

Exhibit 563

Attorney General Ken Paxton Sues Pfizer for
Misrepresenting COVID-19 Vaccine Efficacy and
Conspiring to Censor Public Discourse

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November 30, 2023 | Press Release

Attorney General Ken Paxton Sues Pfizer for Misrepresenting COVID-19 Vaccine Efficacy and Conspiring to Censor Public Discourse

Texas Attorney General Ken Paxton has sued Pfizer, Inc., for unlawfully misrepresenting the effectiveness of the company's COVID-19 vaccine and attempting to censor public discussion of the product.

Pfizer engaged in false, deceptive, and misleading acts and practices by making unsupported claims regarding the company's COVID-19 vaccine in violation of the Texas Deceptive Trade Practices Act.

The pharmaceutical company's widespread representation that its vaccine possessed 95% efficacy against infection was highly misleading. That metric represented a calculation of the so-called "relative risk reduction" for vaccinated individuals in Pfizer's initial, two-month clinical trial results. FDA publications indicate "relative risk reduction" is a misleading statistic that "unduly influence[s]" consumer choice. Pfizer was also put on notice at that time that vaccine protection could not accurately be predicted beyond two months. Nevertheless, Pfizer fostered a misleading impression that vaccine protection was durable and withheld from the public information that undermined its claims about the duration of protection. And, despite the fact that its clinical trial failed to measure whether the vaccine protects against transmission, Pfizer embarked on a campaign to intimidate the public into getting the vaccine as a necessary measure to protect their loved ones.

In fact, Pfizer's product failed to live up to the company's representations. COVID-19 cases increased after widespread vaccine administration, and some areas saw a greater percentage of deaths from COVID-19 among the

vaccinated population than the unvaccinated. When the failure of its product became apparent, Pfizer then pivoted to silencing truth-tellers. The lawsuit notes: “How did Pfizer respond when it became apparent that its vaccine was failing and the viability of its cash cow was threatened? By intimidating those spreading the truth, and by conspiring to censor its critics. Pfizer labeled as ‘criminals’ those who spread facts about the vaccine. It accused them of spreading ‘misinformation.’ And it coerced social media platforms to silence prominent truth-tellers.”

“We are pursuing justice for the people of Texas, many of whom were coerced by tyrannical vaccine mandates to take a defective product sold by lies,” said Attorney General Paxton. “The facts are clear. Pfizer did not tell the truth about their COVID-19 vaccines. Whereas the Biden Administration weaponized the pandemic to force illegal public health decrees on the public and enrich pharmaceutical companies, I will use every tool I have to protect our citizens who were misled and harmed by Pfizer’s actions.”

The lawsuit follows Attorney General Paxton’s [investigation](https://www.texasattorneygeneral.gov/news/releases/paxton-launches-investigation-gain-function-research-and-misrepresentations-covid-19-vaccine?utm_content=&utm_medium=email&utm_name=&utm_source=govdelivery&utm_term=) (https://www.texasattorneygeneral.gov/news/releases/paxton-launches-investigation-gain-function-research-and-misrepresentations-covid-19-vaccine?utm_content=&utm_medium=email&utm_name=&utm_source=govdelivery&utm_term=) in Pfizer and other vaccine manufacturers announced earlier this year.

To read the petition, [click here](#) (</sites/default/files/images/press/Pfizer%20Vaccine%20Petition%20Filed.pdf>).

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CAUSE NO. _____

STATE OF TEXAS,
Plaintiff,

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IN THE DISTRICT COURT OF

v.

LUBBOCK COUNTY, TEXAS

PFIZER, INC.,
Defendant.

_____ JUDICIAL DISTRICT

PLAINTIFF’S ORIGINAL PETITION

TO THE HONORABLE DISTRICT JUDGE:

The COVID-19 vaccines are the miracle that wasn’t. At the end of 2020, Defendant Pfizer, Inc. (Defendant or Pfizer) broadcast to the world that its COVID-19 vaccine was “95% effective.” Based on this and other statements made by Pfizer touting the efficacy of its new vaccine, Americans were given the impression that Pfizer’s vaccine would end the coronavirus pandemic and lift the omnipresent veil of fear and uncertainty from an anxious public. Placing their trust in Pfizer, hundreds of millions of Americans lined up to receive the vaccine. Contrary to Pfizer’s public statements, however, the pandemic did not end; it got worse. More Americans died in 2021, with Pfizer’s vaccine available, than in 2020, the first year of the pandemic. This, in spite of the fact that the vast majority of Americans received a COVID-19 vaccine, with most taking Pfizer’s. Indeed, by the end of 2021, official government reports showed that in at least some places a ***greater percentage of the vaccinated were dying from COVID-19 than the unvaccinated.*** Pfizer’s vaccine plainly was not “95% effective.”

How did this happen? How did Pfizer’s vaccine achieve such widespread adoption, yet fall short of the stated goal of ending the pandemic? In a nutshell, Pfizer deceived the public. First, Pfizer’s widespread representation that its vaccine possessed 95% efficacy against infection was highly misleading from day one. That number was only ever legitimate in a solitary, highly-technical, and artificial way—it represented a calculation of the so-called “relative risk reduction”

for vaccinated individuals in Pfizer’s then-unfinished pivotal clinical trial. But FDA publications indicate “relative risk reduction” is a misleading statistic that “unduly influence[s]” consumer choice. Indeed, per FDA: “when information is presented in a relative risk format, the risk reduction *seems* large and treatments are viewed more favorably than when the same information is presented” using more accurate metrics.

Here, the proof is in the pudding. While Pfizer’s 95% figure made its vaccines *seem* highly effective, the truth was quite different. When it began making those claims, Pfizer possessed on average only *two months* of clinical trial data from which to compare vaccinated and unvaccinated persons. Of 17,000 placebo recipients, only 162 acquired COVID-19 during this two-month period. Based on those numbers, vaccination status had a negligible impact on whether a trial participant contracted COVID-19. The risk of acquiring COVID-19 was *so small* in the first instance during this short window that Pfizer’s vaccine only fractionally improved a person’s risk of infection. And a vaccine recipient’s *absolute* risk reduction—the federal Food & Drug Administration’s (FDA) preferred efficacy metric—showed that the vaccine was *merely 0.85% effective*. Moreover, according to Pfizer’s own data, preventing *one* COVID-19 case required vaccinating *119*. That was the simple truth. But Pfizer’s fusillade of public representations bore no resemblance to reality.

Having seeded the marketplace with its misleading “95% effective” representation, Pfizer expanded its deception campaign across several fronts:

- ***First, duration of protection:*** FDA recognized when it first authorized Pfizer’s vaccine that it was “not possible” to know how effective the vaccine would remain beyond two months. But in early 2021, Pfizer deliberately created the false impression that its vaccine had durable and sustained protection, going so far as to withhold highly relevant data and information from the consuming public showing that efficacy waned

rapidly.

- ***Second, transmission:*** FDA warned Pfizer that it “needed” additional information to determine whether the vaccine protected against “transmission” of COVID-19 between persons. But Pfizer instead engaged in a fear-mongering campaign, exploiting intense public fears over the year-long pandemic by insinuating that vaccination was necessary for Americans to protect their loved ones from contracting COVID-19.
- ***Third, variant protection:*** Pfizer knowingly made false and unsupported claims about vaccine performance against variants, including specifically the so-called Delta variant. The vaccine performed remarkably poorly against the Delta variant, and Pfizer’s own data confirmed this fact. Nonetheless, Pfizer told the public that its vaccine was “very, very, very effective against Delta.”

Pfizer’s product, buoyed by the company’s misrepresentations, enriched the company enormously. But, while Pfizer’s misrepresentations piled up, its vaccine’s performance plummeted. Beginning in late 2020, multiple countries heavily relied on Pfizer’s recently approved vaccine in their first inoculation campaigns. Due to widespread public participation, vaccination rates soared. Beneath the surface of Pfizer’s misrepresentation-fueled success, however, myriad pieces of information demonstrate how Pfizer’s vaccine failed to live up to its claims of efficacy. For example, shortly after Delta’s emergence in Israel in 2021 (the informational canary in the coalmine, according to Pfizer), the vaccine’s relative risk reduction dropped precipitously—*from 64% in June 2021 to 39% just one month later*. Granular data collected by governments worldwide revealed that upon Delta’s introduction, the number of deaths among the fully vaccinated spiked for months. Indeed, certain jurisdictions reported *negative vaccine efficacy* in late 2021 and early 2022—meaning a greater percentage of vaccinated persons contracted, and even died from, COVID-19 than unvaccinated. Others found that the percentage of people infected with COVID-

19 *increased* over time, even in the face of widespread vaccine penetration. In the U.K., for example, infection rates were 7.0% from April 26, 2020 to December 7, 2020 (before the approval and distribution of Pfizer’s product), but 24.2% from May 18, 2021 to December 13, 2021, and 33.6% from December 14, 2021 to February 21, 2022.

How did Pfizer respond when it became apparent that its vaccine was failing and the viability of its cash cow under threat? By intimidating those spreading the truth, and by conspiring to censor the vaccine’s critics. Pfizer labeled as “criminals” those who spread facts about the vaccine. It accused them of spreading “misinformation.” And it coerced social media platforms to silence prominent truth-tellers. Indeed, Pfizer even went so far as to request that social media platforms silence a *former FDA director* because his comments could “driv[e] news coverage” critical of the vaccine.

It is of no moment that Pfizer had FDA-authorization to distribute its vaccine on an emergency basis during the peak of its deception campaign. FDA’s abbreviated sign-off did not afford Pfizer with a blank check to serially disseminate misrepresentations to the public to enrich itself at the expense of a frightened public, much less did FDA’s authorization confer absolution on Pfizer when later held to account. Simply put, Pfizer cannot attempt to hide behind FDA to shield its deception from scrutiny, especially where, as here, FDA itself *explicitly* cautioned the company that it did not have adequate data to support various claims it made. In short, nothing FDA said or did during Pfizer’s lengthy campaign of misrepresentations remotely validated the company’s actions at the heart of this case.

In summary, Pfizer intentionally misrepresented the efficacy of its COVID-19 vaccine and censored persons who threatened to disseminate the truth in order to facilitate fast adoption of the product and expand its commercial opportunity. In light of the multi-billion dollar bet that Pfizer made on the vaccine and its need to quickly establish the product as the marketing leader, Pfizer

was heavily incentivized to, and in fact did, make misrepresentations intended to confuse and mislead the public in order to achieve widespread adoption of its vaccine. This suit seeks to hold Pfizer responsible for its scheme of serial misrepresentations and deceptive trade practices.

I. JURISDICTION

1. This action is brought by the Texas Attorney General's Office through its Consumer Protection Division in the name of the State of Texas (Plaintiff or the State) and in the public interest, pursuant to the authority granted by section 17.47 of the Texas Deceptive Trade Practices Act (DTPA). The State brings this action on the grounds that Pfizer has engaged in "false, deceptive, and misleading acts and practices in the course of trade and commerce" as defined in, and declared unlawful by, subsections 17.46(a) and (b) of the DTPA, at all times described below.

2. In enforcement actions filed pursuant to section 17.47 of the DTPA, the Attorney General may seek civil penalties, redress for consumers, and injunctive relief. In addition, the Attorney General may pursue reasonable attorneys' fees and litigation expenses in connection with the prosecution of the instant action, in accord with Texas Government Code section 402.006(c).

II. DISCOVERY

3. The discovery in this case should be conducted under Level 3 pursuant to Texas Rule of Civil Procedure 190.4. Restrictions concerning expedited discovery under Texas Rule of Civil Procedure 169 do not apply because the State's seeks non-monetary injunctive relief as part of its claims.

4. In addition to injunctive relief, the State claims entitlement to monetary relief in an amount greater than \$1,000,000, including civil penalties, reasonable attorney's fees, litigation expenses, restitution, and costs.

III. DEFENDANT

5. Defendant PFIZER, INC. is a corporation organized under the laws of Delaware, with its principal office and place of business located at 1209 Orange Street, in the City of Wilmington, Delaware. Pfizer marketed and distributed its COVID-19 vaccine in Texas. Pfizer conducts business in Texas. At the time of filing, its registered agent for service of process is CT Corporation System, 1999 Bryan St., Ste. 900, Dallas, Texas 75201.

6. Wherever it is alleged herein that Pfizer did any act, it is meant that performed or participated in the act or that Pfizer's officers, directors, agents, employees, or person under Pfizer's control performed or participated in the act on behalf of and under the authority of Pfizer.

