself uses the 95% relative risk reduction claim” in “[1] the vaccine’s licensing memorandum, [2] the facts sheets provided to patients and physicians, and [3] other communications with the public.” *Id.* But this misstates the public record and ignores the State’s well-pled allegations.⁵ Indeed, FDA’s own guidance indicates that “relative risk reduction” statistics are likely to mislead. In fact, in 2020, FDA’s own Commissioner apologized for using “relative risk reduction” instead of “absolute risk reduction” when describing the efficacy of COVID treatments. *See PBS, FDA Chief Apologizes for Overstating Plasma Effect on Coronavirus* (Aug. 25, 2020), <https://www.pbs.org/newshour/health/fda-chief-apologizes-for->

⁵ Notably, FDA’s “fact sheet” for patients makes no mention of relative risk reduction, much less 95% efficacy. Instead, it just says that “the totality of the scientific evidence available show[ed] that the product may be effective to prevent COVID-19.” FDA, *Pfizer-BioNTech Covid-19 Vaccine Fact Sheet*, <https://www.fda.gov/media/167212/download?attachment>.

overstating-plasma-effect-on-coronavirus. And FDA has stated that if a manufacturer *does* use that statistic, it should also “[p]rovide absolute risks, not just relative risks.” ROA.50 ¶ 31 (FDA Guidance at 56). Yet here, no Pfizer press release or other public statement mentioned that its vaccine’s absolute risk reduction was less than 1%. *Id.* ¶ 45. At best, Pfizer has created a factual dispute unresolvable on the pleadings. *Id.* at ¶ 48.

Even if FDA’s public communications endorsed Pfizer’s “95% efficacy” claim, they would still not preempt state law because only agency action “with the force of law can pre-empt conflicting state requirements.” *Wyeth*, 555 U.S. at 576. That typically includes only regulations formally promulgated with a notice-and-comment period, and does not include letters, fact sheets, or other informal agency pronouncements. *See, e.g., Reid v. Johnson & Johnson*, 780 F.3d 952, 964 (9th Cir. 2015) (FDA letter with “enforcement guidelines” did not “carry the force of law” sufficient to preempt state law); *Fellner v. Tri-Union Seafoods, L.L.C.*, 539 F.3d 237, 256 (3d Cir. 2008) (similar). Here, none of the FDA materials Pfizer cites remotely regulate “with the force of law.” *Wyeth*, 555 U.S. at 576. They were not subject to notice-and-comment and followed no “formal administrative procedure.” *Hardeman v. Monsanto Co.*, 997 F.3d 941, 957 (9th Cir. 2021). So they have no import for the preemption question.

Finally, in all events, even if Pfizer were right (it is not) about the 95% efficacy claim, that is only *one* of the State’s five DTPA claims here. *See supra* at 12–14. The viability of the 95% efficacy claim has no bearing whatsoever on whether the other

claims are preempted. The FDCA does not preempt state claims; it welcomes them. It is no bar to a DTPA claim for deceptive statements.

II. Pfizer Does Not Have Immunity for Misrepresentations

Pfizer also does not have immunity for the misrepresentations laid out in the complaint because the PREP Act immunizes only claims for “loss” (physical harm or mental anguish) resulting from the “administration . . . of a covered countermeasure” (here, the injection of a vaccine) to an “individual.” 47 U.S.C. § 247d-6d(a)(1). In plain terms, it grants Pfizer immunity from personal injury claims from individuals that received Pfizer’s vaccine. It does not touch a government’s power to bring a *parens patriae* action based on misleading marketing claims.

1. As with all questions of interpretation, the Court begins with the language Congress wrote. Here, the PREP Act’s immunity provision provides that:

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.

47 U.S.C. § 247d-6d(a)(1). The Court must interpret this language according to the limitations in its plain text. *Mitchell v. Advanced HCS, L.L.C.*, 28 F.4th 580, 587 (5th Cir. 2022) (interpreting PREP Act immunity based on its “plain text”). In doing so, several courts have already recognized that the PREP Act does not provide an unqualified grant of immunity from state claims. *See, e.g., Lollie v. Colonnades Health*

Care Ctr. Co., 2021 WL 4155805, at *3 (S.D. Tex. Sept. 13, 2021); *Est. of Maglioli v. Andover Subacute Rehab. Ctr.*, 478 F.Supp.3d 518, 529 (D.N.J. 2020).

