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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]

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[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.

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[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]

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[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]

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[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]

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[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]

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[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.

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[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]

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[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.*

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[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.*

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[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
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Exhibit A

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IN THE DISTRICT COURT OF SHAWNEE COUNTY, KANSAS
Div. 9

STATE OF KANSAS, *ex rel.*,
STEVE SIX, Attorney General,

Plaintiff,

v.

PFIZER INC,

Defendant.

No. 08C1576

(Pursuant to K.S.A. Chapter 60)

JOURNAL ENTRY OF CONSENT JUDGMENT

NOW on this 22 day of Oct, 2008, Plaintiff's Journal Entry of Consent Judgment comes before the Court pursuant to K.S.A. 50-623(b). Plaintiff, the State of Kansas, *ex rel.* Steve Six, Attorney General, appears by and through Emilie Burdette, Assistant Attorney General. Defendant Pfizer Inc appears by and through Kathleen A. Hardee of Shughart Thomson & Kilroy P.C.

The parties advise the Court that they have stipulated and agreed to the following matters: Steve Six is the duly appointed and acting Attorney General of the State of Kansas. The Attorney General's authority to bring this action is derived from the statutory and common law of the State of Kansas, specifically the Kansas Consumer Protection Act, K.S.A. 50-623 *et seq.* Defendant Pfizer Inc (hereinafter "Pfizer" or "Defendant") is a Delaware corporation that conducts business nationwide, including in the State of Kansas; its principal place of business is 235 E 42ND ST, NEW YORK, NY 10017-5703. Pfizer transacts business in the State of Kansas

by advertising, soliciting, selling, promoting and distributing prescription drugs, including BEXTRA/CELEBREX®, to consumers in the State of Kansas and nationwide.

DEFINITIONS

1.

The following definitions shall be used in construing this Judgment:

a. "Covered Conduct" shall mean Pfizer's promotional and marketing practices regarding the prescription drugs Celebrex® and Bextra®, that were the subject of an investigation by the Signatory Attorneys General under the State Consumer Protection Laws.

b. "Effective Date" shall mean the date by which Pfizer and ninety percent (90%) of the States that comprise the Multistate Working Group have executed the Consent Judgment.

c. "FDA Amendments Act of 2007" (or "FDA Amendments Act" or "the Act") shall mean Public Law No. 110-85, which among other things, creates a federal clinical trial registry and results data bank.

d. "FDA's Guidance for Industry" shall mean documents published by the United States Department of Health and Human Services, Food and Drug Administration (FDA), that represent the FDA's current recommendations on a topic.

e. "Individual States" and "State" shall mean each Signatory Attorney General who is participating in the Multistate Working Group.

f. "Pfizer" shall mean Pfizer Inc and its United States-based affiliates, subsidiaries, predecessors, successors, and assigns.

g. "Multistate Executive Committee" shall mean the Attorneys General and their staffs representing Arizona, California, Florida, Illinois, Massachusetts, New York, Ohio, Oregon, Texas, and Vermont.

h. "Multistate Working Group" ("MSWG") shall mean the Attorneys General and their staffs representing Alaska, Arizona, Arkansas, California, Connecticut, Florida, District of

Columbia, Idaho, Illinois, Iowa, Kansas, Kentucky, Maine, Maryland, Massachusetts, Michigan, Montana, Nebraska, Nevada, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oregon, Pennsylvania, South Carolina, South Dakota, Tennessee, Texas, Vermont, Washington, and Wisconsin.

i. "Off-Label" shall mean related to an indication that was not approved by the FDA at the time of dissemination or relating to information that was not contained in the FDA label.

j. "Prescriber" shall mean any physician, dentist, physician assistant, nurse practitioners, and all others with legal authority to prescribe any Pfizer product, as well as pharmacists, members of Pharmacy &Therapeutics committees and others who potentially have an impact on the prescribing of any Pfizer product.

k. "Parties" shall mean Pfizer and the Individual States.

l. "Product" shall mean any prescription drug or biological product manufactured, distributed, sold, marketed or promoted in the United States in any way.

m. "Signatory Attorney(s) General" shall mean the Attorney General, or his or her designee, of each state in the Multistate Working Group.

n. "State Consumer Protection Laws" shall mean the consumer protection laws under which the Signatory Attorneys General have conducted their investigation.[1]

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[1] The States' consumer protection statutes are: ALASKA - *Unfair Trade Practices and Consumer Protection Act*, AS 45.50.471 *et seq.*; ARIZONA - *Consumer Fraud Act*, A.R.S. § 44-1521 *et seq.*; ARKANSAS - Ark. Code Ann. § 4-88-101 *et seq.*; CALIFORNIA - Bus. & Prof. Code §§ 17200 *et seq.* and 17500 *et seq.*; CONNECTICUT - Conn. Gen. Stat. §§ 42-110a *et seq.*; DISTRICT OF COLUMBIA - *Consumer Protection Procedures Act*, D.C. Code § 28-3901 *et seq.*; FLORIDA - *Deceptive and Unfair Trade Practices Act*, Fla. Stat. Ch. 501.201 *et seq.*; IDAHO - *Consumer Protection Act*, Idaho Code Section § 48-601 *et seq.*; ILLINOIS - *Consumer Fraud and Deceptive Business Practices Act*, 815 ILCS § 505/1 *et seq.* (2006 State Bar Edition); IOWA - *Iowa Consumer Fraud Act*, Iowa Code Section 714.16; KANSAS - *Consumer Protection Act*, K.S.A. 50-623 *et seq.*; KENTUCKY - *Consumer Protection Statute*, KRS 367.110 *et seq.*; MAINE - *Unfair Trade Practices Act*, 5 M.R.S.A. § 207 *et seq.*; MARYLAND -

o. "Celebrex" shall mean celecoxib.

p. "Bextra" shall mean valdecoxib.

COMPLIANCE PROVISIONS

2.

The parties have agreed to resolve the issues raised by the Covered Conduct by entering into this Consent Judgment (hereinafter "Judgment").

(a) Pfizer is entering into this Judgment solely for the purpose of settlement, and nothing contained herein may be taken as or construed to be an admission or concession of any violation of law, rule, or regulation, or of any other matter of fact or law, or of any liability or wrongdoing, all of which Pfizer expressly denies. Pfizer does not admit any violation of the State Consumer Protection Laws set forth in footnote 1, and does not admit any wrongdoing that was or could have been alleged by any Attorney General before the date of the Judgment under those

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Consumer Protection Act, Md. Code Ann., Com. Law § 13-101 *et seq.*; MASSACHUSETTS - *Consumer Protection Act*, M.G.L. c. 93A *et seq.*; MICHIGAN - *Michigan Consumer Protection Act*, MCL 445.901 *et seq.*; MONTANA - Mont. Code Ann. § 30-14-101 *et seq.*; NEBRASKA - *Uniform Deceptive Trade Practices Act*, NRS § 87-301 *et seq.*; NEW JERSEY - *New Jersey Consumer Fraud Act*, 56:8-1 *et seq.*; NEW YORK - General Business Law Article 22-A Sections 349, 350 and Executive Law Section 63 (12); NEW MEXICO - *Unfair Practices Act*, NMSA 1978, § 57-12-1 *et seq.*; NEVADA - *Deceptive Trade Practices Act*, Nevada Revised Statutes 598.0903 *et seq.*; NORTH CAROLINA - *Unfair and Deceptive Trade Practices Act*, N.C. Gen. Stat. § 75-1.1 *et seq.*; NORTH DAKOTA - *Unlawful Sales or Advertising Practices*, N.D. Cent. Code. § 51-15-02 *et seq.*; OHIO - *Consumer Sales Practices Act*, R.C. 1345.01 *et seq.*; OREGON - *Unlawful Trade Practices Act*, ORS 646.605 to 646.656; PENNSYLVANIA - *Unfair Trade Practices and Consumer Protection Law*, 73 P.S. § 201-1 *et seq.*; SOUTH CAROLINA - *Unfair Trade Practices Act*, S.C. CODE. ANN. Sections 39-5-10 *et seq.*; SOUTH DAKOTA - *Deceptive Trade Practices Act*, S.D. Codified Laws § 37-24 *et seq.*; TENNESSEE - *Consumer Protection Act*, Tenn. Code Ann. §§ 47-18-101 *et seq.*; TEXAS - *Deceptive Trade Practices - Consumer Protection Act*, Tex. Bus. and Com. Code § 17.47 *et seq.*; VERMONT - *Consumer Fraud Act*, 9 V.S.A. § 2451 *et seq.*; WASHINGTON - *Unfair Business Practices/Consumer Protection Act*, R.C.W. 19.86 *et seq.*; WISCONSIN - Wis. Stat. § 100.18 *et seq.* (Fraudulent Representations) and Wis. Stat. § 100.182 *et seq.* (Fraudulent Drug Advertising).

laws. No part of this Judgment, including its statements and commitments, shall constitute evidence of any liability, fault, or wrongdoing by Pfizer. This document and its contents are not intended for use by any third party for any purpose, including submission to any court for any purpose.

(b) This Judgment shall not be construed or used as a waiver or limitation of any defense otherwise available to Pfizer in any action, or of Pfizer's right to defend itself from, or make any arguments in, any private individual, regulatory, governmental, or class claims or suits relating to the subject matter or terms of this Judgment. This Judgment is made without trial or adjudication of any issue of fact or law or finding of liability of any kind. Notwithstanding the foregoing, a State may file an action to enforce the terms of this Judgment.

(c) It is the intent of the Parties that this Judgment not be admissible in other cases or binding on Pfizer in any respect other than in connection with the enforcement of this Judgment.

(d) No part of this Judgment shall create a private cause of action or confer any right to any third party for violation of any federal or state statute except that a State may file an action to enforce the terms of this Judgment.

(e) All obligations undertaken by Pfizer in this Judgment shall apply prospectively, except to the extent permitted by the National Library of Medicine, Pfizer shall submit, as soon as practicable, clinical trial results to the clinical trial registry and results data bank created by the FDA Amendments Act for all "applicable clinical trials" (as that term is defined by the Act) of FDA-approved Pfizer Products that were initiated after July 1, 2005.

3.

Pfizer shall register clinical trials and submit results to the registry and results data bank as required by the FDA Amendments Act and any accompanying regulations that may be promulgated pursuant to that Act.

4.

Pfizer shall not make any written or oral claim that is false, misleading or deceptive regarding any FDA-approved Pfizer Product.

5.

Pfizer shall not make any written or oral promotional claims of safety or effectiveness for any FDA-approved Pfizer Product in a manner that violates the Food, Drug and Cosmetic Act, 21 U.S.C. § 301 et seq. ("FDCA"), accompanying regulations, or voluntary agreements with FDA, as interpreted by the FDA in a writing by the Director of the Center for Drug Evaluation at the FDA.

6.

Nothing in this Judgment shall require Pfizer to:

(a) take an action that is prohibited by the FDCA or any regulation promulgated thereunder, or by FDA; or

(b) fail to take an action that is required by the FDCA or any regulation promulgated thereunder, or by FDA. Any written or oral promotional claim subject to this Judgment which is the same, or materially the same, as the language required or agreed to by the Director of Division of Drug Marketing, Advertising and Communication or the Director of the Center for Drug Evaluation and Research or their authorized designees in writing shall not constitute a violation of this Judgment.

7.

Following the initial approval of any Pfizer Product indicated for pain relief, Pfizer shall delay direct to consumer ("DTC") television advertising that relates to such indication, if the Director of the Center for Drug Evaluation and Research at FDA recommends such a delay in

writing to Pfizer. Pfizer's delay shall be for the same period as recommended by the Director of the Center for Drug Evaluation and Research at FDA, but in no event shall the period of delay required by this provision of this Judgment exceed 18 months from approval. Should Pfizer run television DTC advertising contrary to a recommendation from the Director of the Center for Drug Evaluation and Research after the expiration of this 18 month period, Pfizer shall provide written notice to the Multistate Executive Committee 30 days prior to running the subject advertisement and shall also provide a copy of all correspondence with FDA relating to the subject advertisement.

8.

Pfizer agrees to submit all new DTC television advertising campaigns for any Pfizer Product to FDA for pre-review, to wait a reasonable time (not less than 45 days) until Pfizer receives a response from FDA prior to running the advertising campaign, and to modify such advertising consistent with any written comments from FDA, whenever received. Simultaneous with running any new DTC television advertisement for which FDA has not provided Pfizer with a pre-review response addressing the substance of the advertisement within the 45-day waiting period prescribed herein, Pfizer shall provide written notice to the Multistate Executive Committee that Pfizer is running the advertisement and that the FDA has not provided Pfizer with a pre-review response addressing the substance of the advertising within the 45-day waiting period, and also provide a copy of all material submitted to FDA for the review of the subject advertisement.

9.

Pfizer's obligations with respect to Paragraph 7 shall remain in effect for eight years following the Effective Date. Pfizer's obligations with respect to Paragraph 8 shall remain in effect for seven years following the Effective Date. With respect to Paragraph 7, Pfizer shall abide by any such written recommendation so long as the submission of the TV advertising campaign is made within eight years following the Effective Date. With respect to Paragraph 8,

Pfizer shall abide by any such written recommendation so long as the submission of the TV advertising campaign is made within seven years of the Effective Date.

10.

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 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 evaluations.

11.

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.

12.

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 favorable information or conclusions from a study that is inadequate in design, scope, or conduct to furnish significant support for such information or conclusions; (b) use the concept of statistical significance to support a claim that has not been demonstrated to have clinical significance or validity, or fails to reveal the range of variations around the quoted average results; or (c) 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.

13.

(a) Pfizer shall comply with the ACCME Standards for Commercial Support (a copy of the current version is attached hereto as Appendix 1).

(b) Any person who acts in a promotional capacity for Pfizer with respect to an FDA approved Pfizer Product shall be obligated under his or her contract with Pfizer, as a condition for any future promotional relationship with Pfizer, to disclose to Continuing Medical Education ("CME") participants orally and to the CME provider for inclusion in the written materials the existence, nature and purpose of his or her arrangement with Pfizer when a member of the faculty at a CME program if: (i) the Product the faculty member promoted for Pfizer is in the same therapeutic category as the subject of the CME program, and (ii) the CME program occurs within 12 months of the faculty member performing work for or receiving compensation from Pfizer. Such disclosure shall set forth the type of promotional work engaged in by the faculty member and the name of the therapeutic category with respect to such promotion.

(c) Pfizer shall not provide funding for CME when Pfizer has knowledge at the time the decision to fund the CME is made that a speaker at the CME has also been a promotional speaker in the past 12 months at a Pfizer-sponsored promotional event related to the class of drugs to be discussed in the CME.

14.

Pfizer's obligations with respect to CME shall remain in effect for 9 years following the Effective Date. Pfizer's obligations with respect to Paragraph 13(b) shall only apply to speakers' contracts entered into, amended to extend the contract period, or renewed after the date of this Judgment.

15.

Pfizer shall require all individuals who are named as authors on a Pfizer-sponsored manuscript reporting the results of a Pfizer-sponsored study to fulfill the following conditions: (a) the individual shall have made a substantial contribution to the conception and design, or acquisition of data, or analysis and interpretation of data; (b) the individual shall have been involved in drafting the article or revising it critically for important intellectual content; and (c) the individual shall have final approval rights of the version to be published. When a large, multi-center group has conducted the research, the manuscript shall identify the individuals who accept direct responsibility for the manuscript. These individuals should fully meet the criteria for authorship as set forth in (a), (b), and (c) above.

16.

Pfizer shall not disseminate in a promotional context any patient testimonial relating to a Product that does not clearly and conspicuously disclose what the generally expected performance would be in the depicted circumstances or clearly and conspicuously disclose the limited applicability of the experience described by the patient testimonial to what consumers may generally expect to achieve.

17.

Pfizer shall not market two or more Products in a manner that falsely or misleadingly conflates the various properties of the respective Products.

18.

Pfizer shall not compensate physicians for conducting individual, observational teaching sessions in their offices or in the hospital ("mentorships") in which sales representatives who detail a Product participate.

19.

Pfizer shall instruct investigators of Pfizer sponsored clinical trials regarding a Product to obtain a legally effective informed consent from all study subjects or from the subject's legally authorized representative. If Pfizer provides the investigator (or the investigator's Institutional Review Board) with a model informed consent, Pfizer shall not fail to include (a) a statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental; (b) a description of any reasonably foreseeable risks or discomforts to the subject; and (c) for research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.

20.

Pfizer shall not affirmatively seek the inclusion of a Product in hospital protocols or standing orders unless the Product at issue has been approved by the FDA for the indication for

which it is to be included in the protocol or standing order. Notwithstanding the foregoing, Pfizer may disclose to insurance companies and other third party payors any information regarding the inclusion of a Product in hospital protocols or standing orders even if the Product at issue has not been approved by the FDA for the indication for which it is to be included in the protocol or standing order.

21.

