Frances R. Oleen, #17433
Deputy Attorney General
Kaley Schrader, #27700
Assistant Attorney General
Office of the Attorney General
Public Protection Division
120 SW 10th Ave., 2nd Floor
Topeka, Kansas 66612-1597
Tel: 785-296-3751
Fax: 785-291-3699
kaley.schrader@ag.ks.gov

IN THE DISTRICT COURT OF THOMAS COUNTY, KANSAS

STATE OF KANSAS, *ex rel.*	)
KRIS W. KOBACH, Attorney General,	)
	)
Plaintiff,	)
	)
v.	)
	)
PFIZER INC.,	)
	)
Defendant.	)
	)

Pursuant to K.S.A. Chapter 60

PETITION

COMES NOW the Plaintiff, State of Kansas, *ex rel.* Kris W. Kobach, Attorney General, by and through Assistant Attorney General Kaley Schrader, and for its cause of action against Defendant, alleges and states as follows:

NATURE OF THE ACTION

1. Pfizer misled the public that it had a "safe and effective" COVID-19 vaccine.

2. Pfizer said its COVID-19 vaccine was safe even though it knew its COVID-19 vaccine was connected to serious adverse events, including myocarditis and pericarditis, failed pregnancies, and deaths. Pfizer concealed this critical safety information from the public.

3. Pfizer said its COVID-19 vaccine was effective even though it knew its COVID-19 vaccine waned over time and did not protect against COVID-19 variants. Pfizer concealed this critical effectiveness information from the public.

4. Pfizer said its COVID-19 vaccine would prevent transmission of COVID-19 even though it knew it never studied the effect of its vaccine on transmission of COVID-19.

5. To keep the public from learning the truth, Pfizer worked to censor speech on social media that questioned Pfizer's claims about its COVID-19 vaccine.

6. Pfizer's misrepresentations of a "safe and effective" vaccine resulted in record company revenue of approximately $75 billion from COVID-19 vaccine sales in just two years.

7. Pfizer's actions and statements relating to its COVID-19 vaccine violated previous consent judgments with the State of Kansas.

8. Pfizer's actions and statements relating to its COVID-19 vaccine violated the Kansas Consumer Protection Act, K.S.A. 50-623 *et seq.*, regardless of whether any individual consumer ultimately received Pfizer's COVID-19 vaccine.

9. Pfizer must be held accountable for falsely representing the benefits of its COVID-19 vaccine while concealing and suppressing the truth about its vaccine's safety risks, waning effectiveness, and inability to prevent transmission.

PARTIES

10. Plaintiff Kris W. Kobach is the duly elected, qualified, and acting Attorney General for the State of Kansas.

11. The Attorney General has standing to bring this action in the name of the State of Kansas by statute. K.S.A. 50-628(a)(1), 50-632(a); *see also* K.S.A. 75-702(a).

12. The Attorney General has standing to bring this action under the common law of this State on behalf of all Kansans.

13. The Attorney General has standing to bring this action under consent judgments between the State of Kansas and Pfizer.

14. Defendant Pfizer Inc. ("Pfizer") is a publicly traded corporation organized in the State of Delaware and with a principal place of business in New York, New York. Pfizer has been registered to do business in Kansas since June 8, 1993.

15. Defendant Pfizer may be served through its resident agent CT Corporation System, 112 SW 7th Street, Suite 3C, Topeka, Kansas, 66603.

16. Pfizer's acts include acts by Pfizer and acts by Pfizer's officers, directors, agents, or employees on Pfizer's behalf and under its authority.

17. Actions or statements by Pfizer Chairman and CEO Dr. Albert Bourla and Pfizer Board Member Dr. Scott Gottlieb are attributable to Pfizer.

JURISDICTION AND VENUE

18. This Court has jurisdiction over this case pursuant to K.S.A. 20-301 and K.S.A. 50-638(a).

19. Pfizer is registered to do business in Kansas as a foreign corporation, and the cause of action arose in Kansas from Pfizer conducting business in Kansas. Therefore, Pfizer is subject to personal jurisdiction in Kansas pursuant to K.S.A. 17-7307(c).

20. Pfizer is also subject to personal jurisdiction in Kansas pursuant to K.S.A. 60-308(b)(1)(A) because Pfizer transacts business in Kansas.

21. Venue is proper in this county under K.S.A. 50-638(b). Pfizer's actions and practices that violated the Kansas Consumer Protection Act reached consumers in Thomas County.

ALLEGATIONS COMMON TO ALL COUNTS

22. Plaintiff incorporates all preceding paragraphs by reference.

23. At all times relevant hereto, and in the ordinary course of business, Pfizer acted as a "supplier," as that term is defined by K.S.A. 50-624(l).

24. At all times relevant hereto, and in the ordinary course of business, Pfizer made, caused to be made, or solicited, "consumer transactions," as that term is defined by K.S.A. 50-624(c).

25. Upon information and belief, because of the high public interest in Pfizer's COVID-19 vaccine, Pfizer's actions and statements circulated widely throughout Kansas.

26. Statements on Pfizer's website and social media have made misrepresentations to Kansans from the day they were posted continuing to the present.

27. Pfizer's misrepresentations about its COVID-19 vaccine violated the Kansas Consumer Protection Act and Pfizer's consent judgments with Kansas each time Pfizer made them to a Kansas consumer, regardless of whether an individual consumer decided to receive or forgo Pfizer's COVID-19 vaccine.

28. Millions of Kansans heard Pfizer's misrepresentations about its COVID-19 vaccine. For example, Pfizer administered 3,355,518 Pfizer vaccine doses in Kansas as of February 7, 2024. This accounted for more than 60% of all vaccine doses in Kansas. Kansas Department of Health and Environment, *Data*.[1]

29. In May 2021, Pfizer advertised to Kansans on Facebook about its "life-saving vaccines" and its "cures." Upon information and belief, Pfizer intended for Kansans to think of

[1] *Available at* https://www.coronavirus.kdheks.gov/317/Data. Since this data was collected, the Kansas Department of Health and Environment no longer publicly reports vaccine doses by manufacturer.

its COVID-19 vaccine when it discussed "life-saving vaccines" and "cures." Pfizer ran three different ads between May 4, 2021 and June 1, 2021 that received 165,000 to 190,000 impressions [views] in Kansas. Meta Ad Library, Summary Data for Ads 2974674432763576,[2] 1144557279322749,[3] and 468595664399043.[4]

30. Pfizer took advantage of Kansans' fear of COVID-19 and desire for safety by offering a "safe and effective" COVID-19 vaccine, while concealing, suppressing, and omitting material information that undermined its safety and effectiveness claims.

I. Pfizer's Big Bet on Its COVID-19 Vaccine

31. COVID-19 is caused by the virus SARS-CoV-2 and originated in Wuhan, China.

32. In 2020, Pfizer raced to develop a COVID-19 vaccine.

33. Unlike the other companies involved in the race for a vaccine, Pfizer did not join Operation Warp Speed and declined its vaccine development funding. *Transcript, Pfizer CEO Dr. Albert Bourla on 'Face the Nation*,'" CBS News, Sept. 13, 2020;[5] Carolyn Y. Johnson, *Pfizer's coronavirus vaccine is more than 90 percent effective in first analysis, company reports*, THE WASHINGTON POST (Nov. 9, 2020).[6]

34. Pfizer distanced itself from Operation Warp Speed when it announced the results of its COVID-19 vaccine trials: "We were never part of the Warp Speed," proclaimed Pfizer's senior vice president and head of vaccine research and development. Philip Bump, *No, Pfizer's*

[2] *Available at* https://www.facebook.com/ads/library/?id=2974674432763576.
[3] *Available at* https://www.facebook.com/ads/library/?id=1144557279322749.
[4] *Available at* https://www.facebook.com/ads/library/?id=468595664399043.
[5] *Available at* https://www.cbsnews.com/news/transcript-pfizer-ceo-dr-albert-bourla-on-face-the-nation-september-13-2020/.
[6] *Available at* https://www.washingtonpost.com/health/2020/11/09/pfizer-coronavirus-vaccine-effective/.

apparent vaccine success is not a function of Trump's 'Operation Warp Speed,' THE WASHINGTON POST (Nov. 9, 2020).[7]

35. Pfizer's Chairman and CEO Dr. Bourla, a veterinarian by training, reported that Pfizer declined government funding in order to "liberate" Pfizer's scientists from government oversight of its vaccine development: "But the reason why I did it was because I wanted to liberate our scientists from any bureaucracy. **When you get money from someone that always comes with strings. They want to see how we are going to progress, what type of moves you are going to do. They want reports. I didn't want to have any of that**." *Transcript, Pfizer CEO Dr. Albert Bourla on 'Face the Nation*,'" CBS NEWS, Sept. 13, 2020 (emphasis added).[8]

36. Because Pfizer did not accept government funding, "[t]he government had limited visibility into what was happening at Pfizer, …" Sydney Lupkin, *The U.S. Paid Billions To Get Enough COVID Vaccines Last Fall. What Went Wrong?* NPR (Aug. 25, 2021).[9]

37. "Pfizer worked 'at arm's length' compared with the other companies in Operation Warp Speed," the scientific lead of Operation Warp Speed recounted. *Id.*

38. Pfizer's independence from Operation Warp Speed allowed it to demand a "tailor-made contract" that let Pfizer "retain almost all of its intellectual property rights and forgo the taxpayer protection clauses found in most government contracts that fund inventions." *Id.*; *see also* Statement of Work for COVID-19 Pandemic-Large Scale Vaccine Manufacturing Demonstration, July 21, 2020 ("Pfizer Statement of Work"), ¶¶ 7.1, 7.2 (PDF pp. 19-20).[10]

---

[7] *Available at* https://www.washingtonpost.com/politics/2020/11/09/no-pfizers-apparent-vaccine-success-is-not-function-trumps-operation-warp-speed/.
[8] *Available at* https://www.cbsnews.com/news/transcript-pfizer-ceo-dr-albert-bourla-on-face-the-nation-september-13-2020/.
[9] *Available at* https://www.npr.org/sections/health-shots/2021/08/25/1029715721/pfizer-vaccine-operation-warp-speed-delay.
[10] *Available at* https://www.hhs.gov/sites/default/files/pfizer-inc-covid-19-vaccine-contract.pdf.

39. By self-funding, Pfizer was betting big that its vaccine development would succeed. "[I]f it fails, it goes to our pocket," warned Pfizer Chairman and CEO Dr. Bourla. *Transcript, Pfizer CEO Dr. Albert Bourla on 'Face the Nation*,'" CBS NEWS, Sept. 13, 2020.[11]

40. By September 2020, Pfizer had invested at least $1.5 billion for COVID vaccine development. Losing this money by failing to develop an approved vaccine would be "painful," admitted Pfizer Chairman and CEO Dr. Bourla. *Id.*

41. Based on Pfizer's public statements, Pfizer would lose $1.5 billion to $2 billion if government regulators did not approve its COVID-19 vaccine. *See id.*; Pfizer 2021 Annual Report, *Expanding COVID-19 Manufacturing Efforts to Increase Global Vaccine Access*.[12]

42. Pfizer's contract with the federal government—in which Pfizer would deliver 100 million doses in exchange for $1.95 billion—required Pfizer to obtain approval of its COVID-19 vaccine. *Pfizer and BioNTech Announce an Agreement with U.S. Government for up to 600 Million Doses of mRNA-based Vaccine Candidate Against SARS-CoV-2*, July 22, 2020.[13]

43. Pfizer doubled down on its bet that its vaccine would receive federal government approval by producing a "few million" vaccine doses before it received the efficacy or safety data from its vaccine trial or government approval. *Pfizer CEO says he would've released vaccine data before election if possible*, AXIOS, Nov. 9, 2020.[14]

44. Pfizer's CEO had a personal financial interest in Pfizer succeeding.

---

[11] *Available at* https://www.cbsnews.com/news/transcript-pfizer-ceo-dr-albert-bourla-on-face-the-nation-september-13-2020/.
[12] *Available at* https://www.pfizer.com/sites/default/files/investors/financial_reports/annual_reports/2021/story/expanding-covid-manufacturing-efforts/.
[13] *Available at* https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-announce-agreement-us-government-600.
[14] *Available at* https://www.axios.com/2020/11/09/pfizer-ceo-says-he-wouldve-released-vaccine-data-before-election-if-possible.

45. In August 2020, Pfizer Chairman and CEO Dr. Bourla implemented a plan to sell some of his Pfizer stock if it reached a pre-determined price just one day before Pfizer issued a press release "featuring 'additional Phase 1 safety and immunogenicity data' and confirming that Pfizer and its German partner, BioNTech, were 'on track to seek regulatory review' for its vaccine candidate by October. The financial news channels Fox Business, CNBC, and Bloomberg all covered the August news, with CNBC noting that [Pfizer's] stock appeared to be 'moving sharply higher today on an optimistic vaccine timeline.'" Tom Dreisbach, *Pfizer CEO Sold Millions In Stock After Coronavirus Vaccine News, Raising Questions*, NPR, Nov. 11, 2020.[15]

46. Pfizer Chairman and CEO Dr. Bourla's stock reached the pre-determined price and sold on November 9, 2020, "the same day Pfizer announced that its experimental coronavirus vaccine candidate was found to be more than 90% effective. The company's stock soared on the news." *Id.*

47. Pfizer Chairman and CEO Dr. Bourla made $5.6 million from his November 9, 2020 Pfizer stock sale. *Id.*

48. An insider-trading expert called the sequence of events involving Pfizer Chairman and CEO Dr. Bourla's stock sale "very suspicious," "wholly inappropriate," and "troubling." *Id.*

49. Pfizer had billions of incentives to do whatever it took to ensure that its COVID-19 vaccine received the necessary government approval.

50. Pfizer received emergency use authorization for its COVID-19 vaccine in individuals 16 years of age and older on December 11, 2020. FDA, *FDA Takes Key Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for First COVID-19 Vaccine*,

[15] *Available at* https://www.npr.org/2020/11/11/933957580/pfizer-ceo-sold-millions-in-stock-after-coronavirus-vaccine-news-raising-questio.