2. The plain text of the PREP Act’s immunity provision clearly indicates that it does not foreclose the State’s suit, for at least three reasons.

First, PREP Act immunity only extends to claims “for loss.” 47 U.S.C. § 247d-6d(a)(1). The statute defines loss to include specific ailments that equate to the traditional definition of personal injury. *See id.* § 247d-6d(a)(2)(A) (definition including “death,” “physical, mental, or emotional injury,” *etc.*). But the State’s claims are not ones “for loss” as defined. Indeed, under the DTPA the State does not need to prove “loss” at all. It can bring a suit “[w]hensoever” it “has reason to believe that any person is engaging in, has engaged in, or is about to engage in” any false, misleading, or deceptive conduct in trade or commerce, and the State concludes such action “would be in the public interest.” DTPA § 17.47(a); *accord id.* § 17.46(a). (consumers, by contrast, can bring a DTPA action only if they have suffered “economic damages” or “mental anguish,” *id.* § 17.50(a))

Here, the State’s first four DTPA claims are about misrepresentations unrelated to physical or mental “loss” suffered from vaccine side effects. *See* ROA.87–89 ¶¶ 154–67. The State’s fifth DTPA claim concerns Pfizer’s schemes to conceal the truth. *Id.* ¶¶ 168–70. The harm alleged is that Pfizer’s misrepresentations “prevented and hindered the public from obtaining information material to properly balancing the benefits and risks of its vaccine,” thus “distort[ing] the risk/benefit analysis in Pfizer’s favor by artificially inflating the vaccine’s perceived efficacy.” *Id.* ¶ 141. None of this relates to the statutory “loss” definition or personal injury.

Second, the PREP Act’s immunity language blocks only claims “from the administration” of a covered product to “an individual.” 47 U.S.C. § 247d-6d(a)(1). This further underscores that the immunity is for personal injury suits, not sovereign consumer protection suits in the public interest. Texas is not suing about “administration” of the Pfizer vaccine, much less administration of the vaccine to “an individual.” Instead, the State is enforcing its consumer protection statutes in its “*parens patriae*” capacity. *Hood ex rel. Mississippi v. JP Morgan Chase*, 737 F.3d 78, 81 (5th Cir. 2013). When the State brings such suits, it is acting in a quasi-sovereign capacity on behalf of the public interest of its citizens. *See, e.g., Alfred L. Snapp & Son, Inc. v. Puerto Rico, ex rel. Barez*, 458 U.S. 592, 602 (1982) (*parens patriae* suits are based on “quasi-sovereign interests” that “the State has in the well-being of its populace”). “[T]he State” itself—not an individual—“is the real party in interest.” *People by Underwood v. LaRose Indus.*, 386 F. Supp. 3d 214, 218 (N.D.N.Y. 2019). And the State is “authorized to file suit independently of any consumer complaints, as a *parens patriae*.” *West Virginia ex rel. McGraw v. CVS Pharmacy, Inc.*, 646 F.3d 169, 175–76 (4th Cir. 2011). A State *parens patriae* action based on consumer deception is thus well outside the scope of the PREP Act’s individual immunity.

Third, PREP Act immunity cannot plausibly be read to cover governmental suits for misrepresentations because such a result would lead to numerous absurdities. Courts, however, “should avoid any interpretation that would lead to absurd or unreasonable outcomes.” *Dunn-McCampbell Royalty Int., Inc. v. Nat’l Park Serv.*, 630 F.3d 431, 439 (5th Cir. 2011) (citation omitted).

For example, the PREP Act’s immunity provision provides immunity against both State *and* Federal claims. 47 U.S.C. § 247d-6d(a)(1). That means if Pfizer is immune from the State’s claims about misrepresentations, then not even the federal government—including FDA itself—could sue. Drawn out to its logical conclusion, that would allow Pfizer to claim its vaccines cure cancer with *no* consequences from the federal government or anyone else. That is absurd, and not even Pfizer believes it. *See* ROA.269 (contending instead that “FDA has the exclusive authority to enforce the FDCA’s requirements”).