Pfizer shall not award prizes or other incentives to its sales force as rewards for specifically increasing the Off-Label use of a Product.

22.

Pfizer shall not disseminate any information describing any Off-Label use of a Product if such use has been submitted to the FDA for approval and the FDA has either advised Pfizer that it refuses to approve such application or that FDA-identified deficiencies must be resolved before approval can be granted unless Pfizer has first clearly and conspicuously disclosed to the information recipient that FDA had issued such advice regarding such Off-Label use. Pfizer may disclose to any recipient of such information whether the information was presented to the FDA prior to the FDA's issuance of such advice regarding the Off-Label use.

23.

Pfizer shall not disseminate a Medical Information Letter, an unabridged reprint or copy of an article from a Peer Reviewed Journal or a Reference Publication, or written information through a Regional Medical Research Specialist ("RMRS") describing any Off-Label use of a Product in response to an unsolicited request by a prescriber or other health care professional unless (a) the information is about a clinical investigation with respect to the Product and experts qualified by scientific training or experience to evaluate the safety or effectiveness of the Product

would consider the subject of the clinical investigation to be scientifically sound or the information is an unabridged reprint or copy of an article from a Peer Reviewed Journal or a Reference Publication; (b) the information is accompanied by a comprehensive bibliography of publications discussing adequate and well-controlled clinical studies published in a medical journal or medical or scientific text that have been previously published about the use of the Product covered by the information (unless the information is a Peer Reviewed Journal or Reference Publication which already includes such a bibliography); and (c) in cases in which experts qualified by scientific training or experience to evaluate the safety or effectiveness of the Product would consider the conclusion of the information to have been specifically called into question by another article(s) or text(s) that experts qualified by scientific training or experience to evaluate the safety or effectiveness of the Product would consider to be scientifically sound, the information must be disseminated with a representative publication that reaches contrary or different conclusions regarding the Off-Label use.

24.

Pfizer shall not disseminate any reprint or copy of an article from a Peer Reviewed Journal or a Reference Publication describing any Off-Label use of the Product to physician specialties that do not customarily prescribe the Product if these materials combined with detailing, advertising, sampling, or other promotional activities promote Off-Label use of the Product.

25.

In the event that FDA issues a final "Guidance For Industry: Good Reprint Practices For The Distribution Of Medical Journal Articles And Medical Or Scientific Reference Publications On Unapproved New Uses Of Approved Drugs And Approved Or Cleared Medical Devices,"

and a provision of said Guidance materially conflicts with any of the provisions of Paragraphs 22 through 24 of this Judgment, Pfizer may petition the Court for modification of those paragraphs, after providing thirty (30) days' notice to the Attorney General. The parties by stipulation may agree to such a modification, which agreement shall be presented to this Court for consideration provided that the parties may jointly agree to a modification only by a written instrument signed by or on behalf of both Pfizer and the Attorney General. If Pfizer wishes to seek a stipulation for a modification from the State, it shall send a written request for agreement to such modification to the Attorney General at least 30 days prior to filing a motion with the Court for such modification. Within 30 days of receipt from Pfizer of a written request for agreement to modify, the Attorney General shall notify Pfizer in writing if the Attorney General agrees to the requested modification. The Attorney General shall not unreasonably withhold his/her consent to the modification. The parties agree it would be unreasonable to withhold consent to the terms provided in the draft "Guidance For Industry: Good Reprint Practices For The Distribution Of Medical Journal Articles And Medical Or Scientific Reference Publications On Unapproved New Uses Of Approved Drugs And Approved Or Cleared Medical Devices," dated February 15, 2008, and attached hereto as Appendix 2, in the event that all such terms are included in the final Guidance For Industry. In the event that all such terms are not included in the final Guidance for Industry, the parties agree to consider whether any such terms that are included in the final Guidance for Industry should form the basis of a modification of Paragraphs 22 through 24 of this Judgment.

26.

Pfizer shall not disseminate any Medical Information Letter describing any Off-Label use of a Product that makes any false or misleading representation regarding a Product.

27.

Pfizer shall not disseminate samples of a Product with the intent of increasing Off-label prescribing of the Product.

28.

When submitting clinical trials relating to Off-label indications to journals for publication, Pfizer shall disclose to the journal that the FDA has not approved the drug for the indication that was the subject of the clinical trial.

29.

The Pfizer Medical Education Grants Office shall manage all requests for funding related to CME regarding Products. Approval decisions shall be made by the Pfizer Medical Education Grants Office alone, and shall be kept separate from the Sales and Marketing function. Notwithstanding the foregoing, decisions to approve a request for funding made by the Pfizer Medical Education Grants Office may be subject to actual funding approval by Pfizer's Chief Financial Officer or other designated officials.

30.

Pfizer shall not use grants to advantage or promote Products. This provision includes, but is not limited to, the following prohibitions:

(a) Sales and Marketing personnel shall not initiate, coordinate or implement grant applications on behalf of any customer or Prescriber;

(b) Sales and Marketing personnel shall not be involved in selecting grantees or CME-funded speakers; and

(c) Sales and Marketing personnel shall not measure or attempt to track in any way the impact of grants or speaking fees on the participating Prescribers' subsequent prescribing habits, practices or patterns.

31.

Pfizer Sales and Marketing personnel shall not approve grant requests regarding Products, nor attempt to influence the Pfizer Medical Education Grants Office to reward any customers or Prescribers with grants for their prescribing habits, practices or patterns.

32.

By its execution of this Judgment, The State of Kansas releases Pfizer and all of its past and present subsidiaries, affiliates, predecessors and successors (collectively, the "Released Parties") from the following: all civil claims, causes of action, damages, restitution, fines, costs, and penalties on behalf of the State of Kansas under the above-cited consumer protection statutes arising from the Covered Conduct that is the subject of this Judgment.

33.

Notwithstanding any term of this Judgment, specifically reserved and excluded from the Release in Paragraph 32 as to any entity or person, including Released Parties, are any and all of the following:

(a) Any criminal liability that any person or entity, including Released Parties, has or may have to the State of Kansas.

(b) Any civil or administrative liability that any person or entity, including Released Parties, has or may have to the State of Kansas not expressly covered by the release in Paragraph 32 above, including but not limited to any and all of the following claims:

i) State or federal antitrust violations;

ii) Reporting practices, including "best price", "average wholesale price" or "wholesale acquisition cost;"

iii) Medicaid violations, including federal Medicaid drug rebate statute violations, Medicaid fraud or abuse, and/or kickback violations related to any State's Medicaid program; and,

iv) State false claims violations.

(c) Any liability under the State of Kansas's above-cited consumer protection laws which any person or entity, including Released Parties, has or may have to individual consumers or State program payors of said State, and which have not been specifically enumerated as included herein.

34.

Within ten (10) days of the Effective Date of this Judgment, Pfizer shall pay a total amount of sixty million dollars ($60,000,000) to be divided and paid by Pfizer directly to each Signatory Attorney General in an amount to be designated by and in the sole discretion of the Multistate Executive Committee. Said payment shall be used by the States for attorneys' fees and other costs of investigation and litigation, or to be placed in, or applied to, the consumer protection enforcement fund, consumer education, litigation or local consumer aid fund or revolving fund, used to defray the costs of the inquiry leading hereto, or for other uses permitted by state law, at the sole discretion of each Signatory Attorney General.

35.

For the purposes of resolving disputes with respect to compliance with this Judgment, should any of the Signatory Attorneys General have a reasonable basis to believe that Pfizer has engaged in a practice that violates a provision of this Judgment subsequent to the Effective Date of this Judgment, then such Attorney General shall notify Pfizer in writing of the specific objection, identify with particularity the provisions of this Judgment that the practice appears to violate, and give Pfizer thirty (30) days to respond to the notification; provided, however, that a Signatory Attorney General may take any action if the Signatory Attorney General concludes

that, because of the specific practice, a threat to the health or safety of the public requires immediate action.

Upon receipt of written notice, Pfizer shall provide a good-faith written response to the Attorney General notification, containing either a statement explaining why Pfizer believes it is in compliance with the Judgment, or a detailed explanation of how the alleged violation occurred and a statement explaining how Pfizer intends to cure the alleged breach. Nothing in this paragraph shall be interpreted to limit the state's Civil Investigative Demand ("CID") or subpoena authority, to the extent such authority exists under applicable state law, and Pfizer reserves all of its rights with respect to a CID or subpoena issued pursuant to such authority.

36.

Upon giving Pfizer thirty (30) days to respond to the notification described above, the Signatory Attorney General shall also be permitted reasonable access to inspect and copy relevant, non-privileged, non-work product records and documents in the possession, custody or control of Pfizer that relate to Pfizer's compliance with each provision of this Judgment as to which cause that is legally sufficient in the State has been shown. If the Signatory Attorney General makes or requests copies of any documents during the course of that inspection, the Signatory Attorney General will provide a list of those documents to Pfizer.

37.

The State may assert any claim that Pfizer has violated this Judgment in a separate civil action solely to enforce compliance with this Judgment, or to seek any other relief afforded by law, but only after providing Pfizer an opportunity to respond to the notification described in Paragraph 35 above; provided, however, that a Signatory Attorney General may take any action if the Signatory Attorney General concludes that, because of the specific practice, a threat to the health or safety of the public requires immediate action.

38.

This Judgment represents the full and complete terms of the settlement entered into by the parties hereto. In any action undertaken by either the Attorneys General, or any of them, or Pfizer, no prior versions of this Judgment, and no prior versions of any of its terms, that were not entered by the Court in this Judgment, may be introduced for any purpose whatsoever.

IT IS SO STIPULATED:

I. General Provisions

A. This Judgment represents the full and complete terms of the settlement entered into by the Parties hereto. In any action undertaken by the Parties, no prior versions of this Judgment, no prior versions of any of its terms, that were not entered by the Court in this Judgment, may be introduced for any purpose whatsoever.

B. This Court retains jurisdiction of this Judgment and the Parties hereto for the purpose of enforcing and modifying this Judgment and for the purpose of granting such additional relief as may be necessary and appropriate.

C. All Notices under this Judgment shall be provided to Emilie Burdette, Assistant Attorney General, by Overnight Mail at: Office of the Kansas Attorney General. 120 SW 10th Ave., 2nd Floor in Topeka, Kansas 66612.

IT IS THEREFORE ORDERED, ADJUDGED AND DECREED that the stipulations and agreements of the parties contained herein are adopted and approved as the findings of fact and conclusions of law of the Court and any monies owed hereunder by Defendant immediately become a judgment upon filing.

IT IS FURTHER ORDERED, ADJUDGED AND DECREED that pursuant to the Kansas Consumer Protection Act, K.S.A. 50-632(b), the Court hereby approves the terms of the Consent Judgment and adopts the same as the order of the Court.

JUDGE

Prepared and approved by:

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APPENDIX 1

ACCME STANDARDS FOR COMMERCIAL SUPPORT SM

Standards to Ensure the Independence of CME Activities

ACCME

The ACCME Standards for Commercial Support℠

Standards to Ensure Independence in CME Activities

STANDARD 1: Independence

1.1 A CME provider must ensure that the following decisions were made free of the control of a commercial interest. (See www.accme.org for a definition of a 'commercial interest' and some exemptions.)

(a) Identification of CME needs;
(b) Determination of educational objectives;
(c) Selection and presentation of content;
(d) Selection of all persons and organizations that will be in a position to control the content of the CME;
(e) Selection of educational methods;
(f) Evaluation of the activity.

1.2 A commercial interest cannot take the role of non-accredited partner in a joint sponsorship relationship.⌘

STANDARD 2: Resolution of Personal Conflicts of Interest

2.1 The provider must be able to show that everyone who is in a position to control the content of an education activity has disclosed all relevant financial relationships with any commercial interest to the provider. The ACCME defines "'relevant' financial relationships" as financial relationships in any amount occurring within the past 12 months that create a conflict of interest.

2.2 An individual who refuses to disclose relevant financial relationships will be disqualified from being a planning committee member, a teacher, or an author of CME, and cannot have control of, or responsibility for, the development, management, presentation or evaluation of the CME activity.

2.3 The provider must have implemented a mechanism to identify and resolve all conflicts of interest prior to the education activity being delivered to learners.⌘

STANDARD 3: Appropriate Use of Commercial Support

3.1 The provider must make all decisions regarding the disposition and disbursement of commercial support.

3.2 A provider cannot be required by a commercial interest to accept advice or services concerning teachers, authors, or participants or other education matters, including content, from a commercial interest as conditions of contributing funds or services.

3.3 All commercial support associated with a CME activity must be given with the full knowledge and approval of the provider.

Written agreement documenting terms of support

3.4 The terms, conditions, and purposes of the commercial support must be documented in a written agreement between the commercial supporter that includes the provider and its educational partner(s). The agreement must include the provider, even if the support is given directly to the provider's educational partner or a joint sponsor.

3.5 The written agreement must specify the commercial interest that is the source of commercial support.

3.6 Both the commercial supporter and the provider must sign the written agreement between the commercial supporter and the provider.

Expenditures for an individual providing CME

3.7 The provider must have written policies and procedures governing honoraria and reimbursement of out-of-pocket expenses for planners, teachers and authors.

3.8 The provider, the joint sponsor, or designated educational partner must pay directly any teacher or author honoraria or reimbursement of out-of–pocket expenses in compliance with the provider's written policies and procedures.

3.9 No other payment shall be given to the director of the activity, planning committee members, teachers or authors, joint sponsor, or any others involved with the supported activity.

3.10 If teachers or authors are listed on the agenda as facilitating or conducting a presentation or session, but participate in the remainder of an educational event as a learner, their expenses can be reimbursed and honoraria can be paid for their teacher or author role only.

Expenditures for learners

3.11 Social events or meals at CME activities cannot compete with or take precedence over the educational events.

3.12 The provider may not use commercial support to pay for travel, lodging, honoraria, or personal expenses for non-teacher or non-author participants of a CME activity. The provider may use commercial support to pay for travel, lodging, honoraria, or personal expenses for bona fide employees and volunteers of the provider, joint sponsor or educational partner.

Accountability

3.13 The provider must be able to produce accurate documentation detailing the receipt and expenditure of the commercial support. ⌘

STANDARD 4: Appropriate Management of Associated Commercial Information

4.1 Arrangements for commercial exhibits or advertisements cannot influence planning or interfere with the presentation, nor can they be a condition of the provision of commercial support for CME activities.

4.2 Product-promotion material or product-specific advertisement of any type is prohibited in or during CME activities. The juxtaposition of editorial and advertising material on the same products or subjects must be avoided. Live (staffed exhibits, presentations) or enduring (printed or electronic advertisements) promotional activities must be kept separate from CME.

- For ***print***, advertisements and promotional materials will not be interleafed within the pages of the CME content. Advertisements and promotional materials may face the first or last pages of printed CME content as long as these materials are not related to the CME content they face **and** are not paid for by the commercial supporters of the CME activity.
- For ***computer based***, advertisements and promotional materials will not be visible on the screen at the same time as the CME content and not interleafed between computer 'windows' or screens of the CME content
- For ***audio and video recording***, advertisements and promotional materials will not be included within the CME. There will be no 'commercial breaks.'
- For ***live, face-to-face CME***, advertisements and promotional materials cannot be displayed or distributed in the educational space immediately before, during, or after a CME activity. Providers cannot allow representatives of Commercial Interests to engage in sales or promotional activities while in the space or place of the CME activity.

4.3 Educational materials that are part of a CME activity, such as slides, abstracts and handouts, cannot contain any advertising, trade name or a product-group message.

4.4 Print or electronic information distributed about the non-CME elements of a CME activity that are not directly related to the transfer of education to the learner, such as schedules and content descriptions, may include product-promotion material or product-specific advertisement.

4.5 A provider cannot use a commercial interest as the agent providing a CME activity to learners, e.g., distribution of self-study CME activities or arranging for electronic access to CME activities. ⌘

STANDARD 5: Content and Format without Commercial Bias

5.1 The content or format of a CME activity or its related materials must promote improvements or quality in healthcare and not a specific proprietary business interest of a commercial interest.

5.2 Presentations must give a balanced view of therapeutic options. Use of generic names will contribute to this impartiality. If the CME educational material or content includes trade names, where available trade names from several companies should be used, not just trade names from a single company.⌘

STANDARD 6: Disclosures Relevant to Potential Commercial Bias

Relevant financial relationships of those with control over CME content

6.1 An individual must disclose to learners any relevant financial relationship(s), to include the following information:

- The name of the individual;
- The name of the commercial interest(s);
- The nature of the relationship the person has with each commercial interest.

6.2 For an individual with no relevant financial relationship(s) the learners must be informed that no relevant financial relationship(s) exist.

Commercial support for the CME activity.

6.3 The source of all support from commercial interests must be disclosed to learners. When commercial support is 'in-kind' the nature of the support must be disclosed to learners.

6.4 'Disclosure' must never include the use of a trade name or a product-group message.