Dec. 11, 2020.[16] Emergency Use Authorizations "can be used by the FDA during public health emergencies to provide access to medical products that may be effective in preventing, diagnosing, or treating a disease, provided that the FDA determines that the known and potential benefits of a product, when used to prevent, diagnose, or treat the disease, outweigh the known and potential risks of the product." FDA, *FDA Approves First COVID-19 Vaccine*, Aug. 23, 2021.[17]

51. Pfizer received FDA approval for its COVID-19 vaccine in individuals 16 years of age and older on August 23, 2021. *Id.*

52. From 2021 to 2023, Pfizer received emergency use authorizations for its COVID-19 vaccine in children from six months to 15 years of age, as well as for booster doses. *See, e.g.*, U.S. Dep't of Health and Human Servs., *COVID-19 Vaccine Milestones*.[18]

II. Pfizer's COVID-19 Vaccine and Transparency

A. Pfizer's representations about transparency

53. Pfizer repeatedly assured Kansans that it provided transparency on its data.

54. On December 14, 2020, the day Americans began receiving Pfizer's COVID-19 vaccine, Pfizer Chairman and CEO Dr. Bourla said, "This is a vaccine that was developed without cutting corners from a company with 171 years of credentials. This is a vaccine that was developed in the spotlight in the daylight, with all the data being put in servers." *CNBC Transcript: Pfizer Chairman and CEO Albert Bourla Speaks with CNBC's 'Squawk Box' Today*, CNBC (Dec. 14, 2020).[19]

---

[16] *Available at* https://www.fda.gov/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19.
[17] *Available at* https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine.
[18] *Available at* https://www.hhs.gov/coronavirus/covid-19-vaccines/index.html.
[19] *Available at* https://www.cnbc.com/2020/12/14/cnbc-transcript-pfizer-chairman-and-ceo-albert-bourla-speaks-with-cnbcs-squawk-box-today.html.

55. On September 16, 2021, Pfizer Chairman and CEO Dr. Bourla said, "Since the start of this pandemic, Pfizer and BioNTech have pledged to follow the science and keep people informed about our progress to help bring an end to this global health crisis. We have stayed true to our commitment of full transparency without selectively cherry-picking data." *Continuing to Follow the Science: An Open Letter from Pfizer Chairman and CEO Dr. Albert Bourla*, Pfizer, Sept. 16, 2021.[20]

56. Contrary to its representations, Pfizer has willfully concealed, suppressed, and omitted safety and efficacy data relating to its COVID-19 vaccine.

B. Pfizer used confidentiality agreements to conceal critical data relating to the safety and effectiveness of its COVID-19 vaccine.

57. Pfizer has kept data hidden through confidentiality agreements with governments around the world.

58. Pfizer's contract required the United States government to keep Pfizer's confidential information secret for 10 years. Higher protections applied to Pfizer's trade secret information, which the government promised to keep "in confidence in perpetuity." Pfizer Statement of Work, ¶ 11.10 (PDF p. 25).[21]

59. Pfizer effectively had a veto over the federal government's communications because the parties agreed that they would not make any public announcement relating to the COVID-19 vaccine contract or "the transactions contemplated by it" without the prior written consent of the other. *Id.* at ¶ 11.11 (PDF p. 25).

[20] *Available at* https://www.pfizer.com/news/announcements/continuing-follow-science-open-letter-pfizer-chairman-and-ceo-dr-albert-bourla.
[21] *Available at* https://www.hhs.gov/sites/default/files/pfizer-inc-covid-19-vaccine-contract.pdf.

60. Conversely, Pfizer had exclusive control over its own communications through "the right, but not the obligation, to prepare and submit scientific publications and release information to the public about its COVID-19 development program, without the Government's consent or involvement." *Id.*

61. Upon information and belief, Pfizer used its confidentiality agreements with the United States government and others to conceal, suppress, and omit material facts relating to Pfizer's COVID-19 vaccine, including the safety and efficacy of the vaccine.

C. Pfizer used an extended study timeline to conceal critical data relating to the safety and effectiveness of its COVID-19 vaccine.

62. Pfizer also kept data hidden through a study timeline that Pfizer repeatedly delayed.

63. Pfizer planned to provide researchers with access to patient-level data and full clinical study reports 24 months after study completion. Protocol C4591001, "A Phase 1/2, Placebo-Controlled, Randomized, Observer-Blind, Dose-Finding Study to Describe the Safety, Tolerability, Immunogenicity, and Potential Efficacy of SARS-CoV-2 RNA Vaccine Candidates Against COVID-19 in Healthy Adults," ("Apr. 2020 Protocol"), Pfizer, Apr. 15, 2020, 104 (PDF p. 106), ¶ 10.1.4.[22]

64. Pfizer initially estimated that it would complete the study by January 27, 2023, but that estimated date fell back to February 2024 because of a late vaccination of a single study participant (out of 44,000 participants). Jennifer Block, *COVID-19: Researchers face wait for patient level data from Pfizer and Moderna vaccine trials*, BRITISH MEDICAL JOURNAL, July 12, 2022;[23] *see also* Pfizer's Clinical Study Records.[24]

[22] *Available at* https://www.nejm.org/doi/suppl/10.1056/NEJMoa2027906/suppl_file/nejmoa2027906_protocol.pdf.
[23] *Available at* https://www.bmj.com/content/378/bmj.o1731.
[24] *Available at* https://www.clinicaltrials.gov/study/NCT04368728?term=C4591001&rank=2&tab=history&a=.

65. Scientists were outraged that they still could not review Pfizer's COVID-19 study data. "Pfizer's pivotal COVID vaccine trial was funded by the company and designed, run, analysed, and authored by Pfizer employees. The company and the contract research organisations that carried out the trial hold all the data." *COVID-19 vaccines and treatments: we must have raw data, now*, British Medical Journal, 2022:376 (Jan. 19, 2022).[25]

66. Pfizer's control of the data allowed the company to selectively publish results for which the underlying data could not be independently evaluated. *See id.*

67. As the British Medical Journal editorialized in January 2022:

> Pharmaceutical companies are reaping vast profits without adequate independent scrutiny of their scientific claims. The purpose of regulators is not to dance to the tune of rich global corporations and enrich them further; it is to protect the health of their populations. We need complete data transparency for all studies, we need it in the public interest, and we need it now.

Id.

68. Perhaps due to a production ruling in a Freedom of Information Act ("FOIA") lawsuit against the FDA, *see infra*, and the increased frustration expressed by scientists, Pfizer finally completed its study on February 10, 2023.

69. Pfizer today says it will make data from vaccine trials approved in the United States available 18 months after the primary study completion date. Pfizer, *Data Access Requests*.[26]

70. Upon information and belief, Pfizer has still not made its complete study data available to researchers.

D. Pfizer used FOIA denial and delay to conceal critical data relating to the safety and effectiveness of its COVID-19 vaccine.

[25] *Available at* https://www.bmj.com/content/376/bmj.o102.
[26] *Available at* https://www.pfizer.com/science/clinical-trials/trial-data-and-results/data-requests.

71. The Food and Drug Administration's refusal to immediately produce safety and effectiveness data for Pfizer's COVID-19 vaccine kept Pfizer's data hidden from the public.

72. The Food and Drug Administration granted full approval for Pfizer's COVID-19 vaccine in adults on August 23, 2021. *Pfizer-BioNTech COVID-19 Vaccine COMIRNATY® Receives Full U.S. FDA Approval for Individuals 16 Years and Older*, Aug. 23, 2021.[27]

73. Full approval of Pfizer's COVID-19 vaccine should have made Pfizer's "safety and effectiveness data and information, … adverse reaction reports, product experience reports, [and] consumer complaints … immediately available for public disclosure." *See* 21 C.F.R. 601.51(e).

74. Safety and effectiveness data includes all studies and tests on animals and humans. 21 C.F.R. § 601.51(g).

75. But the FDA did not make the safety and effectiveness data for Pfizer's COVID-19 vaccine immediately available.

76. Because full data was not available, Public Health and Medical Professionals for Transparency in America ("PHMPTA") submitted a FOIA request to the FDA for all data and information for Pfizer's COVID-19 vaccine. *Pub. Health & Med. Pros. for Transparency v. Food & Drug Admin.*, No. 4:21-CV-1058-P, Doc. 1-1 (Aug. 27, 2021 request).

77. Pfizer's contract with the federal government granted Pfizer at least 30 days to review any records the government planned to release and the power to identify documents and information "legally withholdable from release under FOIA." Pfizer Statement of Work, ¶ 7.2 (PDF p. 20).[28]

[27] *Available at* https://www.pfizer.com/news/press-release/press-release-detail/pfizer-biontech-covid-19-vaccine-comirnatyr-receives-full.
[28] *Available at* https://www.hhs.gov/sites/default/files/pfizer-inc-covid-19-vaccine-contract.pdf.

78. FOIA does not provide a third-party like Pfizer with rights to review documents before their release or to identify withholdable documents. Pfizer's COVID-19 vaccine contract thus provided Pfizer with rights over government documents not typically possessed by private businesses.

79. The FDA denied expedited processing of PHMPTA's FOIA request and claimed in litigation that it would take 55 years—until 2076—to produce all of the responsive documents. Jenna Greene, *Wait what? FDA wants 55 years to process FOIA request over vaccine data*, REUTERS, Nov. 18, 2021.[29]

80. Upon information and belief, Pfizer and its contractual rights to review documents before their release and to identify withholdable documents influenced the FDA's decision to deny expedited processing of PHMPTA's FOIA request and propose a 55-year production timeline.

81. Upon information and belief, Pfizer thus had a role in keeping its safety and effectiveness data possessed by the FDA hidden from the public.

82. In January 2022, a federal judge rejected the FDA's proposed production of 500 pages per month and ordered the FDA to instead produce 55,000 pages per month. *Pub. Health & Med. Pros. for Transparency v. Food & Drug Admin.*, No. 4:21-CV-1058-P, 2022 WL 90237, at *2 (N.D. Tex. Jan. 6, 2022).

E. Pfizer destroyed the vaccine control group, which will conceal critical data relating to the safety and effectiveness of its COVID-19 vaccine.

83. Finally, Pfizer kept its COVID-19 vaccine's true effects hidden by destroying the control group participating in its vaccine trial.

[29] *Available at* https://www.reuters.com/legal/government/wait-what-fda-wants-55-years-process-foia-request-over-vaccine-data-2021-11-18/.

84. A double-blind study, in which both the study subjects and study investigators do not know which group received the treatment or the placebo, is "the gold standard in modern clinical trials" and is "designed to test a treatment's safety and efficacy." Pfizer, *How the Placebo Effect Can Cloud Clinical Trial Results*.[30]

85. Pfizer promoted that it was conducting a double-blind study on its COVID-19 vaccine "to obtain safety, immune response, and efficacy data needed for regulatory review." Pfizer, *Pfizer and BioNTech Choose Lead mRNA Vaccine Candidate Against COVID-19 and Commence Pivotal Phase 2/3 Global Study*, July 27, 2020;[31] *see also* Apr. 2020 Protocol, *supra*, 30 (PDF p. 32).

86. Pfizer planned to follow COVID-19 vaccine study participants, both vaccine and placebo recipients, for 24 months to monitor the safety and effectiveness of its vaccine. Apr. 2020 Protocol, *supra*, 94-95 (PDF p. 96-97).

87. Once the FDA approved Pfizer's COVID-19 vaccine through an emergency use authorization in December 2020, Pfizer unblinded the study participants and offered vaccine placebo recipients the option to receive the Pfizer COVID-19 vaccine. Stephen J. Thomas et al., *Safety and Efficacy of the BNT162b2 mRNA COVID-19 Vaccine through 6 months*, N. Eng. J. Med., Sept. 15, 2021.[32]

88. Of the 21,921 vaccine trial participants who received the placebo, more than 20,000 placebo participants decided to receive the Pfizer COVID-19 vaccine as of March 13, 2021. BLA Clinical Review Memorandum, Aug. 23, 2021, at 32.[33]

---

[30] *Available at* https://www.pfizer.com/news/articles/how_the_placebo_effect_can_cloud_clinical_trial_results.
[31] *Available at* https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-choose-lead-mrna-vaccine-candidate.
[32] *Available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8461570/.
[33] *Available at* https://www.fda.gov/media/152256/download.

89. Taken together, only 1,544 placebo participants had not received the Pfizer COVID-19 vaccine as of March 13, 2021, just 7% of the original placebo group. *See id.*

90. Because Pfizer unblinded the original control group and allowed them to receive Pfizer's COVID-19 vaccine, Pfizer, government regulators, and independent scientists cannot fully compare the safety and efficacy of Pfizer's COVID-19 vaccine against unvaccinated individuals.

91. Pfizer's extensive and aggressive efforts to keep its COVID-19 vaccine information hidden conflict with its public transparency pledges and raise serious questions about what Pfizer is hiding and why it is hiding it.

III. Pfizer's COVID-19 Vaccine and Safety

A. Pfizer's representations about its COVID-19 vaccine and safety

92. In an open letter to the public, Pfizer Chairman and CEO Dr. Bourla dedicated his company to producing a safe vaccine: "The second requirement is to prove that the vaccine is safe. Our internal standards for vaccine safety and those required by regulators are set high. . . . **Safety is, and will remain, our number one priority**, and we will continue monitoring and reporting safety data for all trial participants for two years." *An Open Letter from Pfizer Chairman and CEO Albert Bourla*, Pfizer, Oct. 15, 2020 (emphasis added).[34]

93. After committing to Kansans that safety was Pfizer's number one priority with its COVID-19 vaccine, Pfizer and its employees, directors, and agents repeatedly misrepresented to Kansans that Pfizer's COVID-19 vaccine was safe.

94. On November 9, 2020, Pfizer Chairman and CEO Dr. Bourla said, "We feel very good about the safety" of Pfizer's COVID-19 vaccine and that there were "no safety concerns"

[34] *Available at* https://www.pfizer.com/news/announcements/open-letter-pfizer-chairman-and-ceo-albert-bourla.

reported to Pfizer by a review committee. Tommy Brooksbank, *Pfizer CEO on coronavirus vaccine: 'We feel very good about the safety,'* GOOD MORNING AMERICA, Nov. 9, 2020.[35]

95. On April 1, 2021, Pfizer issued a press release confirming "no serious safety concerns through up to six months following second dose" of the Pfizer COVID-19 vaccine. *Pfizer and BioNTech Confirm High Efficacy and No Serious Safety Concerns Through Up to Six Months Following Second Dose in Updated Topline Analysis of Landmark COVID-19 Vaccine Study*, Pfizer, Apr. 1, 2021.[36]

96. On August 23, 2021, Pfizer Chairman and CEO Dr. Bourla said that the Pfizer vaccine "is effective and safe." Antonio Planas, *'Effective and safe': Pfizer CEO says FDA's full approval should result in more vaccinations*, NBC NEWS, Aug. 23, 2021.[37]

97. On September 16, 2021, Pfizer Chairman and CEO Dr. Bourla said, "We have been very successful in developing an effective and safe vaccine." *Continuing to Follow the Science: An Open Letter from Pfizer Chairman and CEO Dr. Albert Bourla*, Pfizer, Sept. 16, 2021.[38]

98. On September 20, 2021, Pfizer announced in a press release that "[i]n participants 5 to 11 years of age, the vaccine was safe, well tolerated and showed robust neutralizing antibody responses." *Pfizer and BioNTech Announce Positive Topline Results From Pivotal Trial of COVID-19 Vaccine in Children 5 to 11 Years*, Pfizer, Sept. 20, 2021.[39]

---

[35] *Available at* https://www.goodmorningamerica.com/news/story/pfizer-ceo-coronavirus-vaccine-feel-good-safety-74105879.
[36] *Available at* https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-confirm-high-efficacy-and-no-serious.
[37] *Available at* https://www.nbcnews.com/news/us-news/effective-safe-pfizer-ceo-says-fda-s-full-approval-should-n1277478.
[38] *Available at* https://www.pfizer.com/news/announcements/continuing-follow-science-open-letter-pfizer-chairman-and-ceo-dr-albert-bourla.
[39] *Available at* https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-announce-positive-topline-results.