IV. VENUE

7. Venue of this suit lies in Lubbock County, Texas, pursuant to DTPA subsection 17.47(b), because Pfizer has done business in Lubbock County and because transactions at issue in this suit have occurred in Lubbock County.

V. PUBLIC INTEREST

8. The State has reason to believe that Pfizer is engaging in or has engaged in the unlawful acts or practices set forth below. In addition, the State has reason to believe that Pfizer has caused injury, loss, and damage to it, as well as caused adverse effects to the lawful conduct of trade and commerce, thereby directly or indirectly affecting the people of this State. Therefore, the Consumer Protection Division of the Office of the Attorney General initiates this proceeding in the public interest. *See* DTPA § 17.47.

VI. PRE-SUIT NOTICE

9. The Consumer Protection Division provided Pfizer notice of the general nature of unlawful conduct challenged herein at least seven days before filing suit, as potentially required by subsection 17.47(a) of the DTPA.

VII. FACTUAL ALLEGATIONS

A. Relevant Background on Emergency Use Authorizations.

10. Under federal law, FDA must approve any new drug product prior to a manufacturer making it available to the consuming public. *See, e.g.*, 21 U.S.C. § 355 (drugs); 42 U.S.C. § 262 (biologics).¹ FDA maintains and follows a rigorous approval process for virtually all drug products submitted for approval. This formalized process requires a manufacturer to submit voluminous amounts of scientific data and information for purposes of persuading FDA that the proposed drug is safe and effective for its intended use. Conducting the scientific testing necessary to support a viable new drug application ordinarily takes many years, followed by time-consuming internal FDA review before a manufacturer obtains approval.

11. FDA has an alternative, radically different drug authorization power known as the “Emergency Use Authorization” (EUA) process. The EUA process, however, is rarely used and only available when the United States Secretary of Health and Human Services declares an emergency. 21 U.S.C. § 360bbb-3(a)(1), (b).

12. By law, the EUA process requires a much lower quantum of scientific evidence and FDA review to obtain marketing authorization compared to the typical process. This reduced scrutiny is justifiable in cases of true emergency on the theory that even a hastily tested drug with uncertain efficacy and safety is better than having nothing at all. *See* Jonathan Iwry, *From 9/11 to COVID-19: A Brief History of FDA Emergency Use Authorization* (Jan. 28, 2021). Federal law further cabins the availability of reduced scrutiny under the EUA process to circumstances where

¹ Whereas “drugs” are “chemically synthesized” with “known” structure, “most biologics are complex mixtures that are not easily identified or characterized,” including those “manufactured by biotechnology [that are] heat sensitive and susceptible to microbial contamination.” FDA, *What Are ‘Biologics’ Questions and Answers* (Feb. 6, 2018). The regulatory regime for drug versus biologic approval, however, is highly similar.

“there is *no* adequate, approved, and available alternative to the product” under consideration. 21 U.S.C. § 360bbb-3(c)(3) (emphasis added).

13. As part of the ordinary review process, 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). *See also* 42 U.S.C. § 262(a)(2)(C) (requiring proof that biologic product actually “***is . . . potent***” before granting approval) (emphasis added). In sharp contrast, FDA has the discretion to grant an EUA if the applicant shows that its product “***may*** be effective” in treating the relevant disease or condition. 21 U.S.C. § 360bbb-3(c)(2)(A) (emphasis added). In keeping with the above, FDA has stated that the EUA process “provides for a lower level of evidence” of “effectiveness” compared to the robust evaluation the agency typically uses for formal approvals. *See* FDA, *Emergency Use Authorization of Medical Products and Related Authorities; Guidance for Industry and Other Stakeholders* 8 (Jan. 2017) (FDA EUA Guidance). Importantly, FDA will approve EUA products on incomplete information and considers it unlikely that “comprehensive effectiveness data” will be available before an EUA grant. *Id.* at 14.

14. In addition, FDA ordinarily “shall” deny approval if the applicant “do[es] ***not*** show that such drug ***is*** safe.” 21 U.S.C. § 355(d)(2) (emphasis added). *See also* 42 U.S.C. § 262(a)(2)(RB) (biologic approved only if it actually “***is . . . safe***”) (emphasis added). On the other hand, FDA may grant an EUA so long as the applicant shows that the “known and potential benefit of the product” merely “***outweigh[s]*** the known and potential risks.” 21 U.S.C. § 360bbb-3(c)(2)(B) (emphasis added).

15. The procedural framework for formal drug approval compared to EUA grants also underscores the substantive difference between the two processes. An application for formal approval must contain full reports of the scientific studies and testing undertaken to demonstrate whether a proposed drug is safe and effective for its intended use. An applicant typically must

conduct animal testing before it can even begin human testing. After successfully completing the animal testing stage, an applicant must next submit for FDA approval an investigational new drug application (INDA) that explains the scientific basis for proceeding with human testing. *See, e.g.,* FDA’s Drug Review Process: Continued (Aug. 24, 2015).

16. Upon approval for human testing, an applicant commences “[c]linical testing for safety and effectiveness requir[ing] three or sometimes four phases” in succession. *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 495 F.3d 695, 698 (D.C. Cir. 2007). Specifically:

- A. Phase 1 studies include 20-80 persons and are principally designed to measure safety. A Phase 1 study may also provide very “early evidence on effectiveness.”
- B. Phase 2 studies consist of “well controlled” and “closely monitored” clinical trials of several hundred persons to evaluate both efficacy and short-term side effects and risks.
- C. Phase 3 studies consist of “expanded clinical trials of several hundred to several thousand subjects.” These pivotal trials are designed to “gather additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis” for a drug’s labeling.
- D. Phase 4 studies are not automatically performed, but sometimes are necessary to “delineate[] additional information about the drug's risks, benefits, and optimal use.”

17. All told, the research, development, and formal evaluation and approval process for new drugs requires a staggering amount of time. For example, one study found that “[b]etween

January 2010 and June 2020, the FDA approved 21 vaccines” (outside of the EUA process) and that “[t]he median premarket clinical development period” *exceeded eight years*. Jeremy Puthumana et al., *Speed, Evidence, and Safety Characteristics of Vaccine Approvals by the US Food and Drug Administration*, JAMA Intern Med. 2021;181(4):559-560.0.

18. In sharp contrast, the EUA statute expressly contemplates a more *ad hoc* process for drug development, testing, and authorization. Unlike the standard approval pathway, FDA does *not* require “adequate and well-controlled clinical trials” to grant an EUA; clinical trial results need only be submitted “*if available.*” 21 § U.S.C. 360bbb-3(c)(2) (emphasis added). Instead of abiding by a rigid regulatory process for testing and approval, FDA invites EUA applicants to dialogue with FDA on a case-by-case basis to evaluate what procedures and testing best suits the specific circumstances. *See* FDA EUA Guidance at 10.

19. Consistent with the above, the EUA statute also reflects Congress’s expectation that EUA products will likely have inferior guarantees of safety and efficacy compared to formally approved drugs. For this reason, among others, unlike traditionally approved drugs, Congress mandated that FDA directly inform “health care professionals administering” the EUA product of any “significant known and potential benefits and risks.” 21 U.S.C. § 360bbb-3(e)(1)(A)(II) (emphasis added). Similarly, Congress directed FDA to ensure that individuals *receiving* the product obtain the same information. *Id.* § 360bbb-3(e)(1)(A)(II).

20. In addition, FDA has issued specific guidance for COVID-19 vaccine EUAs. *See, e.g., FDA Emergency Use Authorization for Vaccines to Prevent COVID-19; Guidance for Industry* (Mar. 31, 2022) (FDA COVID-19 EUA Guidance). Consistent with FDA’s general guidance document, the agency’s COVID-19-specific guidance made clear that an EUA grant does not reflect a fulsome or even complete efficacy determination. Specifically, FDA announced that it would grant EUAs based on *interim data*, and, upon issuing an EUA, the agency expected an

applicant to “continue to collect data in any ongoing trials” for purposes of supporting a formal approval. *Id.* at 4. *See also id.* at 10 (“FDA acknowledges the potential to request an EUA for a COVID-19 vaccine based on an interim analysis of a clinical endpoint from a Phase 3 efficacy study.”).

B. The Regulation of Deceptive Marketing of Vaccines and Drugs.

21. Multiple overlapping federal and state laws regulate and forbid misrepresentations and other deceptive trade practices by drug and vaccine manufacturers.

22. The federal Food, Drug, and Cosmetic Act (FDCA) prohibits “misbrand[ing]” of regulated products. 21 U.S.C. § 331(c). A product is misbranded under federal law if its “labeling” contains misleading content or if the manufacturer’s “advertising” is misleading. *Id.* § 331(n). This determination must take into account whether the “advertising fails to reveal facts material in the light of representations” at issue. *Id.*

23. Additionally, the Federal Trade Commission (FTC) Act prohibits deceptive behavior in commerce generally. 15 U.S.C. § 45. And the Covid-19 Consumer Protection Act expressly made the FTC Act’s deceptive conduct bar 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).

24. The Texas Health and Safety Code contains prohibitions that closely resemble those under federal law. Like the FDCA, Texas law prohibits “misbranded” products, which broadly encompasses “advertising” for the product at issue, as well as material omissions within the advertising. Tex. Health & Safety Code § 431.003. Texas’s DTPA also prohibits “false, misleading, or deceptive acts” generally. Tex. Bus. & Com. Code § 17.46(a). In particular, Texas’s statutory bar on deceptive conduct specifically incorporates applications and interpretations of the FTC Act. *Id.* § 17.46(c).

25. In addition to these general prohibitions applicable to drug and vaccine manufacturers' marketing, FDA has issued more granular guidance on specific kinds of misrepresentations that are highly relevant here. Specifically, FDA has emphatically recognized that the average consumer is unable to properly interpret and evaluate statistical representations in context, particularly with respect to the benefits of pharmaceutical products. *See* FDA, *Communicating Risks and Benefits: An Evidence-Based User's Guide* 53 (2011) (asserting that “innumeracy” “plagues Americans” and has a “profound impact” on their “ability to understand . . . risks and benefits of treatment options”).

26. FDA has issued detailed guidance on how to accurately convey risks and efficacy to patients using statistics. In particular, the agency has recognized at least three possible ways to numerically convey the risks and efficacy associated with a given pharmaceutical product: (1) absolute risk reduction, (2) relative risk reduction, and (3) number needed to treat. *Id.* at 56.

27. *First*, absolute risk represents the likelihood that an individual experiences a particular treatment outcome. For example, an individual might have a baseline 1 in 10,000 chance of developing a certain cancer—Cancer X (a .01% baseline risk). Absolute risk reduction measures the reduction in the baseline risk if the individual engages in some course of treatment. For example, an individual might take an experimental drug intended to lower the risk of Cancer X, such that the baseline risk drops from 1 in 10,000 to 1 in 20,000 (a .005% post-treatment risk). The absolute risk reduction is calculated by subtracting the post-treatment risk rate from the baseline risk rate (.01% minus .005%). Therefore, in this hypothetical the absolute risk reduction is 0.05%.

28. *Second*, relative risk represents the likelihood of an individual experiencing a certain treatment outcome by comparing two scenarios. For example, the same individual as above has a baseline 1 in 10,000 chance of developing Cancer X, and a 1 in 20,000 chance if she takes a specific experimental treatment. Therefore, her relative risk of Cancer X if she takes the treatment

is half of her risk if she does not. The same individual, then, experiences a relative risk reduction of 50% from the treatment. In other words, relative risk reduction reflects the percentage of baseline risk that is removed as a result of the new therapy.

29. *Third*, “number needed to treat” (NNT) reflects the number of patients that would have to be treated by a particular intervention in order to prevent one additional negative outcome. A drug with a NNT of 10 means 10 people require treatment with the drug to avoid one negative outcome that the drug is intended to prevent.