Timing of disclosure

6.5 A provider must disclose the above information to learners prior to the beginning of the educational activity. ⌘

APPENDIX 2

Guidance for Industry:

Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit comments to Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For single copies of this draft guidance, please contact: Office of Policy, Food and Drug Administration, 5600 Fishers Lane, rm. 14-101, HF-11, Rockville, MD 20857, (301) 827-3360.

For questions regarding this draft document, contact Jarilyn Dupont, Office of Policy, Food and Drug Administration, (301) 827-3360.

U.S. Department of Health and Human Services
Food and Drug Administration

February 2008

Contains Nonbinding Recommendations
Draft – Not for Implementation

Table of Contents

Contains Nonbinding Recommendations
Draft – Not for Implementation

Guidance for Industry: Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices

This draft guidance document represents the Food and Drug Administration's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You may use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, please contact the appropriate FDA staff.

I. Introduction

This draft guidance is intended to describe the Food and Drug Administration's (FDA or Agency) current thinking regarding "Good Reprint Practices" with regard to the distribution of medical journal articles and scientific or medical reference publications (referred to generally as medical and scientific information) that discuss unapproved new uses for approved drugs[1] or approved or cleared medical devices marketed in the United States to healthcare professionals and healthcare entities.

FDA's guidance documents, including this draft guidance, do not establish legally enforceable rights or responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word should in Agency guidances means that something is suggested or recommended, but not required.

II. Background

Section 401 of the Food and Drug Administration Modernization Act (FDAMA (21 U.S.C. § 360aaa, § 551, Federal Food, Drug, and Cosmetic Act (FD&C Act))), described certain conditions under which a drug or medical device manufacturer[2] could choose to disseminate medical and scientific information discussing unapproved uses of approved drugs and cleared or approved medical devices to healthcare professionals and certain entities (including pharmacy benefits managers, health insurance issuers, group health plans, and Federal or State governmental agencies). FDAMA section 401 provided that, if these conditions were met, dissemination of such journal articles or reference publications would not be considered as evidence of the manufacturer's intent that the product be used for an unapproved new use. FDA implementing regulations were codified at 21 C.F.R. Part 99.

In 2000, subsequent to a decision by the United States Court of Appeals for the District of Columbia Circuit, FDA published a Notice (65 Fed. Reg. 14286, March 16, 2000) clarifying the applicability of the FDAMA section 401 provision and the FDA implementing regulations. In that Notice, FDA stated that the statute and implementing regulations constituted a "safe harbor" for a manufacturer that complies with them before and while disseminating journal articles and reference publications about "new uses" of approved or cleared products. If a manufacturer complied with the FDAMA provision, the distribution of such journal articles or reference publications would not be used as evidence of an intent that the product distributed by the manufacturer be used for an unapproved use. The Notice stated that if a manufacturer chose to disseminate materials but not proceed under FDAMA section 401, that failure would not constitute an independent violation of law.

FDAMA section 401 ceased to be effective on September 30, 2006, and the implementing regulations are no longer applicable. In light of the statute's sunset, FDA is providing its current views on the dissemination of medical journal articles and medical or scientific reference publications on unapproved uses of approved drugs and approved or cleared medical devices to healthcare professionals and healthcare entities.

III. Purpose

As explained in FDA's March 16, 2000 Notice, the FD&C Act and FDA's implementing regulations generally prohibit manufacturers of new drugs or medical devices from distributing products in interstate commerce for any intended use that FDA has not approved as safe and effective or cleared through a substantial equivalence determination. (E.g., FD&C Act §§ 505(a), 502(o), 501(f)(1)(B), 301(a) and (d); 21 U.S.C. §§ 355, 352(o), 351(f)(1)(B), 331(a) and (d)). An approved new drug that is marketed for an unapproved use becomes misbranded and an unapproved new drug with respect to that use. Similarly, a medical device that is promoted for a use that has not been approved or cleared by FDA is adulterated and misbranded.

FDA does, however, recognize the important public policy reasons for allowing manufacturers to disseminate truthful and non-misleading medical journal articles and medical or scientific reference publications on unapproved uses of approved drugs and approved or cleared medical devices to healthcare professionals and healthcare entities. Once a drug or medical device has been approved or cleared by FDA, generally healthcare professionals may lawfully use or prescribe that product for uses or treatment regimens that are not included in the product's approved labeling (or, in the case of a medical device cleared under the 510(k) process, in the product's statement of intended uses). These off-label uses or treatment regimens may be important and may even constitute a medically recognized standard of care. Accordingly, the public health may be advanced by healthcare professionals' receipt of medical journal articles and medical or scientific reference publications on unapproved or new uses of approved or cleared medical products that are truthful and not misleading.

FDA's legal authority to determine whether distribution of medical or scientific information constitutes promotion of an unapproved "new use," or whether such activities cause a product to be misbranded or adulterated has not changed. In recognition of the public health value to healthcare professionals of receiving truthful and non-misleading scientific and medical information, FDA is providing recommendations concerning "Good Reprint Practices" for the dissemination of medical journal articles and medical or scientific reference publications on unapproved uses of drugs and medical devices.[3]

IV. Agency Recommendations for Good Reprint Practices

Scientific and medical information that concerns the safety or effectiveness of an approved drug or approved or cleared medical device for a new use that is not included in the product's approved labeling or statement of intended uses (including unapproved or new uses of approved drugs and approved or cleared devices) is often published in journal articles or reference publications. These publications are often distributed by manufacturers to healthcare professionals or healthcare entities. When a manufacturer disseminates such medical and scientific information, FDA recommends that the following principles of "Good Reprint Practices" be followed.

A. Types of Reprints/Articles/Reference Publications

A scientific or medical journal article that is distributed should:

- be published by an organization that has an editorial board that uses experts who have demonstrated expertise in the subject of the article under review by the organization and who are independent of the organization to review and objectively select, reject, or provide comments about proposed articles, and that has a publicly stated policy, to which the organization adheres, of full disclosure of any conflict of interest or biases for all authors, contributors, or editors associated with the journal or organization;
- be peer-reviewed and published in accordance with the peer-review procedures of the organization; and
- not be in the form of a special supplement or publication that has been funded in whole or in part by one or more of the manufacturers of the product that is the subject of the article.

A scientific or medical reference publication that is distributed should not be:

- primarily distributed by a drug or device manufacturer, but should be generally available in bookstores or other independent distribution channels where medical textbooks are sold;
- written, edited, excerpted, or published specifically for, or at the request of, a drug or device manufacturer; or
- edited or significantly influenced by a drug or device manufacturer or any individuals having a financial relationship with the manufacturer.

The information contained in the above scientific or medical journal article or reference publications should address adequate and well-controlled clinical investigations that are considered scientifically sound by experts with scientific training and experience to evaluate the safety or effectiveness of the drug or device[4]. The information must not:

- be false or misleading, such as a journal article or reference text that is inconsistent with the weight of credible evidence derived from adequate and well-controlled clinical investigations (e.g., where a significant number of other studies contradict the article or reference text's conclusions), that has been withdrawn by the journal or disclaimed by the author, or that discusses a clinical investigation where FDA has previously informed the company that the clinical investigation is not adequate and well-controlled; or
- pose a significant risk to the public health.

The following publications are examples of publications that would not be considered consistent with the Good Reprint Practices outlined in this draft guidance:

- letters to the editor;
- abstracts of a publication;
- reports of Phase 1 trials in healthy subjects; or
- reference publications that contain little or no substantive discussion of the relevant investigation or data.

B. Manner in which to Disseminate Scientific and Medical Information

Scientific or medical information that is distributed should:

- be in the form of an unabridged reprint, copy of an article, or reference publication;
- not be marked, highlighted, summarized, or characterized by the manufacturer in any way;
- be accompanied by the approved labeling for the drug or medical device;
- be accompanied by a comprehensive bibliography of publications discussing adequate and well-controlled clinical studies published in a medical journal or medical or scientific text that have been previously published about the use of the drug or medical device covered by the information disseminated (unless the information already includes such a bibliography);
- in cases where the conclusions of article or text to be disseminated have been specifically called into question by another article(s) or text(s), be disseminated with a representative publication that reaches contrary or different conclusions regarding the unapproved use; and

- be distributed separately from information that is promotional in nature. For example, if a sales representative delivers a reprint to a physician in his office, the reprint should not be physically attached to any promotional material the sales representative uses or delivers during the office visit and should not be the subject of discussion between the sales representative and the physician during the sales visit.[5] Similarly, while reprints may be distributed at medical or scientific conferences in settings appropriate for scientific exchange, reprints should not be distributed in promotional exhibit halls or during promotional speakers' programs.

The journal reprint or reference publication should be accompanied by a prominently displayed and permanently affixed statement disclosing:

- that the uses described in the information have not been approved or cleared by FDA, as applicable to the described drug or medical device;
- the manufacturer's interest in the drug or medical device that is the subject of the journal reprint or reference text;
- any author known to the manufacturer as having a financial interest in the product or manufacturer or receiving compensation from the manufacturer, if applicable;
- any person known to the manufacturer who has provided funding for the study, if applicable; and
- any significant risks or safety concerns known to the manufacturer concerning the unapproved use that are not discussed in the journal article or reference text.

V. Summary

FDA recognizes that the public health can be served when health care professionals receive truthful and non-misleading scientific and medical information on unapproved uses of approved or cleared medical products. Accordingly, if a manufacturer follows the recommendations described in Section IV of this draft guidance and there is no unlawful promotion of the product, FDA does not intend to use the distribution of such medical and scientific information as evidence of an intent by the manufacturer that the product be used for an unapproved use.[6]

Footnotes

[1] As used in this draft guidance, the term "drug" includes biological products licensed under Section 351(a) of the Public Health Service Act. See 42 U.S.C. § 262(j).

[2] As used in this draft guidance, the term "manufacturer" means a person who manufactures a drug or device or who is licensed by such person to distribute or market the drug or device. The term may also include the sponsor of the approved, licensed, or cleared drug or device.

[3] This draft guidance does not apply to scientific or medical information distributed in response to unsolicited requests for scientific or medical information from health care professionals. See 59 Fed. Reg. 59820, 59823 (November 18, 1994).

[4] In the case of medical devices, journal articles or reference publications discussing significant non-clinical research may be consistent with this draft guidance.

[5] To the extent that the recipients of such information have questions, the Agency recommends that the sales representative refer such questions to a medical/scientific officer or department, and that the officer or department to which the referral is made be separate from the sales and/or marketing departments.

[6] Given the sunset of FDAMA § 401, the other elements that comprised § 401 which are not specifically described in this draft guidance are no longer applicable.

For More Information

Press Release *(February 15, 2008)*
Federal Register (Docket No. FDA-2008-D-0053, OC 2007268)

Exhibit B

STATE OF KANSAS
OFFICE OF THE ATTORNEY GENERAL

KRIS W. KOBACH
ATTORNEY GENERAL

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April 22, 2024

Pfizer Inc.
c/o Milton Marquis
1200 19th Street, NW
3rd Floor
Washington, D.C. 20036
mmarquis@cozen.com

SENT BY ELECTRONIC MAIL

RE: Notice of Consent Judgment Violations

Dear Pfizer and Pfizer representatives:

This notice is provided pursuant to Paragraph 35 of the Final Consent Judgment in *State of Kansas, ex rel. Steve Six v. Pfizer Inc.*, No. 08CV1576 (Oct. 23, 2008) ("Celebrex Consent Judgment"); Paragraph 6.1 of the Final Consent Judgment in *State of Kansas, ex rel. Derek Schmidt v. Pfizer Inc.*, No. 12CV1339 (Dec. 13, 2012); ("Lyrica Consent Judgment"); and Paragraph 6.1 of the Final Consent Judgment in *State of Kansas, ex rel. Derek Schmidt. v. Wyeth Pharmaceuticals Inc.*, No. 2014CV777 (Aug. 6, 2014). Pursuant to the terms in these consent judgments, please provide a good-faith written response to this notice within 30 days.

I. False, misleading, or deceptive written or oral claims

All three consent judgments prohibit false, misleading, or deceptive claims regarding Pfizer products. Celebrex Consent Judgment, ¶ 4; Lyrica Consent Judgment, ¶ 3.1; Rapamune Consent Judgment, ¶ 3.1. The consent judgments broadly cover any Pfizer "prescription drug or biological product manufactured, distributed, sold, marketed or promoted by Pfizer in the United States." Celebrex Consent Judgment, ¶ 1(l); Lyrica Consent Judgment, ¶ 2.18; Rapamune Consent Judgment, ¶ 2.17. The consent judgments do not limit these prohibitions on false, misleading, or deceptive claims by time or by specific Pfizer product.

These broad provisions apply to claims Pfizer made or that it caused to be made about its COVID-19 vaccine. Federal law defines "biological product" to include vaccines. 42 U.S.C. § 262(i)(1); *see also* 21 U.S.C. § 360bbb-3(a)(4)(A). Pfizer manufactured, distributed, sold,

marketed, and promoted its COVID-19 vaccine in the United States, including in Kansas.

A. False, Misleading, or Deceptive Safety Claims

Pfizer appears to have made, or caused to be made, numerous claims about its COVID-19 vaccine's safety that are false, misleading, or deceptive. The examples provided below are illustrative and are not intended to be an exhaustive list of all safety statements.

1. "No serious safety concerns." 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.[1] However, as of February 28, 2021, Pfizer had received more than 42,000 case reports containing more than 158,000 adverse events from its COVID-19 vaccine, including injuries, adverse pregnancy outcomes, and fatalities.[2] In addition, at the time of its press release, Pfizer knew the results of a June 29, 2020 to October 12, 2020 lab rat study. In that study, pregnant rats receiving variations of Pfizer's COVID-19 vaccine had the following effects at a higher rate than the control group rats:
    a. lost their entire litters;
    b. delivered stillborn offspring;
    c. pre-implantation loss (twice as high as the control group);
    d. pre-birth loss (almost twice as high as the control group);
    e. delivered fewer offspring;
    f. had lower body weight;
    g. consumed less food;
    h. had multiple fetuses with severe soft tissue anomalies;
    i. had multiple fetuses with skeletal anomalies;
    j. had a smaller mean live litter size.[3]

2. "Effective and safe." On August 23, 2021, Pfizer CEO Dr. Bourla said that the Pfizer vaccine "is effective and safe."[4] Similarly, on September 16, 2021, Pfizer CEO Dr. Bourla said, "We have been very successful in developing an effective and safe vaccine."[5] Yet according to an internal Pfizer document, "[s]ince April 2021, increased cases of

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

[2] 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, 6, *at* https://phmpt.org/wp-content/uploads/2022/04/reissue_5.3.6-postmarketing-experience.pdf.

[3] 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, at 13, *at* https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/110122/125742_S1_M4_20256434.pdf.

[4] Antonio Planas, *'Effective and safe': Pfizer CEO says FDA's full approval should result in more vaccinations*, NBC NEWS (Aug. 23, 2021), *at* https://www.nbcnews.com/news/us-news/effective-safe-pfizer-ceo-says-fda-s-full-approval-should-n1277478.

[5] *Continuing to Follow the Science: An Open Letter from Pfizer Chairman and CEO Dr. Albert Bourla*, Pfizer (Sept. 16, 2021), *at* https://www.pfizer.com/news/announcements/continuing-follow-science-open-letter-pfizer-chairman-and-ceo-dr-albert-bourla.

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)."[6] After the CDC had received 1,200 reports of heart inflammation relating to the COVID-19 vaccine, in June 2021, the FDA added a warning about the risk of myocarditis and pericarditis to the Pfizer COVID-19 vaccine fact sheet.[7]

3. "Not a single safety signal." On January 18, 2023, in response to questions about stroke and myocarditis concerns related to the Pfizer vaccine, Pfizer 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."[8] At the time Dr. Bourla made his statement, the CDC website contained the following statement: "In April 2021, increased cases of myocarditis and pericarditis were reported in the United States after mRNA COVID-19 vaccination (Pfizer-BioNTech and Moderna). Data from multiple studies show a rare risk for myocarditis and/or pericarditis following receipt of mRNA COVID-19 vaccines. These rare 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). There has not been a similar reporting pattern observed after receipt of the Janssen COVID-19 Vaccine (Johnson & Johnson)."[9] In addition, days before Pfizer's January 2023 claim, 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, . . ."[10] Finally, at least by May 2021, government studies had connected the Pfizer vaccine to fatalities: "[a]mong 100 reported deaths, a causal link to the vaccine was considered probable in 10 cases, possible in 26, and unlikely in 59. Five were unclassifiable."[11]

Based on the contradictions between Pfizer's public statements and internal reports, Pfizer appears to have made false, misleading, or deceptive claims about its COVID-19 vaccine's safety in violation of its consent judgments with the State of Kansas.