99. On November 22, 2021, Pfizer announced that its COVID-19 vaccine "demonstrated 100% efficacy against COVID-19 in longer-term analysis, with no serious safety concerns identified" in children 12 through 15 years of age. *Follow-Up Data From Phase 3 Trial of Pfizer-BioNTech COVID-19 Vaccine Support Safety and High Efficacy in Adolescents 12 Through 15 Years of Age*, Pfizer, Nov. 22, 2021.[40]

B. Pfizer made unsupported representations and concealed material facts relating to safety of its COVID-19 vaccine.

100. What Pfizer knew about its COVID-19 vaccine demonstrates that Pfizer made unsupported representations and concealed material facts relating to its COVID-19 vaccine.

1. Pfizer's vaccine trials provided limited safety information because Pfizer tested only healthy individuals.

101. Vaccine development normally includes testing on "people with typically varying health statuses and from different demographic groups." FDA, *Vaccine Development – 101* (Dec. 14, 2020) (discussing Phase 2).[41] Indeed, vaccine development includes "trial participants who have characteristics (such as age and physical health) similar to the intended recipients for the vaccine." CDC, *How Vaccines are Developed and Approved for Use* (Mar. 30, 2023).

102. Pfizer only tested its COVID-19 vaccine on healthy individuals. Protocol C4591001, "A Phase 1/2/3, Placebo-Controlled, Randomized, Observer-Blind, Dose-Finding Study to Evaluate the Safety, Tolerability, Immunogenicity, and Efficacy of SARS-CoV-2 RNA Vaccine Candidates Against COVID-19 in Healthy Individuals" ("Sept. 2020 Protocol"), Pfizer, Sept. 8, 2020, 36 (PDF p. 164), ¶ 5.1.2.[42]

---

[40] *Available at* https://www.pfizer.com/news/press-release/press-release-detail/follow-data-phase-3-trial-pfizer-biontech-covid-19-vaccine.
[41] Available at https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/vaccine-development-101.
[42] *Available at* https://www.nejm.org/doi/suppl/10.1056/NEJMoa2027906/suppl_file/nejmoa2027906_protocol.pdf.

103. Pfizer excluded unhealthy individuals from its COVID-19 vaccine trials. *Id.* at 37-38 (PDF pp. 165-66), ¶ 5.2.

104. For example, Pfizer excluded from its COVID-19 vaccine trials any individual who had been diagnosed with COVID-19. *Id.* at 37 (PDF p. 165), ¶ 5.2.5.

105. Pfizer excluded from its COVID-19 vaccine trials any immunocompromised individual. *Id.* at 38 (PDF p. 166), ¶ 5.2.8.

106. Pfizer excluded from its COVID-19 vaccine trials any woman who was pregnant or breastfeeding. *Id.* at 38 (PDF p. 166), ¶ 5.2.11.

107. Pfizer excluded individuals who health officials opined were vulnerable to COVID-19, and who accordingly were likely to be interested in a vaccine for COVID-19.

108. Pfizer's representations that its COVID-19 vaccine did not have any safety concerns failed to disclose the material facts that it had only been tested on healthy individuals.

109. Pfizer did not have data to support representations that its vaccine was safe for the general population, such as in individuals who had been diagnosed with COVID-19, who were immunocompromised, or who were pregnant or breastfeeding.

2. Pfizer failed to disclose limitations of its COVID-19 vaccine trials.

110. When Pfizer announced that the FDA had authorized Pfizer's COVID-19 vaccine for emergency use, Pfizer did not disclose that its trial included only healthy individuals and excluded unhealthy individuals. *See Pfizer and BioNTech Celebrate Historic First Authorization in the U.S. of Vaccine to Prevent COVID-19*, Dec. 11, 2020.[43]

[43] *Available at* https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-celebrate-historic-first-authorization.

111. In its press release announcing emergency use authorization of its COVID-19 vaccine, Pfizer claimed that a "primary endpoint" of the trial of its COVID-19 vaccine was "prevention of COVID-19 regardless of whether participants have previously been infected by SARS-CoV-2." *Id.*

112. Pfizer's statement was misleading since it had excluded any individual who had been diagnosed with COVID-19 from its vaccine trial.

113. In its press release announcing emergency use authorization of its COVID-19 vaccine, Pfizer did not disclose that it had excluded immunocompromised individuals from its COVID-19 vaccine trials. *See id.*

114. Instead, in "Important Safety Information" in its press release, Pfizer noted that "[i]mmunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the Pfizer BioNTech COVID-19 Vaccine." *Id.*

115. Because it excluded immunocompromised individuals from its COVID-19 vaccine trials, Pfizer did not have a reasonable basis to make representations about the possible effect its COVID-19 vaccine would have on immunocompromised individuals.

116. In its press release announcing emergency use authorization of its COVID-19 vaccine, Pfizer did not disclose that it had excluded pregnant or breastfeeding women from its COVID-19 vaccine trials. *See id.*

117. Instead, Pfizer reported that it planned additional studies to evaluate its COVID-19 vaccine in pregnant women. *Id.*

118. In addition, in "Important Safety Information" in its press release, Pfizer reported, "[a]vailable data on Pfizer BioNTech COVID-19 Vaccine administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy." *Id.*

119. Pfizer also reported, "[d]ata are not available to assess the effects of Pfizer BioNTech COVID-19 Vaccine on the breastfed infant or on milk production/excretion." *Id.*

120. Pfizer did not disclose that data was insufficient and unavailable to assess the effects of Pfizer's COVID-19 vaccine on pregnant and breastfeeding women because Pfizer excluded all pregnant and breastfeeding women from its COVID-19 vaccine trials.

121. Six months after vaccinating individuals in its COVID-19 vaccine trial, Pfizer issued another press release that again failed to disclose that Pfizer excluded all unhealthy individuals, immunocompromised individuals, and women who are pregnant or breastfeeding from its COVID-19 vaccine trial. *Pfizer and BioNTech Confirm High Efficacy and No Serious Safety Concerns Through Up to Six Months Following Second Dose in Updated Topline Analysis of Landmark COVID-19 Vaccine Study*, Apr. 1, 2021.[44]

122. Pfizer's April 1, 2021 press release contains the same statements about immunocompromised individuals and women who are pregnant or breastfeeding as its December 11, 2020 press release.

123. Pfizer made representations about its COVID-19 vaccine's safety knowingly or with reason to know that it did not possess a reasonable basis to represent that it was safe for individuals who had been diagnosed with COVID-19, who were immunocompromised, or who were pregnant or breastfeeding.

124. Pfizer made representations knowingly or with reason to know that the safety of its COVID-19 vaccine had not been proven or otherwise substantiated in individuals who had been diagnosed with COVID-19, who were immunocompromised, or who were pregnant or

[44] *Available at* https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-confirm-high-efficacy-and-no-serious.

breastfeeding. Pfizer did not rely upon or possess the type and amount of proof or substantiation it represented to exist.

125. Pfizer's decision to exclude individuals who had been diagnosed with COVID-19, who were immunocompromised, or who were pregnant or breastfeeding from its vaccine trials were material facts to Kansans making decisions about COVID-19 vaccination.

126. On multiple occasions, Pfizer willfully concealed, suppressed, or omitted material facts about who it had excluded from its COVID-19 vaccine trials, and how those exclusions might affect Pfizer's safety representations.

C. Pfizer's knowledge of COVID-19 vaccine safety issues

127. Pfizer possessed data presenting significant safety concerns associated with its COVID-19 vaccine when Pfizer made public statements in 2021 that its COVID-19 vaccine was safe. *See* Worldwide Safety and Pfizer, *5.3.6 Cumulative Analysis of Post-Authorization Adverse Event Reports of PF-07302048 (BNT162B2) Received Through 28-Feb-2021*, approved Apr. 30, 2021 ("Pfizer Feb. 28, 2021 Adverse Event Data").[45]

128. The FDA defines an adverse event as "any undesirable experience associated with the use of a medical product in a patient." FDA, *What is a Serious Adverse Event?*, content current as of May 18, 2023.[46]

129. The FDA and CDC co-manage the Vaccine Adverse Event Reporting System (VAERS), "a national early warning system to detect possible safety problems in U.S.-licensed vaccines." U.S. Dept. of Health & Human Servs., *About VAERS*.[47]

[45] *Available at* https://phmpt.org/wp-content/uploads/2022/04/reissue_5.3.6-postmarketing-experience.pdf.
[46] *Available at* https://www.fda.gov/safety/reporting-serious-problems-fda/what-serious-adverse-event.
[47] *Available at* https://vaers.hhs.gov/about.html.

130. VAERS is a passive reporting system that relies on reports submitted by patients and health care providers, "a system that is believed to miss many potential side effects." JoNel Aleccia, *COVID vaccine safety system has gaps that may miss unexpected side effects, experts say*, NBC NEWS (May 2, 2021).[48]

131. Separate from VAERS, Pfizer maintained its own adverse events database that "contain[ed] cases of [adverse events (AEs)] reported spontaneously to Pfizer, cases reported by the health authorities, cases published in the medical literature, cases from Pfizer-sponsored marketing programs, non-interventional studies, and cases of serious AEs reported from clinical studies regardless of causality assessment." Pfizer Feb. 28, 2021 Adverse Event Data, at 5.

132. Upon information and belief, Pfizer's adverse events database contained more adverse event data than VAERS because it included both information in VAERS and information not in VAERS.

133. Pfizer did not publicly release adverse events data from its database.

134. The Pfizer Feb. 28, 2021 Adverse Event Data document was only obtained through the Public Health and Medical Professionals for Transparency in America FOIA litigation.

135. As of February 28, 2021, Pfizer's adverse events database contained 158,893 adverse events (from 42,086 case reports) from its COVID-19 vaccine. *Id.* at 6.

136. As of February 28, 2021, Pfizer's database contained 1,223 fatalities after taking Pfizer's COVID-19 vaccine, although Pfizer did not make causality findings. *Id.* at 7.

137. Pfizer was receiving so many adverse event reports that it had to hire 600 additional full-time staff and expected to hire more than 1,800 additional resources by June 2021. *Id.* at 6.

[48] Available at https://www.nbcnews.com/health/health-news/covid-vaccine-safety-system-has-gaps-may-miss-unexpected-side-n1265986.

138. Pfizer had such a backlog of adverse events that it might take 90 days to code "non-serious cases." *Id.*

139. Pfizer did not know "the magnitude of underreporting" *id.* at 5, but significant underreporting was likely. *See* Hazell L, Shakir SA. Under-reporting of adverse drug reactions: a systematic review. Drug Saf. 2006;29(5):385-96. doi: 10.2165/00002018-200629050-00003. PMID: 16689555 (systematic review of 37 studies concluding that the median under-reporting of adverse drug reactions to spontaneous reporting systems was 94%).

140. Pfizer's representations that its COVID-19 vaccine did not have any safety concerns was inconsistent with the adverse events data it possessed.

141. Pfizer concealed, suppressed, or omitted material facts it possessed showing significant safety concerns associated with Pfizer's COVID-19 vaccine.

D. Pfizer's knowledge of the safety of its COVID-19 vaccine on pregnant women

1. The concerning findings in Pfizer's secret animal study.

142. While Pfizer tested its COVID-19 vaccine on healthy individuals in 2020, Pfizer and its partner BioNTech also quietly tested its COVID-19 vaccine on pregnant rats from June 29, 2020 to October 12, 2020. Charles River, "A Combined Fertility and Development Study (Including Teratogenicity and Postnatal Investigations) of BNT162b1, BNT162b2 and BNT162b3 by Intramuscular Administration in the Wistar Rat," approved Dec. 22, 2020 ("Pfizer Rat Fertility Study"), at 13.[49]

[49] *Available at* https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/110122/125742_S1_M4_20256434.pdf.

143. According to the lab that performed the research, "[t]he rat genome is comparable to the human genome, which makes rats desirable models for the study of diseases that affect humans." Charles River, *Laboratory Rats*.[50]

144. The rat fertility study contained a positive conclusion: "Intramuscular administration of BNT162b1, BNT162b2 and BNT162b3 before and during gestation to female Wistar (CRL:WI[Han]) rats was associated with non-adverse effects (body weight, food consumption and effects localized to the injection site) after each dose administration. There were no effects of any of the 3 vaccine candidates on mating performance or fertility in F0 female rats or on embryo-fetal or postnatal survival, growth, or development of the F1 offspring." Pfizer Rat Fertility Study, at 38.

145. The rat fertility study's details tell a much more concerning story.

146. Rats that received BNT162b2, Pfizer's COVID-19 vaccine:

a. Had multiple fetuses with severe soft tissue and skeletal malformations, *id.* at 34;

b. Did not become pregnant, *id.* at 22 Text Table 5, n. b;

c. Failed to implant embryos at more than double (9.77%) the rate of the control group (4.09%), *id.* at 33;

d. Lost body weight, *id.* at 31; and

e. Consumed less food, *id*.

147. Rats that received other variations of Pfizer's COVID-19 vaccine experienced these issues and others, such as losing their entire litters and delivering stillborn offspring. *Id.* at 30.

148. Pfizer did not issue a press release announcing the rat fertility study's findings.

[50] *Available at* https://www.criver.com/products-services/research-models-services/animal-models/rats?region=3616.

149. Pfizer did not publish a study relating to the rat fertility study's findings.

150. Pfizer issued press releases and published studies for other animal study findings relating to its COVID-19 vaccine. *See, e.g.*, *Pfizer and BioNTech Public Preclinical Data from Investigational COVID-19 Vaccine Program in Nature*, Feb. 1, 2021.[51]

151. Pfizer's rat study was not publicly released until November 2022 in the Public Health and Medical Professionals for Transparency in America FOIA lawsuit.

2. Pfizer announces study on pregnant women but omits material facts already in its possession.

152. On February 18, 2021, Pfizer announced "that the first participants have been dosed in a global Phase 2/3 study to further evaluate the safety, tolerability, and immunogenicity of the Pfizer-BioNTech COVID-19 vaccine (BNT162b2) in preventing COVID-19 in healthy pregnant women 18 years of age and older." *Pfizer and BioNTech Commence Global Clinical Trial to Evaluate COVID-19 Vaccine in Pregnant Women*, Feb. 18, 2021.[52]

153. In its February 18, 2021 press release, Pfizer did not disclose material facts relating to pregnancy in its possession. *See* Pfizer, *Pregnancy and Lactation Cumulative Review*, approved Apr. 20, 2021 ("Pfizer Feb. 28, 2021 Pregnancy Data");[53] *see also* Pfizer Feb. 28, 2021 Adverse Event Data, *supra*, at 12; Pfizer Rat Fertility Study; *supra*.