In short, the Supreme Court requires “language much plainer than the text” of the PREP Act before a court could conclude that Congress intended “the perverse effect of granting complete immunity” in such situations. *Medtronic*, 518 U.S. at 487. This is a case about how Pfizer’s misstatements led Texas consumers to make choices they would not have otherwise made, and Pfizer’s censorship of scientists that set the record straight. Pfizer enriched itself based on these misleading statements to the tune of billions of dollars. None of that relates to a “claim for loss” from the “administration” of Pfizer’s vaccine to an “individual.” Pfizer is not immune.

3. Here, the district court offered no analysis on this point. The district court never explained why adopting Pfizer’s theory comports with the language Congress wrote, nor why Pfizer’s theory does not lead to absurdity. The district court also did not attempt to reconcile its decision with the principle that Congress does not lightly strip the State of its power to protect the public from deceptive claims about the efficacy of medical care. Nothing suggests that Congress intended to preempt Texas’s effort to ensure that advertised claims to the public are accurate, and the district

court's summary rejection of the State's complaint—without any discovery, let alone summary judgment briefing or trial—was erroneous. *See, e.g., Spano as next friend of C.S. v. Whole Foods, Inc.*, 65 F.4th 260, 264–65 (5th Cir. 2023) (reversing dismissal where the plaintiffs alleged each of their tort claims were “based in state law,” not FDCA violations); *Hernandez v. W. Tex. Treasures Estate Sales, L.L.C.*, 79 F.4th 464, 469–70 (5th Cir. 2023) (reversing the district court's dismissal where the complaint plausibly alleged an ADA violation and holding “it is generally inappropriate for a court to consider affirmative defenses on a motion to dismiss if it forces the court to look at matters outside of the complaint”).

For its part, before the district court, Pfizer cites two nonbinding, out-of-circuit cases purporting to hold that PREP Act immunity blocks misrepresentation claims. Both, however, concern personal injuries sustained from the administration of the Pfizer vaccine, not misleading marketing statements. In *Gibson v. Johnson & Johnson*, 2023 WL 4851413 (E.D. Pa. July 28, 2023), the plaintiff, an incarcerated pro se litigant, complained that he was “misled” into “accepting the administration” of a COVID-19 vaccine, resulting in “serious physical and psychiatric adverse effects” from receiving the vaccine. *Id.* at *2. As such, it was a claim “for loss”—the normal situation calling for PREP Act immunity. And in *M.T. ex rel. M.K. v. Walmart Stores*, 528 P.3d 1067 (Kan. Ct. App. 2023), the court concluded that a mother could not sue for improper administration of a vaccine to her daughter, and that her “misrepresentation” claims were in fact disguised claims about “alleged improper administration of a covered countermeasure,” *id.* at 1079. Neither case is relevant.

III. The State Adequately Pled Its DTPA Claims

Finally, the State has plausibly alleged each required element of a DTPA claim for all five counts. To plead a DTPA claim, the State must plausibly allege Pfizer “is engaging in, has engaged in, or is about to engage in any act or practice” unlawful under the DTPA, and that the State’s lawsuit “would be in the public interest.” DTPA § 17.47(a). An act or practice violates the DTPA if it is “[f]alse, misleading, or deceptive” and occurred “in the conduct of any trade or commerce.” DTPA § 17.46(a). The DTPA is “construed liberally to promote its central purpose” of protecting Texas consumers. *Miller v. Keyser*, 90 S.W.3d 712, 715 (Tex. 2002).

The State’s complaint easily satisfies that standard. In fact, Pfizer never meaningfully contested before the district court that the State’s complaint contains “sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face.” *Gonzalez v. Kay*, 577 F.3d 600, 603 (5th Cir. 2009). Instead, Pfizer raised three statutory arguments in rebuttal, two of which were accepted by the district court in its order. ROA.843. But all three arguments fail.