Under the consent judgments, during Pfizer's time to respond to this notice, the Kansas Attorney General "shall also be permitted reasonable access to inspect and copy relevant, non-

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[6] Pfizer, *Myocarditis/Pericarditis After mRNA COVID-19 Vaccine Administration: Potential Mechanisms and Recommended Future Actions*, Feb. 11, 2022, at 18, *at* https://downloads.ctfassets.net/syq3snmxclc9/7AqXvmHTBMFOxeGxwMBxxS/7d21477d2697da8adf980ccce52b983f/3-16-23_-_Pfizer_Docs_Watermarked.pdf.

[7] Lauren Mascarenhas, *FDA adds a warning to Covid-19 vaccines about risk of heart inflammation*, CNN, June 26, 2021, *at* https://www.cnn.com/2021/06/25/health/fda-covid-vaccine-heart-warning/index.html.

[8] *Pfizer CEO Albert Bourla discusses new vaccines in the pipeline*, CNBC, Jan. 18, 2023, 3:18 *at* https://www.cnbc.com/video/2023/01/18/pfizer-ceo-albert-bourla-discusses-new-vaccines-to-be-released.html.

[9] CDC, *Clinical Considerations: Myocarditis and Pericarditis after Receipt of mRNA COVID-19 Vaccines Among Adolescents and Young Adults*, archived from January 18, 2023, *at* https://web.archive.org/web/20230118015839/https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html.

[10] Ben Leonard and Lauren Gardner, *CDC, FDA see possible link between Pfizer's bivalent shot and strokes*, Politico, Jan. 13, 2023, *at* https://www.politico.com/news/2023/01/13/cdc-fda-pfizer-bivalent-vaccine-possible-strokes-00077933.

[11] 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. https://tidsskriftet.no/en/2021/05/originalartikkel/nursing-home-deaths-after-covid-19-vaccination.

privileged, non-work product records and documents in the possession, custody or control of Pfizer that relate to Pfizer's compliance with each provision" of the consent judgments. Celebrex Consent Judgment, ¶ 36; Lyrica Consent Judgment, ¶ 6.2; Rapamune Consent Judgment, ¶ 6.2. In addition to the review provided by these consent judgments, the Kansas Attorney General has the right to request these records under Kansas law. K.S.A. 50-631.

Pursuant to the authority provided by the consent judgments and Kansas law, please provide, or make available for inspection and copying, the following documents within 30 days, by May 23, 2024:

1. All emails to or from Pfizer's communications team relating to the April 1, 2021 press release before the press release was issued.

2. All emails between Pfizer personnel and the CDC or FDA relating to Pfizer's "5.3.6 Cumulative Analysis of Post-Authorization Adverse Event Reports of PF-07302048 (BNT162B2) Received Through 28-Feb-2021."

3. All emails received by Pfizer personnel from a CDC or FDA email address between December 1, 2020 and October 1, 2021 containing "myocarditis" or "pericarditis."

4. All emails Pfizer personnel sent in 2021 or 2022 to a CDC or FDA email address containing the words "safety signal" or "safety signals."

Requests #2, #3, and #4 are intended to encompass emails between those Pfizer personnel and CDC and/or FDA personnel communicating about Pfizer's COVID-19 vaccine, and not emails sent or received by rank-and-file Pfizer employees that contain search terms.

B. False, Misleading, or Deceptive Efficacy Claims

Pfizer appears to have made, or caused to be made, numerous claims about its COVID-19 vaccine's efficacy that are false, misleading, or deceptive. The examples provided below are illustrative and are not intended to be an exhaustive list of all efficacy statements.

1. "Prevent." On November 9, 2020, when Pfizer issued a press release to promote its vaccine Phase 3 trial results, Pfizer CEO Dr. Bourla said, "The first set of results from our Phase 3 COVID-19 vaccine trial provides the initial evidence of our vaccine's ability to prevent COVID-19."[12] Dr. Bourla further claimed, "With today's news, we are a significant step closer to providing people around the world with a much-needed breakthrough to help bring an end to this global health crisis."[13] However, as the FDA found when it reviewed Pfizer's results, "[a]s the interim and the final analyses have a limited length of follow-up, it is not possible to assess sustained efficacy over a period longer than 2 months."[14] The

[12] *Pfizer and BioNTech Announce Vaccine Candidate Against COVID-19 Achieved Success in First Interim Analysis from Phase 3 Study*, Pfizer, Nov. 9, 2020, *at* https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-announce-vaccine-candidate-against.
[13] *Id.*
[14] FDA, Emergency Use Authorization (EUA) for an Unapproved Product Review Memorandum, Dec. 11, 2020, 49, *at* https://www.fda.gov/media/144416/download.

FDA also found that "[a]dditional evaluations including data from clinical trials and from vaccine use post-authorization will be needed to assess the effect of the vaccine in preventing virus shedding and transmission, in particular in individuals with asymptomatic infection."[15]

2. "Highly effective with 91.3% vaccine efficacy." 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.[16] 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."[17] However, at that time, Pfizer possessed data showing that more than four months after the second dose of Pfizer's COVID-19 vaccine, the efficacy rate was 83.7%.[18] Blood samples collected six months after the second dose indicated that effectiveness continued to wane.[19] Pfizer did not publicly disclose that effectiveness waned to 83.7% until July 28, 2021, in a Pfizer preprint study.[20]

3. Variants. On February 25, 2021, Pfizer CEO Dr. Bourla said data suggested that individuals fully vaccinated with Pfizer's COVID-19 were protected against any variant currently known, including the South African, Brazilian, and UK variants.[21] 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."[22] In fact, Pfizer's COVID-19 vaccine was ineffective against variants. For example, government officials and researchers found that Pfizer's COVID-19 vaccine was just 53% to 64% effective against the Delta variant.[23]

Based on the contradictions between Pfizer's public statements and internal reports, it appears that Pfizer made false, misleading, or deceptive claims about its COVID-19 vaccine's efficacy in violation of its consent judgments with the State of Kansas.

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[15] *Id.* at 51.
[16] *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, *at* https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-confirm-high-efficacy-and-no-serious.
[17] *Id.*
[18] *2.7.3 Summary of Clinical Efficacy*, approved on Apr. 30, 2021, at 38, *at* https://clinical-information.canada.ca/ci-rc-vu.pdf?file=m2/27-clin-sum/summary-clin-efficacy-covid19-1.pdf&id=252736.
[19] *Id.* at 169, 171.
[20] Alexa Lardieri, *Pfizer Vaccine Protection Declines After Six Months, Boosters Protect Against Delta Variant*, U.S. NEWS & WORLD REPORT, July 28, 2021, *at* https://www.usnews.com/news/health-news/articles/2021-07-28/pfizer-vaccine-protection-declines-after-six-months-boosters-protect-against-delta-variant.
[21] *Exclusive interview with Pfizer CEO Albert Bourla*, NBC News (Feb. 25, 2021), at 0:15 *at* https://www.nbcnews.com/nightly-news/video/exclusive-interview-with-pfizer-ceo-albert-bourla-101605957789.
[22] Berkeley Lovelace Jr., *Pfizer Covid shot protects people form hospitalization even as effectiveness against infection falls, Lancet study confirms*, CNBC (Oct. 4, 2021), *at* https://www.cnbc.com/2021/10/04/pfizer-covid-vaccine-protection-against-infection-tumbles-to-47percent-study-confirms.html.
[23] *Id.*; Dov Lieber, *Pfizer Vaccine Less Effective Against Delta Infections but Prevents Severe Illness, Israeli Data Show*, THE WALL STREET JOURNAL (July 6, 2021), *at* https://www.wsj.com/articles/pfizers-covid-19-vaccine-is-less-effective-against-delta-variant-israeli-data-show-11625572796.

Pursuant to the authority provided by consent judgments and Kansas law,[24] please provide, or make available for inspection and copying, the following documents within 30 days, by May 23, 2024:

1. All emails to or from Pfizer's communications team relating to the July 28, 2021 preprint study before the study was released.

2. All emails between Pfizer personnel and the CDC or FDA relating to Pfizer's "2.7.3 Summary of Clinical Efficacy."

3. All data Pfizer CEO Dr. Bourla relied on for his February 25, 2021 statement that Pfizer's COVID-19 vaccine protected against any variant currently known.

C. False, Misleading, or Deceptive Transmission Claims

Pfizer appears to have made, or caused to be made, numerous claims about its COVID-19 vaccine's effect on transmission that are false, misleading, or deceptive. The examples provided below are illustrative and are not intended to be an exhaustive list of all efficacy statements.

Pfizer CEO Dr. Bourla repeatedly represented to the American people that Pfizer's COVID-19 vaccine prevented transmission because the lives of loved ones were in jeopardy without it.

- Pfizer's CEO Dr. Bourla told the American people on December 14, 2020, that not receiving a COVID-19 vaccine would affect the lives of those around them: "[T]his 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. So, I think, trust science."[25]

- In January 2021, Pfizer CEO Dr. Bourla repeated his warning to Americans that not receiving a COVID-19 vaccine would affect the lives of those around them: "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."[26]

- Pfizer CEO Dr. Bourla continued this warning in 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

[24] Celebrex Consent Judgment, ¶ 36; Lyrica Consent Judgment, ¶ 6.2; Rapamune Consent Judgment, ¶ 6.2; K.S.A. 50-631.

[25] *CNBC Transcript: Pfizer Chairman and CEO Albert Bourla Speaks with CNBC's 'Squawk Box' Today*, CNBC (Dec. 14, 2020), *at* https://www.cnbc.com/2020/12/14/cnbc-transcript-pfizer-chairman-and-ceo-albert-bourla-speaks-with-cnbcs-squawk-box-today.html.

[26] John Micklethwait, *Pfizer CEO Says Science Will Prevail with Covid-19 Here to Stay*, BLOOMBERG, Jan. 28, 2021, *at* https://www.bloomberg.com/news/features/2021-01-28/covid-is-here-to-stay-pfizer-ceo-albert-bourla.

> 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."[27]

However, evaluating transmission was not an objective of Pfizer's COVID-19 trial protocol.[28]

Based on the contradictions between Pfizer's public statements and its trial protocol, it appears that Pfizer made false, misleading, or deceptive claims about its COVID-19 vaccine's effect on transmission in violation of the consent judgments with the State of Kansas.

Pursuant to the authority provided by consent judgments and Kansas law,[29] please provide, or make available for inspection and copying, the following documents within 30 days, by May 23, 2024:

1. All data Pfizer CEO Dr. Bourla relied on for his statements that not receiving Pfizer's COVID-19 vaccine would affect the lives of loved ones.

2. All emails between Pfizer personnel and the CDC, FDA, or White House from January 1, 2021 to October 1, 2021 relating to Pfizer's COVID-19 vaccine effect on transmission.

D. False, Misleading, or Deceptive Misinformation Claims

Pfizer appears to have coordinated directly and indirectly with social media platforms to remove information that was critical of Pfizer's COVID-19 vaccine.[30]

Pfizer's efforts to suppress and conceal material facts relating to its COVID-19 vaccine raise concerns that Pfizer made false, misleading, or deceptive claims about its COVID-19 vaccine in violation of the consent judgments with the State of Kansas. Pursuant to the authority provided by consent judgments and Kansas law,[31] please provide, or make available for inspection and copying, the following documents within 30 days, by May 23, 2024:

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[27] *Pfizer's Albert Bourla on how the pandemic ends*, ATLANTIC COUNCIL, Nov. 9, 2021, *at* https://www.atlanticcouncil.org/blogs/new-atlanticist/pfizers-albert-bourla-on-how-the-pandemic-ends/.
[28] Final C4591001 Protocol, "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," Pfizer, Apr. 15, 2020, 1 (PDF p. 3), *at* https://www.nejm.org/doi/suppl/10.1056/NEJMoa2027906/suppl_file/nejmoa2027906_protocol.pdf; 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," Pfizer, Sept. 8, 2020 ("Sept. 2020 Protocol"), 1 (PDF p. 129), *at* https://www.nejm.org/doi/suppl/10.1056/NEJMoa2027906/suppl_file/nejmoa2027906_protocol.pdf.
[29] Celebrex Consent Judgment, ¶ 36; Lyrica Consent Judgment, ¶ 6.2; Rapamune Consent Judgment, ¶ 6.2; K.S.A. 50-631.
[30] *See, e.g.*, Alex Berenson, *From the Twitter Files: Pfizer board member Scott Gottlieb secretly pressed Twitter to hide posts challenging his company's massively profitable Covid jabs*, SUBSTACK, Jan. 9, 2023, *at* https://alexberenson.substack.com/p/from-the-twitter-files-pfizer-board.
[31] Celebrex Consent Judgment, ¶ 36; Lyrica Consent Judgment, ¶ 6.2; Rapamune Consent Judgment, ¶ 6.2; K.S.A. 50-631.

1. All documents and information provided by Pfizer to the United States House of Representatives Committee on the Judiciary in response to its July 18, 2023 request and any subsequent requests.[32]

2. All emails between Pfizer personnel and The Virality Project, including but not limited to Stanford Internet Observatory, the University of Washington's Center for an Informed Public, the Atlantic Council's Digital Forensic Research Lab, Graphika, the National Conference on Citizenship's Algorithmic Transparency Institute, and New York University's Center for Social Media and Politics and Tandon School of Engineering.

3. All emails between Pfizer and the Biotechnology Innovation Organization or the Public Good Project relating to the Public Good Project's "Stronger" campaign.

II. Inadequate study claims

As agreed in its consent judgment with Kansas, Pfizer's public communications about clinical study information must:

> (a) accurately reflect the methodology 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.

Celebrex Consent Judgment, ¶ 10.

In addition, Pfizer's public communications about clinical study information must 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.

[32] Letter from U.S. House Judiciary Chairman Jim Jordan to Pfizer's Dr. Albert Bourla, July 18, 2023, *at* https://judiciary.house.gov/sites/evo-subsites/republicans-judiciary.house.gov/files/evo-media-document/2023-07-18-jdj-to-bourla-pfizer.pdf.

Pfizer appears to have made, or caused to be made, numerous claims about its COVID-19 vaccine's safety and effectiveness that are false, misleading, or deceptive and that violate these consent judgment provisions. The examples provided below are illustrative and are not intended to be an exhaustive list of all efficacy statements.

1. Pfizer excluded from its COVID-19 vaccine trials any individual with a medical or psychiatric condition that "may increase the risk of study participation or, in the investigator's judgment, make the participant inappropriate for the study;"[33] any individual with a history of severe adverse reaction to vaccines;[34] any individual who had been diagnosed with COVID-19;[35] any immunocompromised individual;[36] and any woman who was pregnant or breastfeeding.[37]

2. When Pfizer sought approval for a third shot 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.[38] Pfizer did not test the booster on any participant older than 85 years old.

Pfizer's representations that its COVID-19 vaccine was safe and effective for the general public violated its disclosure obligations under the consent judgment.

* * *

The State of Kansas looks forward to Pfizer providing the documents requested within 30 days and a good-faith written response to the issues raised in this letter within 30 days. The State of Kansas reserves its rights to take any necessary enforcement action.

[33] Sept. 2020 Protocol, at 37 (PDF p. 165), ¶ 5.2.1.
[34] *Id.* at 37 (PDF p. 165), ¶ 5.2.3.
[35] *Id.* at 37 (PDF p. 165), ¶ 5.2.5.
[36] *Id.* at 38 (PDF p. 166), ¶ 5.2.8.
[37] *Id.* at 38 (PDF p. 166), ¶ 5.2.11.
[38] 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, *at* https://www.fda.gov/media/152176/download.

Sincerely,

Frances R. Oleen
Frances R. Oleen
Deputy Attorney General
Public Protection Division

Kaley Schrader
Kaley Schrader
Assistant Attorney General
Consumer Protection Section

Exhibit C

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May 22, 2024
VIA E-MAIL

CONFIDENTIAL TREATMENT REQUESTED BY PFIZER INC
EXEMPT UNDER THE KANSAS OPEN RECORDS ACT

Frances R. Oleen
Kaley Schrader
State of Kansas Office of the Attorney General
120 SW 10th Avenue, 2nd Floor
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Re: Notice of Consent Judgment Violations

Dear Mss. Oleen and Schrader:

On behalf of our client, Pfizer Inc. ("Pfizer" or "the Company"), we write in response to your April 22, 2024 letter notifying Pfizer about alleged consent judgment violations. Pfizer hereby provides this good faith written response as requested in your letter.

Your letter alleges that Pfizer has made false, misleading, or deceptive claims regarding the Company's COVID-19 vaccine, as well as worked with social media platforms to suppress and conceal material facts about the vaccine, in violation of historical consent judgments relating to Celebrex (2008), Lyrica (2012), and Rapamune (2014). The Company disputes that these consent judgments apply to the COVID-19 vaccine and denies your allegations in the strongest possible terms.