154. As of February 28, 2021, Pfizer possessed reports for 458 pregnant women exposed to its COVID-19 vaccine during pregnancy. Pfizer Feb. 28, 2021 Pregnancy Data, at 2.

[51] *Available at* https://cdn.pfizer.com/pfizercom/2021-02/BNT162_Nature_Preclinical_Data_Publication_Statement_to_Upload_VF.pdf.
[52] *Available at* https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-commence-global-clinical-trial-evaluate.
[53] *Available at* https://www.phmpt.org/wp-content/uploads/2023/04/125742_S2_M1_pllr-cumulative-review.pdf.

155. More than half of the pregnant women (248 cases, or 54%) reported an adverse event from Pfizer's COVID-19 vaccine, while fewer than half (210 cases, or 46%) did not report an adverse event. *Id.* at 2-3.

156. More than 1-in-10 women (52) who received Pfizer's COVID-19 vaccine during their pregnancy reported a miscarriage, many within days of vaccination. *Id.* at 3-4.

157. Six women who received Pfizer's COVID-19 vaccine during their pregnancy reported premature deliveries; several babies died. *Id.* at 3.

158. Pfizer's February 18, 2021 press release also did not disclose other adverse effects on the reproductive systems of women who received Pfizer's COVID-19 vaccine.

159. For example, by April 2022, Pfizer knew of tens of thousands of adverse events connected to its COVID-19 vaccine including heavy menstrual bleeding (27,685); menstrual disorders (22,145); irregular periods (15,083); delayed periods (13,989); absence of periods (11,363); and other reproductive system effects. Pfizer, *Appendix 2.1 Cumulative Number of Case Reports (Serious and Non-Serious, Medically Confirmed and Non Medically-Confirmed) from Post-Marketing Data Sources, Overall, by Sex, Country, Age Groups and in Special Populations and Summary Tabulation by Preferred Term and MedDRA System Organ Class*, approved May 6, 2022, at 333-340 (PDF pp. 6-13).[54]

160. Upon information and belief, Pfizer possessed many reports on these adverse events relating to women's reproductive systems at the time of its February 18, 2021 press release.

3. Pfizer's study on pregnant women failed and the results are secret.

[54] *Available at* https://www.tga.gov.au/sites/default/files/2022-08/foi-3727-01.pdf.

161. According to Pfizer's February 18, 2021 press release, Pfizer sought to study approximately 4,000 healthy pregnant women. *Pfizer and BioNTech Commence Global Clinical Trial to Evaluate COVID-19 Vaccine in Pregnant Women*, Feb. 18, 2021.[55]

162. However, Pfizer only enrolled a fraction of this amount (683) in its study. National Library of Medicine, *To Evaluate the Safety, Tolerability, and Immunogenicity of BNT162b2 Against COVID-19 in Healthy Pregnant Women 18 Years of Age and Older*, ID NCT04754594, last update posted July 13, 2023.[56]

163. Upon information and belief, Pfizer destroyed the placebo control group during the study, preventing Pfizer from evaluating differences in safety and efficacy between vaccinated pregnant women and unvaccinated pregnant women.

164. Although Pfizer completed its study of its COVID-19 vaccine on pregnant women on July 15, 2022, it still has not completed the quality control review process for the study. *Id.* at Results Submitted.[57]

E. Pfizer's misrepresentations about its COVID-19 vaccine and safety signals

165. On January 18, 2023, when asked whether the Pfizer COVID-19 vaccine caused strokes or myocarditis, Pfizer Chairman and CEO Dr. Bourla said, "We constantly review and analyze the data. We've seen not a single [safety] signal although we have distributed billions of doses." *Pfizer CEO Albert Bourla discusses new vaccines in the pipeline*, CNBC, Jan. 18, 2023, 3:18.[58]

---

[55] *Available at* https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-commence-global-clinical-trial-evaluate.
[56] *Available at* https://clinicaltrials.gov/study/NCT04754594.
[57] *Available at* https://clinicaltrials.gov/study/NCT04754594?tab=results.
[58] *Available at* https://www.cnbc.com/video/2023/01/18/pfizer-ceo-albert-bourla-discusses-new-vaccines-to-be-released.html.

166. The FDA has defined "safety signal" as "a concern about an excess of adverse events compared to what would be expected to be associated with a product's use." A "single well-documented case report can be viewed as a signal, …" U.S. Department of Health and Human Services et al., *Guidance for Industry: Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment*, Mar. 2005, at 4 (PDF p. 7).[59]

167. Upon information and belief, contrary to Pfizer Chairman and CEO Dr. Bourla's representations, Pfizer has been aware of numerous safety signals relating to its COVID-19 vaccine.

1. Pfizer's knowledge of a safety signal for myocarditis and pericarditis

168. Upon information and belief, at the time Pfizer Chairman and CEO Dr. Bourla represented that Pfizer had not seen a single safety signal, Pfizer was aware of a safety signal for myocarditis and pericarditis caused by its COVID-19 vaccine.

169. "Myocarditis is inflammation of the heart muscle, and pericarditis is inflammation of the outer lining of the heart." CDC, *Myocarditis and Pericarditis After mRNA COVID-19 Vaccination*, Nov. 3, 2023.[60]

170. From the start, a clear connection existed between Pfizer's COVID-19 vaccine and cases of myocarditis and pericarditis.

i. The United States military detected a safety signal for myocarditis.

171. In early 2021, the U.S. military noticed cases of myocarditis in male military members occurring within four days of administration of Pfizer's COVID-19 vaccine. Report to the Committee on Armed Services of the House of Representatives, *Department of Defense Report*

[59] *Available at* https://www.fda.gov/media/71546/download.
[60] *Available at* https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/myocarditis.html.

on Cardiac and Kidney Issues in Service Members Prior to and Following the COVID Vaccine Requirement, Sept. 2023 ("DOD COVID Vaccine Report"), 3;[61] Patricia Kime, *Pentagon Tracking 14 Cases of Heart Inflammation in Troops After COVID-19 Shots*, MILITARY.COM (Apr. 26, 2021).[62]

172. By June 2021, military doctors found an association between the COVID-19 vaccine and myocarditis in at least 23 military patients who had no known cardiac issues until 12 to 96 hours following a mRNA COVID-19 vaccination, after which they developed myocarditis. Jay Montgomery *et al.*, *Myocarditis Following Immunization With mRNA COVID-19 Vaccines in Members of the US Military*, JAMA Cardiol. 2021;6(10):1202-1206. doi:10.1001/jamacardio.2021.2833.[63]

173. When the Department of Defense reviewed its health system data for 2021, it found that "[t]hose who were recently vaccinated had a rate ratio that showed their incidences of myocarditis and pericarditis were 2.6 and 2.0 times higher compared to those who were never vaccinated." DOD COVID Vaccine Report, *supra*, 10.

ii. The United States government detected a safety signal for myocarditis.

174. On March 3, 2021, Israel's Ministry of Health contacted the CDC about myocarditis and pericarditis connected to Pfizer's COVID-19 vaccine: "We are seeing a large number of myocarditis and pericarditis cases in young individuals soon after Pfizer COVID-19 vaccine. We would like to discuss the issue with a relevant expert at CDC."

[61] *Available at* https://www.health.mil/Reference-Center/Reports/2023/09/29/DOD-Report-on-Cardiac-and-Kidney-Issues-in-Service-Members-Prior-to-and-Following-the-COVID-Vaccine-Requirement.
[62] *Available at* https://www.military.com/daily-news/2021/04/26/pentagon-tracking-14-cases-of-heart-inflammation-troops-after-covid-19-shots.html.
[63] *Available at* https://jamanetwork.com/journals/jamacardiology/fullarticle/2781601.

175. Israel had been tracking myocarditis cases arising shortly after receipt of Pfizer's COVID-19 vaccine. Maayan Jaffe-Hoffman, *19-year-old hospitalized in ICU days after receiving second Pfizer vaccine*, THE JERUSALEM POST (Feb. 1, 2021).[64]

176. Upon information and belief, Pfizer had knowledge of the medical reports in Israel related to its vaccine and myocarditis and pericarditis because Israel agreed to share medical data with Pfizer. Daniel Estrin, *Vaccines for Data: Israel's Pfizer Deal Drives Quick Rollout – And Privacy Worries*, NPR (Jan. 31, 2021);[65] Real-World Epidemiological Evidence Collaboration Agreement, Jan. 6, 2021, §§ 1.8, 2.3, 3, Ex. A.[66]

177. On June 1, 2021, a CDC Advisory Committee on Immunization Practices work group issued a notice stating "that within 30 days of receiving the second dose of either Pfizer or Moderna vaccines, 'there was a higher number of observed than expected myocarditis/pericarditis cases in 16-24-year-olds.'" Elizabeth Cohen, *A link between COVID-19 vaccination and a cardiac illness may be getting closer*, CNN (June 10, 2021).[67]

178. A Pfizer spokesperson provided a statement that said "the company is aware of the myocarditis reports, and that 'a causal link to the vaccine has not been established.'" *Id.*

179. Also on June 1, 2021, Israel's Ministry of Health reported that "it had found the small number of heart inflammation cases observed mainly in young men who received Pfizer's

[64] *Available at* https://www.jpost.com/health-science/19-year-old-hospitalized-with-heart-inflammation-after-pfizer-vaccination-657428.
[65] *Available at* https://www.npr.org/2021/01/31/960819083/vaccines-for-data-israels-pfizer-deal-drives-quick-rollout-and-privacy-worries.
[66] *Available at* https://www.gov.il/BlobFolder/news/17012021-02/he/files_publications_corona_pfizer_agreement.pdf.
[67] *Available at* https://www.cnn.com/2021/06/09/health/myocarditis-covid-vaccination-link-clearer/index.html.

COVID-19 vaccine in Israel were likely linked to their vaccination." Jeffrey Heller, *Israel sees probable link between Pfizer vaccine and myocarditis cases*, Reuters (June 2, 2021).[68]

180. After the CDC had received 1,200 reports of heart inflammation relating to the COVID-19 vaccine, in late June 2021, the FDA added a warning about the risk of myocarditis and pericarditis to the Pfizer (and Moderna) COVID-19 vaccine fact sheet. Lauren Mascarenhas, *FDA adds a warning to COVID-19 vaccines about risk of heart inflammation*, CNN, June 26, 2021.[69]

181. According to a September 2021 FDA briefing document, "[p]ost-EUA safety surveillance reports received by FDA and CDC identified serious risks for myocarditis and pericarditis following administration of the primary series (Dose 1 and Dose 2)" of Pfizer's COVID-19 vaccine. *Vaccines and Related Biological Products Advisory Committee Meeting, Sept. 17, 2021, FDA Briefing Document, Application for licensure of a booster dose for COMIRNATY (COVID-19 Vaccine, mRNA)*, 7.[70]

182. According to a presentation to the CDC's Advisory Committee in Immunization Practices, analysis through May 2022 found a safety signal for myocarditis and pericarditis (as well as acute myocardial infarction and venous thromboembolism). Nicola Klein, *COVID-19 Vaccine Safety Surveillance: Summary from VSD RCA*, CDC Advisory Committee in Immunization Practices (Sept. 12, 2023), at 42.[71]

183. At the time of Pfizer Chairman and CEO Dr. Bourla's January 18, 2023 denial of any safety signals, the CDC's website reported that "[d]ata from multiple studies show a rare risk for myocarditis and/or pericarditis following receipt of mRNA COVID-19 vaccines. These rare

[68] *Available at* https://www.reuters.com/world/middle-east/israel-sees-probable-link-between-pfizer-vaccine-small-number-myocarditis-cases-2021-06-01/.
[69] *Available at* https://www.cnn.com/2021/06/25/health/fda-covid-vaccine-heart-warning/index.html.
[70] *Available at* https://www.fda.gov/media/152176/download.
[71] *Available at* https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2023-09-12/07-covid-klein-508.pdf.

cases of myocarditis or pericarditis have occurred most frequently in adolescent and young adult males, ages 16 years and older, within 7 days after receiving the second dose of an mRNA COVID-19 vaccine (Pfizer-BioNTech and Moderna)." CDC, *Clinical Considerations: Myocarditis and Pericarditis after Receipt of mRNA COVID-19 Vaccines Among Adolescents and Young Adults* (captured Jan. 17, 2023).[72]

184. The CDC currently reports "a causal association between mRNA COVID-19 vaccines (i.e., Moderna or Pfizer-BioNTech) and myocarditis and pericarditis." CDC, *Clinical Considerations: Myocarditis and Pericarditis after Receipt of COVID-19 Vaccines Among Adolescents and Young Adults* (last reviewed Oct. 10, 2023).[73]

iii. Pfizer detected a safety signal for myocarditis.

185. According to a leaked confidential February 2022 Pfizer document, "[s]ince April 2021, increased cases of myocarditis and pericarditis have been reported in the United States after mRNA COVID-19 vaccination (Pfizer-BioNTech and Moderna), particularly in adolescents and young adults (CDC 2021)." Pfizer, *Myocarditis/Pericarditis After mRNA COVID-19 Vaccine Administration: Potential Mechanisms and Recommended Future Actions*, Feb. 11, 2022, at 18.[74]

186. After Pfizer obtained FDA approval through emergency use authorization to provide its COVID-19 vaccine to 12-15-year-olds in August 2021, Pfizer decided to study "how often" its vaccine may cause myocarditis or pericarditis in children by testing 5-16-year-olds for troponin I. *CT05-GSOP-RF05 7.0 Phase 1/2/3/4 Informed Consent Pediatric Study Template,*

[72] *Available at* https://web.archive.org/web/20230117155359/https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html.
[73] *Available at* https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html.
[74] *Available at* https://downloads.ctfassets.net/syq3snmxclc9/7AqXvmHTBMFOxeGxwMBxxS/7d21477d2697da8adf980ccce52b983f/3-16-23_-_Pfizer_Docs_Watermarked.pdf.

Phase 2/3 Obtaining Serum Samples for Potential Troponin I Testing (all age groups, Pfizer (Sept. 13, 2021), 2.[75]

187. Troponin I, an enzyme in the heart muscle, "could be an early sign of two conditions that affect the heart called myocarditis or pericarditis." *Id.*

188. Pfizer warned children participants that after receiving Pfizer's COVID-19 vaccine, "[y]ou might get chest pain, shortness of breath, or feelings of having a fast-beating, fluttering or pounding heart. You may need to come in to see the study doctor for further assessments if you have these symptoms." *Id.* at 8.

189. Pfizer press releases did not disclose an increased risk of myocarditis from Pfizer's COVID-19 vaccine until November 2021. *Posts falsely claim Pfizer 'officially admits' heart inflammation is COVID jab side effect in 2023*, AFP FRANCE (Dec. 11, 2023).[76]

190. Upon information and belief, at the time of Pfizer Chairman and CEO Dr. Bourla's January 2023 representation that Pfizer had not observed a single safety signal related to Pfizer's COVID-19 vaccine, Pfizer was aware of a safety signal relating to myocarditis and pericarditis.