1. The district court ruled that Pfizer’s misrepresentations had no effect on “trade” or “commerce” within the meaning of the DTPA, presumably agreeing with Pfizer’s argument that because the U.S. government paid for the Pfizer vaccine, and consumers got it for free, the DTPA did not apply. ROA.275. But Texas courts have long held that goods or services provided for free can still violate the DTPA. “It is immaterial whether [defendants] provide[] a service in exchange for money; the statute as a whole supports the conclusion that transfer of valuable consideration

is not necessary.” *Mother & Unborn Baby Care of N. Texas, Inc. v. State*, 749 S.W.2d 533, 538 (Tex. App. 1988), *writ denied* (Nov. 16, 1988). Before the district court, Pfizer’s brief neglected to mention that its only cited case to the contrary, *Word of Faith World Outreach Ctr. Church, Inc. v. Morales*, 787 F.Supp. 689, 697 (W.D. Tex. 1992), was overturned by this Court. *See Word of Faith World Outreach Ctr. Church, Inc. v. Morales*, 986 F.2d 962, 969 (5th Cir. 1993) (reversing the trial court’s holdings interpreting the DTPA).⁶ This Court must apply Texas law as Texas courts would, and Texas courts “liberally construe[]” the DTPA “to protect consumers from deceptive business practices.” *Weitzel v. Barnes*, 691 S.W.2d 598 (Tex. 1985).

Nor does it matter that Pfizer sold its vaccine to the U.S. government instead of direct to consumers, because that sale and the later distribution of Pfizer vaccines in Texas both fit squarely with the DTPA’s definition of “trade” and “commerce.” The DTPA defines “trade” and “commerce” to include, among other things, the “advertising, . . . sale, . . . or distribution of any good or service . . . and shall include any trade or commerce directly or indirectly affecting the people of this state.” DTPA § 17.45(6). Pfizer’s sale and distribution of its vaccine in Texas thus qualifies as an act of “trade” or “commerce” in at least three ways: Pfizer directly *advertised* its vaccine in Texas; Pfizer *distributed* its vaccine to millions of Texans; and Pfizer’s *sale* of vaccines “directly [and] indirectly affect[ed] the people of” Texas. Pfizer’s

⁶ In ordering the district court to abstain from adjudicating state law issues under *Railroad Comm’n v. Pullman Co.*, 312 U.S. 496 (1941), the Fifth Circuit vacated the lower court’s finding as to “whether the investigative powers provided the Attorney General by the DTPA . . . may be invoked against” an organization providing free services. 986 F.2d at 969.

own motion to dismiss conceded the “ordinary meaning” of “distribution” applies to its Texas distribution of vaccines. ROA.276 n.22. The only case it cited to the contrary—*Greater Houston Partnership v. Paxton*, 468 S.W.3d 51, 61 (Tex. 2015)—dealt with a different phrase in a different statute, and in any event, held the ordinary meaning of that word should be used. *Id.* at 66 (holding that the Houston chamber of commerce did not qualify as a “governmental body” under the Texas Public Information Act).

Additionally, a DTPA defendant does not need to sell its product directly to the consumer. In consumer DTPA lawsuits, the Texas Supreme Court has held that “[p]rivacy between the plaintiff and defendant is not a consideration . . . The only requirement is that the goods or services sought or acquired . . . form the basis of his complaint.” *Flenniken v. Longview Bank & Tr. Co.*, 661 S.W.2d 705, 707 (Tex. 1983). That logic applies with at least equal force to an Attorney General DTPA lawsuit, where the state represents its own state interests in a *parens patriae* capacity, not the interests of individual consumers. *See supra* Section II (discussing *McGraw*).

Finally, Pfizer’s claim that its misleading statements “took place long after Pfizer contracted to provide hundreds of millions of doses” is both inapposite and wrong. ROA.277. It is *inapposite* because under the DTPA, “there is no requirement that the defendant’s unconscionable act occur simultaneously with the sale or lease of the goods or services that form the basis of the consumer’s complaint.” *Flenniken*, 661 S.W.2d at 707. It is also *wrong*, because Pfizer’s misrepresentations resulted in several additional billion dollars of revenue after they were made. As alleged, Pfizer’s original, pre-vaccination sale was for only \$1.95 billion and 100 million doses.