The Company's public statements were consistent with and, in some cases, identical to the consensus view of global public health authorities. Among these are the U.S. Food & Drug Administration ("FDA"), which continues to endorse the safety and efficacy of the COVID-19 vaccine based on the totality of the scientific evidence, and the U.S. Centers for Disease Control and Prevention ("CDC"), which continues to recommend COVID-19 vaccinations for individuals aged 6 months and older to this very day. Your letter suggests the Kansas Attorney General's Office disagrees with FDA and CDC on these critical public health matters. Your Office may take a different view about the vaccine than federal regulatory authorities, but such disagreement does not create a violation of the consent judgments, nor does it render Pfizer's past statements about the vaccine false, misleading, or deceptive.

In our view, your letter draws incorrect conclusions about Pfizer's public statements as well as the overall safety and efficacy of the COVID-19 vaccine, and it takes words and phrases from Pfizer's voluminous public statements about the COVID-19 vaccine out of context. Pfizer stands behind its public statements concerning the safety and efficacy of the vaccine—including the specific statements identified in your letter—which were truthful, accurate, and non-misleading.

FACTUAL BACKGROUND

CDC issued its first publication identifying SARS-CoV-2, the novel coronavirus that causes the infectious disease now known as COVID-19, on January 10, 2020. Due to the rapid spread of this deadly, previously unknown virus, the World Health Organization declared COVID-19 a pandemic on March 11, 2020. Two days later, President Donald Trump declared COVID-19 a national emergency in the United States.

In the early months of the pandemic, there was no vaccine to protect against COVID-19. To address this urgent and unmet need, the Trump Administration launched Operation Warp Speed on May 15, 2020. Because large numbers of people were getting sick and dying from COVID-19, the federal government "refused to accept business-as-usual timelines for vaccines and other essential tools" and pledged, in collaboration with private industry, to "squeeze every last inefficiency out of the process and pour every resource" into an unprecedented effort to produce, among other things, hundreds of millions of doses of COVID-19 vaccines by January 2021.[1] This was an audacious, but necessary, goal; at the time, potential vaccine candidates, including Pfizer's, were still in the early phases of clinical development, and their prospects were uncertain.

In connection with Operation Warp Speed, FDA issued guidance to industry in June 2020 concerning the agency's expectations before it would consider licensing any COVID-19 vaccine candidate, including for Emergency Use Authorization ("EUA").[2, 3] "FDA would expect that a COVID-19 vaccine would prevent disease or decrease its severity in at least 50% of people who are vaccinated" before the agency would issue an EUA.

On July 27, 2020, Pfizer and its partner, BioNTech, launched the pivotal study that led to the current established efficacy and safety of the vaccine. This was a placebo-controlled, randomized, observer-blind study to evaluate the safety, tolerability, immunogenicity, and efficacy of the Pfizer-BioNTech vaccine against COVID-19 in healthy individuals.[4] Approximately 40,000 participants were enrolled in the study at 153 clinical research sites. Under Pfizer's clinical trial protocol, about half of the participants received two

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

[2] U.S. Dept. of Health & Human Servs., Food & Drug Admin., Coronavirus (COVID-19) Update: FDA Takes Action to Help Facilitate Timely Development of Safe, Effective COVID-19 Vaccines, June 30, 2020, https://tinyurl.com/znavfbfp.

[3] U.S. Dept. of Health & Human Servs., Food & Drug Admin., Emergency Use Authorization for Vaccines to Prevent COVID-19 Guidance for Industry, Mar. 31, 2022, https://tinyurl.com/mrxhdwhu (referencing guidance from June 2020).

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

doses of the vaccine, with 21 days between each dose, and the remaining participants received placebo injections on the same schedule.

Pfizer and BioNTech announced initial results from the pivotal study, which showed a two-dose regimen of the vaccine demonstrated an efficacy rate above 90 percent from seven days after the second dose, in November 2020. Based on the results of the study, Pfizer and BioNTech asked FDA to authorize the vaccine for emergency use in individuals 16 years of age and older, and FDA issued the EUA on December 11, 2020.[5] President Trump called this authorization "really good news" and issued the following statement: "Today, our nation achieved a medical miracle. We have delivered a safe and effective vaccine in just nine months. It is one of the greatest scientific accomplishments in history. It will save millions of lives and soon end the pandemic once and for all."[6]

Immediately after receiving the EUA, Pfizer started shipping the first batches of the vaccine to the U.S. government, which had previously contracted to purchase 100 million doses of the vaccine upon FDA authorization or approval.[7] The government opted to provide the vaccine to the public for free, and the first doses of the vaccine were administered in the U.S. outside of the clinical trial setting on December 14, 2020.[8]

FDA has since issued additional EUAs for use of the Pfizer-BioNTech COVID-19 Vaccine in different age groups and for booster doses, and FDA approved the vaccine, now known by the brand name "Comirnaty," for individuals ages 16 and older on August 23, 2021.[9] The agency has since expanded Comirnaty's approval for adolescents 12 to 15 years of age.[10]

FDA has consistently expressed confidence in the safety and efficacy of the Pfizer-BioNTech vaccine in the face of politically motivated attacks. For example, FDA issued multiple letters to the Florida Department

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

[6] Anne Flaherty, et al., *FDA Authorizes 1st COVID-19 Vaccine in United States*, GOODMORNINGAMERICA.COM, Dec. 11, 2020, https://tinyurl.com/mr2hz895.

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

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

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

[10] Pfizer Press Release, Pfizer and BioNTech Announce U.S. FDA Approval of their COVID-19 Vaccine Comirnaty For Adolescents 12 through 15 Years of Age, July 8, 2022, https://tinyurl.com/2vajxc9p.

of Health, most recently stating: "We stand firmly behind our regulatory decision making with the authorizations and approvals of the COVID-19 vaccines, which have a highly favorable safety profile, and which have saved, and continue to save, many lives."[11] In the same letter, FDA cautioned that "the challenge we continue to face is the ongoing proliferation of misinformation and disinformation about these vaccines which results in vaccine hesitancy," "lowers vaccine uptake," and "contribut[es] to the continued death and serious illness toll of COVID-19."

The Justice Department recently summarized the federal government's current position on the Pfizer and BioNTech COVID-19 vaccine, and vaccination in general, as follows:

> FDA has had continued access—as the information has become available—to the Pfizer COVID-19 vaccine clinical trial protocol and results, reported adverse event data and scientific research[.] . . . As recently as January 5, 2024, FDA Commissioner Robert Califf, MD and Director of FDA's Center for Biologics Evaluation and Research, Peter Marks, MD, Ph.D., published an editorial in the Journal of the American Medical Association reiterating the importance of vaccination, including vaccination to protect against COVID-19. They noted "contrary to a wealth of misinformation available on social media and the internet, data from various studies indicate that since the beginning of the COVID-19 pandemic tens of millions of lives [worldwide] were saved by vaccination."[12]

On a similar note, in February of this year, Dr. Marks testified before Congress that "COVID-19 vaccines have been shown to be safe. COVID-19 vaccines have been shown to be effective. They are supported by the best available scientific data; they underwent FDA's rigorous regulatory authorization and approval processes; and their safety over time is closely monitored."[13]

RESPONSE TO ALLEGATIONS

Your April 22, 2024 letter alleges that Pfizer appears to have made numerous claims about the Company's COVID-19 vaccine that are false, misleading, or deceptive. The primary focus of your letter is certain Pfizer press releases and other public statements that include references to the vaccine's safety profile. In particular, your letter suggests that Pfizer and BioNTech's COVID-19 vaccine is not safe because of alleged

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

[12] U.S. Motion to Intervene and to Dismiss Pursuant to 31 U.S.C. § 3730(c)(2)(A), *United States ex rel. Jackson v. Ventavia Rsch. Grp., LLC*, Case No. 1:21-cv-00008, Dkt. 137 at 7–8 (E.D. Tex.) (quoting Peter Marks & Robert, Califf, *Is Vaccination Approaching a Dangerous Tipping Point?*, JAMA, Jan. 5, 2024, https://tinyurl.com/55x693u7).

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

adverse event reports concerning (1) cardiovascular events like strokes, (2) myocarditis and pericarditis, and (3) adverse pregnancy outcomes.

The statements identified in your letter, when read in context and in light of the totality of scientific evidence available at the time, were truthful and non-misleading. Moreover, the identified statements are consistent with the letter and spirit of FDA's authorizations and approval of Pfizer and BioNTech's COVID-19 vaccine, as well as CDC's recommendations to the American people concerning vaccination against COVID-19. As such, the challenged statements cannot be considered false, misleading, or deceptive.

Cardiovascular Events

To challenge the vaccine's safety, your letter points to historical information about case reports containing hundreds of thousands of adverse events allegedly experienced by individuals who received Pfizer and BioNTech's COVID-19 vaccine, including some reports of cardiovascular events like strokes in people aged 65 and over. This statement and others like it in your letter are highly misleading. FDA and CDCrecently explained why in a communication to the Florida Surgeon General:[14]

- "The [FDA] and the [CDC] continue to diligently monitor a variety of data sources to identify any potential risks of the vaccines and to ensure that information is available to the public. That said, focusing on adverse events in the absence of causal association and without the perspective of countervailing benefits is a great disservice to both individuals and public health. Like every other medical intervention, there are adverse effects from vaccination. Serious adverse events from COVID-19 vaccines are rare and are far outweighed by the benefits of these vaccines for every age group."

- "***The claim that the increase of [] reports of life-threatening conditions reported from Florida and elsewhere represents an increase of risk caused by the COVID-19 vaccines is incorrect, misleading and could be harmful to the American public***. The FDA-approved and FDA-authorized COVID-19 vaccines have met FDA's rigorous scientific and regulatory standards for safety and effectiveness and these vaccines continue to be recommended for use by CDC for all people six months of age and older. Both FDA and CDC have continued to collect outcome data from multiple sources that demonstrate the clear benefit of COVID-19 vaccines in preventing death, serious illness, and hospitalization from SARS-CoV-2 infection, along with indicating a modest benefit in the prevention of infection and transmission that wanes over time, even as new variants have emerged. Additional benefits include a reduced risk of known complications from

[14] U.S. Ctrs. for Disease Control and Prevention, FDA and CDC Response to the Florida Surgeon General, Mar. 10, 2023, https://tinyurl.com/5n8tck2f (emphasis added).

SARS-CoV-2 infection, including post-COVID conditions, COVID-19-associated stroke and heart disease, and COVID-19-induced venous thromboembolism."

- "***Reports of adverse events . . . following vaccination do not mean that a vaccine caused the event***. Since December 2020, almost 270 million people have received more than 670 million doses of COVID-19 vaccines in the U.S., with over 50 million people having received the updated bivalent vaccine. The [EUAs] for the COVID-19 Vaccines require sponsors and vaccine providers to report certain adverse events through VAERS,[15] so more reports should be expected. Recent concerns about increased reports of cardiovascular events provide an instructive example of the need to do further analysis when increased reporting of an event occurs. ***Despite increased reports of these events, when the concern was examined in detail by cardiovascular experts, the risk of stroke and heart attack was actually lower in people who had been vaccinated, not higher***."

- "Adverse events must be compared to background rates in the population. . . . Based on available information for the COVID-19 vaccines that are authorized or approved in the United States, the known and potential benefits of these vaccines clearly outweigh their known and potential risks. Additionally, not only is there no evidence of increased risk of death following mRNA vaccines, but available data have shown quite the opposite: that being up to date on vaccinations saves lives compared to individuals who did not get vaccinated. ***Multiple well conducted, peer-reviewed, published studies . . . demonstrate that the risk of death, serious illness and hospitalization is higher for unvaccinated individuals for every age group***."

- "Because we are not the only country in the world using COVID-19 vaccines, we also benefit from the experience of other countries. More than 13 billion doses of COVID-19 vaccines have been given around the world, including hundreds of millions of doses of mRNA vaccines and hundreds of millions of doses to children. Consistent with our data, these multiple international partners have robust monitoring for both safety and effectiveness. They find little evidence of widespread adverse events, also detect rare events as we do, and conclude that the benefits of the vaccines generally far outstrip their risks."

Myocarditis and Pericarditis

Two of the rare events detected among individuals who received Pfizer's vaccine are myocarditis and pericarditis, predominantly in male adolescents and young adults. Your letter's suggestion that Pfizer has downplayed or concealed these issues is false. The Company has been fully transparent regarding adverse event reports concerning individuals who have received Pfizer's vaccine and, when public health authorities

[15] U.S. Ctrs. for Disease Control and Prevention, Vaccine Adverse Event Reporting System (VAERS), Oct. 19, 2023, https://tinyurl.com/3wdb623h.

noted a likely association in June 2021, Pfizer immediately revised the patient and provider fact sheets for the Pfizer-BioNTech COVID-19 Vaccine regarding the suggested increased risks of myocarditis and pericarditis following vaccination.

These safety risks continue to be prominently disclosed, including in the vaccine's current FDA-approved labeling, which provides: "Postmarketing data demonstrate increased risks of myocarditis and pericarditis, particularly within 7 days following the second dose. The observed risk is higher among males under 40 years of age than among females and older males. The observed risk is highest in males 12 through 17 years of age. Although some cases required intensive care support, available data from short-term follow-up suggest that most individuals have had resolution of symptoms with conservative management. Information is not yet available about potential long-term sequelae."[16]

While there is an increased risk of myocarditis for individuals who receive Pfizer's vaccine, there are data showing the overall risk of myocarditis is substantially higher immediately after being infected with the virus that causes COVID-19 than it is in the weeks following vaccination.[17] In other words, the risk of myocarditis from being infected by COVID-19 is far greater than the risk of myocarditis from receiving the vaccine. And, despite the warnings about myocarditis and pericarditis, CDC continues to recommend COVID-19 vaccinations, including Pfizer's vaccine, for individuals aged 6 months and older.[18]

Pregnancy and Fertility

CDC's recommendation explicitly extends to people who are pregnant, breastfeeding, trying to get pregnant now, or who might become pregnant in the future. The agency's website, which was last updated on March 8, 2024, is unequivocal: "COVID-19 vaccination during pregnancy is safe and effective," and "COVID-19 vaccines are not associated with fertility problems in women or men."[19] The same website provides that people who are pregnant or who were recently pregnant are: (1) "[m]ore likely to get very sick from COVID-19 compared to those who are not pregnant;" (2) "[m]ore likely to need hospitalization, intensive care, or the use of a ventilator or special equipment to breathe if [they] do get sick from COVID-19;" and (3) "[a]t

[16] Comirnaty Prescribing Information, https://tinyurl.com/5xmf8kck (last revised Oct. 2023).

[17] Hannah Rosenblum, M.D., Pfizer-BioNTech COVID-19 Vaccine and Myocarditis in Individuals Aged 16-29 Years: Benefits-Risk Discussion, Aug. 30, 2021, https://tinyurl.com/3zhkvfs2 (presentation to CDC's Advisory Committee on Immunization Practices stating the "[r]isk of myocarditis in individuals post-SARS-CoV-2 infection was 6-34 times higher compared to those who received mRNA vaccine").

[18] U.S. Ctrs. for Disease Control and Prevention, Myocarditis and Pericarditis After mRNA COVID-19 Vaccination, https://tinyurl.com/3tywzane (last updated Nov. 3, 2023).

[19] U.S. Ctrs. for Disease Control and Prevention, COVID-19 Vaccines While Pregnant or Breastfeeding, https://tinyurl.com/56uyfkmt (last updated Mar. 8, 2024).

increased risk of complications that can affect [their] pregnancy and baby including preterm birth or stillbirth."

The FDA-approved labeling for Pfizer and BioNTech's COVID-19 vaccine also states that a "developmental toxicity study has been performed in female rats administered the equivalent of a single human dose of Comirnaty . . . on 4 occasions" and the study "revealed no evidence of harm to the fetus due to the vaccine."[20]

The CDC website includes citations to "studies including hundreds of thousands of people around the world" showing that "COVID-19 vaccination before and during pregnancy is safe, effective, and beneficial to both the pregnant person and the baby." Per CDC, the cited studies establish that it is "safe to receive an mRNA COVID-19 vaccine (Moderna or Pfizer-BioNTech), before and during pregnancy" and these vaccines in particular "show no increased risk for complications like miscarriage, preterm delivery, stillbirth, or birth defects."

CDC's recommendations align with those from professional medical organizations including the American College of Obstetricians and Gynecologists,[21] the Society for Maternal Fetal Medicine,[22] and the American Society for Reproductive Medicine.[23] This expert consensus, along with the totality of the scientific evidence developed since the pandemic's onset, stand in stark contrast to your Office's unsupported suggestion that the vaccine is associated with "adverse pregnancy outcomes."

DOCUMENT REQUESTS

Your letter not only alleges that Pfizer violated the historical consent judgments, but also requests fourteen exceptionally broad categories of documents pursuant to Paragraph 36 of the Celebrex consent judgment, Paragraph 6.2 of the Lyrica consent judgment, and Paragraph 6.2 of the Rapamune consent judgment. These document requests are premature under the plain text of the consent judgments.

The Celebrex consent judgment, for example, states that the Attorney General's right of "reasonable access" to Pfizer's "relevant, non-privileged, non-work product records and documents" only attaches "[u]pon giving Pfizer thirty (30) days to respond" to the State's "written notice" of potential consent judgment violations. *See* Celebrex consent judgment, ¶¶ 35 & 36. The other consent judgments are substantially

[20] *See supra* n.16.