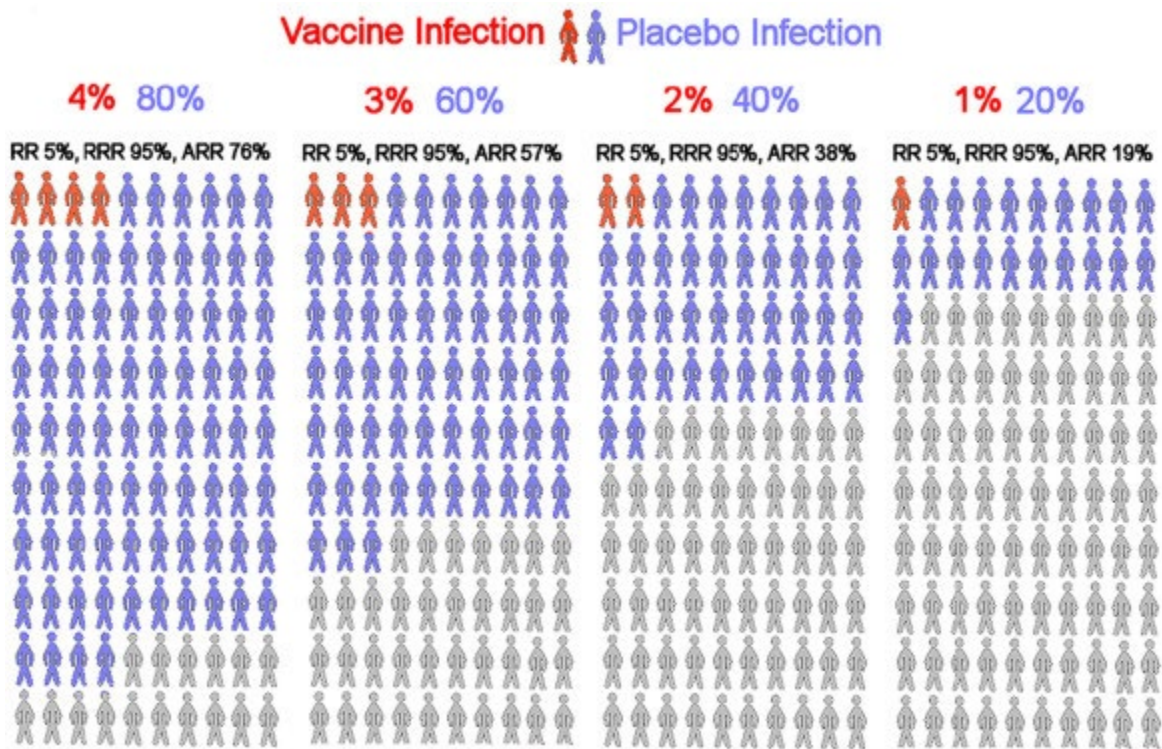
30. As the foregoing illustrates, absolute risk reduction, relative risk reduction, and NNT are drastically different numerical ways to measure and depict the substance of treatment efficacy, and they can generate significantly different numbers to convey the same product’s efficacy. FDA recognizes this, and specifically advises industry against using relative risk reduction alone. FDA has made clear that “When information is presented” in this “relative risk format” the amount risk “reduction *seems* large and treatments are viewed more favorably than when the same information is presented using an absolute risk format.” *Id.* at 56 (emphasis added).

31. Accordingly, FDA instructs drug manufacturers and industry participants to “[p]rovide absolute risks, not just relative risks” because patients “are unduly influenced when risk information is presented using a relative risk approach.” Presenting patients with only relative risk reduction metrics results, in FDA’s own words, “in suboptimal decisions.” *Id.* Notably, FDA scientists have published literature in highly respected, peer-reviewed journals explaining how relative risk reduction can be “misused” to “exaggerate” a drug’s benefits. Stadel et al., *Misleading use of risk ratios* 365 *The Lancet* 1306-1307 (Apr. 9, 2005).

32. FDA’s concerns with reliance on relative over absolute risk reduction metrics is well founded. Specifically, many scientists have observed that a vaccine’s benefit “at a given relative risk could vary considerably as the baseline risk changes.” Ronald B. Brown, *Relative risk*

reduction: Misinformative measure in clinical trials and COVID-19 vaccine efficacy, 1 Dialogues in Health (Dec. 2022). The potential for substantial variation is a principal reason why describing efficacy in terms of relative risk is so misleading and uninformative for the public.

33. The following graphic illustrates how wildly differing disease infection/vaccine protection configurations can generate identical relative risk reduction numbers—in the graphic, 5% across all four configurations—that obscure the underlying reality of vaccination. By contrast, the graphic depicts how absolute risk reduction takes these differences into account by capturing and reporting the differing overall reduction in infection levels across configurations.



Id.

34. In sum, “[w]ithout reporting the [absolute risk reduction] and correcting the public’s misunderstanding of vaccine efficacy, dissemination of vaccine efficacy as the [relative risk reduction] is meaningless and misleading disinformation.” *Id.*

C. Pfizer’s Narrow Emergency Use Authorization for the COVID-19 Vaccine and FDA’s Limited Response.

35. On January 31, 2020, the U.S. Secretary of HHS declared a public-health emergency related to COVID-19. Shortly thereafter, on March 13, 2020, the President declared a national emergency.

36. On March 17, 2020, Pfizer and BioNTech SE announced that the companies had agreed to co-develop and distribute a potential vaccine for COVID-19 based on so-called mRNA technology.² The collaboration built on earlier research and development work undertaken by the companies to develop mRNA-based vaccines for influenza. Pfizer believed that a commercially successful COVID-19 vaccine could very well generate billions, if not tens of billions, of dollars in revenues and profits, and even more significantly validate mRNA technology. In the end, Pfizer could stand in the highly desirable position of having a potentially cutting-edge vaccine platform that could revitalize the legacy pharmaceutical company using COVID-19 revenues to fund commercial endeavors more broadly for years to come.

37. Demonstrating its importance as a business opportunity, Pfizer invested \$2 billion dollars in total in the COVID-19 vaccine project, with the vast majority incurred in 2020. Notably, Pfizer did not take any money from the United States government in conjunction Operation Warp Speed to provide financial support for vaccine research and development. The Pfizer-U.S. government supply agreement entered into on July 22, 2020, *see infra* ¶¶ 52-55, provided that Pfizer fully retained all patents and other intellectual property arising from the project.

38. On November 20, 2020, Pfizer submitted an EUA request for its COVID-19 vaccine, designated “BNT162b2.” *See FDA, Emergency Use Authorization (EUA) for an*

² The technology uses a novel genetics-based approach called messenger RNA; no mRNA vaccine had been approved to prevent infectious disease prior to Pfizer and Moderna’s COVID-19 vaccines.

Unapproved Product Review Memorandum (Dec. 11, 2020) (FDA PFIZER EUA). As part of that application, Pfizer submitted “safety and efficacy data from an *ongoing* Phase 3” trial—not a completed clinical trial. *Id.* at 6. The specifics of that trial bear great relevance to the efficacy representations Pfizer made immediately after receiving the EUA.

39. Pfizer’s EUA application primarily relied on a single clinical trial known as “C4591001” that combined Phases 1, 2, and 3. *Id.* at 12.³ Pfizer commenced Phase 1 trials on April 23, 2020 in a very limited number of subjects. On July 27, 2020, after receiving initial Phase 1 results, Pfizer began enrolling subjects in a joint Phase 2/3 trial. *Id.* at 23. Participants were randomized into two equally sized groups and received “2 doses of either BNT162b2 or placebo, 21 days apart.” *Id.* at 13. For purposes of the EUA, Pfizer monitored those subjects’ status and whether they developed COVID-19 through November 14, 2020. *Id.* at 23.

40. The Phase 2/3 study investigated two primary efficacy endpoints—that is, the metrics used to determine whether the vaccine had its intended effect. As described by FDA, the first primary efficacy endpoint measured “COVID-19 incidence per 10,000 person-years of follow-up in participants without serological or virological evidence of past SARS-CoV-2 infection before and during vaccination regimen—cases confirmed ≥ 7 days after Dose 2.” *Id.* at 13 (emphasis in original).⁴ In plain English, the first endpoint sought to measure how often COVID-19 occurred in persons seven days after the second vaccine dose, among persons who had presumably not been infected with COVID-19 before that time.

³ Pfizer also conducted a preliminary Phase 1 trial known as BNT162-01. Given that the trial involved only 12 participants and tested different vaccine formulations and dosing regimens than BNT162b2, FDA did not deem it material for purposes of issuing the EUA. *Id.*

⁴ FDA used “SARS-CoV-2” to refer to the disease agent itself and “COVID-19” to refer to the resulting sickness. That distinction is immaterial for purposes of this Original Petition, which on occasion uses the terms interchangeably.

41. The second primary efficacy endpoint measured “COVID-19 incidence per 1000 person-years of follow-up in participants with and without evidence of past SARS-CoV-2 infection before and during vaccination regimen—cases confirmed ≥ 7 days after Dose 2.” *Id.* (emphasis in original). In lay terms, the second endpoint sought to measure how often COVID-19 arose seven days after the second vaccine dose, among all persons, including those who may have been infected some earlier time.

42. In the Phase 2/3 trial, Pfizer used a specific standard to determine when a participant had contracted COVID-19 for purposes of the two primary efficacy endpoints. Specifically, “the case definition for a confirmed COVID-19 case was the presence of at least one” of several COVID-19 symptoms in the participant *in addition to* “a positive” COVID-19 test. *Id.* at 14. In other words, an individual with a COVID-19 infection *alone*, as determined by a diagnostic test, would not qualify as an actual COVID-19 case for purposes of evaluating the vaccine’s efficacy.

43. The study results submitted to FDA comprised 43,448 participants, including 21,720 who received the Pfizer vaccine and 21,728 who received a placebo. Although Pfizer “initially enrolled approximately 30,000 participants” in July 2020, the “enrolled study population had a median follow-up of less than 2 months” when it finally submitted the data to FDA. *Id.* at 17. That is at least partly because Pfizer belatedly added 14,000 additional participants, which substantially reduced the median follow-up time. Indeed, as of November 14, 2020, FDA found that only 43.9% of vaccine recipients completed at least two months of follow-up after receiving the second dose. *Id.* at 16.

44. Pfizer’s clinical trial results showed that as of November 14, 2020, 8 out of 17,411 participants (0.04%) who received its vaccine and did not have evidence of a prior infection experienced a defined COVID-19 case during the trial. *Id.* at 23. The results further showed that as of November 14, 2020, 162 out of 17,511 participants (0.9%) in the placebo group who did not

have evidence of a prior infection experienced a defined COVID-19 case during the trial. The relative risk reduction between the placebo group and the treatment group was 95%. *Id.* Put differently, the relative risk reduction metric reflects the percentage of baseline risk of COVID-19 infection present in the control/placebo group that Pfizer’s vaccine removed, not the amount of risk reduction present in the overall population.

45. However, the absolute risk reduction for defined COVID-19 cases was only 0.85%. As previously noted, a vaccine’s absolute risk reduction is determined by subtracting the post-treatment risk rate from the baseline risk rate. Using Pfizer’s Phase 2/3 data, this calculation is performed by subtracting the post-treatment risk rate of 0.04% (8/17,411 persons) found in the vaccine group from the baseline risk rate of 0.9% (162/17,511 persons) found in the placebo group, which after rounding yields 0.85%. This less-than-one-percent total reduction in risk is a product of the fact that *very few people* in either the placebo or treatment group qualified as a defined COVID-19 case.

46. In addition, the NNT according to Pfizer’s results was 119. In other words, the trial showed that it was necessary for 119 people to receive Pfizer’s vaccine in order to avoid a single defined COVID-19 case.⁵

47. Other results from the initial Phase 2/3 trial called into significant question how efficacious the vaccine was in a more practical sense. As noted above, Pfizer designed the trial such that “defined COVID-19 cases” were counted starting only seven days after a participant received the second of two shots (at least 28 days after the first shot). Put differently, COVID-19 cases that occurred *before* that point—that is, between shot one and seven days after shot two—were not considered when evaluating the efficacy of Pfizer’s vaccine. That was a highly significant

⁵ Overall, the results for Pfizer’s other primary efficacy endpoint (persons “with and without evidence of prior SARS-CoV-2 infection”) were not materially different.

qualifier because 409 “[s]uspected” COVID-19 cases occurred *after* the participant received the first vaccine shot, but before seven days elapsed after taking the second shot. *Id.* at 41. By contrast, only 287 suspected COVID-19 cases occurred among placebo recipients in that same interval. In other words, *more people in the trial’s treatment group experienced COVID-19 than in the placebo group*, even though the former had taken *at least one ostensibly immunity enhancing dose*.

48. On December 11, 2020, FDA issued an EUA for Pfizer’s vaccine. The FDA-reviewed fact sheet for providers and patients re-produced some of Pfizer’s clinical trial results, but did not make or endorse any distinct representations submitted by Pfizer regarding efficacy.

49. Notably, 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. *Id.* at 49-51. Specifically, FDA made the following findings:

- A. “[I]t is *not possible* to assess sustained efficacy over a period longer than 2 months.” In other words, the clinical trial thus far showed nothing about long-term efficacy.
- B. “Data are limited to assess the effect of the vaccine against *asymptomatic* infection.” The clinical trials, after all, primarily evaluated *symptomatic* infection.
- C. The clinical trials did not provide meaningful data on *mortality*—instead, “A large number of individuals at high risk of COVID-19 and higher attack rates would be needed to confirm efficacy of the vaccine against” death.
- D. Finally, that “[a]dditional evaluations . . . will be needed to assess the effect of the vaccine in preventing virus shedding and transmission.”