2. Pfizer's knowledge of a safety signal for strokes

191. Upon information and belief, Pfizer also detected a safety signal relating to strokes.

192. Days before Pfizer Chairman and CEO Dr. Bourla denied any safety signal, the CDC's and FDA's "surveillance system flagged a possible link between the new Pfizer-BioNTech bivalent COVID-19 vaccine and strokes in people aged 65 and over, . . ." Ben Leonard and Lauren

[75] *Available at* https://www.phmpt.org/wp-content/uploads/2023/10/019736_S488_M5_c4591007-p2-3-older-children-assent-troponin-icd.pdf.
[76] *Available at* https://factcheck.afp.com/doc.afp.com.346Z3GD.

Gardner, *CDC, FDA see possible link between Pfizer's bivalent shot and strokes*, POLITICO, Jan. 13, 2023.[77]

193. Although CDC later suggested a link was "very unlikely," a FDA study found that individuals 85 years or older who received both a flu vaccine and Pfizer's COVID-19 vaccine "saw a 20 percent increase in the risk of ischemic stroke." Apoorva Mandavilli, *COVID Shots May Slightly Raise Stroke Risk in the Oldest Recipients*, THE NEW YORK TIMES (Oct. 24, 2023).[78]

194. Pfizer inadequately studied its vaccine's effects on the elderly.

195. When Pfizer sought approval for a third shot—a "booster"—for its COVID-19 vaccine, it requested approval to vaccinate individuals 16 years of age and older, including the elderly. However, Pfizer only tested the booster shot on 12 trial participants who were in the 65- to 85-year-old age range. Vaccines and Related Biological Products Advisory Committee Meeting, Sept. 17, 2021, FDA Briefing Document, Application for licensure of a booster dose for COMIRNATY (COVID-19 Vaccine, mRNA), 22 ("While evaluated in only 12 participants in the age cohort of 65 through 85 years, . . .").[79]

196. Pfizer should not have represented that the booster was "safe" for 65- to 85-year-olds after only testing 12 trial participants in that age range.

197. Pfizer did not test the booster on any participant older than 85 years old. *Id.*

198. Pfizer should not have represented that the booster was "safe" for individuals 85 years old and older when it had not tested any trial participants in that age range.

[77] *Available at* https://www.politico.com/news/2023/01/13/cdc-fda-pfizer-bivalent-vaccine-possible-strokes-00077933.
[78] *Available at* https://www.nytimes.com/2023/10/24/health/covid-flu-vaccine-stroke.html.
[79] *Available at* https://www.fda.gov/media/152176/download.

199. Upon information and belief, at the time of Pfizer Chairman and CEO Dr. Bourla's representation in January 2023, that Pfizer had not observed a single safety signal related to Pfizer's COVID-19 vaccine, Pfizer was aware of a safety signal relating to strokes.

3. Pfizer's knowledge of a safety signal for increased fatalities

200. Upon information and belief, Pfizer also detected a safety signal relating to deaths.

201. As of February 28, 2021, Pfizer's adverse events database contained 1,223 fatalities after taking Pfizer's COVID-19 vaccine. Pfizer Feb. 28, 2021 Adverse Event Data, *supra*, at 7, table 1.

202. An expert review by the Norwegian Medicines Agency published on May 19, 2021 determined that "[a]mong 100 reported deaths, a causal link to the [Pfizer COVID-19] vaccine was considered probable in 10 cases, possible in 26 and unlikely in 59. Five were unclassifiable." Wyller TB, Kittang BR, Ranhoff AH, Harg P, Myrstad M. Nursing home deaths after COVID-19 vaccination. *Tidsskr Nor Legeforen* 2021;141. doi:10.4045/tidsskr.21.0383.[80]

203. By December 2021, New Zealand's health authorities had linked multiple deaths to Pfizer's COVID-19 vaccine. *New Zealand links 26-year-old man's death to Pfizer COVID-19 vaccine*, REUTERS (Dec. 19, 2021).[81]

204. Upon information and belief, Pfizer was aware of other reports of death related to its COVID-19 vaccine.

205. Upon information and belief, at the time of Pfizer Chairman and CEO Dr. Bourla's representation in January 2023 that Pfizer had not observed a single safety signal related to Pfizer's COVID-19 vaccine, Pfizer was aware of a safety signal relating to deaths.

[80] *Available at* https://tidsskriftet.no/en/2021/05/originalartikkel/nursing-home-deaths-after-covid-19-vaccination.
[81] *Available at* https://www.reuters.com/world/asia-pacific/new-zealand-links-26-year-old-mans-death-pfizer-covid-19-vaccine-2021-12-20/.

IV. Pfizer Made Unsupported Representations and Concealed Material Facts Relating to Efficacy of its COVID-19 Vaccine.

A. Pfizer misrepresented and concealed material facts relating to the durability of protection provided by its COVID-19 vaccine.

206. In November 2020, Pfizer announced, "[p]rimary efficacy analysis demonstrates BNT162b2 to be 95% effective against COVID-19 beginning 28 days after the first dose." *Pfizer and BioNTech Conclude Phase 3 Study of COVID-19 Vaccine Candidate, Meeting All Primary Efficacy Endpoints*, Pfizer, Nov. 18, 2020.[82]

207. Pfizer did not report the absolute risk reduction of its COVID-19 vaccine, which was just 0.84%. Piero Olliaro *et al.*, *COVID-19 vaccine efficacy and effectiveness—the elephant (not) in the room*, 2 LANCET e279, 279 (July 2021).[83] Absolute risk reduction "measures the precise magnitude and strength of the reduced risk," compared to relative risk reduction that "is a proportion of risk outcomes in separate groups." Brown RB. *Relative risk reduction: Misinformative measure in clinical trials and COVID-19 vaccine efficacy*, at 3. Dialogues Health. 2022 Dec;1:100074. doi: 10.1016/j.dialog.2022.100074. Epub 2022 Nov 10. PMID: 36785641; PMCID: PMC9647013.

208. On February 25, 2021, when asked in an interview how long Pfizer's COVID-19 two-dose vaccine provided protection, Pfizer Chairman and CEO Dr. Bourla stated, "at six months, the protection is robust." *Exclusive interview with Pfizer CEO Albert Bourla*, NBC News (Feb. 25, 2021), at 3:55.[84]

---

[82] *Available at* https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-conclude-phase-3-study-covid-19-vaccine.
[83] *Available at* https://doi.org/10.1016/S2666-5247(21)00069-0.
[84] *Available at* https://www.nbcnews.com/nightly-news/video/exclusive-interview-with-pfizer-ceo-albert-bourla-101605957789.

209. "Robust" is defined as "exhibiting strength" and "capable of performing without failure under a wide range of conditions." Merriam-Webster, *Robust*.[85]

210. Upon information and belief, Pfizer had insufficient data on February 25, 2021 to conclude that protection at six months was robust.

211. On April 1, 2021, Pfizer issued a press release that celebrated "high efficacy" in Pfizer's COVID-19 vaccine through up to six months after the second dose. *Pfizer and BioNTech Confirm High Efficacy and No Serious Safety Concerns Through Up to Six Months Following Second Dose in Updated Topline Analysis of Landmark COVID-19 Vaccine Study*, Pfizer, Apr. 1, 2021.[86]

212. Pfizer represented that "[a]nalysis of 927 confirmed symptomatic cases of COVID-19 demonstrates BNT162b2 is highly effective with 91.3% vaccine efficacy observed against COVID-19, measured seven days through up to six months after the second dose." *Id.*

213. Pfizer cited data in its press release that also appears in a Pfizer efficacy summary document. *2.7.3 Summary of Clinical Efficacy*, approved on Apr. 30, 2021, at 55.[87]

214. Upon information and belief, Pfizer possessed the data contained in the efficacy summary document at the time it published the April 1, 2021 press release.

215. In its efficacy summary document, Pfizer reported an 83.7% efficacy rate four months after the second dose of its COVID-19 vaccine. *Id.* at 68.

216. In its efficacy summary document, Pfizer reported blood sample data showing effectiveness continued to wane at six months. *Id.* at 169, 171.

---

[85] *Available at* https://www.merriam-webster.com/dictionary/robust.
[86] *Available at* https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-confirm-high-efficacy-and-no-serious.
[87] *Available at* https://clinical-information.canada.ca/ci-rc-vu.pdf?file=m2/27-clin-sum/summary-clin-efficacy-covid19-1.pdf&id=252736.

217. Waning effectiveness of Pfizer's COVID-19 vaccine was a material fact for Kansans considering the vaccine.

218. Pfizer did not disclose the material fact of measurable waning effectiveness of its COVID-19 vaccine in its April 1, 2021 press release.

219. Pfizer did not publicly disclose that effectiveness waned to 83.7% until July 28, 2021, in a Pfizer preprint study. Alexa Lardieri, *Pfizer Vaccine Protection Declines After Six Months, Boosters Protect Against Delta Variant*, U.S. News & World Report, July 28, 2021.[88]

220. Pfizer issued a press release on July 28, 2021 that promoted positive results from a booster study, but it did not mention the pre-print study or the waning effectiveness of its COVID-19 vaccine. *Pfizer Reports Second-Quarter 2021 Results*, July 28, 2021, 11.[89]

221. "It's clear from the documents that these analyses were almost four months old by the time they became public," said Peter Doshi, an associate professor at the University of Maryland School of Pharmacy. "It's disappointing that neither Pfizer, nor regulators, disclosed these data until it was too obvious to ignore new outbreaks in Israel and Massachusetts, which made it clear that vaccine performance was not holding up." Maryanne Demasi, *Pfizer Hid Data on Waning Immunity*, Brownstone Institute, Apr. 7, 2023.[90]

222. Pfizer's concealment, suppression, and omission of the waning effectiveness of its COVID-19 vaccine allowed Pfizer to profit from vaccinations of Kansans who may have been deterred from Pfizer's COVID-19 vaccine had they known about its waning effectiveness.

[88] *Available at* https://www.usnews.com/news/health-news/articles/2021-07-28/pfizer-vaccine-protection-declines-after-six-months-boosters-protect-against-delta-variant.
[89] *Available at* https://s21.q4cdn.com/317678438/files/doc_financials/2021/q2/Q2-2021-PFE-Earnings-Release.pdf.
[90] *Available at* https://brownstone.org/articles/pfizer-hid-data-on-waning-immunity/.

223. Pfizer collected $7.8 billion in direct sales and alliance revenues from its COVID-19 vaccine in the second quarter of 2021, or the time between its April 1, 2021 press release failing to disclose the waning effectiveness of its COVID-19 vaccine and June 30, 2021, more than one month before its belated disclosure on waning effectiveness of its COVID-19 vaccine. *Pfizer Reports Second-Quarter 2021 Results*, July 28, 2021, 5.[91]

B. Pfizer misrepresented and concealed material facts relating to the effectiveness against variants provided by its COVID-19 vaccine.

224. On February 25, 2021, Pfizer Chairman and CEO Dr. Bourla said data suggested that individuals fully vaccinated with Pfizer's COVID-19 vaccine were protected against any variant currently known, including the South African, Brazilian, and UK variants. *Exclusive interview with Pfizer CEO Albert Bourla*, NBC NEWS (Feb. 25, 2021), at 0:15.[92]

225. On June 15, 2021, Pfizer Chairman and CEO Dr. Bourla reiterated his belief that his company's COVID-19 vaccine would protect against variants: "I feel quite comfortable that we cover it. . . . We will not need a special vaccine for it. The current vaccine should cover it." *CEO 'comfortable' Pfizer COVID-19 vaccine protects against more severe Delta variant*, CBS NEWS (June 15, 2021).[93]

226. On June 24, 2021, Pfizer's medical director in Israel reported that Pfizer's COVID-19 vaccine was "very effective, around 90%" against the Delta variant. Maayan Lubell, *Pfizer says COVID vaccine is highly effective against Delta variant*, REUTERS (June 24, 2021).[94]

---

[91] *Available at* https://s21.q4cdn.com/317678438/files/doc_financials/2021/q2/Q2-2021-PFE-Earnings-Release.pdf.
[92] *Available at* https://www.nbcnews.com/nightly-news/video/exclusive-interview-with-pfizer-ceo-albert-bourla-101605957789.
[93] *Available at* https://www.cbsnews.com/news/pfizer-vaccine-delta-variant/.
[94] *Available at* https://www.reuters.com/business/healthcare-pharmaceuticals/pfizer-says-covid-vaccine-highly-effective-against-delta-variant-2021-06-24/.

227. But on July 6, 2021, Israel's Health Ministry announced that Pfizer's COVID-19 vaccine effectiveness was just 64%. *Israel sees drop in Pfizer COVID vaccine protection, still strong in severe illness*, REUTERS (July 6, 2021).[95]

228. On July 8, 2021, Pfizer publicly admitted the declining effectiveness of its COVID-19 vaccine after six months post-vaccination and against the Delta variant. *Pfizer and BioNTech Provide Update on Booster Program in Light of the Delta Variant*, Pfizer (July 8, 2021).[96]

229. Pfizer announced it was conducting an "ongoing booster trial of a third dose" of its COVID-19 vaccine and "developing an updated version of the Pfizer-BioNTech COVID-19 vaccine that targets the full spike protein of the Delta variant." *Id.*

230. Upon information and belief, Pfizer already was conducting a booster trial and developing an updated version of its COVID-19 vaccine because, despite its public statements to the contrary, it knew its COVID-19 vaccine was not effective against the Delta variant.

231. Just two weeks later, on July 23, 2021, Israel reported Pfizer's COVID-19 vaccine was only 39% effective. Berkeley Lovelace, *Israel says Pfizer COVID vaccine is just 39% effective as delta spreads, but still prevents severe illness*, CNBC (July 23, 2021).[97]

232. But when contacted for the report about its COVID-19 vaccine's 39% effectiveness, Pfizer continued to misrepresent effectiveness of its COVID-19 vaccine: "In a statement to CNBC, Pfizer said it remains confident its two-dose regimen is protective against the coronavirus and its variants." *Id.*

---

[95] *Available at* https://www.reuters.com/world/middle-east/israel-sees-drop-pfizer-vaccine-protection-against-infections-still-strong-2021-07-05/.
[96] *Available at* https://cdn.pfizer.com/pfizercom/2021-07/Delta_Variant_Study_Press_Statement_Final_7.8.21.pdf?IPpR1xZjlwvaUMQ9sRn2FkePcBiRPGqw.
[97] *Available at* https://www.cnbc.com/2021/07/23/delta-variant-pfizer-covid-vaccine-39percent-effective-in-israel-prevents-severe-illness.html.