[21] Am. College of Obstetricians and Gynecologists, COVID-19 Vaccination Considerations for Obstetric–Gynecologic Care, Sept. 25, 2023, https://tinyurl.com/mpvr4pd4.

[22] Soc'y for Maternal Fetal Med., COVID-19 Vaccination in Pregnancy, Sept. 14, 2023, https://tinyurl.com/bp6cxtsr.

[23] Am. Society for Reproductive Med., Patient Management and Clinical Recommendations During the Coronavirus (COVID-19) Pandemic, Apr. 20, 2022, https://tinyurl.com/3vv539jw.

identical on this score. *See* Lyrica consent judgment, ¶¶ 6.1 & 6.2; Rapamune consent judgment, ¶¶ 6.1 & 6.2.

As previously stated, we do not believe the consent judgments apply to issues concerning the vaccine, but even if the consent judgments did apply, your requests for Pfizer's confidential documents are premature. If, after reviewing this letter, you continue to believe that review of documents would be helpful to your review, we would be happy to meet and confer with your Office about appropriate next steps.

We look forward to discussing these issues with you further. Please do not hesitate to contact me.

* * *

Pfizer believes that this letter is protected from disclosure under the Kansas Open Records Act, K.S.A. 45-215, *et. seq*. Pfizer hereby requests that your Office, department, and all constituent agencies withhold any records or other material, including but not limited to this letter, containing or disclosing confidential commercial information, or law enforcement or investigative files, that relate to or reference Pfizer, under applicable exemptions or other provisions of the Kansas Open Records Act, and any other relevant statute or regulation. We further request that, if your Office believes disclosure is authorized by applicable law, it alert the recipient that the confidentiality of the information must be maintained.

We also hereby request that your Office, department, and all constituent agencies provide notice to us of any public records request for, or intended disclosure of, this letter. Pfizer also requests that your Office provide reasonably prompt notice to Pfizer, through its undersigned counsel, of any request by a third party for discovery of any part of this letter or of any proposal or apparent intention by a third party or your Office to enter any part of this letter in the public record, such notice to be provided reasonably in advance of satisfying any such discovery request or, to the extent possible, of any such entry in the public record, to enable Pfizer to seek confidential treatment of this letter or to seek relief in an appropriate court. Pfizer does not intend anything in this letter to affect any legal rights Pfizer may have to seek, in any proceeding in which your Office is a party, a protective order limiting dissemination of this letter by or to any third parties.

Very truly yours,

Carl Wessel
DLA Piper LLP (US)

Milton Marquis
Cozen O'Connor

Exhibit D

Meghan E. Stoppel, #23685
Assistant Attorney General
Office of the Kansas Attorney General
120 SW 10th Avenue, 2nd Floor
Topeka, Kansas 66612
(785) 296-3751

IN THE DISTRICT COURT OF SHAWNEE COUNTY, KANSAS
Division 10

STATE OF KANSAS, *ex rel.*
DEREK SCHMIDT, Attorney General,

Plaintiff,

v.

PFIZER INC,

Defendant.

Case No. 12C1339

(Pursuant to K.S.A. Chapter 60)

JOURNAL ENTRY OF CONSENT JUDGMENT

NOW on this 13th day of December, 2012, Plaintiff's Journal Entry of Consent Judgment comes before the Court pursuant to K.S.A. 50-632(b). The Plaintiff, State of Kansas, *ex rel.* Derek Schmidt, Attorney General, appears by and through Meghan E. Stoppel, Assistant Attorney General. Defendant Pfizer Inc (hereinafter "Pfizer") appears by and through the undersigned counsel.

WHEREUPON the parties advise the Court that they have stipulated and agreed to the following:

PARTIES, JURISDICTION AND VENUE

1. Derek Schmidt is the duly elected, qualified and acting Attorney General for the State of Kansas.

2. The Attorney General's authority to bring this action is derived from the statutory and common law of the State of Kansas, specifically the Kansas Consumer Protection Act, K.S.A. 50-623 *et seq.*

3. At all times relevant hereto, Pfizer engaged in "consumer transactions" in Kansas, as defined by K.S.A. 50-624(c).

4. Venue is proper under K.S.A. 50-638 in the Third Judicial District of Kansas (Shawnee County).

IT IS HEREBY ORDERED THAT:

1. FINDINGS

1.1 This Court has jurisdiction over the subject matter of this lawsuit and over all Parties, pursuant to the Kansas Consumer Protection Act, K.S.A. 50-623 *et seq.*

1.2 The terms of this Judgment shall be governed by the laws of the State of Kansas.

1.3 Entry of this Judgment is in the public interest and reflects a negotiated agreement among the Parties.

1.4 The Parties have agreed to resolve the issues resulting from the Covered Conduct involving the prescription drugs Zyvox® and Lyrica® by entering into this Judgment.

1.5 Pfizer is willing to enter into this Judgment regarding the Covered Conduct in order to resolve the Attorneys General's concerns under the State Consumer Protection Laws as to the matters addressed in this Judgment and thereby avoid significant expense, inconvenience, and uncertainty.

1.6 The Parties have agreed to resolve the issues raised by the Covered Conduct by entering into this Judgment.[1]

A. Pfizer is entering into this Judgment solely for the purpose of settlement, and nothing contained herein may be taken as or construed to be an admission or concession of any violation of law, rule, or regulation, or of any other matter of fact or law, or of any liability or wrongdoing, all of which Pfizer expressly denies. Pfizer does not admit any violation of the State Consumer Protection Laws set forth in footnote 3, and does not admit any wrongdoing that was or could have been alleged by any Attorney General before the date of the Judgment under those laws. No part of this Judgment, including its statements and commitments, shall constitute evidence of any liability, fault, or wrongdoing by Pfizer. This document and its contents are not intended for use by any third party for any purpose, including submission to any court for any purpose.

B. This Judgment shall not be construed or used as a waiver or limitation of any defense otherwise available to Pfizer in any action, or of Pfizer's right to defend itself from, or make any arguments in, any private individual, regulatory, governmental, or class claims or suits relating to the subject matter or terms of this Judgment. This Judgment is made without trial or adjudication of any issue of fact or law or finding of liability of any kind. Notwithstanding the foregoing, a State may file an action to enforce the terms of this Judgment.

C. It is the intent of the Parties that this Judgment not be admissible in other cases or binding on Pfizer in any respect other than in connection with the enforcement of this Judgment.

[1] This agreement is entered into pursuant to and subject to the State Consumer Protection laws cited in footnote 3.

D. No part of this Judgment shall create a private cause of action or confer any right to any third party for violation of any federal or state statute except that a State may file an action to enforce the terms of this Judgment.

1.7 This Judgment (or any portion thereof) shall in no way be construed to prohibit Pfizer from making representations with respect to any Pfizer Product that are required under Federal law or Regulations or in Food and Drug Administration ("FDA") approved Labeling.

1.8 Nothing in this Judgment shall require Pfizer to:

(a) take any action that is prohibited by the Food, Drug and Cosmetic Act, 21 U.S.C. §301 *et seq*. ("FDCA") or any regulation promulgated thereunder, or by the FDA; or

(b) fail to take any action that is required by the FDCA or any regulation promulgated thereunder, or by the FDA. Any written or oral Promotional claim subject to this Judgment/Order which is the same, or materially the same, as the language required or agreed to by the Director of the Office of Prescription Drug Promotion, the Director of the Advertising and Promotional Labeling Branch, the Director of the Center for Drug Evaluation and Research, or the Director of the Center for Biologics Evaluation and Research, or their authorized designees in writing shall not constitute a violation of this Judgment, unless facts are or become known to Pfizer that cause the claim to be false, misleading, or deceptive.

2. DEFINITIONS

The following definitions shall be used in construing this Judgment:

2.1 "Clearly and Conspicuously" shall mean a disclosure in size, color, contrast, font, and location that is readily noticeable, readable and understandable and is presented in proximity to all information necessary to prevent it from being misleading or deceptive. A statement may

not contradict or be inconsistent with any other information with which it is presented. If a statement modifies, explains, or clarifies other information or is necessary to prevent other information from being misleading or deceptive, then the statement must be presented in close proximity to that information, in a manner that is readily noticeable, readable, and understandable, and it must not be obscured in any manner.

2.2 "Covered Conduct" shall mean Pfizer's Promotional and marketing practices, sampling practices, and dissemination of information and remuneration to HCPs regarding the prescription drugs Zyvox® and Lyrica® through the Effective Date of the Judgment.

2.3 "Effective Date" shall mean the date on which a copy of this Judgment, duly executed by Pfizer and by the Signatory Attorney General, is approved by, and becomes a Judgment of the Court.

2.4 "FDA Guidances for Industry" shall mean final documents issued by the FDA pursuant to 21 U.S.C. §371(h) that represent the FDA's current thinking on a topic.

2.5 "Health Care Professional" or "HCP" shall mean any physician or other health care practitioner, who is licensed to provide health care services or to prescribe pharmaceutical products.

2.6 "Healthcare Organization" shall mean an entity, public or private, that is intended and incentivized to tie patient care to quality metrics and value models and includes organizations such as payors, Health Maintenance Organizations (HM), Long Term Care (LTC) pharmacy providers, Pharmacy Benefit Management (PBM), Integrated Delivery Networks (IDN), Accountable Care Organizations (ACO), and hospital formulary committees.

2.7 "Labeling" shall mean all FDA-approved labels and other written, printed, or graphic matter (a) upon any article or any of its containers or wrappers, or (b) accompanying such article.

2.8 "Lyrica®" shall mean all Pfizer Products that are FDA-approved drug formulations containing pregabalin.

2.9 "Medical Information Response" shall mean a non-Promotional, scientific communication to address Unsolicited Requests for medical information from HCPs.

2.10 "Medical Outcome Specialists" shall mean Pfizer personnel who work with Healthcare Organizations that determine the drugs to be placed on a formulary.

2.11 "Multistate Executive Committee" shall mean the Attorneys General and their staffs representing Arizona, Illinois, Maryland, New Jersey, Pennsylvania, South Carolina, and Texas.

2.12 "Multistate Working Group" shall mean the Attorneys General and their staff representing Alabama, Arizona, Arkansas, California, Colorado, Delaware, District of Columbia, Florida, Hawaii, Idaho, Illinois, Indiana, Kansas, Kentucky, Maryland, Michigan, Montana, Nebraska, Nevada, New Jersey, New Mexico, North Carolina, Ohio, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Vermont, Virginia, Washington, and Wisconsin.[2]

[2] Hawaii is being represented on this matter by its Office of Consumer Protection, an agency which is not part of the state Attorney General's Office, but which is statutorily authorized to undertake consumer protection functions, including legal representation of the State of Hawaii. For simplicity, the entire group will be referred to as the "Attorneys General," and such designation, as it includes Hawaii, refers to the Executive Director of the State of Hawaii Office of Consumer Protection.

2.13 "Off-Label" shall mean a use related to an indication that was not approved by the FDA or information that was not contained in the FDA label at the time information regarding such use was communicated.

2.14 "Parties" shall mean Pfizer and the Signatory Attorney General.

2.15 "Pfizer Inc" or "Pfizer" shall mean Pfizer Inc, including all of its affiliates over which it has a controlling interest, subsidiaries and divisions, predecessors, successors, and assigns doing business in the United States.

2.16 "Pfizer Marketing" shall mean Pfizer personnel responsible for marketing Zyvox® or Lyrica® in the United States.

2.17 "Pfizer Medical" shall mean Pfizer personnel assigned to the Pfizer medical organization, including those personnel assigned to Pfizer's Medication Information Department ("USMI") or any successor group performing the same functions as the USMI.

2.18 "Pfizer Product" or "Product" shall mean any FDA-approved prescription drug or biological product manufactured, distributed, sold, marketed or Promoted by Pfizer in the United States.

2.19 "Pfizer Sales" shall mean the Pfizer sales force responsible for U.S. Zyvox® or Lyrica® sales, including, but not limited to, the field force and all management personnel such as district managers, regional managers, vice president(s) over sales, and president over sales.

2.20 "Promotional," "Promoting," or "Promote" shall mean representations about a Pfizer Product and other practices intended to increase sales or that attempt to influence prescribing practices of HCPs, including direct-to-consumer.

2.21 "Promotional Materials" shall mean any item used to Promote Zyvox® or Lyrica®

2.22 "Promotional Media" shall mean Promotional Materials in any media format for use in speaker programs.

2.23 "Promotional Speaker" shall mean an HCP speaker engaged by Pfizer to Promote Zyvox® or Lyrica® .

2.24 "Reprints Containing Off-Label Information" shall mean articles or reprints from a scientific or medical journal, as defined in 21 C.F.R. 99.3(j), or reference publication, as defined in 21 C.F.R. 99.3(i), describing an Off-Label use of Zyvox® or Lyrica®.

2.25 "Signatory Attorney General" shall mean the Attorney General of Kansas, or his/her authorized designee, who has agreed to this Judgment.

2.26 "State Consumer Protection Laws" shall mean the consumer protection laws cited in footnote 3 under which the Attorneys General have conducted the investigation.[3]

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[3] ALABAMA – *Alabama Deceptive Trade Practices Act* § 8-19-1 *et. seq.* (2002); ARIZONA – *Arizona Consumer Fraud Act*, A.R.S. § 44-1521 *et seq.*; ARKANSAS – Arkansas Deceptive Trade Practices Act, Ark. Code Ann. § 4-88-101, *et seq.*; CALIFORNIA – Bus. & Prof Code §§ 17200 *et seq.* and 17500 *et seq.*; COLORADO – *Colorado Consumer Protection Act*, Colo. Rev. Stat. § 6-1-101 *et seq.*; DELAWARE – *Delaware Consumer Fraud Act*, Del. CODE ANN. tit. 6, §§ 2511 to 2536; DISTRICT OF COLUMBIA, *District of Columbia Consumer Protection Procedures Act*, D.C. Code §§ 28-3901 *et seq.*; FLORIDA – *Florida Deceptive and Unfair Trade Practices Act, Part II*, Chapter 501, Florida Statutes, 501.201 *et. seq.*; HAWAII – *Uniform Deceptive Trade Practice Act*, Haw. Rev. Stat. Chpt. 481A and Haw. Rev. Stat.Chpt. 480 [501.201 *et seq.*]; IDAHO – *Consumer Protection Act*, Idaho Code Section 48-601 *et seq.*; ILLINOIS – *Consumer Fraud and Deceptive Business Practices Act*, 815 ILCS 505/2 *et seq.*; INDIANA – *Deceptive Consumer Sales Act*, I.C. §24-5-0.5 *et seq.*; KANSAS - *Kansas Consumer Protection Act*, K.S.A. 50-623 et seq. KENTUCKY – *Kentucky Consumer Protection Act*, KRS Ch. 367.110, *et seq.*; MARYLAND - *Maryland Consumer Protection Act*, Md. Code Ann., Com. Law §§ 13-101 *et seq.*; MICHIGAN – *Michigan Consumer Protection Act*, MCL § 445.901 *et seq.*; MONTANA – Montana Code Annotated 30-14-101 *et seq.*; NEBRASKA – *Uniform Deceptive Trade Practices Act*, NRS §§ 87-301 *et seq.*; NEVADA – Deceptive Trade Practices Act, Nevada Revised Statutes 598.0903 *et seq.*; NEW JERSEY – *New Jersey Consumer Fraud Act*, NJSA 56:8-1 *et seq.*; NEW MEXICO – NMSA 1978, § 57-12-1 *et seq.*; NORTH CAROLINA – North Carolina Unfair and Deceptive Trade Practices Act, N.C.G.S. 75-1.1, *et seq.*; OHIO – *Ohio Consumer Sales Practices Act*, R.C. 1345.01, *et seq.*; PENNSYLVANIA – *Pennsylvania Unfair Trade Practices and Consumer Protection Law*, 73 P.S. 201-1 *et seq.*; RHODE ISLAND – *Rhode Island Deceptive Trade Practices Act*, Rhode Island General laws § 6-13.1-1 *et seq.* ; SOUTH CAROLINA – *South Carolina Unfair Trade Practices Act*, sections 39-5-10 *et seq.*; SOUTH DAKOTA – *South Dakota Deceptive Trade Practices and Consumer Protection*, SDCL ch. 37-24; TENNESSEE – *Tennessee Consumer Protection Act*, Tenn. Code Ann. 47-18-101 *et seq.*; TEXAS – *Texas Deceptive Trade Practices-Consumer Protection Act*, Tex. Bus. And Com. Code 17.41, *et seq.*; VERMONT – *Consumer Fraud Act*, 9 V.S.A. §§ 2451 *et seq.*; VIRGINIA-*Virginia Consumer Protection Act*, Va Code Ann. §59.1-196 *et seq.*; WASHINGTON – *Unfair Business Practices/Consumer Protection Act*, RCW §§ 19.86 *et seq.*; WEST VIRGINIA – *West Virginia Consumer Credit and Protection Act*, W. Va. Code § 46A-1101 *et seq.*; WISCONSIN – Wis. Stat. § 100.18 (Fraudulent Representations).