D. Pfizer Embarks on a Campaign to Systemically Mislead the Public About the Effectiveness of Its COVID-19 Vaccine to Secure Public Uptake and Win Highly Lucrative Government Contracts.

50. Notwithstanding the serious limitations in Pfizer’s clinical trial data, after receiving the EUA on December 11, 2020, Pfizer embarked on a multifaceted and systemic campaign to mislead the public into believing that its COVID-19 vaccine was substantially more effective than in reality. Pfizer repeatedly made material misrepresentations on at least four different dimensions related to vaccine efficacy: (1) the claim of broad “95% efficacy”; (2) claims related to vaccine efficacy against transmission; (3) claims related to the duration of vaccine protection; and (4) claims about the efficacy of the vaccine against variants, including specifically the Delta variant.

51. In late 2020, Pfizer faced challenging competitive conditions and internal business realities with respect to its COVID-19 vaccine. Several significant competitors in the global pharmaceutical and vaccine market had viable vaccine candidates under development, including AstraZeneca, Johnson & Johnson, Novavax, and Sanofi/GSK, with some of those likely to obtain EUA authorizations around the time as Pfizer. In particular, just like Pfizer, Moderna had developed a vaccine using mRNA technology on the cusp of FDA approval.

52. In 2020, before obtaining EUA grants from FDA, vaccine manufacturers began competing for and entering into supply agreements with national governments. For example, in May 2020 AstraZeneca reached the first agreement with the U.S. government to supply 300 million doses of its vaccine. On the heels of AstraZeneca, Novavax and Sanofi/GSK each landed separate 100 million-dose deals over the next two months.

53. On July 22, 2020, Pfizer announced that the company and the U.S. government had entered into a \$1.95 billion supply agreement under which Pfizer would provide 100 million vaccine doses upon EUA approval, with the government having the option to acquire up to 500 million more doses. Pfizer understood that if its vaccine achieved widescale penetration amongst the public and the government exercised the option even in part, industry participants and national governments would interpret such events as validation of Pfizer’s vaccine. That, in turn, would

expand commercial opportunities for the product both in the United States and abroad.

54. The need for the U.S. government to exercise the purchase option and the strength of competition provided Pfizer with a clear and strong incentive to prioritize rapid and widespread penetration of its vaccine in the United States amongst the public. That incentive was strengthened by Pfizer's and its management's need to make good on the decision to take the significant risk by investing \$2 billion of the company's own capital in the COVID-19 projects, while at the same time foregoing substantial financial support from the government, thus avoiding the negative fallout associated with a high-profile failure.

55. To advance its commercial interests, Pfizer began laying groundwork to mislead the public *well before* it received the EUA for its vaccine. For example, in July 2020, Pfizer CEO Albert Bourla talked about how “the vaccine [works] in humans.” He said that it creates immune responses that are “able to kill the virus” and that “th[e] vaccine can neutralize the virus.” But, as the EUA data later showed, Pfizer measured efficacy only against *symptomatic* COVID-19—not whether the vaccine “neutralized” or “killed” the virus. Time, *Pfizer CEO Albert Bourla Raises Expectations That the Pharmaceutical Giant Can Deliver a COVID-19 Vaccine by Fall* (Updated: July 12, 2020, Originally Published: July 9, 2020).

Misrepresentations concerning 95% relative risk reduction

56. As soon as Pfizer received the preliminary clinical trial results it ramped up its misleading campaign. For example, on November 9, 2020, Pfizer issued a press release describing certain results from its Phase 2/3 trial to an eagerly awaiting public. The press release repeatedly touted how the trial showed that BNT162b2 was “more than 90% effective in preventing COVID-19 in [p]articipants.” However, as explained above, this broad representation was based on and reflected the vaccine's relative risk reduction only—not the more important absolute risk reduction number. And Pfizer's press release nowhere mentioned or explained the distinction between

absolute and relative risk reduction, much less disclosed the fact that the misleading statements in its marketing promotion press release were based on relative risk reduction or that the absolute risk reduction equaled only 0.85%. At bottom, however, Pfizer concealed and, ultimately, never informed the public of the highly material fact that amongst the general population Pfizer's own trial results showed that the vaccine would reduce the incidence of the non-vaccinated contracting COVID-19 *by less than one percent*.

57. Moreover, the press release included statements from Pfizer CEO Dr. Albert Bourla emphasizing the broad effectiveness of its vaccine. Bourla stated that the trial's efficacy data "provides the initial evidence of our vaccine's ability to *prevent COVID-19*." He further expounded, "With today's news, we are a significant step closer to providing people around the world with a much-needed breakthrough to help bring an end to this global health crisis."

58. Pfizer's Phase 2/3 trial, however, did not support these statements. As previously noted, Pfizer's study was designed to evaluate efficacy on a narrow basis—that is, whether participants contracted symptomatic COVID-19 after receiving the vaccine. Moreover, Pfizer's data in its EUA submission that purported to answer that question could do so only for a limited period of time (two months after the second dose). As described above, even FDA recognized that further evaluation was required to determine whether Pfizer's vaccine prevented contracting asymptomatic COVID-19, or the duration of protection it conferred. *See supra* ¶ 49.

59. In making these statements, Bourla exacerbated the misleading nature of his and the company's 90%+ efficacy claim by broadly and recklessly claiming that the vaccine prevented COVID-19 full stop and would end the global pandemic. These statements had no scientific basis and were well outside the boundaries of Pfizer's narrowly designed Phase 2/3 trial.

60. Pfizer disseminated further deceptive promotional marketing material in the form of a press release on November 18, 2020, touting its "vaccine efficacy rate of 95%." Pfizer's highly

anticipated press release failed to mention that its central efficacy representation relied on the confusing, misleading, and uninformative relative risk reduction calculation. Nor did it distinguish relative risk reduction from absolute risk reduction or NNT, much less provide the calculations for those to counteract the cloud of deception cast by this and previous Pfizer press releases. Finally, the press release did not disclose other pieces of critical information, such the absence of knowledge regarding the vaccine’s duration of protection and ability to prevent transmission.

61. Taken alone and in combination, Pfizer’s misleading statements created the false impression that 95% of vaccine recipients would never obtain COVID-19, full stop.

62. Because of the extraordinary fear amongst the American public stemming from the pandemic and its attendant social and economic problems, Pfizer understood that mainstream media outlets would adopt and broadly disseminate the company’s statements about its COVID-19 vaccine—especially those about effectiveness—and could readily anticipate that the media would serve as an amplifier of its deception campaign. Indeed, prominent mainstream media outlets rapidly picked up on, and perpetuated, Pfizer’s misleading talking points.

63. For example, on November 18, 2020, Forbes broadcast the headline that “Pfizer-BioNTech Says Covid-19 Vaccine Is 95% Effective.” In the news report, Forbes parroted Pfizer’s deceptive and misleading press release from earlier in the day, adopting Pfizer’s claim that “new trial data showed it to be 95% effective, following initial news of 90% efficacy in its Phase 3 trials.”

64. On the same day, CNN reported that “Pfizer and BioNTech say final analysis shows coronavirus vaccine is 95% effective with no safety concerns,” writing, “A final analysis of the Phase 3 trial of Pfizer's coronavirus vaccine shows it was 95% effective in preventing infections, even in older adults, and caused no serious safety concerns.” And CBS likewise reported that “Pfizer and its partner BioNTech announced . . . test results show[ing] their vaccine candidate was

95% effective at preventing COVID-19.”

65. Pfizer’s misrepresentations extended well beyond this 95% efficacy statement. Over the following year, Pfizer would go on to mislead the public across multiple critical COVID-19-related dimensions, including specifically the ability of the vaccine to prevent viral transmission from asymptomatic to uninfected people, the reality of waning vaccine efficacy, and the vaccine’s ineffectiveness against the Delta variant.

Misrepresentations regarding transmission

66. As explained above, Pfizer’s clinical trial did not evaluate whether the vaccine prevented COVID-19 transmission or shedding, a fact that FDA emphasized when it granted the EUA. Among other limitations, the Phase 2/3 trial did not consider participants infected by COVID-19 during its duration who remained asymptomatic to qualify as a confirmed COVID-19 case for purposes of the primary efficacy endpoints. *See supra* ¶¶ 42, 49.B. Nevertheless, over the following year Pfizer made multiple false and misleading statements about vaccine efficacy against asymptomatic infection and ability to prevent transmission.

67. For example, on or around December 14, 2020, Albert Bourla admonished viewers in a CNBC interview that “I [will] repeat once more. The decision not to vaccinate will not affect only your health or your life,” but also “[u]nfortunately it will affect the lives of others, and likely the lives of the people you love the most.” CNBC, *CNBC Transcript: Pfizer Chairman and CEO Albert Bourla Speaks with CNBC’s “Squawk Box” Today* (Dec. 14, 2020). He underscored in the same interview that persons do not “have the luxury to think about” whether to take the vaccine, or whether to “wait a few months.” The most reasonable implication to the public here is that vaccination would prevent transmission; otherwise, it makes no sense to say one’s vaccination decision was relevant not only to their own health, but also the health of “people you love.”

68. Similarly, in a March 31, 2021 press release, Pfizer emphasized in conjunction with

new results on vaccine efficacy in adolescents that “[i]t is very important to enable [adolescents] to get back to everyday school life and to meet friends and family while protecting them and their loved ones.” However, just like Pfizer’s main Phase 2/3 trial, Pfizer’s clinical trial in adolescents did not evaluate transmission. Similarly, it was highly misleading to convey to the public that adolescent vaccine uptake was important for adolescents to “protect . . . their loved ones.”

69. On June 8 Albert Bourla also tweeted that “[w]idespread vaccination is a **critical** tool to help stop transmission.”

70. And in an interview on or around June 14 Albert Bourla once again emphasized that “[t]he decision to vaccinate or not is not going to affect only your life but unfortunately will affect the health of others” including “people you love most.” CBS Mornings, *Pfizer CEO Albert Bourla on vaccine supply, herd immunity* (June 14, 2021).

71. ***Pfizer’s clinical trial data did not support any of these statements.*** Moreover, data that Pfizer would later submit for formal approval of its vaccine likewise confirmed that Pfizer lacked *bona fide* data that could substantiate these statements. *See infra* ¶ 96.

72. Pfizer’s false and misleading statements had a cascading effect in the media, which through multiple formats repackaged and disseminated Pfizer’s deception campaign to the public. For example, on May 19, 2021, CNN published “10 reasons why young, healthy people should get vaccinated,” and featured as one reason that “If young people don’t get vaccinated, it could leave everyone vulnerable.”

Misrepresentations regarding waning efficacy

73. As previously discussed in detail, Pfizer’s clinical trial did not evaluate vaccine efficacy beyond two months, and FDA emphasized the same fact in its EUA evaluation, *supra* ¶¶ 43, 49.B.

74. This limitation represented a critical gap in Pfizer’s efficacy data, particularly in

light of the fact that Pfizer and the scientific community more broadly knew that the vaccine's efficacy *would* likely wane. For example, existing literature was replete with findings based on the previous SARS-CoV virus clearly indicating that there likely would be “*substantial waning*” at some time after initial inoculation. Jayanathan et al., *Immunological considerations for COVID-19 vaccine strategies* Nature (Sept. 2020) (emphasis added). For this reason, among others, Pfizer was, at minimum, on notice that it was “possible that the populations that receive the first round of vaccines will have waning immunity and require boosting.” *Id.* And the scientific community expressed that “effective planning of mass immunization campaigns and strategies [for COVID-19] will require knowledge of the duration of such protection.” Mehrotra et al., *Clinical Endpoints for Evaluation Efficacy in COVID-19 Vaccine Trials* (Feb. 2021). Quickly determining the duration of protection—and properly conveying that information to the public—was critical in light of this backdrop.

75. Nevertheless, over the course of 2021, Pfizer issued numerous false and misleading statements obfuscating the facts about waning protection. Pfizer even went so far as to conceal and withhold contrary internal data. In sum, Pfizer knowingly cultivated the false impression that its COVID-19 vaccine provided long-lasting immunity to perpetuate its deception campaign and prevent a loss in public confidence in the vaccine's overall efficacy.