233. In August 2021, a study "found the Pfizer vaccine was only 42% effective against infection in July, when the Delta variant was dominant." Caitlin Owens, *New data on coronavirus vaccine effectiveness may be 'a wakeup call*,' AXIOS (Aug. 11, 2021).[98]

234. Despite data showing its COVID-19 vaccine was not effective, Pfizer's chief medical officer said in October 2021, "[o]ur variant-specific analysis clearly shows that the BNT162b2 vaccine is effective against all current variants of concern, including delta." Berkeley Lovelace Jr., *Pfizer COVID shot protects people from hospitalization even as effectiveness against infection falls, Lancet study confirms*, CNBC (Oct. 4, 2021).[99]

235. Finally, by December 2021, Pfizer acknowledged potential effectiveness issues with its COVID-19 vaccine and the Omicron variant. "Sera from individuals who received two doses of the current COVID-19 vaccine did exhibit, on average, more than a 25-fold reduction in neutralization titers against the Omicron variant compared to wild-type, indicating that two doses of BNT162b2 may not be sufficient to protect against infection with the Omicron variant." *Pfizer and BioNTech Provide Update on Omicron Variant*, Pfizer (Dec. 8, 2021).[100]

236. Pfizer attempted to soften this news by claiming that two doses still protected against "severe forms of the disease." *Id.*

237. But in January 2022, Pfizer Chairman and CEO Dr. Bourla admitted that the vaccine lost effectiveness at both preventing infections and hospitalizations: "We have seen with a second dose very clearly that the first thing that we lost was the protection against infections. . . . But then two months later, what used to be very strong in hospitalization also went down. And

[98] *Available at* https://www.axios.com/2021/08/11/coronavirus-vaccines-pfizer-moderna-delta-biden.
[99] *Available at* https://www.cnbc.com/2021/10/04/pfizer-covid-vaccine-protection-against-infection-tumbles-to-47percent-study-confirms.html.
[100] *Available at* https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-provide-update-omicron-variant.

I think this is what everybody's worried about." Spencer Kimball, *Pfizer CEO says two COVID vaccine doses aren't 'enough for omicron,'* CNBC (Jan. 10, 2022).[101]

238. Pfizer Chairman and CEO Dr. Bourla acknowledged that "two doses, they're not enough for omicron." *Id.*

239. Indeed, United Kingdom data reported that two doses of Pfizer's COVID-19 vaccine "are only about 10% effective at preventing infection from omicron 20 weeks after the second dose." *Id.*

240. Upon information and belief, Pfizer was aware that its COVID-19 vaccine was not effective at preventing infection or hospitalization from variants, such as Delta and Omicron, at the time it was publicly representing the opposite information.

241. The ineffectiveness of Pfizer's COVID-19 vaccine against variants was a material fact.

V. Pfizer Made Unsupported Representations Relating to Transmission of its COVID-19 Vaccine.

A. Pfizer's statements and knowledge about the effect of its COVID-19 vaccine on transmission of COVID-19

242. When the FDA issued the Emergency Use Authorization for Pfizer's COVID-19 vaccine in December 2020, the FDA reported that there was no "evidence that the vaccine prevents transmission of SARS-CoV-2 from person to person." *FDA Takes Key Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for First COVID-19 Vaccine*, Dec. 11, 2020.[102]

[101] *Available at* https://www.cnbc.com/2022/01/10/pfizer-ceo-says-two-covid-vaccine-doses-arent-enough-for-omicron.html.
[102] *Available at* https://wayback.archive-it.org/7993/20201217195048/https://www.fda.gov/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19.

243. According to Pfizer's trial protocol, evaluating transmission was not an objective of the trial. Apr. 2020 Protocol, *supra*, 11-12 (PDF pp. 13-14);[103] Sept. 2020 Protocol, *supra*, 10-13 (PDF p. 138-141).[104]

244. Pfizer has publicly confirmed that it did not test its COVID-19 vaccine on stopping transmission. When asked, "Was the Pfizer COVID vaccine tested on stopping the transmission of the virus before it entered the market?" Pfizer's Director of International Developed Markets Janine Small responded, "No." Frank Chung, *Pfizer did not know whether COVID vaccine stopped transmission before rollout, executive admits*, NEWS.COM.AU, Oct. 13, 2022.[105]

245. In November 2020, Pfizer Board Member Dr. Scott Gottlieb reported that more research was needed on transmission after receiving a Pfizer COVID-19 vaccination. "I think initially it's probably going to be given on a general schedule until we learn more about the real-world benefits of the vaccine and how much it cuts down on transmission of the virus. You know, does it just prevent you from getting COVID symptoms or does it actually prevent you from getting the infection and spreading the infection? That's one of the things we're going to need to determine about the vaccine and how long the immunity is." *Full transcript of 'Face the Nation' on November 22, 2020*, CBS NEWS, Nov. 22, 2020.[106]

246. Pfizer Chairman and CEO Dr. Bourla also wanted more transmission research in December 2020. "Even though I've had the protection, am I still able to transmit [COVID-19] to other people?" Bourla told NBC News' Lester Holt. "I think this is something that needs to be examined. We are not certain about that right now with what we know." Joseph Choi, *Pfizer*

[103] *Available at* https://www.nejm.org/doi/suppl/10.1056/NEJMoa2027906/suppl_file/nejmoa2027906_protocol.pdf.
[104] *Available at* https://www.nejm.org/doi/suppl/10.1056/NEJMoa2027906/suppl_file/nejmoa2027906_protocol.pdf.
[105] *Available at* https://www.news.com.au/technology/science/human-body/pfizer-did-not-know-whether-covid-vaccine-stopped-transmission-before-rollout-executive-admits/news-story/f307f28f794e173ac017a62784fec414.
[106] *Available at* https://www.cbsnews.com/news/full-transcript-of-face-the-nation-on-november-22-2020/.

chairman: We're not sure if someone can transmit virus after vaccination, THE HILL, Dec. 3, 2020.[107]

B. Pfizer's representations that its COVID-19 vaccine would prevent transmission.

247. Despite admissions by Pfizer Chairman and CEO Dr. Bourla and Board Member Dr. Scott Gottlieb that Pfizer did not know if its vaccine prevented transmission, Pfizer Chairman and CEO Dr. Bourla warned Kansans on multiple occasions that not receiving a COVID-19 vaccine would affect the lives of those around them, thus implying that Pfizer's COVID-19 vaccine prevented transmission.

a. December 2020: "I repeat once more, that this choice not to vaccinate will not affect only your health or your life. Unfortunately, it will affect the lives of others and likely the lives of the people you love the most, who are the people that usually you are in contact with." *CNBC Transcript: Pfizer Chairman and CEO Albert Bourla Speaks with CNBC's 'Squawk Box' Today*, CNBC (Dec. 14, 2020).[108]

b. January 2021: "What I would say to people who fear the vaccine is that they need to recognize that the decision to take it or not will not affect only their own lives. It will affect the lives of others. And most likely it will affect the lives of people that they love the most, who are the people that they socialize the most with." John Micklethwait, *Pfizer CEO Says Science Will Prevail with COVID-19 Here to Stay*, BLOOMBERG, Jan. 28, 2021.[109]

---

[107] *Available at* https://thehill.com/news-by-subject/healthcare/528619-pfizer-chairman-were-not-sure-if-someone-can-transmit-virus-after/.
[108] *Available at* https://www.cnbc.com/2020/12/14/cnbc-transcript-pfizer-chairman-and-ceo-albert-bourla-speaks-with-cnbcs-squawk-box-today.html.
[109] *Available at* https://www.bloomberg.com/news/features/2021-01-28/covid-is-here-to-stay-pfizer-ceo-albert-bourla.

c. June 2021: "I try to explain to them that the decision to vaccinate or not is not only going to affect only your life. . . . But unfortunately will affect the health of others and likely will affect the health of people you like and you love the most. . . . When you try to explain that their fear could stand in the way of protecting their loved ones, I think this is the argument that mostly works." *CEO 'comfortable' Pfizer COVID-19 vaccine protects against more severe Delta variant*, CBS NEWS (June 15, 2021).[110]

d. November 2021: "The only thing that stands between the new way of life and the current way of life, frankly, is the hesitancy to get vaccinated, the people that are afraid to get the vaccines, and they create issues not only for them. Unfortunately, they are going to affect the lives of others and, frankly, the lives of the people that they love the most because they are putting at risk the people that they hug, they kiss, [and] they socialize with." *Pfizer's Albert Bourla on how the pandemic ends*, ATLANTIC COUNCIL, Nov. 9, 2021.[111]

248. In other words, on multiple occasions, Pfizer Chairman and CEO Dr. Bourla represented to Kansans that Pfizer's COVID-19 vaccine prevented transmission since not getting vaccinated threatened the lives of loved ones with whom a person closely interacted.

249. In December 2021, a Pfizer press release quoted Chairman and CEO Dr. Bourla in a manner that again suggested that Pfizer's COVID-19 vaccine prevented transmission: "Ensuring as many people as possible are fully vaccinated with the first two dose series and a booster remains

[110] *Available at* https://www.cbsnews.com/news/pfizer-vaccine-delta-variant/.
[111] *Available at* https://www.atlanticcouncil.org/blogs/new-atlanticist/pfizers-albert-bourla-on-how-the-pandemic-ends/.

the best course of action **to prevent the spread of COVID-19**." *Pfizer and BioNTech Provide Update on Omicron Variant*, Pfizer (Dec. 8, 2021) (emphasis added).[112]

250. Pfizer Board Member Dr. Scott Gottlieb also represented to Kansans that Pfizer's COVID-19 prevented transmission: "And final point, I mean, some of the optimism is also being driven by growing science, suggesting that these vaccines, all the vaccines not only prevent COVID disease, prevent symptoms, but also prevent transmission. So they could have a dramatic effect on reducing the overall tenor of the epidemic." *Full transcript of 'Face the Nation' on March 7, 2021*, CBS News, Mar. 7, 2021.[113]

251. Pfizer even used comic books to suggest that the vaccine prevented transmission. In 2022, Pfizer partnered with Marvel to produce an "Avengers"-themed comic book that called individuals waiting for a Pfizer COVID-19 vaccine "Everyday Heroes." *See* Avengers: Everyday Heroes, 2022.[114]

252. According to one of the characters in the Pfizer comic book, "it's also important for entire communities to come together and help fight the threat." "And that's exactly what we're doing today!" says another character. As the group heads to the examination room to get their Pfizer COVID-19 vaccinations, the first character announces, "The Avengers are doing their part to help keep us safe. Now it's time for us to do ours." *Id.* at 13.

253. One of the final pages reinforces the need for individuals to get a Pfizer COVID-19 vaccine in order to protect the community. "Everyday heroes don't wear capes! But they do wear a small bandage on their upper arm after they get their latest COVID-19 vaccination—

[112] *Available at* https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-provide-update-omicron-variant.
[113] *Available at* https://www.cbsnews.com/news/full-transcript-of-face-the-nation-on-march-7-2021/.
[114] *Available at* https://www.marvel.com/pfizereverydayheroes#open_text-5/.

because everyday heroes are concerned about their health. **And they're people who choose to unite with their communities and do their part to help protect against COVID-19**." *Id*. at 15 (emphasis added).

254. Pfizer released the "Everyday Heroes" comic book as a digital comic and provided print editions at some offices and retail locations around the country. *Avengers Assemble! Teaming Up with Marvel to Illustrate the Importance of COVID-19 Vaccination*, PFIZER.[115]

255. Pfizer represented that its COVID-19 vaccine could prevent transmission of COVID-19, even though it had no basis for the representation since Pfizer never tested its COVID-19 vaccine to determine whether it could prevent transmission of COVID-19.

256. Pfizer misled Kansans about the effect of the COVID-19 vaccine on transmission of COVID-19.

VI. Pfizer's Efforts to Censor and Suppress Material Facts related to its COVID-19 Vaccines

257. When Pfizer's efforts to hide material facts from public scrutiny failed, Pfizer took action to conceal and suppress material facts related to its COVID-19 vaccines.

A. Pfizer's view that "misinformation spreaders" are "criminals" who have "literally cost millions of lives"

258. A Pfizer website page on "Fighting Misinformation" states: "The spread of rumors and falsehoods can be dangerous. It is a threat to truth that misleads and manipulates people's perceptions. We are dedicated to helping people find accurate, science-based information as they make healthcare decisions that impact their lives." Pfizer, *Fighting Misinformation*.[116]

[115] *Available at* https://www.pfizer.com/news/articles/avengers_assemble_teaming_up_with_marvel_to_illustrate_the_importance_of_covid_19_vaccination.
[116] *Available at* https://www.pfizer.com/about/responsibility/misinformation.

259. On July 19, 2021, Pfizer Board Member Dr. Scott Gottlieb claimed social media companies had an "obligation" and an "affirmative responsibility" to prevent the spread of COVID-19 vaccine misinformation on their platforms. Pia Singh, *Dr. Scott Gottlieb urges social media platforms to curb COVID vaccine misinformation*, CNBC, July 19, 2021.[117]

260. Pfizer Chairman and CEO Dr. Bourla called people who spread misinformation on COVID-19 vaccines "criminals" who have "literally cost millions of lives." *Pfizer's Albert Bourla on how the pandemic ends*, ATLANTIC COUNCIL, Nov. 9, 2021.[118]

B. Pfizer worked to conceal and suppress material facts.

261. Pfizer worked to conceal and suppress material facts on social media platforms.

262. Pfizer Board Member Dr. Scott Gottlieb pressed Twitter on multiple occasions to censor speech critical of COVID-19 vaccines and the response to the pandemic.

263. On August 24, 2021, Pfizer Board Member Dr. Scott Gottlieb contacted Twitter to complain about a column written by Alex Berenson that criticized Dr. Anthony Fauci. "This is whats [*sic*] promoted on Twitter. This is why Tony needs a security detail," Gottlieb wrote. Charles Creitz, *Alex Berenson says Pfizer-linked former FDA official got him banned from Twitter in 'months-long conspiracy,'* FOX NEWS (Oct. 13, 2022).[119]

264. On August 27, 2021, Pfizer Board Member Dr. Scott Gottlieb had a conference call with Twitter employees to discuss Mr. Berenson. Twitter banned Mr. Berenson the next day.

[117] *Available at* https://www.cnbc.com/2021/07/19/scott-gottlieb-social-media-must-act-to-curb-covid-vaccine-misinformation.html.
[118] *Available at* https://www.atlanticcouncil.org/blogs/new-atlanticist/pfizers-albert-bourla-on-how-the-pandemic-ends/.
[119] *Available at* https://www.foxnews.com/media/alex-berenson-pfizer-linked-former-fda-official-banned-twitter-months-long-conspiracy.