2.27 "Unsolicited Request" shall mean a request for information regarding Zyvox® or Lyrica® communicated to an agent of Pfizer that has not been prompted by or on behalf of Pfizer.

2.28 "Zyvox®" shall mean all Pfizer Products that are FDA-approved drug formulations containing linezolid.

2.29 Any reference to a written document shall mean a physical paper copy of the document, an electronic version of the document, or electronic access to such document.

3. COMPLIANCE PROVISIONS

IT IS FURTHER ORDERED, ADJUDGED AND DECREED THAT:

Promotional Activities

3.1 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, including, but not limited to, any false, misleading, or deceptive claim when comparing the efficacy or safety of Zyvox® to vancomycin.

3.2 Pfizer shall not make any claim comparing the safety or efficacy of a Pfizer Product to another product when that claim is not supported by substantial evidence as defined by Federal law and regulations.

3.3 Pfizer shall not Promote Zyvox® or Lyrica® to an HCP who practices in a specialty that is unlikely to prescribe for a use in Zyvox®'s or Lyrica®'s FDA approved Labeling.

3.4 Pfizer shall not make any written or oral Promotional claim of safety or effectiveness for any Pfizer Product in a manner that violates the FDCA, accompanying

regulations, or voluntary agreements with FDA, as interpreted by the FDA in a writing by the Director of the Center for Drug Evaluation at the FDA.

3.5 Pfizer shall not Promote any Pfizer Product for Off-Label uses.

3.6 Pfizer shall not present patient profiles/types based on selected symptoms of the FDA-approved indication(s) when Promoting Zyvox® or Lyrica® for six years from the Effective Date of this Judgment, unless:

A. Zyvox®'s or Lyrica®'s specific FDA-approved indication(s) is/are stated Clearly and Conspicuously in the same spread (e.g. on the same page or on a facing page) in any Promotional Materials that reference the selected symptoms;

B. Promotional Materials have a statement indicating that prescribers should take into consideration the full range of a patient's symptoms and other relevant information before making a treatment decision.

3.7 Pfizer shall not make any claim that contradicts or minimizes a precaution, warning, or adverse reaction that is described in product Labeling for Zyvox® or Lyrica®.

3.8 In Promotional Materials, Pfizer shall Clearly and Conspicuously disclose all material facts regarding the following: the risks associated with Zyvox® or Lyrica® as set forth in the products' FDA- approved Labeling; information in any boxed warning; and facts about the negative consequences and side effects that can result from use of Zyvox® or Lyrica®. Pfizer shall present information about effectiveness and risk in a balanced manner. Whenever Pfizer knows or has reason to believe the current Labeling does not reflect the efficacy or risks of Zyvox® or Lyrica®, Pfizer shall promptly notify the Food and Drug Administration.

3.9 Pfizer shall not affirmatively seek the inclusion of Zyvox® or Lyrica® in hospital protocols or standing orders unless Zyvox® or Lyrica® has been approved by the FDA for the indication for which it is to be included in the protocol or standing order.

3.10 Pfizer shall require that all Promotional Speakers comply with Pfizer's obligations in paragraphs 3.1 through 3.8, 3.26, and 3.33 of this Judgment, including, but not limited to, ensuring that all Promotional Speakers' Promotional Materials and Promotional Media for Zyvox® and Lyrica® comply with Pfizer's obligations in this Judgment.

3.11 Pfizer shall notify its sales force promptly of any warning letter received from the FDA which affects the conduct of any sales representative in Promoting the relevant Pfizer Product and shall promptly provide a detailed explanation of the effect of the letter on the Promotion of Pfizer Products.

Financial incentives to Pfizer Sales, Medical Outcome Specialists, and/or Marketing

3.12 Pfizer's financial incentives shall be designed to ensure that Pfizer Sales, Medical Outcome Specialists, and/or Pfizer Marketing are not motivated to engage in improper Promoting, selling, and marketing of Zyvox® or Lyrica®.

3.13 Pfizer's financial incentives shall not include mechanisms to provide incentive compensation for sales that may be attributable to the Off-Label uses of any Pfizer Product.

3.14 For six years from the Effective Date of this Judgment, Pfizer shall continue to implement measures whereby sales goals for Zyvox® or Lyrica® can be met without including Off-Label prescriptions.

3.15 For six years from the Effective Date of this Judgment, Pfizer shall not award prizes or other incentives to its sales force as rewards for the Off-Label sale or use of any FDA-approved Pfizer Product.

Dissemination and Exchange of Medical Information

The following provisions shall be effective for six years from the Effective Date of this Judgment.

3.16 Pfizer shall not knowingly disseminate any Medical Information Response, including one that describes any Off-Label use of Zyvox® or Lyrica®, that makes any false, misleading, or deceptive representation regarding Zyvox® or Lyrica® or any false, misleading, or deceptive statement concerning a competing product.

3.17 Pfizer Sales, Pfizer Marketing, and Medical Outcomes Specialists shall not develop the medical content of Medical Information Responses regarding Zyvox® or Lyrica®. Notwithstanding the foregoing, Medical Outcomes Specialists may assist in the development of pharmacoeconomic content of Medical Information Responses.

3.18 Medical Information Responses to Unsolicited Requests for Off-Label information regarding Zyvox® or Lyrica® may be disseminated only by Pfizer Medical.

3.19 Pfizer Medical shall have ultimate responsibility for developing and approving all Medical Information Responses regarding Zyvox® or Lyrica®. Additional approvals may be provided by Pfizer's legal department. Pfizer shall not distribute any such materials unless:

A. Clinically relevant information is included in these materials to provide scientific balance;

B. Data in these materials are presented in an unbiased, non-Promotional manner; and

C. These materials are clearly distinguishable from sales aids and other Promotional Materials.

Responses to Unsolicited Requests for Off-Label Information

The following provisions shall be effective for six years from the Effective Date of this Judgment.

3.20 If Pfizer elects to respond to an Unsolicited Request for Off-Label information Pfizer Medical shall provide specific, accurate, objective, and scientifically balanced responses. Any such response shall not Promote Zyvox® or Lyrica® for any Off-Label use(s).

3.21 Any written Pfizer response to an Unsolicited Request for Off-Label information regarding Zyvox® or Lyrica® shall be a Medical Information Response and shall include:

A. A copy of the FDA-required Labeling, if any, for the product (e.g., FDA-approved package insert and, if the response is for a consumer, FDA-approved patient labeling);

B. A prominent statement notifying the recipient that the FDA has not approved or cleared the product as safe and effective for the Off-Label use addressed in the accompanying materials;

C. A prominent statement disclosing the indication(s) for which FDA has approved or cleared the product;

D. A prominent statement providing all important safety information including, if applicable, any boxed warning for the product;

E. Non-biased information or data relating to the particular Off-Label use that is the subject of the request, including applicable data that are not supportive or that cast doubt on the safety or efficacy of that use; and

F. A comprehensive list of references for all of the information disseminated in the response (e.g., a bibliography of publications in peer-reviewed medical journals or in medical or scientific texts; citations for data on file, for summary documents, or for abstracts).

3.22 Pfizer Sales, Pfizer Marketing, and Medical Outcome Specialists may respond orally to an Unsolicited Request for Off-Label information regarding Zyvox® or Lyrica® only by offering to request on behalf of the HCP that a Medical Information Response be sent to the HCP in follow up or by offering to put the HCP in touch with Pfizer Medical. Notwithstanding the foregoing, Medical Outcomes Specialists may respond to inquiries related to pharmacoeconomics or health outcomes from formulary decision makers or the groups responsible for the management of health benefits within Healthcare Organizations, but not prescribers unless employed or engaged by a Healthcare Organizationin a role connected to formulary decisions or the management of health benefits.

3.23 Information distributed by USMI in response to an Unsolicited Request for Off-Label information shall be:

A. Provided only to the individual making the request;

B. Tailored to answer only the specific Off-Label question(s) asked;

C. Scientific in nature; and

D. Unaccompanied by other material or information that is Promotional in nature or tone.

Reprints

3.24 Pfizer shall not disseminate any information describing any Off-Label use of any Pfizer Product if such use has been submitted to the FDA for approval and the FDA has either advised Pfizer that it refuses to approve such application or that FDA-identified deficiencies must be resolved before approval can be granted unless Pfizer has first Clearly and Conspicuously disclosed to the recipient of the information that the FDA has issued such advice. Pfizer may disclose to any recipient of such information whether the information was presented to the FDA prior to the FDA's issuance of such advice regarding the Off-Label use.

3.25 Pfizer shall not disseminate information describing any Off-Label or unapproved use of Zyvox® or Lyrica® unless such information and materials comply with applicable FDA regulations and the recommended actions in FDA Guidances for Industry.

3.26 Reprints Containing Off-Label Information

A. Pfizer Medical shall be responsible for the identification, selection, approval and dissemination of Reprints Containing Off-Label Information regarding Zyvox® or Lyrica®.

B. Reprints Containing Off-Label Information regarding Zyvox® or Lyrica®:

(i) shall be accompanied by the FDA approved Labeling for the product and contain a disclosure in a prominent location, which would

include the first page or as a cover page where practicable, indicating that the article may discuss Off-Label information; and

(ii) shall not be referred to or used in a Promotional manner.

C. Reprints Containing Off-Label Information regarding Zyvox® or Lyrica® may only be disseminated by Pfizer Medical to HCPs. Notwithstanding the foregoing, Medical Outcomes Specialists may disseminate reprints relating to pharmacoeconomics or health outcomes to formulary decision makers or the groups responsible for the management of health benefits within Healthcare Organizations, but not prescribers unless employed or engaged by a Healthcare Organization in a role connected to formulary decisions or the management of health benefits.

3.27 Nothing in this Judgment shall preclude Pfizer from disseminating reprints which have only an incidental reference to Off-Label information. If reprints have an incidental reference to Off-Label information, such reprints shall not be subject to the requirements of Section 3.24 and such incidental reference to Off-Label information shall not be referred to or used in a Promotional manner as prohibited by Section 3.26. B.ii.

Product Samples

The following provisions shall be effective for six years from the Effective Date of this Judgment.

3.28 Pfizer shall only provide samples of Zyvox® or Lyrica® to those HCPs who have specialties that customarily treat patients who have diseases for which treatment with Zyvox® or Lyrica® would be consistent with that product's FDA- approved Labeling.

3.29 Pfizer shall not disseminate samples of Zyvox® or Lyrica® with the intent of increasing Off-Label prescribing.

Sales Force Monitoring

3.30 Pfizer shall maintain a compliance program consistent with its Corporate Integrity Agreement signed on August 31, 2009 that includes a chief compliance officer; a compliance committee; a written code of conduct; written policies and procedures; education and training initiatives; a disclosure program that allows for confidential disclosure and investigation of potential compliance violations and appropriate disciplinary procedures; and regular internal auditing procedures. The compliance program shall include a sales force monitoring program designed to directly and indirectly observe the appropriateness of the sales force's interactions with HCPs and to identify potential Off-Label Promotional activities. The sales force monitoring program shall also include a Promotional speaker monitoring program, direct field observations of the sales force, and the monitoring and review of other records related to the sales force's interactions with HCPs. Pfizer's sales force monitoring program shall also include a centralized electronic system to be used by the sales force in connection with the detailing of HCPs that is consistent with the Corporate Integrity Agreement signed on August 31, 2009. The centralized electronic system shall include a detailing system that allows for and does not discourage the entry of free text summaries of interactions with HCPs. This paragraph shall be effective until December 31, 2014.

3.31 Pfizer shall maintain a disclosure program which allows for the anonymous disclosure of compliance policy violations and contains a nonretaliation policy.

Clinical Research

3.32 Pfizer shall report clinical research regarding Zyvox® and Lyrica® in an accurate, objective and balanced manner, and as required by applicable law. For all Pfizer-sponsored clinical trials and to the extent permitted by the National Library of Medicine, Pfizer shall register clinical trials and submit clinical trial results to the federal clinical trial registry and results data bank regarding Zyvox® and Lyrica® on the publicly accessible NIH website (www.clinicaltrials.gov) as required by the FDA Amendments Act of 2007, Public Law No. 110-85, 121 Stat 823, and any accompanying regulations that may be promulgated pursuant to that Act.

3.33 When presenting information about a clinical study regarding Zyvox® or Lyrica® in any Promotional materials, Pfizer shall not do any of the following:

A. Present information or conclusions from a study that is inadequate in design, scope, or conduct to furnish significant support for such information or conclusions;

B. Use the concept of statistical significance to support a claim that has not been demonstrated to have clinical significance or validity or fails to reveal the range of variations around the cited average results;

C. 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 the study the design or protocol of which is not amenable to formal statistical evaluations;

D. Present the information in a way that implies that the study represents larger or more general experience with the drug than it actually does;

E. Use statistics on numbers of patients, or counts of 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. If any results derived from pooling data are presented, Pfizer shall disclose the method of pooling;

F. Use tables or graphs to distort or misrepresent the relationships, trends, differences, or changes among the variables or products studied; or

G. Use reports or statements represented to be statistical analyses, interpretations, or evaluations that are inconsistent with or violate the established principles of statistical theory, methodology, applied practice and inference, or that are derived from clinical studies the design, data, or conduct of which substantially invalidate the application of statistical analyses, interpretation, or evaluation.

4. PAYMENT

4.1 No later than 30 days after the Effective Date of this Judgment, Pfizer shall pay a total amount of Forty-Two Million Nine Hundred Thousand Dollars ($42,900,000.00) to be divided and paid by Pfizer directly to each Signatory Attorney General of the Multistate Working Group in an amount to be designated by and in the sole discretion of the Multistate Executive Committee. Said payment shall be used by the States as attorneys' fees and other costs of

investigation and litigation, or to be placed in, or applied to, the consumer protection enforcement fund, including future consumer protection enforcement, consumer education, litigation or local consumer aid fund or revolving fund, used to defray the costs of the inquiry leading hereto, at the sole discretion of each Signatory Attorney General. The Parties acknowledge that the payment described herein is not a fine, penalty, or payment in lieu thereof.

5. RELEASE

5.1 By its execution of this Judgment, the State of Kansas releases Pfizer and all of its past and present affiliates over which it has a controlling interest, subsidiaries and divisions, predecessors, successors, and assigns (collectively, the "Released Parties") from the following: all civil claims, causes of action, damages, restitution, fines, costs, and penalties that the Kansas Attorney General has asserted or could have asserted against the Released Parties under the Kansas Consumer Protection Act, K.S.A. 50-623 *et seq*. resulting from the Covered Conduct up to and including the Effective Date.

5.2 Notwithstanding any term of this Judgment, specifically reserved and excluded from the release in Paragraph 5.1 as to any entity or person, including Released Parties, are any and all of the following:

A. Any criminal liability that any person and/or entity, including Released Parties, has or may have to the State of Kansas.

B. Any civil or administrative liability that any person and/or entity, including Released Parties, has or may have to the State of Kansas not expressly covered by the release in Paragraph 5.1 above, including, but not limited to, any and all of the following claims:

i) State or federal antitrust violations;

ii) Claims involving "best price", "average wholesale price," "wholesale acquisition cost," or any reporting practices;

iii) Medicaid claims, including, but not limited to, federal Medicaid drug rebate statute violations, Medicaid fraud or abuse, and/or kickback violations related to any State's Medicaid program;

iv) State false claims violations; and

v) Actions on behalf of state program payors of the State of Kansas arising from the purchase of a Pfizer Product.

C. Any liability under the Kansas Consumer Protection Act, K.S.A. 50-623 *et seq*. which any person and/or entity, including Released Parties, has or may have to individual consumers.

5.3 Nothing contained in this Judgment shall relieve Pfizer of the obligations it maintains under any other Judgment or agreement relating to any Pfizer Product.

6. DISPUTE RESOLUTION

6.1 For the purposes of resolving disputes with respect to compliance with this Judgment, should any of the Signatory Attorneys General have a reasonable basis to believe that Pfizer has engaged in a practice that violates a provision of this Judgment subsequent to the Effective Date of this Judgment, then such Attorney General shall notify Pfizer in writing of the specific objection, identify with particularity the provision of this Judgment that the practice appears to violate, and give Pfizer thirty (30) days to respond to the notification; provided, however, that a Signatory Attorney General may take any action if the Signatory Attorney

General concludes that, because of the specific practice, a threat to the health or safety of the public requires immediate action. Upon receipt of written notice, Pfizer shall provide a good-faith written response to the Attorney General notification, containing either a statement explaining why Pfizer believes it is in compliance with the Judgment, or a detailed explanation of how the alleged violation occurred and a statement explaining how Pfizer intends to remedy the alleged breach. Nothing in this section shall be interpreted to limit the state's Civil Investigative Demand ("CID") or investigative subpoena authority, to the extent such authority exists under applicable law, and Pfizer reserves all of its rights in responding to a CID or investigative subpoena issued pursuant to such authority.