76. For example, in a February 2021 interview CEO Albert Bourla was asked “how long” vaccine protection lasted. Bourla responded that “at 6 months, the protection is robust.”⁶ At this time, however, Pfizer's clinical trial data had *not* yet even collected six months of post-vaccination data for its participants. NBC News, *Exclusive Interview with Pfizer CEO Albert Bourla* (Feb. 25, 2021). And, in fact, the data Pfizer had collected at that point indicated that

⁶ NBC News, *Exclusive Interview with Pfizer CEO Albert Bourla* (February 25, 2021).

efficacy was *already waning*. See *infra* ¶¶ 80, 94.

77. In March 2021, Pfizer’s own clinical trial results revealed *substantial* waning efficacy. See *infra* ¶¶ 80, 94. Nevertheless, on March 31, 2021 and April 1, 2021, Pfizer released press releases that obfuscated and failed to disclose this critical information. First, on March 31, 2021, Pfizer issued a press release simply stating that its vaccine has a 100% efficacy rate for adolescents, with no disclosure about waning efficacy. And on April 1, 2021, Pfizer issued a press release with “updated” results on its original clinical trial, claiming 91.3% efficacy and emphasizing “high vaccine efficacy observed through up to six months,” again, without disclosing material facts about the significant waning as time progressed.

78. On April 1, 2021, Albert Bourla tweeted that the vaccine was 100% effective against a South African variant. <https://twitter.com/AlbertBourla/status/1377618480527257606>. That was based on a study with a highly limited sample size—specifically, a mere nine observed COVID-19 cases out of only 800 persons. As a result, the confidence interval for the inherently misleading relative risk reduction metric ranged as low as 53.5%, meaning massive uncertainty existed over the precise level of protection that the vaccine conferred against this variant. Additionally, Pfizer had no reason to believe that its vaccine would have greater potency against the South African variant than against the original strain. Indeed, Pfizer separately confirmed that its vaccine induced a *lower* “antibody response” to this variant compared to the original.

79. Continuing Pfizer’s deception campaign, on or around April 15, Bourla represented that Pfizer had new data addressing “duration of the immunity” and that the vaccine provided “extremely, extremely high protection” against COVID-19 infection. Jerusalem Post, *Pfizer CEO: Third COVID-19 Vaccine, Annual Booster Shots Likely Scenario* (April 15, 2021).

80. Contrary to its public deception campaign, Pfizer knew by around mid-March 2021 that vaccine efficacy quickly deteriorated. See *infra* ¶ 94. But, while Pfizer knowingly and widely

disseminated misleading statements about vaccine efficacy duration, it withheld specific and highly material information that undermined those claims from the public until July 28, 2021. On that date, Pfizer published the ultimate clinical trial results in pre-print in medRxiv. At around that time, the media ran articles perpetuating Pfizer's misleading impression that this represented "new data" when in fact Pfizer had sat on the data for months in a transparent attempt to not undermine the successful deception campaign and rising vaccine uptake.

81. Pfizer's false and misleading statements and omissions about the duration of vaccine protection had a cascading effect in the media, and were repeated in multiple formats to the public. Relying on Pfizer's statements, the media repeatedly parroted Pfizer's misleading claim that the COVID-19 vaccines would "be effective" for at least "six months and counting." On April 1 for example, NBC published an article parroting how "Pfizer and BioNTech said Thursday that trials suggest their vaccine" showed "high levels of protection against Covid-19 six months after their second dose."

82. Similarly, on April 1, 2021, U.S News and World Report reported that "Pfizer Coronavirus Vaccine Protection Lasts At Least Six Months." And at around the same time, Yahoo! News similarly published that "Pfizer-BioNTech COVID-19 Shot Safe, Effective Through Six Months After Second Dose."

Misrepresentations regarding efficacy against the Delta variant

83. On June 1, 2021, the Center for Disease Control (CDC) announced that a mutation of the original COVID-19 virus known as the Delta variant had become the "dominant variant" in the United States. By the end of July, CDC Director Rochelle Walensky testified to Congress that the Delta variant was responsible for the vast majority (83%) of COVID-19 infections in the United States. *See, e.g., Cheyenne Haslett, Delta variant now makes up 83% of cases, CDC director says, pressed on booster shots* ABC News (July 20, 2021) Indeed, former FDA Commissioner and Pfizer

board of director's member Scott Gottlieb publicly claimed that "for most people," a Delta infection would amount to "the most serious virus that they get in their lifetime in terms of risk of putting them in the hospital." See Aya Elamroussi & Holly Yan, *The Delta variant is so contagious, those unprotected will likely get it, a Trump administration FDA chief says* CNN (July 18, 2021).

84. Pfizer's clinical trial did not evaluate vaccine efficacy against SARS-CoV-2 variants. Nevertheless, Pfizer publicly made multiple false and misleading statements about its vaccine's efficacy against SARS-CoV-2 variants, including specifically the Delta variant.

85. For example, on or around March 24, 2021, Bourla stated that "I don't worry about variants," emphasizing that "the worst thing is to start making vaccines for things that we don't need." The most reasonable interpretation of Bourla's statement was that Pfizer's then-current vaccine was effective against variants.

86. Bourla compounded this misrepresentation by claiming a seemingly impossible "100%" vaccine efficacy rate against variants, such as the South African variant, even though Pfizer's Phase 2/3 trial did not test efficacy against this variant. Bourla used this remarkable representation to leap even further and claim that "[n]o variant identified so far . . . escapes the protection of our vaccine."

87. Having exposed the public to a steady barrage of misleading statements concerning variants generally, Pfizer extended the deception campaign to the Delta variant specifically. For instance, on or about June 14, 2021, Bourla stated he was "quite comfortable" that Pfizer's vaccine would "cover" the Delta variant. CBS Mornings, *Vaccinating The World Pfizer CEO on Efficacy Against Variants, Boosters, and Donating Doses* (June 14, 2021).

88. Pfizer continued to make misleading statements concerning the efficacy of its vaccine against the Delta variant throughout the summer. The following are representative

examples of Pfizer's continued campaign of deception:

- A. On or around June 24, 2021, a Pfizer medical director told the media that Pfizer's "data from those places where the Indian variant, Delta, has [become] the common variant, point to our vaccine being very effective, around 90%." Maayan Lubell, *Pfizer says COVID vaccine is highly effective against Delta variant*, Reuters (June 24, 2021).
- B. On or around July 28, 2021, Bourla stated that Pfizer is "very very confident that a third dose, a booster [of the original vaccine], will take up the immune response to levels that will be enough to protect against the delta variant."
- C. On August 16, 2021, Pfizer issued a press release touting how a booster would "preserve and even exceed the high levels of protection against . . . relevant variants."
- D. And on August 23, 2021, Bourla represented that "[t]he current vaccine is very, very, very effective against Delta."

89. In fact, however, what little data was available on vaccine efficacy against Delta during this time period devastated Pfizer's unsupported claims. *See infra* ¶¶ 110-16, 120-22.

90. Just like Pfizer's other misrepresentations, Pfizer's false and misleading statements about vaccine efficacy against the Delta variant had a cascading effect in the media and were repeated in multiple formats to the public.

91. As alleged above, Pfizer knowingly misrepresented the efficacy of its COVID-19 vaccine on multiple dimensions with the intent to facilitate the vaccine's adoption and expand its commercial opportunity. And Pfizer's strategy succeeded spectacularly. Exploiting the widespread fear and anxiety over the pandemic and the public's trust in new vaccines to end it, Pfizer's deception campaign quickly accelerated and Pfizer's vaccine assumed the position of market

leader in the United States, and thereafter maintained nearly 70% market penetration among the public by the end of 2021. Pfizer's position as the market leader for COVID-19 vaccines was established on a worldwide basis when the U.S. government decided to exercise its right to buy 500 million more doses from Pfizer over the course of 2021.

E. Clinical Trial Results and Real-World Data Confirm the Misleading Nature of Pfizer's Baseless Efficacy Representations.

92. At the same time as Pfizer executed its public deception campaign, data both in Pfizer's hands and in the scientific community more broadly was sharply undermining what Pfizer was telling the public.

93. **Formal FDA Approval Data.** First, Pfizer's clinical trial that supported the EUA grant continued to generate results up through March 13, 2021. Pfizer used the data collected up through that time point in its application requesting formal FDA approval of its COVID-19 vaccine, which it submitted to the agency on May 18, 2021. *See* FDA, Summary Basis for Regulatory Action on COMIRNATY 1, 18 (Nov. 8, 2021).

94. Pfizer's data as of March 13 showed a material decrease in efficacy corresponding to the time after a subject received dose two. Specifically, whereas the risk reduction rate for the window beginning seven days after Dose 2 and ending less than two months thereafter stood at 96%, the relative risk reduction for the window beginning four months after Dose 2 and ending six months after Dose 2 collapsed to 83.7%. *See* COMIRNATY CRM at 51-52.

95. Moreover, **none** of the clinical trial data in the formal approval application supported efficacy against the Delta variant. *See id.* at 52 ("Updated efficacy analyses were conducted in March 2021, prior to the emergency of the B.1.617.2 (Delta) variant in the US."). FDA recognized that this posed a major problem, noting that it was "[u]ncertain[]" whether Pfizer's vaccine possessed "effectiveness against SARS-CoV-2 variants that are different from

those circulating” as of March 13, 2021—when Pfizer’s trial ended. *Id.* at 95.

96. FDA further recognized the existence of “[u]ncertain[t]y” regarding the “duration of protection” and, relatedly, whether Pfizer’s vaccine protected against “asymptomatic infection and transmissibility of the virus.” *Id.* at 95.

97. There were also problems with the integrity of the data itself. After FDA granted the EUA, Pfizer gave clinical trial participants the ability to “unblind” themselves. This meant that people in the original placebo group had the opportunity to get vaccinated *before* the clinical trial ended.

98. However, when FDA initially granted Pfizer’s EUA, the agency emphasized that it was “critical” for Pfizer to “continue to gather data about the vaccine even after it is made available under EUA.” FDA PFIZER EUA at 11. To this end, FDA sharply cautioned Pfizer against “immediately unblind[ing] their trials upon issuance of an EUA.” *Id.* “FDA and its advisers pushed hard for volunteers to remain on placebo as long as possible to gather more safety and efficacy data.” Matthew Harper, Pfizer and BioNTech speed up timeline for offering Covid-19 vaccine to placebo volunteers STAT NEWS (Jan. 1, 2021).

99. Nevertheless, according to Pfizer’s own data, by January 21, 2021, **7,446** participants who received placebo during the trial had elected to take the actual vaccine. Contrary to FDA’s directive, Pfizer’s “aim” was for *every* placebo subject to “have the opportunity to receive their first dose of” the vaccine by March 1, 2021. Pfizer.com., *Pfizer-BioNTech COVID-19 Vaccine Trial Overview*. Accordingly, by the time Pfizer’s trial ended on March 13, almost all placebo participants had been unblinded and given BNT162b2. *See* FDA, BLA Clinical Review Memorandum for COMIRNATY 67 (Aug 23, 2021) (“Overall, 19,525 original placebo participants were unblinded and received BNT162b2.”) (COMIRNATY CRM)

100. FDA’s review of the formal application also revealed significant safety concerns.

Specifically, “FDA and CDC identified serious risks for myocarditis and pericarditis following administration of” Pfizer’s vaccine, including “some cases [that] required intensive care support.” FDA, Summary Basis for Regulatory Action on COMIRNATY 23 (Nov. 8, 2021). Indeed, there were 38 deaths during the clinical trial. COMINARTY CRM at 70. The majority of deaths were in the *vaccinated* (twenty-one vaccine recipient deaths versus seventeen placebo deaths). *Id.* Many of the vaccinated deaths were a result of “[c]ardiac conditions.” *Id.* at 71.

101. FDA ultimately concluded that it was “unlikely” the vaccine caused any deaths. *Id.* But the deaths are nevertheless critical because they underscore that Pfizer’s vaccine unequivocally failed at preventing persons from dying on the whole. *Id.* The clinical trials produced *no* evidence that Pfizer’s vaccine prevented death altogether, even if there was evidence that the vaccine (temporarily) prevented some COVID-19 cases.

102. Over the course of 2021, additional data points emerged corroborating the fact that Pfizer had no scientific support to justify many of its efficacy claims. Indeed, much of this data undermined Pfizer’s efficacy claims.