265. On Friday, August 27, 2021, Dr. Brett P. Giroir, who served as the assistant secretary for health from 2018 to 2021 and approximately one month as the acting FDA Commissioner in late 2019, posted to Twitter that natural immunity was superior to vaccine immunity. Joseph A. Wulfsohn, *Twitter Files: Pfizer board member Dr. Scott Gottlieb flagged tweets questioning COVID vaccine*, FOX NEWS (Jan. 9, 2023).[120]

266. In response, Pfizer Board Member Dr. Scott Gottlieb reached out to Twitter's top lobbyist in Washington, D.C., to complain that the post was "corrosive," "draws a sweeping conclusion," and "will end up going viral and driving news coverage." *Id.*

267. The Twitter lobbyist forwarded Pfizer Board Member Dr. Scott Gottlieb's email to the Twitter "Strategic Response" team, which "later slapped [Girori's tweet] with a 'misleading' label and blocked any ability to like or share the tweet." *Id.*

268. Upon information and belief, Pfizer Board Member Dr. Scott Gottlieb contacted social media platforms to request censorship of other COVID-19-related posts.

269. Upon information and belief, Pfizer coordinated with and through others to conceal and suppress other material facts about its COVID-19 vaccine.

270. On December 11, 2020, the same day that Pfizer's COVID-19 vaccine received emergency use authorization from the FDA, a Zoom calendar appointment entitled "Vaccine Disinformation Response" invited personnel at the Department of Health and Human Services, Pfizer and other pharmaceutical companies, and Stanford University to discuss "a coalition to

[120] *Available at* https://www.foxnews.com/media/twitter-files-pfizer-board-member-dr-scott-gottlieb-flagged-tweets-questioning-covid-vaccine.

respond to COVID-19 vaccine disinformation." Letter from U.S. House Judiciary Chairman Jim Jordan to Pfizer's Dr. Albert Bourla, July 18, 2023, at 1-2.[121]

271. Upon information and belief, at or around this December 11, 2020 meeting, Pfizer, the Department of Health and Human Services, and Stanford University agreed to work together to conceal and suppress material facts about Pfizer's COVID-19 vaccine, including concealing and suppressing posts about the safety and efficacy of Pfizer's COVID-19 vaccine.

272. The CDC is within the Department of Health and Human Services. U.S. Dep't of Health and Human Servs., *HHS Organizational Charts Office of Secretary and Divisions*.[122]

273. In 2021, the CDC actively worked to censor speech critical of COVID-19 vaccines. Robby Soave, *Inside the Facebook Files: Emails Reveal the CDC's Role in Silencing COVID-19 Dissent*, REASON (Jan. 19, 2023).[123]

274. Shortly after the December 11, 2020 meeting, Stanford University co-launched the Virality Project.

275. For at least the next year, Stanford and members of the Virality Project pressured social media companies to conceal and suppress information about Pfizer's COVID-19 vaccine, including information about safety and efficacy. *See general Memes, Magnets, and Microchips: Narrative dynamics around COVID-19 vaccines*, THE VIRALITY PROJECT, Apr. 26, 2022, at 39 (PDF p. 46); 46 (PDF p. 53); 56 (PDF p. 63); 84 (PDF p. 91).[124]

[121] *Available at* https://judiciary.house.gov/sites/evo-subsites/republicans-judiciary.house.gov/files/evo-media-document/2023-07-18-jdj-to-bourla-pfizer.pdf.
[122] *Available at* https://www.hhs.gov/about/agencies/orgchart/index.html.
[123] *Available at* https://reason.com/2023/01/19/facebook-files-emails-cdc-covid-vaccines-censorship/.
[124] *Available at* https://stacks.stanford.edu/file/druid:mx395xj8490/Virality_project_final_report.pdf.

276. Upon information and belief, the Virality Project flagged supposed "misinformation" to platforms on a massive scale, with a high degree of success in inducing the platforms to censor it.

277. The Virality Project admits that six social-media platforms "engaged with VP tickets," "acknowledge[ed] content flagged for review" by the VP, "and act[ed] on it in accordance with their policies"—in other words, censored it. *Id.* at 18 (PDF p. 25).

278. The Virality Project was not the only organization pressuring social media companies to conceal and suppress speech about Pfizer's COVID-19 vaccine on behalf of Pfizer.

279. The Virality Project partnered with a campaign called "Stronger." Stronger, *About*.[125] Stronger described itself as "a first-of-its-kind national advocacy campaign against misinformation and for vaccines." *National Public Health Campaign Designed to Mobilize Support of Vaccines*, July 15, 2020.[126]

280. Pfizer was a top funder and served as a board member for the group, Biotechnology Innovation Organization, that paid for the Stronger campaign. Lee Fang (@lhfang), Twitter, Jan. 16, 2023 at 11:13 a.m.;[127] Biotechnology Innovation Organization "Helix Sponsor;"[128] John D. Young.[129]

[125] *Available at* https://stronger.org/about.
[126] *Available at* https://www.prnewswire.com/news-releases/national-public-health-campaign-designed-to-mobilize-support-of-vaccines-301093876.html?tc=eml_cleartime&fbclid=IwAR0y3GEys3DsmxdPz3WDpkvN7iJyA4PsmNh2tWWL7K6d7MdshMSicIvQukc.
[127] *Available at* https://twitter.com/lhfang/status/1615019469516197891.
[128] *Available at* https://www.bio.org/.
[129] *Available at* https://www.novartis.com/about/board-directors/john-d-young

281. According to Stronger, "Our mission is to dispel vaccine misinformation so that more adults get vaccinated, kids receive their routine immunizations, and everybody who can get a COVID-19 vaccine does." Stronger.[130]

282. Stronger "regularly communicated with Twitter on regulating content related to the pandemic. The firm worked closely with the San Francisco social media giant to help develop bots to censor vaccine misinformation and, at times, sent direct requests to Twitter with lists of accounts to censor and verify." Lee Fang, *COVID-19 Drugmakers Pressured Twitter to Censor Activists Pushing for Generic Vaccine*, THE INTERCEPT, Jan. 16, 2023.[131]

283. Upon information and belief, Pfizer worked to conceal and suppress material facts relating to its COVID-19 vaccine.

VII. Pfizer's Record-Breaking COVID-19 Vaccine Profits

284. Pfizer's misrepresentations and suppression, concealment, and omission of material facts paid off handsomely for Pfizer because they allowed Pfizer to acquire and keep market share for its COVID-19 vaccine.

285. In 2020, Pfizer reported more than $9.1 billion in profit. Ryan King, *Pfizer reports nearly $37 billion in COVID-19 vaccine sales in 2021*, WASHINGTON EXAMINER, Feb. 8, 2022.[132]

286. In 2021, Pfizer reported approximately $37 billion in global direct sales and alliance revenue from its COVID-19 vaccine. *Id.*

287. Thanks to Pfizer's COVID-19 vaccine, Pfizer more than doubled its profits from 2020 to 2021, reporting $22 billion in total profits in 2021. *Id.*

---

[130] *Available at* https://stronger.org/.
[131] *Available at* https://theintercept.com/2023/01/16/twitter-covid-vaccine-pharma/.
[132] *Available at* https://www.washingtonexaminer.com/policy/healthcare/pfizer-reports-nearly-37-billion-in-covid-19-vaccine-sales-in-2021.

288. In 2022, Pfizer reported approximately $38 billion in global direct sales and alliance revenue from its COVID-19 vaccine. Spencer Kimball, *The COVID pandemic drives Pfizer's 2022 revenue to a record $100 billion*, CNBC, Jan. 31, 2023.[133]

289. Overall, Pfizer reported a record $100 billion in revenue in 2022. *Id.* Pfizer's COVID-19 vaccine made up approximately 40% of Pfizer's total revenue.

290. Pfizer made record-breaking profits because it misrepresented, suppressed, concealed, and omitted material facts relating to its COVID-19 vaccine.

291. Pfizer's profit would have been lower if Pfizer had not misrepresented, suppressed, concealed, and omitted material facts relating to its COVID-19 vaccine.

VIII. Pfizer's Violation of Past Consent Judgments with the State of Kansas

292. Pfizer entered consent judgments with the State of Kansas to resolve consumer protection claims that govern Pfizer's future conduct, including relating to its COVID-19 vaccine.

A. The 2008 Consent Judgment

293. In 2008, Pfizer paid $60 million to resolve claims by a group of states, including Kansas, relating to Pfizer's promotional and marketing practices regarding the prescription drugs Celebrex® and Bextra®. Final Consent Judgment, *State of Kansas, ex rel. Steve Six v. Pfizer Inc.*, No. 08CV1576 (Oct. 23, 2008), attached as Exhibit A.

294. According to the 2008 Consent Judgment, "Pfizer shall not make any written or oral claim that is false, misleading or deceptive regarding any FDA-approved Pfizer Product." *Id.* at ¶ 4.

[133] *Available at* https://www.cnbc.com/2023/01/31/the-covid-pandemic-drives-pfizers-2022-revenue-to-a-record-100-billion.html.

295. The 2008 Consent Judgment defined "Product" to mean "any prescription drug or biological product manufactured, distributed, sold, marketed or promoted in the United States in any way." *Id.* at § 2, ¶ 5(l).

296. While the 2008 Consent Judgment does not define "biological product," the FDA defines "biological product" to include vaccines. FDA, *What Are "Biologics" Questions and Answers*, content current as of Feb. 6, 2018;[134] *see also* 42 U.S.C. § 262.

297. Under the 2008 Consent Judgment, Pfizer's COVID-19 vaccine is a biological product manufactured, distributed, sold, marketed or promoted in the United States in any way.

298. Pfizer received FDA approval for its COVID-19 vaccine, including but not limited to through an emergency use authorization on December 11, 2020 for individuals 16 years old and older; through an amended emergency use authorization on May 10, 2021 for children 12 years old to 15 years old; through full approval on August 23, 2021 for individuals 16 years old and older; through emergency use authorization on October 29, 2021 for children five years old to 11 years old; through emergency use authorization on June 17, 2022 for children 6 months through four years; and through full approval on July 8, 2022 for children 12 through 15 years of age.

299. The 2008 Consent Judgment also governs communications about clinical studies of Pfizer's COVID-19 vaccine.

300. According to the 2008 Consent Judgment:

> When presenting information in detailing pieces, brochures, booklets, mailing pieces, published journals, magazines, other periodicals and newspapers, and broadcast through media such as radio, television, the Internet, and telephone communications systems, about a Clinical Study that relates to an FDA-approved Pfizer Product, Pfizer shall: (a) accurately reflect the methodology

[134] *Available at* https://www.fda.gov/about-fda/center-biologics-evaluation-and-research-cber/what-are-biologics-questions-and-answers.

> used to conduct the Clinical Study; (b) not present favorable information or conclusions from a study that is inadequate in design, scope, or conduct to furnish significant support for such information or conclusions; and (c) not use statistical analyses and techniques on a retrospective basis to discover and cite findings not soundly supported by the study, or to suggest scientific validity and rigor for data from studies the design or protocol of which are not amenable to formal statistical evaluation.

Id. at ¶ 10; *see also* ¶ 12.

301. Similarly, according to the next paragraph in the 2008 Consent Judgment:

> When presenting information in detailing pieces, brochures, booklets, mailing pieces, published journals, magazines, other periodicals and newspapers, and broadcast through media such as radio, television, the Internet, and telephone communications systems, about a Clinical Study or analysis of Clinical Studies as evidence of an FDA-approved Pfizer Product's safety, Pfizer shall not: (a) present information from a study in a way that implies that the study represents larger or more general experience with the drug than it actually does; or (b) use statistics on numbers of patients, or counts of favorable results or side effects derived from pooling data from various insignificant or dissimilar studies in a way that suggests either that such statistics are valid if they are not or that they are derived from large or significant studies supporting favorable conclusions when such is not the case.

Id. at ¶ 11.

302. As set forth in the 2008 Consent Judgment, *id.* at ¶ 35, the Kansas Attorney General provided Pfizer notice of his reasonable belief that Pfizer has engaged in practices that violate the 2008 Consent Judgment. Letter from Kansas Attorney General's Office to Pfizer Inc., Apr. 22, 2024, attached as Exhibit B.

303. In response to the notice from Plaintiff Kansas Attorney General, Pfizer did not address all of the issues identified by Plaintiff, did not respond to evidence cited by Plaintiff, and did not produce documents requested by Plaintiff. Letter from Pfizer's Counsel to Kansas Attorney General's Office, May 22, 2024, attached as Exhibit C.

304. The 2008 Consent Judgment empowers the Kansas Attorney General to assert any claim that Pfizer has violated this Judgment in a separate civil action and to enforce compliance with the Consent Judgment and to seek any other relief afforded by law, pursuant to K.S.A. 50-636(b). Ex. A, at ¶ 36.

B. The 2012 Consent Judgment

305. In 2012, Pfizer paid $42.9 million to resolve claims by a group of states, including Kansas, relating to Pfizer's promotional and marketing practices regarding the prescription drugs Zyvox® and Lyrica®. Final Consent Judgment, *State of Kansas, ex rel. Derek Schmidt v. Pfizer Inc.*, No. 12CV1339 (Dec. 13, 2012), attached as Exhibit D.

306. According to the 2012 Consent Judgment, "Pfizer shall not make, or cause to be made, any written or oral claim that is false, misleading, or deceptive regarding any FDA-approved Pfizer Product, . . ." *Id.* at ¶ 3.1.

307. The 2012 Consent Judgment defined "Pfizer Product" to mean "any FDA-approved prescription drug or biological product manufactured, distributed, sold, marketed or Promoted by Pfizer in the United States." *Id.* at ¶ 2.18.

308. While the 2012 Consent Judgment does not define "biological product," the FDA defines "biological product" to include vaccines. FDA, *What Are "Biologics" Questions and Answers*, content current as of Feb. 6, 2018;[135] *see also* 42 U.S.C. § 262.

309. Under the 2012 Consent Judgment, Pfizer's COVID-19 vaccine is a biological product manufactured, distributed, sold, marketed or Promoted in the United States.

[135] *Available at* https://www.fda.gov/about-fda/center-biologics-evaluation-and-research-cber/what-are-biologics-questions-and-answers.

310. Pfizer's COVID-19 vaccine received FDA approval beginning on December 11, 2020.

311. As set forth in the 2012 Consent Judgment, *id.* at ¶ 6.1, the Kansas Attorney General provided Pfizer notice of his reasonable belief that Pfizer has engaged in practices that violate the 2012 Consent Judgment. *See* Ex. B.

312. In response to the notice from Plaintiff Kansas Attorney General, Pfizer did not address all of the issues identified by Plaintiff, did not respond to evidence cited by Plaintiff, and did not produce documents requested by Plaintiff. *See* Ex. C.

313. The 2012 Consent Judgment empowers the Kansas Attorney General to assert any claim that Pfizer has violated this Judgment in a separate civil action and to enforce compliance with the Consent Judgment and to seek any other relief afforded by law pursuant to K.S.A. 50-636(b). Ex. D, at ¶ 6.3.

C. The 2014 Consent Judgment

314. In 2014, Pfizer paid $35 million to resolve claims by a group of states, including Kansas, relating to Wyeth Pharmaceuticals Inc.'s ("Wyeth") promotional and marketing practices regarding the prescription drug Rapamune®. Pfizer acquired Wyeth five years before the Consent Judgment. Pfizer signed the Consent Judgment on behalf of itself and Wyeth. Final Consent Judgment, *State of Kansas, ex rel. Derek Schmidt. v. Wyeth Pharmaceuticals Inc.*, No. 2014CV777 (Aug. 6, 2014), attached as Exhibit E.