ROA.57–58 ¶ 53. By making misrepresentations about the vaccine’s efficacy, Pfizer created huge consumer demand for its vaccine that resulted in the U.S. government exercising its option for an additional 500 million doses, earning an additional \$10.05 billion. *Id.* ¶ 147. This artificially inflated consumer demand led the federal government to execute a new contract for an additional \$3.2 billion of vaccines in 2022. *Id.* ¶ 148. As the market leader for COVID-19 vaccines—a market position established at least in part due to its misrepresentations—Pfizer continues to sell its vaccine directly to the public and to consumers. *Id.* ¶ 151.

2. The district court’s view that Pfizer’s misrepresentations were not related to any “consumer transaction” is irrelevant because the DTPA does not require that lawsuits brought by the Attorney General involve a “consumer.” While “[a]n aggrieved *individual*” seeking to bring suit “must meet the statutory definition of ‘consumer,’” that “issue is not applicable where the cause of action is brought by the AG.” *Household Retail Servs., Inc. v. State*, No. 04-00-00734-CV, 2001 WL 984779, at *3 n.4 (Tex. App. Aug. 29, 2001) (emphasis added) (comparing DTPA § 17.50 (consumer lawsuits) to DTPA §§ 17.46(a), 17.47(a) (Attorney General lawsuits)). That is because the DTPA’s definition of “consumer” “only describes the class of persons entitled to bring suit under section 17.50 [the consumer cause of action]; it does not define the class of persons subject to liability under the DTPA.” *Flenniken*, 661 S.W.2d at 706. The Attorney General can bring suit against “[a]ny person engaging in such deceptive practices,” if he determines the suit is in the public interest. *Riverside Nat. Bank v. Lewis*, 603 S.W.2d 169, 173 (Tex. 1980) (citing DTPA

§ 17.47(a)). Preventing misrepresentations that warp Texans' medical decisions is plainly in the public interest.

3. Finally, Pfizer's position below (at ROA.280) that the State's allegations are implausible would require this Court to ignore dozens of pages of well-pleaded statistics from FDA and Pfizer's own data, as well as Pfizer's own public statements, without explanation. Indeed, even the district court's ruling—which accepted every other one of Pfizer's arguments without comment—did not find the State's allegations implausible. The State's complaint specifically identifies several claims about vaccine efficacy that FDA told Pfizer *not* to make—and several instances where Pfizer publicly made those claims anyway. That is misrepresentation under the DTPA, and it is well-pled.

CONCLUSION

For the foregoing reasons, this Court should reverse the district court and remand for further proceedings.

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Respectfully submitted,

KEN PAXTON
Attorney General of Texas

BRENT WEBSTER
First Assistant Attorney General

RALPH MOLINA
Deputy First Assistant Attorney General

AUSTIN KINGHORN
Deputy Attorney General for Civil Litigation

JOHNATHAN STONE
Chief, Consumer Protection Division

/s/ Abigail E. Smith
ABIGAIL E. SMITH
Assistant Attorney General
Texas Bar No. 24141756
Abby.Smith@oag.texas.gov

Office of the Texas Attorney General
Consumer Protection Division
12221 Merit Drive, Suite 650
Dallas, Texas 75251
Phone: 214-290-8830
Fax: (214) 969-7615

Counsel for Plaintiff-Appellant

CERTIFICATE OF SERVICE

On April 16, 2025, this document was served via CM/ECF on all registered counsel and transmitted to the Clerk of the Court. Counsel further certifies that: (1) any required privacy redactions have been made in compliance with Fifth Circuit Rule 25.2.13; (2) the electronic submission is an exact copy of the paper document in compliance with Fifth Circuit Rule 25.2.1; and (3) the document has been scanned with the most recent version of CrowdStrike Falcon and is free of viruses.

/s/ Abigail E. Smith

ABIGAIL E. SMITH

CERTIFICATE OF COMPLIANCE

This brief complies with: (1) the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B) because it contains 10,161 words, excluding the parts of the brief exempted by Rule 32(f); and (2) the typeface requirements of Rule 32(a)(5) and the type style requirements of Rule 32(a)(6) because it has been prepared in a proportionally spaced typeface (14-point Equity) using Microsoft Word (the same program used to calculate the word count).

/s/ Abigail E. Smith

ABIGAIL E. SMITH