103. ***Transmissibility data.*** Substantial additional evidence emerged throughout 2021 showing that Pfizer’s vaccine did not prevent transmission. On July 30, 2021, the CDC released a devastating report about an outbreak of COVID-19 at large gatherings in Barnstable County, Massachusetts. *See* CDC, *Outbreak of SARS-CoV-2 Infections, Including COVID-19 Vaccine Breakthrough Infections, Associated with Large Public Gathering—Barnstable County, Massachusetts, July 2021* (Aug. 6, 2021). The CDC’s analysis demonstrated that vaccinated persons caused a significant outbreak of symptomatic COVID-19 among other *vaccinated* persons at multiple large public gatherings in a Massachusetts. Of the COVID-19 infections associated with the outbreak, nearly three quarters occurred in fully vaccinated persons, a plurality of which

had received Pfizer's vaccine. *Id.*⁷

104. In addition, the medical journal *The Lancet* published a study on October 29, 2021, showing that vaccinated individuals caused infections within their households *at materially the same rate as unvaccinated individuals*. Specifically, “fully vaccinated individuals” infected with COVID-19 caused approximately 25% of persons in their household to contract COVID-19, whereas “unvaccinated individuals” with COVID-19 caused infections within their household at a rate of 23%. See Singanayagam et al., *Community transmission and viral load kinetics of the SARS-CoV-2 delta (B.1.617.2) variant in vaccinated and unvaccinated individuals in the UK: a prospective, longitudinal, cohort study* *The Lancet* (Oct. 29, 2021). Another study published in October 2021 found that to the extent vaccination prevents “[t]ransmission,” that transmission reduction “decline[s] over time” and “attenuate[s] substantially” for Pfizer recipients a mere “3 months post-second” dose. Eyre et al., *The impact of SARS-CoV-2 vaccination on Alpha & Delta variant transmission* medRxiv (Oct. 15, 2021).

105. ***Waning Efficacy Data.*** Substantial additional evidence also emerged throughout 2021 showing that Pfizer's vaccine had serious waning efficacy, bolstering the conclusion that Pfizer lacked a scientific basis when it represented that its vaccine had robust and long-lasting efficacy in the first instance.

106. For example, in many respects, including with regard to waning efficacy, Israel's data was considered the gold standard. Indeed, Pfizer's Chief Scientific Officer, Philip Dormitzer, expressed that Israel was “sort of [a] laboratory” and that “[w]hat we see happening in Israel happens again in the US a couple months later.” This makes sense because the vast majority of

⁷ Moreover, the vaccine apparently did not reduce the rate of hospitalization. Five persons in total were hospitalized, and four of those were vaccinated. The one unvaccinated person “had multiple underlying medical conditions.” *Id.*

Israelis received the Pfizer vaccine. But Israel's data showed time and again that vaccine efficacy waned rapidly.

107. By June 6, 2021, Israel's Health Ministry was reporting that vaccine relative risk reduction at preventing infection *and* symptomatic disease fell to just 64%. On August 30, 2021, an Israeli study found a "strong effect of waning immunity in all age groups after six months." Goldberg et al., *Waning immunity of the BNT162b2 vaccine: A nationwide study from Israel* (Aug. 30, 2021). Individuals who received their second dose in March 2021 were 160% more protected than those who received their second dose a mere two months earlier.

108. According to an FDA presentation, 60% of Israel's severe COVID in July and August 2021 occurred in vaccinated people. FDA, Vaccines and Related Biological Products Advisory Committee Meeting Slideshow at 12 (Sept. 17, 2021).

109. United States-based studies performed by CDC yielded similar results. On September 24, 2021, the CDC issued a report on efficacy against hospitalization. While it found the vaccine had an average 91% relative risk reduction rate against hospitalization two months after dose two, that efficacy quickly dropped to 77% at only three months later. *See* CDC, Comparative Effectiveness of Moderna, Pfizer-BioNTech, and Janssen (Johnson & Johnson) Vaccines in Preventing COVID-19 Hospitalizations Among Adults Without Immunocompromising Conditions—United States, March-August 2021 (Sept. 24, 2021).

110. ***Delta variant data:*** Substantial evidence also emerged showing that the vaccine had little, and arguably *negative* efficacy against the Delta variant. As such, this subsequent evidence confirmed that Pfizer had no factual basis to make its efficacy representations about Delta in the first instance.

111. On or around July 23, 2021, the Israeli Health Ministry announced, while "the delta variant [wa]s the dominant strain," that "Pfizer and BioNTech's Covid-19 vaccine is just 39%

effective.” CNBC, *Israel says Pfizer Covid vaccine is just 39% effective as delta spreads, but still prevents severe illness* (July 23, 2021). Illustrating the precipitous drop in vaccine efficacy against Delta, Israeli officials estimated efficacy at 64% just weeks before.

112. Worse, in September 2021, FDA’s Vaccines and Related Biological Products Advisory Committee recognized that Israel was experiencing its worst “levels of infection (delta variant) in spite of widespread” vaccination. FDA, Vaccines and Related Biological Products Advisory Committee Meeting Slideshow at 10 (Sept. 17, 2021).

113. There is also evidence that the Pfizer vaccine did little, or perhaps nothing, to prevent *death* from the Delta variant. Specifically, the United Kingdom’s Office for National Statistics retained and publicized remarkably granular vaccine efficacy statistics during COVID-19, broken out according to unvaccinated, vaccinated, or boosted deaths involving COVID-19 on a per-month basis. This is highly informative data because Pfizer’s vaccine was the most used COVID-19 vaccine in the U.K. In March 2021, for example, U.K. data shows 1,309 unvaccinated deaths involving COVID-19, versus only 35 deaths involving COVID-19 in persons 21 days or more after their second dose. In other words, in the early days after vaccination, Pfizer’s product appeared to at least be effective at preventing death. But by July 2021—during Delta’s peak—those numbers were nearly flipped. Specifically, in July 2021, there were only 331 unvaccinated deaths involving COVID-19. But there were **750** deaths involving COVID-19 among persons 21 days or more after their second dose.

114. The overall trend in the U.K. of (1) decreasing deaths among the unvaccinated, along with (2) increasing deaths among the vaccinated, increased in a dramatic way for months after the Delta variant inundated the U.K. For example, in October 2021, the U.K.’s data showed 419 unvaccinated deaths involving COVID-19. But there were **2,102** deaths involving COVID-19 in persons 21 days or more after the second vaccine dose. Indeed, even though relatively few

people had received booster shots by October 2021, there were also 163 deaths involving COVID-19 among persons who had received a booster shot.

115. Data from other jurisdictions was arguably even worse. Scotland published granular information, including specifically the ratio of persons vaccinated (or not) who were infected with, hospitalized, or died because of COVID-19. That data devastates Pfizer’s claims of vaccine efficacy against Delta. For example, in late December 2021 and early January 2022, Scotland’s official reports demonstrate *negative* vaccine efficacy. Put differently, a *greater* ratio of vaccinated persons acquired COVID-19 than unvaccinated persons. For example, in the last week of 2021, Scotland’s data shows approximately 1,000 COVID-19 cases for every 100,000 unvaccinated persons, but 2,550 cases for every 100,000 vaccinated persons. The ratio of boosted persons who acquired COVID-19 (1,526.50 out of 100,000) was likewise higher than among unvaccinated persons.

Table 13: COVID-19 age-standardised case rate per 100,000 individuals by vaccine status, seven-day rolling average from 10 May 2021 to 21 January 2022

Week	Unvaccinated			1 Dose		
	No. tested positive by PCR	Population	Age-standardised case rate per 100,000 with 95% confidence intervals	No. tested positive by PCR	Population	Age-standardised case rate per 100,000 with 95% confidence intervals
25 December - 31 December 2021	9,486	998,916	966.34 (932.78 - 999.89)	3,355	347,509	1,408.50 (1,346.45 - 1,470.54)
01 January - 07 January 2022	9,060	988,860	922.84 (892.58 - 953.11)	3,040	340,199	1,397.40 (1,329.08 - 1,465.72)
08 January - 14 January 2022	3,684	980,373	423.87 (400.75 - 447.00)	1,111	338,860	556.69 (509.91 - 603.47)
15 January - 21 January 2022	2,696	976,349	297.18 (278.32 - 316.05)	779	318,752	386.90 (350.61 - 423.19)
Week	2 Doses			Booster or 3 Doses		
	No. tested positive by PCR	Population	Age-standardised case rate per 100,000 with 95% confidence intervals	No. tested positive by PCR	Population	Age-standardised case rate per 100,000 with 95% confidence intervals
25 December - 31 December 2021	50,658	1,524,657	2,549.61 (2,520.21 - 2,579.02)	30,055	2,429,633	1,526.50 (1,504.02 - 1,548.97)
01 January - 07 January 2022	34,347	1,122,958	2,416.51 (2,381.77 - 2,451.25)	35,449	2,847,489	1,360.84 (1,345.00 - 1,376.67)
08 January - 14 January 2022	9,614	997,216	885.69 (859.48 - 911.91)	13,950	2,982,334	494.45 (485.58 - 503.32)
15 January - 21 January 2022	6,027	932,716	568.49 (548.76 - 588.22)	10,495	3,070,963	374.56 (366.97 - 382.14)

116. Scotland’s official reports likewise show the ratio of vaccinated persons who *died* because of COVID-19 in late December 2021 and early January 2022 was higher than the ratio among unvaccinated persons. For example, the age-standardized mortality rate among the

unvaccinated from COVID-19 in the week of December 18, 2021 was 1.69 for every 100,000 individuals. But for the vaccinated in the same week, the rate was more than triple—6.55 out of 100,000.

Table 15: Number of confirmed COVID-19 related deaths by vaccination status at time of test and age-standardised mortality rate per 100,000, 18 December 2021 to 14 January 2022

Week	Unvaccinated			1 Dose		
	No. of deaths	Population	Age Standardised Mortality Rate per 100,000 with 95% confidence intervals	No. of deaths	Population	Age Standardised Mortality Rate per 100,000 with 95% confidence intervals
18 December - 24 December 2021	6	1,568,607	1.69 (0.22 - 3.16)	7	356,597	15.36 (2.89 - 27.82)
25 December - 31 December 2021	9	1,560,599	5.41 (0.77 - 10.06)	1	347,533	0.36 (0.00 - 1.06)
01 January – 07 January 2022	12	1,550,542	7.60 (2.38 - 12.83)	3	340,224	7.42 (0.00 - 16.28)
08 January – 14 January 2022	16	1,542,053	10.40 (4.07 - 16.73)	3	338,887	4.79 (0.00 - 11.13)
Week	2 Doses			Booster or 3 Doses		
	No. of deaths	Population	Age Standardised Mortality Rate per 100,000 with 95% confidence intervals	No. of deaths	Population	Age Standardised Mortality Rate per 100,000 with 95% confidence intervals
18 December - 24 December 2021	24	1,868,657	6.55 (3.80 - 9.30)	15	2,069,874	0.33 (0.16 - 0.49)
25 December - 31 December 2021	21	1,524,657	7.14 (3.87 - 10.42)	9	2,429,634	0.21 (0.07 - 0.34)
01 January – 07 January 2022	26	1,122,958	12.00 (7.21 - 16.79)	21	2,847,490	0.46 (0.26 - 0.65)
08 January – 14 January 2022	33	997,216	14.05 (8.88 - 19.22)	71	2,982,335	1.50 (1.15 - 1.85)

117. *Pfizer’s booster dose data.* Pfizer’s own data assembled to gain authorization for booster shots also eviscerated the representations the Pfizer had made to the public and made clear that the company knew it had no scientific evidence to support making the false statements in the first instance. On August 23, 2021, FDA approved Pfizer’s Biologics License Application for “Comirnaty”—the trade name for BNT162b2. Two days later, on August 25, Pfizer sought a supplemental approval for booster shots of Comirnaty in persons sixteen years or older. *See* FDA Emergency Use Authorization (EUA) for an Unapproved Product Review Memorandum 4 (Sept. 21, 2021) (FDA Booster Amendment). However, the agency’s independent Vaccines and Related Biological Products Advisory Committee (VRBPAC) overwhelmingly recommended FDA *deny*

approval, citing “concerns about insufficient data.” FDA Booster Amendment at 5.⁸

118. On September 21, 2021, Pfizer re-submitted the same data in the form of an amendment to its original December 2020 EUA. Pfizer took this step because, as noted previously, an EUA grant requires a lower amount of proof of efficacy and safety compared to a formal FDA approval.

119. Even by EUA standards, however, Pfizer’s data was remarkably weak. As FDA noted, “[e]fficacy against COVID-19 was not evaluated following the booster dose” in a well-controlled and appropriately designed clinical study. Instead, Pfizer proposed proving the “effectiveness of the booster dose” against the original COVID-19 strain using so-called “immunobridging analyses” comparing antibody rates from persons one month after a booster to the same rates from persons one month after the original two-dose series.