315. According to the 2014 Consent Judgment, "Pfizer shall not make, or cause to be made, any written or oral claim that is false, misleading, or deceptive regarding any Pfizer Product." *Id.* at ¶ 3.1.

316. The 2014 Consent Judgment defined "Pfizer Product" to mean "any FDA-approved prescription drug or biological product manufactured, distributed, sold, marketed or Promoted by Pfizer in the United States." *Id.* at ¶ 2.17.

317. While the 2014 Consent Judgment does not define "biological product," the FDA defines "biological product" to include vaccines. FDA, *What Are "Biologics" Questions and Answers*, content current as of Feb. 6, 2018;[136] *see also* 42 U.S.C. § 262.

318. Under the 2014 Consent Judgment, Pfizer's COVID-19 vaccine is a biological product manufactured, distributed, sold, marketed or Promoted in the United States.

319. Pfizer's COVID-19 vaccine received FDA approval beginning on December 11, 2020.

320. As set forth in the 2014 Consent Judgment, *id.* at ¶ 6.1, the Kansas Attorney General provided Pfizer notice of his reasonable belief that Pfizer has engaged in practices that violate the 2014 Consent Judgment. *See* Ex. B.

321. In response to the notice from Plaintiff Kansas Attorney General, Pfizer did not address all of the issues identified by Plaintiff, did not respond to evidence cited by Plaintiff, and did not produce documents requested by Plaintiff. *See* Ex. C.

322. The 2014 Consent Judgment empowers the Kansas Attorney General to assert any claim that Pfizer has violated this Judgment in a separate civil action and to enforce compliance with the Consent Judgment and to seek any other relief afforded by law, pursuant to K.S.A. 50-636(b). Ex. E, at ¶ 6.3.

[136] *Available at* https://www.fda.gov/about-fda/center-biologics-evaluation-and-research-cber/what-are-biologics-questions-and-answers.

COUNT I
KANSAS CONSUMER PROTECTION ACT
Violation of the 2008 Consent Judgment, K.S.A. 50-636(b)
(False, misleading, and deceptive claims)

323. All preceding paragraphs are incorporated by reference herein.

324. Pfizer made written and oral claims that were false, misleading and deceptive regarding its COVID-19 vaccine, including but not limited to: Pfizer's COVID-19 vaccine was safe, effective, and prevented transmission of the virus.

325. Pfizer's false, misleading and deceptive claims regarding its COVID-19 vaccine violated the 2008 Consent Judgment, for which the Court should assess an enhanced civil penalty of not more than twenty thousand dollars ($20,000.00) per violation, pursuant to K.S.A. 50-636(b).

326. The State of Kansas has been harmed by Pfizer's breach of provisions in the 2008 Consent Judgment.

COUNT II
KANSAS CONSUMER PROTECTION ACT
Violation of the 2008 Consent Judgment, K.S.A. 50-636(b)
(Clinical studies communications)

327. All preceding paragraphs are incorporated by reference herein.

328. Pfizer made public statements that were published and broadcast through media relating to its COVID-19 vaccine that did not accurately reflect the methodology used to conduct the clinical study, presented favorable information or conclusions from a study that was inadequate in design, scope, or conduct to furnish significant support for such information or conclusions, and/or used statistical analyses and techniques on a retrospective basis to discover and cite findings not soundly supported by the study, or to suggest scientific validity and rigor for data from studies

the design or protocol of which are not amenable to formal statistical evaluation, including but not limited to:

a. Statements about Pfizer's original COVID-19 clinical trial on healthy individuals;

b. Statements about Pfizer's COVID-19 trial on pregnant women; and

c. Statements about Pfizer's COVID-19 vaccine booster trial on individuals 65 years old and older.

329. Pfizer also made public statements that were published and broadcast through media relating to its COVID-19 vaccine that presented information from a study in a way that implied that the study represents larger or more general experience with the drug than it actually did, and/or used statistics on numbers of patients, or counts of favorable results or side effects derived from pooling data from various insignificant or dissimilar studies in a way that suggests either that such statistics are valid if they are not or that they are derived from large or significant studies supporting favorable conclusions when such is not the case, including but not limited to:

a. Statements about Pfizer's original COVID-19 clinical trial on healthy individuals;

b. Statements about Pfizer's COVID-19 trial on pregnant women; and

c. Statements about Pfizer's COVID-19 vaccine booster trial on individuals 65 years old and older.

330. Pfizer's public statements about its COVID-19 vaccine that referenced or relied on clinical studies violated the 2008 Consent Judgment, for which the Court should assess an enhanced civil penalty of not more than twenty thousand dollars ($20,000.00) per violation, pursuant to K.S.A. 50-636(b).

331. The State of Kansas has been harmed by Pfizer's breach of provisions in the 2008 Consent Judgment.

COUNT III
KANSAS CONSUMER PROTECTION ACT
Violation of the 2012 Consent Judgment, K.S.A. 50-636(b)
(False, misleading, and deceptive claims)

332. All preceding paragraphs are incorporated by reference herein.

333. Pfizer made, or caused to be made, written and oral claims that were false, misleading, and deceptive regarding its COVID-19 vaccine, including but not limited to: Pfizer's COVID-19 vaccine was safe, effective, and prevented transmission of the virus.

334. Pfizer's false, misleading, and deceptive claims regarding its COVID-19 vaccine violated the 2012 Consent Judgment, for which the Court should assess an enhanced civil penalty of not more than twenty thousand dollars ($20,000.00) per violation, pursuant to K.S.A. 50-636(b).

335. The State of Kansas has been harmed by Pfizer's breach of provisions in the 2012 Consent Judgment.

COUNT IV
KANSAS CONSUMER PROTECTION ACT
Violation of the 2014 Consent Judgment, K.S.A. 50-636(b)
(False, misleading, and deceptive claims)

336. All preceding paragraphs are incorporated by reference herein.

337. Pfizer made, or caused to be made, written and oral claims that were false, misleading, and deceptive regarding its COVID-19 vaccine, including but not limited to: Pfizer's COVID-19 vaccine was safe, effective, and prevented transmission of the virus.

338. Pfizer's false, misleading, and deceptive claims regarding its COVID-19 vaccine violated the 2014 Consent Judgment, for which the Court should assess an enhanced civil penalty of not more than twenty thousand dollars ($20,000.00) per violation, pursuant to K.S.A. 50-636(b).

339. The State of Kansas has been harmed by Pfizer's breach of provisions in the 2014 Consent Judgment.

COUNT V
KANSAS CONSUMER PROTECTION ACT
Deceptive Acts or Practices, K.S.A. 50-626(b)(1)(F)

340. All preceding paragraphs are incorporated by reference herein.

341. Beginning in 2020, Pfizer made representations to Kansas consumers knowingly or with reason to know that its COVID-19 vaccine had uses, benefits or characteristics that Pfizer could not rely upon and did not possess a reasonable basis for making such representation, in violation of K.S.A. 50-626(b)(1)(F), including but not limited to: Pfizer's COVID-19 vaccine was safe, effective, and prevented transmission of the virus.

342. Pfizer's representations to consumers are continuing deceptive acts and practices and each day it exists is a separate violation of the KCPA. Civil penalties of not more than ten thousand dollars ($10,000.00) per violation may be imposed, pursuant to K.S.A. 50-636(d).

343. Consumers have been damaged by Pfizer's violation of the Kansas Consumer Protection Act.

COUNT VI
KANSAS CONSUMER PROTECTION ACT
Deceptive Acts or Practices, K.S.A. 50-626(b)(1)(G)

344. All preceding paragraphs are incorporated by reference herein.

345. Beginning in 2020, Pfizer made representations knowingly or with reason to know that the use, benefit or characteristic of its COVID-19 vaccine had not been proven or otherwise substantiated and Pfizer did not rely upon and possess the type and amount of proof or substantiation represented to exist, in violation of K.S.A. 50-626(1)(G), including but not limited to: Pfizer's COVID-19 vaccine was safe, effective, and prevented transmission.

346. Pfizer's representations to consumers are continuing deceptive acts and practices and each day it exists is a separate violation of the KCPA. Civil penalties of not more than ten thousand dollars ($10,000.00) per violation may be imposed, pursuant to K.S.A. 50-636(d).

347. Consumers have been damaged by Pfizer's violation of the Kansas Consumer Protection Act.

COUNT VII
KANSAS CONSUMER PROTECTION ACT
Deceptive Acts or Practices, K.S.A. 50-626(b)(2)

348. All preceding paragraphs are incorporated by reference herein.

349. Beginning in 2020, Pfizer willfully used, in any oral or written representation, of exaggerations, falsehoods, innuendo, or ambiguity as to a material fact, in violation of K.S.A. 50-626(b)(2), including but not limited to: Pfizer's COVID-19 vaccine was safe, effective, and prevented transmission.

350. Pfizer's deceptive acts and practices are continuing and each day it exists is a separate violation of the KCPA. Civil penalties of not more than ten thousand dollars ($10,000.00) per violation may be imposed, pursuant to K.S.A. 50-636(d).

351. Consumers have been damaged by Pfizer's violation of the Kansas Consumer Protection Act.

COUNT VIII
KANSAS CONSUMER PROTECTION ACT
Deceptive Acts or Practices, K.S.A. 50-626(b)(3)

352. All preceding paragraphs are incorporated by reference herein.

353. Beginning in 2020, Pfizer willfully failed to state a material fact or willfully concealed, suppressed, or omitted a material fact in violation of K.S.A. 50-626(b)(3), including but not limited to:

a. Pfizer's COVID-19 vaccine safety data, including from its clinical trials and confidential internal company documents on adverse events, pregnant animals and pregnant women, and safety signals;

b. Pfizer's COVID-19 vaccine's efficacy, including waning effectiveness; and

c. Pfizer's direct efforts to censor truthful information on social media about Pfizer's COVID-19 vaccine.

354. Pfizer's deceptive acts and practices are continuing and each day it exists is a separate violation of the KCPA. Civil penalties of not more than ten thousand dollars ($10,000.00) per violation may be imposed, pursuant to K.S.A. 50-636(d).

355. Consumers have been damaged by Pfizer's violation of the Kansas Consumer Protection Act.

COUNT IX
KANSAS CONSUMER PROTECTION ACT
Unconscionable Acts or Practices, K.S.A. 50-627(b)(6)

356. All preceding paragraphs are incorporated by reference herein.

357. Beginning in 2020, Pfizer knew or had reason to know that it made a misleading statement of opinion on which the consumer was likely to rely to the consumer's detriment in

violation of K.S.A. 50-627(b)(6), including but not limited to: Pfizer's vaccine was safe, effective, and prevented transmission.

358. Pfizer's unconscionable acts or practices are continuing and each day it exists is a separate violation of the KCPA. Civil penalties of not more than ten thousand dollars ($10,000.00) per violation may be imposed, pursuant to K.S.A. 50-636(d).

359. Consumers have been damaged by Pfizer's violation of the Kansas Consumer Protection Act.

COUNT X
Civil Conspiracy

360. All preceding paragraphs are incorporated by reference herein.

361. Upon information and belief, Pfizer conspired with two or more persons from the federal government and third-party businesses and organizations to willfully conceal, suppress, or omit material facts relating to Pfizer's COVID-19 vaccine.

362. Upon information and belief, Pfizer, the Department of Health and Human Services, and members of the Virality Project, including Stanford, had a meeting of the minds no later than December 2020 to willfully conceal, suppress, or omit material facts relating to Pfizer's COVID-19 vaccine.

363. Upon information and belief, Pfizer, the Biotechnology Innovation Organization, and the Public Goods Project had a meeting of the minds no later than July 2020 to willfully conceal, suppress, or omit material facts relating to Pfizer's COVID-19 vaccine.

364. Pfizer and its co-conspirators took actions to willfully conceal, suppress, or omit material facts relating to Pfizer's COVID-19 vaccine in violation of the Kansas Consumer Protection Act, including K.S.A. 50-626(b)(3).

365. Kansans have been damaged as a proximate result of Pfizer's conspiracy.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff State of Kansas respectfully prays that this Court grant them the following relief:

A. Declare that Pfizer's written and oral claims violate the 2008 Consent Judgment;

B. Order Pfizer to pay the State of Kansas enhanced civil penalties of twenty thousand dollars ($20,000.00) for each violation of the 2008 Consent Judgment pursuant to K.S.A. 50-636(b);

C. Declare that Pfizer's written and oral claims violate the 2012 Consent Judgment;

D. Order Pfizer to pay the State of Kansas enhanced civil penalties of twenty thousand dollars ($20,000.00) for each violation of the 2012 Consent Judgment pursuant to K.S.A. 50-636(b);

E. Declare that Pfizer's written and oral claims violate the 2014 Consent Judgment pursuant to K.S.A. 50-636(b);

F. Order Pfizer to pay the State of Kansas enhanced civil penalties of twenty thousand dollars ($20,000.00) for each violation of the 2014 Consent Judgment;

G. Declare, pursuant to K.S.A. 50-632(a)(1), that Pfizer's deceptive or unconscionable acts or practices violate the Kansas Consumer Protection Act, K.S.A. 50-623, *et seq*.;

H. Order Pfizer to pay a civil penalty of ten thousand dollars ($10,000.00) for each violation of the Kansas Consumer Protection Act pursuant to K.S.A. 50-636;

I. Order Pfizer to pay a civil penalty of ten thousand dollars ($10,000.00) for each day Pfizer's act or practice exists pursuant to K.S.A. 50-636(d);

J. Award Plaintiff State of Kansas damages for Pfizer's violations of the Kansas Consumer Protection Act, K.S.A. 50-636(a);

K. Award Plaintiff State of Kansas reasonable expenses and investigation fees pursuant to K.S.A. 50-636(c);

L. Award Plaintiff State of Kansas damages caused by Pfizer's civil conspiracy; and

M. Grant such other and further relief as the Court deems just and proper.

Dated: June 17, 2024

Respectfully submitted,

KRIS W. KOBACH
ATTORNEY GENERAL

/s/ Kaley Schrader
Frances R. Oleen, #17433
Deputy Attorney General
Kaley Schrader, #27700
Assistant Attorney General
Office of the Attorney General
Public Protection Division
120 SW 10th Ave., 2nd Floor
Topeka, Kansas 66612-1597
Tel: 785-296-3751
Fax: 785-291-3699
kaley.schrader@ag.ks.gov

JAMES OTIS LAW GROUP, LLC

/s/ Justin D. Smith
Justin D. Smith, Mo. Bar No. 63253*
William O. Scharf, Mo. Bar No. 66676*
Michael C. Martinich-Sauter, Mo. Bar. No. 66065*
13321 North Outer Forty Road, Suite 300
St. Louis, Missouri 63017
(816) 678-2103
Justin.Smith@james-otis.com

* *pro hac vice* forthcoming