120. In response, FDA requested that Pfizer provide information on how the two-dose series performed in persons vaccinated in July and August 2021—the period corresponding with Delta. This represented a critical dataset because if the two-dose series failed to protect against the then-dominant Delta variant, it would be reasonable to conclude that a booster of the same vaccine would not either. The supplemental data that Pfizer submitted did not support approval. As FDA noted, Pfizer’s data “appear[ed] to indicate that the incidence of SARS-CoV-2 during the analysis period . . . was 70.3 cases per 1,000 person-years.” By comparison, the *placebo group* in the Phase 2/3 study in the original EUA had an incidence rate of 72.9 cases per 1,000 person years. In other words, *vaccinated* persons experienced nearly identical rates of COVID-19 infection in July and August 2021 as *unvaccinated* persons when Pfizer originally submitted its clinical trial results to FDA in November 2020.

⁸ FDA’s VRBPAC is an independent committee designed to provide expert advice to FDA on vaccine and other biological product issues.

121. FDA also requested that Pfizer submit other specific data to support effectiveness of a vaccine booster dose against the Delta variant. *Id.* at 19. Pfizer responded with “exploratory descriptive analyses” of data measuring antibody levels collected in a limited Phase 1 study of individuals who received a booster dose. That study included only *twenty-three people* and, as a result, only “[a] very limited number of serum samples were available for this analysis.” And Pfizer used a non-validated method for ascertaining whether a booster increased the antibody levels. The increased antibodies in this highly limited pool of people was the full extent of Pfizer’s showing that a booster would be effective against Delta.

122. Pfizer’s untested “antibodies only” approach to demonstrating efficacy against Delta was also remarkable because, at the very same time, FDA was publicly taking the position that antibodies did not constitute evidence of protection. For example, on May 19, 2021, FDA explained in a publicly issued report that “results from currently authorized SARS-CoV-2 antibody tests should not be used to evaluate a person’s level of immunity or protection from COVID-19 at any time.” FDA, *Antibody Testing is not Currently Recommended to Assess Immunity After COVID-19 Vaccination: FDA Safety Communication* (May 19, 2021).

123. Under political pressure from the White House, FDA ultimately granted Pfizer’s EUA amendment for booster shots for a massive share of the population. *See* Sarah Owerhohle, *Biden’s top-down booster plan sparks anger at FDA*, Politico (Aug. 31, 2021). Politico further reported that “two top vaccine regulators resigned” as a result of the White House pressure. FDA, however, made clear the myriad limitations present in Pfizer’s booster submission, and heavily qualified its approval. FDA stated that not only did Pfizer continue to lack data to directly demonstrate efficacy of a booster dose “to provide additional protection against the currently circulating Delta variant,” but also to “directly demonstrate” booster efficacy against “clinical disease outcomes from” COVID-19 altogether. In sum, FDA concluded that Pfizer’s limited data

only “support[ed]”—it did not demonstrate—the mere “potential” that the booster dose *could possibly* provide enhanced protection against Delta. *Id.* at 29.

124. In addition, FDA drew attention to two repeated shortcomings in Pfizer’s COVID-19 data. First, FDA recognized that it was not “possible to assess” the amount of time a booster worked beyond just “1 month.” Second, FDA determined that Pfizer had not submitted data to establish the “effectiveness of a booster dose against transmission.” FDA Booster Amendment at 29.

F. Pfizer Intimidated and Silenced Persons Who Spread Information About the Vaccine that Undermined Its False Efficacy Narrative.

125. Pfizer also took overt action to intimidate and silence persons who spread factual information about vaccine efficacy. On information and belief, Pfizer engaged in this misconduct to prolong the effectiveness of the company’s deception campaign, thereby maintaining the false impression that its COVID-19 vaccine had more efficacy than in reality. Over the course of 2021, Pfizer’s censorship campaign helped secure commitments to purchase at least 415 million and 2.7 billion doses from the U.S. and foreign governments respectively, displacing Pfizer’s rivals and achieving the status of first-choice vaccine.

126. One of the persons Pfizer sought to intimidate and silence was journalist Alex Berenson. Throughout early 2021, Berenson maintained a highly active Twitter page with hundreds of thousands of followers where he explained his findings and views concerning COVID-19, Pfizer’s vaccine, and other related issues. Many of Berenson’s claims were true at the time he made them and have been corroborated by subsequent data and analyses. Indeed, it recently has been revealed that Pfizer had reason to *know* of the veracity of Berenson’s claims when he made them and that the company nonetheless plotted to silence Berenson and eliminate his speech from public discourse. Ultimately, Pfizer succeeded in having Berenson censored and widely derided as

a “conspiracy theorist” for his views that dared to challenge Pfizer’s deception campaign.

127. For example, on August 24, 2021, Dr. Scott Gottlieb complained directly to Twitter about Berenson’s content that was being “promoted on Twitter.” Gottlieb claimed that this content was the reason “why Tony [presumably Anthony Fauci] needs a security detail.”

From: **Scott Gottlieb, MD** <scott.gottlieb@gmail.com>
Date: Tue, Aug 24, 2021 at 3:26 PM
Subject: Fwd: Quite frankly
To: [REDACTED]@twitter.com>

This is whats promoted on Twitter. This is why Tony needs a security detail.

From: Alex Berenson from Unreported Truths <alexberenson@substack.com>
Date: August 24, 2021 at 3:04:38 PM EDT
Subject: Quite frankly
Reply-To: Alex Berenson from Unreported Truths
<reply+o0pj7&mzdy&&ac14e9c6f744799332435cdc1fcb904ef27f6d068cb41dad8165c3fd5788d762@mg1.substack.com>

128. At this time, Gottlieb led Pfizer’s regulatory and compliance committee and was one of seven members of Pfizer’s executive committee. On information and belief, Pfizer was aware that Twitter might permanently ban Berenson if his account incurred a sufficient number of perceived violations of Twitter policy. Twitter’s internal communications indicate that just three days after Gottlieb’s email Twitter employees met with the senior Pfizer executive and discussed Berenson’s assumed violations of Twitter policy, including Berenson’s so-called “4th COVID-19 strike.”

129. On August 28, Berenson tweeted that Pfizer’s vaccine “doesn’t stop infection . . . [o]r transmission,” as well as that it has a “limited window of efficacy.” These were indisputably true statements based on the scientific record at that time, including data from Pfizer’s own studies, as well as FDA’s own findings. Nevertheless, Gottlieb emailed this tweet to senior Twitter employees. Given the context of Gottlieb’s communications with Twitter at that time, this was likely intended to provoke Twitter into banning Berenson’s account. Later that same day, Twitter permanently suspended Berenson’s account.

130. Shortly after his permanent suspension, Berenson created a new account on Twitter. On August 29, Gottlieb emailed Twitter to flag this new account, telling Twitter that it “seems he switched accounts on you.”

Message

From: Scott Gottlieb, MD [scott.gottlieb@gmail.com]
Sent: 8/29/2021 1:53:03 AM
To: [REDACTED]@twitter.com
Subject: Fwd: Hello Twitter!

seems he switched accounts on you.

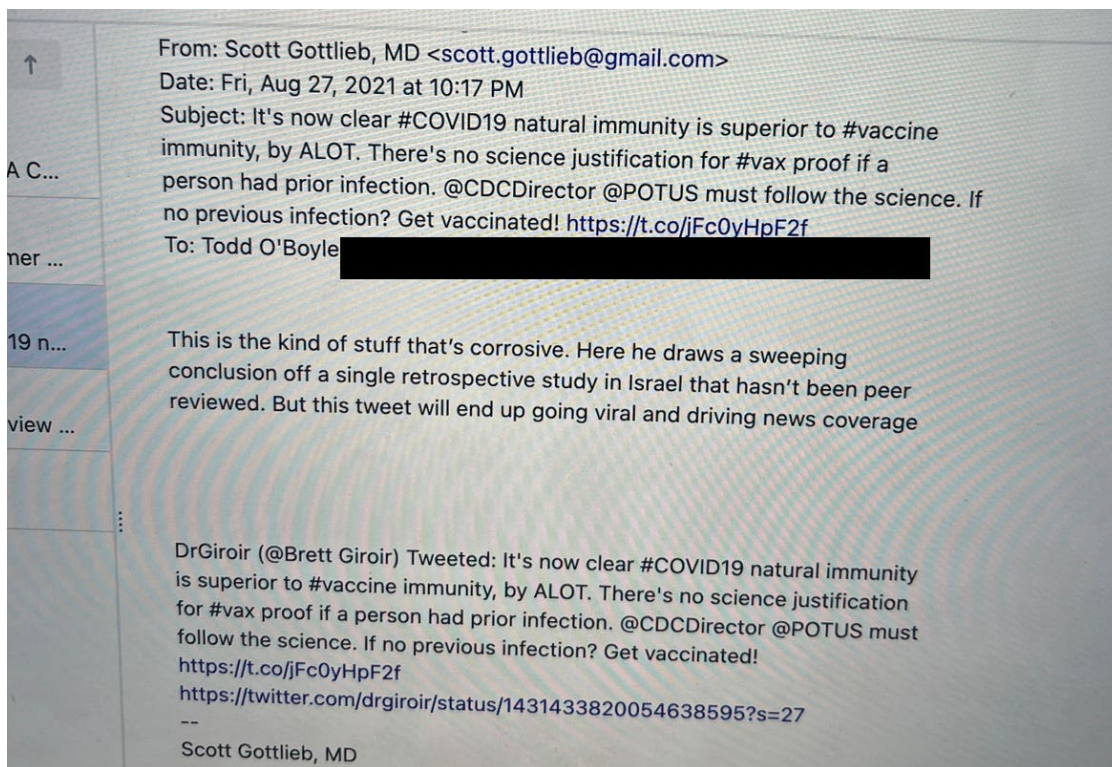
From: Alex Berenson from Unreported Truths <alexberenson@substack.com>
Date: August 28, 2021 at 8:21:32 PM EDT
To:
Subject: Hello Twitter!
Reply-To: Alex Berenson from Unreported Truths
<reply+o6ftg&mzdyt&&ec648eb0cfd3601448f92c3309a72138946c072221a3563c33a1e16a7df6a92a@mg1.substack.com>

131. Pfizer’s campaign against Berenson had the goal and effect of eliminating a prominent skeptic of Pfizer’s vaccine and deceptive marketing campaign touting the vaccine’s ability to combat COVID-19, as well as a source of truthful information that undercut Pfizer’s misrepresentations to the public.

132. Pfizer targeted many other skeptics in addition to Berenson. Gottlieb persistently contacted senior persons at Twitter and, on information and belief, other social media platforms, in a clandestine effort to silence challengers to Pfizer’s deceptive scheme to promote sales and use of its vaccine products. For example, in August 2021, former FDA Director Brett Giroir tweeted that “#COVID19 natural immunity is superior to #vaccine immunity, by A LOT,” and stated “no science justification” exists to demand proof of vaccination from an already infected person.

133. On August 27, Gottlieb quickly moved to squelch his fellow FDA alumnus, flagging Giroir’s tweet to Gottlieb’s Twitter contacts. Illustrating that Pfizer understood the need to protect its highly lucrative vaccine platform from information spreading to the general public that undermined its previous misrepresentations of efficacy, Gottlieb took pains to emphasize the

risk that Giroir’s comments would “driv[e] news coverage.” In a moment of candor, Gottlieb acknowledged that Giroir’s tweet would be “corrosive” to the public’s confidence in Pfizer’s vaccine.



134. Based on his access to Twitter and previous experience, Gottlieb had ample reason to believe that his act of flagging this content would likely result in Twitter taking adverse action against Giroir. And, sure enough, Twitter flagged Giroir’s tweet as “misleading.” Notwithstanding Pfizer’s disinformation scheme, Israeli Ministry of Health data from this exact time period unequivocally supported Giroir’s claim that natural immunity was superior to vaccine immunity. Goldberg et al., *Protection and waning of natural immunity and hybrid COVID-19 immunity* (Dec. 5, 2021).

135. On September 3, 2021, according to reports from persons given access to Twitter’s internal files, Gottlieb engaged in similar conduct regarding another prominent skeptic. Specifically, Gottlieb complained to Twitter about a post noting, “Sticks and stones may break my

bones but a viral pathogen with a child mortality rate of $\lt; 0\%$ has cost our children nearly three years of schooling.” On information and belief, Pfizer employed multiple other methods, directly or indirectly, with the intent to provoke and ultimately cause censorship on social media platforms of content adverse to sales or consumption of its vaccine. Recent reporting has revealed that a Pfizer-funded entity benevolently known as the “Public Good Projects” regularly corresponded with Twitter for the purpose of suppressing content critical of the vaccines. *See* Lee Fang, *COVID-19 Drugmakers Pressured Twitter to Censor Activists Pushing for Generic Vaccine* (Jan. 16, 2023).

136. In addition to coercing social media platforms to censor truthful information that undermined Pfizer’s false statements and misrepresentations, Pfizer affirmatively intimidated vaccine skeptics to perpetuate its scheme to confuse and deceive the public.

137. For example, on November 9, 2021, CEO Albert Bourla charged that persons who spread so-called “misinformation” concerning COVID-19 vaccines are “criminals” who have “literally cost millions of lives.”

138. On that same day, Pfizer Tweeted a message with the clear implication that persons questioning the efficacy of Pfizer’s vaccine are spreading “misinformation.”

 Pfizer Inc. ✓
@pfizer

It's easy to get distracted by misinformation these days, but don't worry...Science has got your back.

#ScienceWillWin



3:27 PM · Nov 9, 2021

G. The Public Relied on Pfizer's Misleading Marketing to Its Detriment.

139. As set forth above, Pfizer knowingly and recklessly engaged in a multi-faceted

scheme to mislead the American public about the efficacy of its COVID-19 vaccine, including making affirmative misrepresentations, withholding material information, and taking steps to censor and suppress individuals who disseminated truthful information adverse Pfizer's deceptive scheme to increase sales and consumption of its vaccine. As a result of its deceptive conduct, Pfizer sold hundreds of millions of doses to the U.S. government, and its vaccine quickly penetrated the market through widespread public adoption. In an April 22, 2022, securities filing, Pfizer recognized, "the market share of our COVID-19 vaccine has continued to grow, representing 70% of all doses distributed across the U.S. and EU."

140. As a result of Pfizer's unlawful misconduct, Pfizer immunized approximately 3.5 million people, in Texas, by the end of October 2021 – representing about double that of Moderna and Johnson and Johnson, combined. As of November 10, 2023, Texans have been administered almost 30 million Pfizer doses. Pfizer's vaccines represent the majority of vaccines administered in and distributed into the state.

141. Pfizer misrepresented and obscured the truth about highly relevant aspects concerning its vaccine's efficacy, thereby directly impacting the public's decision-making process concerning vaccination status to their detriment. Specifically, Pfizer's deception prevented and hindered the public from obtaining information material to properly balancing the benefits and risks of its vaccine. Therefore, the public was lulled into misunderstanding and misperceiving the vaccine's actual level of effectiveness, and this flawed understanding inherently distorted the risk/benefit analysis in Pfizer's favor by artificially inflating the vaccine's perceived efficacy.

142. Pfizer's distortion of the public vaccination decision is particularly harmful because Pfizer's vaccine possesses significant safety concerns. As previously noted, FDA's review of Pfizer's formal application concluded that "FDA and CDC *identified serious risks for myocarditis and pericarditis following administration of*" the Pfizer's vaccine, including "some cases [that]

required intensive care support.” FDA, Summary Basis for Regulatory Action on COMIRNATY 96 (Nov. 8, 2021).

143. Myocarditis is a serious medical condition involving inflammation of the heart that reduces the muscle’s ability to pump blood. Severe myocarditis weakens the heart such that the remainder of the body doesn’t receive enough blood. As a result, blood clots can form in the heart, leading to a stroke or heart attack. Many of the vaccinated deaths in Pfizer’s full Phase 2/3 study were a result of “[c]ardiac conditions.” *See supra* ¶ 100.

144. Pfizer’s misrepresentations resulted in the public engaging in an artificial and flawed consideration and balancing of Pfizer’s vaccine’s benefits and risks, including that of myocarditis, when making their vaccination decision. 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.

145. In addition, the public was more susceptible to trusting and acting upon Pfizer’s misrepresentation campaign because of the significant levels of fear and anxiety amongst the public regarding the negative health, financial, and social impacts caused by the pandemic. Pfizer further capitalized on the public’s vulnerabilities by misleadingly casting itself and its vaccine as the champions of “science” that would bring about an end of the pandemic and return America to normal.

H. Pfizer Has Been Grossly and Unfairly Enriched by Its Deceptive Acts.

146. As set forth above, Pfizer intentionally misrepresented the efficacy of its COVID-19 vaccine to facilitate its adoption and expand its commercial opportunity. Pfizer’s plan was successful. Buoyed by a pervasive campaign of misrepresentations, Pfizer’s vaccine quickly established itself as the market leader in the United States, achieving nearly 70% market penetration among the public by the end of 2021. Pfizer secured the goal of cementing itself as the

leading vaccine on a worldwide basis when the U.S. government exercised its right under its supply agreement to purchase an additional 500 million doses over the course of 2021.

147. Pfizer received roughly \$12 billion for the 600 million doses it provided under the initial supply agreement, which ended on or about October 29, 2021, earning \$7.8 billion in revenue.

148. In addition, in June 2022 Pfizer and the U.S. government announced a new supply agreement covering 105 million additional doses and providing the government with the ability to buy 195 million more. For this agreement, Pfizer raised the price of its vaccine by over 50%, receiving \$3.2 billion for the sale.

149. Pfizer has been unfairly enriched by securing, retaining, and utilizing for its own purposes the revenues and profits attributable to its unlawful deceptive trade practices in the promotion, marketing, and sale of its COVID-19 vaccine in the United States.. In addition to the breath-taking windfall in the United States, Pfizer reaped tens of billions of dollars more in revenues and profits from selling over 4 billion doses of its COVID-19 vaccine to other national governments and purchasers over the course of the pandemic, including 2.7 billion doses alone in 2021.

150. As a direct and proximate result of the deceptive acts challenged here, Pfizer increased its financial revenues in 2021 by an eye-popping **\$38.4 billion**, nearly all of which represented proceeds from the sale of its COVID-19 vaccine, almost **doubling Pfizer's revenue** from 2020. And in 2022, Pfizer reported revenues of **\$37.8 billion**. Taken together, Pfizer's revenues and profits on COVID-19 provides more than ample financial nest egg for the company's ultimate goals of revitalizing the business and, relatedly, expanding the mRNA platform into new vaccines.

151. In addition, while the U.S. government was initially Pfizer's principal U.S.

purchaser, Pfizer had plans all along to commercialize its vaccine to the public and consumers along more traditional payor models. And more recently Pfizer has in fact converted to traditional payment and distributions models, with State Medicaid, private insurance, and individual consumers picking up the tab. *See, e.g.*, Letter from HHS Secretary on COVID-19 Vaccine Coverage (Sept. 22, 2023). But Pfizer still has not cured its false and misleading representations about its vaccine, which were crucial to Pfizer securing and maintaining the vaccine's level of success. And Pfizer's commercialization of the vaccine into the normal payor model occurs as the company is entrenched—thanks to its misrepresentations—as the dominant COVID-19 vaccine provider in the United States with little realistic prospect of losing that position.

XII. DTPA VIOLATIONS

152. The State incorporates and adopts by reference the allegations pled in this Original Petition, including paragraphs ¶¶ 1-151, as if fully set forth herein.

153. As alleged herein, Pfizer has in the course and conduct of trade and commerce, with the requisite mental state, engaged in various false, misleading, or deceptive acts or practices declared unlawful by and in violation of section 17.46(a) of the DTPA, including by intentionally, knowingly, and/or recklessly engaging in conduct specifically defined to be false, deceptive, or misleading under section 17.46(b).

Count I: Misrepresentations Concerning Relative Risk Reduction.

154. Pfizer misrepresented that its vaccine was 95% effective at preventing COVID-19 infections in all people, when in fact the data Pfizer relied on was inapposite for such representations, and Pfizer distorted the truth.

155. Pfizer chose a self-serving and deceptive metric reflecting percentage reduction in the rate of infection present in its limited Phase 2/3 trial *on a relative basis*, not the absolute risk reduction for its vaccine, information that it withheld from the consuming public. *See supra* ¶¶ 43-

46, 56-65.

156. In doing so, Pfizer violated sections 17.46(a), 17.46(b)(5), 17.46(b)(7), and 17.46(b)(24) of the DTPA.

Count II: Misrepresentations Concerning Durability of Protection.

157. Pfizer misrepresented that its vaccine provided durable and sustained protection against COVID-19 infection, *see supra* ¶¶ 73-82, when in fact FDA had previously informed the company that it was not possible to know the duration of the vaccine’s effectiveness beyond two months. *See supra* ¶¶ 43, 49.A,

158. Data revealed throughout the course of 2021 demonstrated that protection from Pfizer’s vaccine waned rapidly. *See supra* ¶¶ 94, 96, 105-09, 120.

159. Moreover, Pfizer withheld highly relevant data not only showing that efficacy waned rapidly but confirming that Pfizer’s representations about durable efficacy were unwarranted and deceiving when made. *See supra* ¶ 80.

160. In doing so, Pfizer violated sections 17.46(a), 17.46(b)(5), 17.46(b)(7), and 17.46(b)(24) of the DTPA.

Count III: Misrepresentations Concerning Transmission.

161. Pfizer misrepresented that vaccination against COVID-19 prevented “transmission” between persons, *see supra* ¶¶ 66-72, including from vaccinated persons with symptomatic or asymptomatic COVID-19 infections, when in fact FDA previously made clear to Pfizer that more information was needed to make transmission-related claims. *See supra* ¶¶ 42, 47, 49.B, 49.D.

162. Data developed throughout the course of 2021 revealed that Pfizer’s vaccine was highly ineffective at preventing vaccinated persons from transmitting infections to other persons. *See supra* ¶¶ 96, 103-04.

163. Pfizer created this false impression by exploiting the heightened fear and uncertainty amongst the public, insinuating that vaccination constituted an imperative to protect loved ones. *See supra* ¶¶ 68-70.

164. In doing so, Pfizer violated sections 17.46(a), 17.46(b)(5), 17.46(b)(7), and 17.46(b)(24) of the DTPA.

Count IV: Misrepresentations Concerning Protection Against Variants.

165. Pfizer misrepresented that its vaccine had substantial efficacy against COVID-19 variants—in particular, the Delta variant. *See supra* ¶¶ 83-90. At minimum, Pfizer created the false impression and led the public to reasonably believe that the vaccine performed comparatively well against variants as compared to the initial virus.

166. In reality, Pfizer clearly lacked data to support such claims, and the modest amount in its possession instead pointed to the opposite conclusion, as well as underscored the baselessness of Pfizer’s claims in the first instance. *See supra* ¶¶ 95, 110-16, 120-22.

167. In doing so, Pfizer violated sections 17.46(a), 17.46(b)(5), 17.46(b)(7), and 17.46(b)(24) of the DTPA.

Count V: Scheme to Conceal Vaccine Underperformance.

168. Pfizer created the false impression that its vaccine provided a substantially greater amount of protection against COVID-19 infection than what it afforded in reality. Pfizer undertook a continuous and widespread campaign comprised of the deceptive concerning alleged above for the purpose of misleading the public about the efficacy of its vaccine, *see supra* ¶¶ 125-38.

169. This course deceptive conduct was reinforced and extended by Pfizer’s efforts to censor persons who sought to disseminate truthful information that would undermine its ongoing deception. *See supra* ¶¶ 125-38.

170. In doing so, Pfizer violated sections 17.46(a) and 17.46(b)(8) of the DTPA.

XIII. CONDITIONS PRECEDENT

171. All conditions precedent to Plaintiff's claims for relief have been performed or have occurred.

XIV. PRAYER

172. The State prays that the Court permanently enjoin Pfizer from violating the DTPA by, for example, enjoining Pfizer from:

- A. making representations about the efficacy of its COVID-19 vaccine the same as, or similar to, the misrepresentations outlined in this petition; and
- B. coordinating with social media platforms to silence truthful speech about Pfizer's COVID-19 vaccine efficacy.

173. The State further requests that Defendant be ordered to pay to the State of Texas:

- A. Civil penalties of up to \$10,000.00 per violation of the DTPA, which when aggregated together exceed the sum of \$10 million;
- B. Pre-judgment and post-judgment interest on all awards of restitution, damages, or civil penalties, as provided by law; and
- C. All costs of Court, costs of investigation, and reasonable attorney's fees pursuant to Texas Government Code section 402.006(c).

174. The State further requests that the Court:

- A. Decree that all of Defendants' fines, penalties or forfeitures are not dischargeable in bankruptcy. *See* 11 U.S.C. Section 523(a)(7).
- B. Award the State all further relief, at law or in equity, including but not limited to disgorgement, to which it is justly entitled.

Respectfully submitted,

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