6.2 Upon giving Pfizer thirty (30) days to respond to the notification described above, the Signatory Attorney General shall also be permitted reasonable access to inspect and copy relevant, non-privileged, non-work product records and documents in the possession, custody, or control of Pfizer that relate to Pfizer's compliance with each provision of this Judgment pursuant to that State's CID or investigative subpoena authority. If the Signatory Attorney General makes or requests copies of any documents during the course of that inspection, the Signatory Attorney General will provide a list of those documents to Pfizer.

6.3 The State may assert any claim that Pfizer has violated this Judgment in a separate civil action to enforce compliance with this Judgment, or may seek any other relief afforded by law, but only after providing Pfizer an opportunity to respond to the notification described in paragraph 6.1 above; provided, however, that a Signatory Attorney General may take any action if the Signatory Attorney General concludes that, because of the specific practice, a threat to the health or safety of the public requires immediate action.

7. GENERAL PROVISIONS

7.1 Pfizer shall not cause or encourage third parties, nor knowingly permit third parties acting on its behalf, to engage in practices from which Pfizer is prohibited by this Judgment.

7.2 The acceptance of this Judgment by the Kansas Attorney General shall not be deemed approval by the Kansas Attorney General of any of Pfizer's advertising or business practices. Further, neither Pfizer nor anyone acting on its behalf shall state or imply, or cause to be stated or implied, that the Kansas Attorney General or any other governmental unit of the State of Kansas has approved, sanctioned or authorized any practice, act, advertisement, or conduct of Pfizer.

7.3 Any failure by any party to this Judgment to insist upon the strict performance by any other party of any of the provisions of this Judgment shall not be deemed a waiver of any of the provisions of this Judgment, and such party, notwithstanding such failure, shall have the right thereafter to insist upon the specific performance of any and all of the provisions of this Judgment.

7.4 This Judgment represents the full and complete terms of the settlement entered into by the Parties hereto. In any action undertaken by the Parties, no prior versions of this Judgment and no prior versions of any of its terms that were not entered by the Court in this Judgment, may be introduced for any purpose whatsoever.

7.5 This Court retains jurisdiction of this Judgment and the Parties hereto for the purpose of enforcing and modifying this Judgment and for the purpose of granting such additional relief as may be necessary and appropriate.

7.6 This Judgment may be executed in counterparts, and a facsimile or .pdf signature shall be deemed to be, and shall have the same force and effect as, an original signature.

7.7 All Notices under this Order shall be provided to the following via email and Overnight Mail:

For Pfizer Inc:
Joshua S. Levy
ROPES & GRAY LLP
Prudential Tower, 800 Boylston Street
Boston, MA 02199-3600
joshua.levy@ropesgray.com

Gary F. Giampetruzzi
Vice President and Assistant General Counsel, Head of Government Investigations
Pfizer Inc.
150/2/04
150 East 42nd Street
New York, NY 10017
Gary.Giampetruzzi@Pfizer.com

For Office of the Kansas Attorney General:
Office of the Kansas Attorney General
Consumer Protection/Antitrust Division
c/o Meghan E. Stoppel
120 SW 10th Ave., 2nd Floor
Topeka, Kansas 66612-1597
Meghan.Stoppel@gmail.com

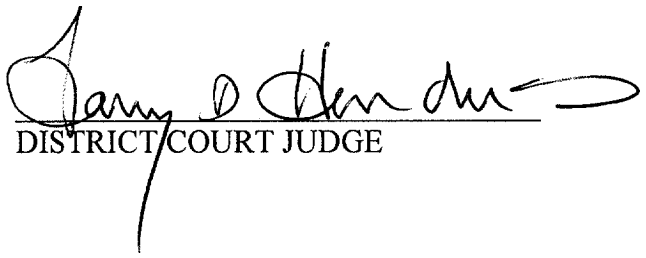
7.8 To the extent that any provision of this Judgment obligates Pfizer to change any policy(ies) or procedure(s) and to the extent not already accomplished, Pfizer shall implement the policy(ies) or procedure(s) as soon as reasonably practicable, but no later than 120 days after the Effective Date of this Judgment.

IT IS THEREFORE ORDERED, ADJUDGED AND DECREED that the stipulations and agreements of the Parties contained herein are adopted and approved as the findings of fact

and conclusions of law of the Court and any monies owed hereunder by Defendant immediately become a Judgment upon filing.

IT IS FURTHER ORDERED, ADJUDGED AND DECREED that pursuant to the Kansas Consumer Protection Act and the provisions of K.S.A. 50-632(b), the Court hereby approves the terms of this Judgment and adopts the same as the Order of the Court.

IT IS SO ORDERED.



DISTRICT COURT JUDGE

JOINTLY APPROVED AND
SUBMITTED FOR ENTRY:

FOR PLAINTIFF, STATE OF KANSAS

Derek Schmidt, KS #17781
Attorney General
Office of the Kansas Attorney General
120 SW 10th Ave., 2nd Floor
Topeka, Kansas 66612-1597
Phone: (785) 296-2215

Date: 12/10/2012

Meghan E. Stoppel, KS #23685
Assistant Attorney General
Office of the Kansas Attorney General
120 SW 10th Ave., 2nd Floor
Topeka, Kansas 66612-1597
Phone: (785) 296-3751
Fax: (785) 291-3699

Date: 12/10/12

FOR PFIZER INC

By: _____

Joshua S. Levy
Ropes & Gray LLP
Prudential Tower, 800 Boylston Street
Boston, MA 02199

Date: 12/5/12

By: _____

Ross B. Galin
O'Melveny & Myers LLP
Times Square Tower, 7 Times Square
New York, NY 10036

Date: 12/3/12

By: Mark S. Gunnison (as to form)
Mark S. Gunnison, KS # 11090
Payne & Jones Chtd.
11000 King St.
Overland Park, KS 66210

Date: 12/4/12

FOR PFIZER INC

By: _____ Date: 12/3/12

Gary F. Giampetruzzi
Vice President and Assistant General Counsel, Head of Government Investigations
Pfizer Inc
150/2/04
150 East 42nd Street
New York, NY 10017

Exhibit E

Meghan E. Stoppel, #23685
Assistant Attorney General
Office of the Kansas Attorney General
120 SW 10th Avenue, 2nd Floor
Topeka, Kansas 66612
Ph: (785) 296-3751
Fax: (785) 291-3699
meghan.stoppel@ag.ks.gov

IN THE DISTRICT COURT OF SHAWNEE COUNTY, KANSAS
Division 1

STATE OF KANSAS, *ex rel.*	)	
DEREK SCHMIDT, Attorney General,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**Case No.** 2014 CV 777
	)	
WYETH	)	
PHARMACEUTICALS INC.,	)	
	)	
Defendant.	)	
	)	

(Pursuant to K.S.A. Chapter 60)

JOURNAL ENTRY OF CONSENT JUDGMENT

NOW on this 6 day of August, 2014, Plaintiff's Journal Entry of Consent Judgment comes before the Court pursuant to K.S.A. 50-632(b). The Plaintiff, State of Kansas, *ex rel.* Derek Schmidt, Attorney General, appears by and through Meghan E. Stoppel, Assistant Attorney General. Defendant Wyeth Pharmaceuticals Inc. (hereinafter "Wyeth") and Pfizer Inc ("Pfizer"), as current parent of Defendant Wyeth, appear by and through the undersigned counsel.

WHEREUPON the Parties advise the Court that they have stipulated and agreed to the following:

PARTIES, JURISDICTION AND VENUE

1. Derek Schmidt is the duly elected, qualified and acting Attorney General for the State of Kansas.

2. The Attorney General's authority to bring this action is derived from the statutory and common law of the State of Kansas, specifically the Kansas Consumer Protection Act, K.S.A. 50-623 *et seq.*

3. Venue is proper under K.S.A. 50-638 in the Third Judicial District of Kansas (Shawnee County).

4. At all times relevant hereto, Wyeth engaged in "consumer transactions" in Kansas, as defined by K.S.A. 50-624(c).

5. In October 2009, Pfizer Inc ("Pfizer") acquired Wyeth, and Wyeth became a wholly owned subsidiary of Pfizer. Pfizer represents that the conduct at issue occurred prior to this acquisition. Plaintiff, by its counsel, and Pfizer, by its counsel, have agreed to the entry of this Consent Judgment ("Judgment") by the Court without trial or adjudication of any issue of fact or law, and without finding or admission of wrongdoing or liability of any kind. Pfizer, as parent of Wyeth, agrees to be bound by the terms of this Judgment.

IT IS HEREBY ORDERED THAT:

1. FINDINGS

1.1 This Court has jurisdiction over the subject matter of this lawsuit and over all Parties, pursuant to the Kansas Consumer Protection Act, K.S.A. 50-623 *et seq*.

1.2 The terms of this Judgment shall be governed by the laws of the State of Kansas.

1.3 Entry of this Judgment is in the public interest and reflects a negotiated agreement among the Parties.

1.4 The Parties have agreed to resolve the issues resulting from the Covered Conduct by entering into this Judgment.

1.5 Pfizer is willing to enter into this Judgment regarding the Covered Conduct in order to resolve the Attorneys General's concerns under the State Consumer Protection Laws as to the matters addressed in this Judgment and thereby avoid significant expense, inconvenience, and uncertainty.

1.6 The Parties have agreed to resolve the issues raised by the Covered Conduct by entering into this Judgment.[1]

1.7 Pfizer is entering into this Judgment solely for the purpose of settlement, and nothing contained herein may be taken as or construed to be an admission or concession of any violation of law, rule, or regulation, or of any other matter of fact or law, or of any liability or wrongdoing, all of which Pfizer expressly denies. Pfizer does not admit any violation of the State Consumer Protection Laws set forth in footnote 6, and does not admit any wrongdoing that was or could have been alleged by any Attorney General before the date of the Judgment under those laws. No part of this Judgment, including its statements and commitments, shall constitute evidence of any liability, fault, or wrongdoing by Pfizer. This document and its contents are not intended for use by any third party for any purpose, including submission to any court for any purpose.

[1] This agreement is entered into pursuant to and subject to the State Consumer Protection laws cited in footnote 6.

1.8 This Judgment shall not be construed or used as a waiver or limitation of any defense otherwise available to Pfizer in any action, or of Pfizer's right to defend itself from, or make any arguments in, any private individual, regulatory, governmental, or class claims or suits relating to the subject matter or terms of this Judgment. This Judgment is made without trial or adjudication of any issue of fact or law or finding of liability of any kind. Notwithstanding the foregoing, a State may file an action to enforce the terms of this Judgment.

1.9 It is the intent of the Parties that this Judgment not be admissible in other cases or binding on Pfizer in any respect other than in connection with the enforcement of this Judgment.

1.10 No part of this Judgment shall create a private cause of action or confer any right to any third party for violation of any federal or state statute except that a State may file an action to enforce the terms of this Judgment.

1.11 This Judgment (or any portion thereof) shall in no way be construed to prohibit Pfizer from making representations with respect to any Pfizer Product that are required under Federal law or regulations or in Food and Drug Administration ("FDA") approved Labeling.

1.12 Nothing in this Judgment shall require Pfizer to:

(a) take any action that is prohibited by the Food, Drug and Cosmetic Act, 21 U.S.C. §301 *et seq.* ("FDCA") or any regulation promulgated thereunder, or by the FDA; or

(b) fail to take any action that is required by the FDCA or any regulation promulgated thereunder, or by the FDA. Any written or oral Promotional claim subject to this Judgment which is the same, or materially the same, as the language required or agreed to by the Director of the Office of Prescription Drug Promotion, the

Director of the Advertising and Promotional Labeling Branch, the Director of the Center for Drug Evaluation and Research, or the Director of the Center for Biologics Evaluation and Research, or their authorized designees in writing shall not constitute a violation of this Judgment, unless facts are or become known to Pfizer that cause the claim to be false, misleading, or deceptive.

2. DEFINITIONS

The following definitions shall be used in construing this Judgment:

2.1 "Clearly and Conspicuously" shall mean a disclosure in size, color, contrast, font, and location that is readily noticeable, readable and understandable and is presented in proximity to all information necessary to prevent it from being misleading or deceptive. A statement may not contradict or be inconsistent with any other information with which it is presented. If a statement modifies, explains, or clarifies other information or is necessary to prevent other information from being misleading or deceptive, then the statement must be presented in close proximity to that information, in a manner that is readily noticeable, readable, and understandable, and it must not be obscured in any manner.

2.2 "Covered Conduct" shall mean Wyeth's Promotional and marketing practices, and dissemination of information and remuneration to HCPs regarding the prescription drug Rapamune® through the Effective Date of the Judgment.

2.3 "Effective Date" shall mean the date on which a copy of this Judgment, duly executed by Pfizer and by the Signatory Attorney General, is approved by, and becomes a Judgment of the Court.

2.4 "FDA Guidances for Industry" shall mean final documents issued by the FDA pursuant to 21 U.S.C. §371(h) that represent the FDA's current thinking on a topic.

2.5 "Health Care Professional" or "HCP" shall mean any physician or other health care practitioner, who is licensed to provide health care services or to prescribe pharmaceutical products.

2.6 "Healthcare Organization" shall mean an entity, public or private, that is intended and incentivized to tie patient care to quality metrics and value models and includes organizations such as payors, Health Maintenance Organizations (HMO), Long Term Care (LTC) pharmacy providers, Pharmacy Benefit Management (PBM), Integrated Delivery Networks (IDN), Accountable Care Organizations (ACO), and hospital formulary committees.

2.7 "Labeling" shall mean all FDA-approved labels and other written, printed, or graphic matter (a) upon any article or any of its containers or wrappers, or (b) accompanying such article.

2.8 "Medical Information Response" shall mean a non-Promotional, scientific communication to address Unsolicited Requests for medical information from HCPs.

2.9 "Medical Outcome Specialists" shall mean Pfizer personnel who work with Healthcare Organizations that determine the drugs to be placed on a formulary.

2.10 "Multistate Executive Committee" shall mean the Attorneys General and their staffs representing California, Florida, Illinois, Maryland, New York, North Carolina, Oregon, Pennsylvania, and Texas.

2.11 "Multistate Working Group" shall mean the Attorneys General and their staff representing Alabama, Arizona, Arkansas, California, Colorado, Delaware, District of Columbia,

Florida, Georgia[2], Hawaii[3], Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, South Dakota, Tennessee, Texas, Utah[4], Virginia, Washington, and Wisconsin.

2.12 "Off-Label" shall mean a use related to an indication that was not approved by the FDA or information that was not contained in the FDA label at the time information regarding such use was communicated.

2.13 "Parties" shall mean Wyeth, Pfizer, and the Signatory Attorney General.

2.14 "Pfizer" shall mean Pfizer Inc and its wholly owned subsidiary, Wyeth Pharmaceuticals Inc., including all of its subsidiaries and divisions, predecessors, successors, and assigns doing business in the United States.

2.15 "Pfizer Marketing" shall mean Pfizer personnel responsible for marketing Rapamune in the United States.

2.16 "Pfizer Medical" shall mean Pfizer personnel assigned to the Pfizer medical organization, including those personnel assigned to Pfizer's Medication Information Department ("USMI") or any successor group performing the same functions as the USMI.

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[2] With regard to Georgia, the Administrator of the Fair Business Practices Act, appointed pursuant to O.C.G.A. § 10-1-395, is statutorily authorized to undertake consumer protection functions for the State of Georgia. References to the "States," "Parties," or "Attorneys General," with respect to Georgia, include the Administrator of the Fair Business Practices Act.

[3] Hawaii is being represented on this matter by its Office of Consumer Protection, an agency which is not part of the state Attorney General's Office, but which is statutorily authorized to undertake consumer protection functions, including legal representation of the State of Hawaii. For simplicity, the entire group will be referred to as the "Attorneys General," and such designation, as it includes Hawaii, refers to the Executive Director of the State of Hawaii Office of Consumer Protection.

[4] With regard to Utah, the Utah Division of Consumer Protection is charged with administering and enforcing the Consumer Sales Practices Act, the statute relevant to this judgment. References to the "States," "Parties," or "Attorneys General," with respect to Utah, refers to the Utah Division of Consumer Protection.

2.17 "Pfizer Product" or "Product" shall mean any FDA-approved prescription drug or biological product manufactured, distributed, sold, marketed or Promoted by Pfizer in the United States.

2.18 "Pfizer Sales" shall mean the Pfizer sales force, if any, responsible for United States Rapamune sales, including, but not limited to, the field force and all management personnel such as district managers, regional managers, vice president(s) over sales, and president over sales.[5]

2.19 "Promotional," "Promoting," or "Promote" shall mean representations about a Pfizer Product and other practices intended to increase sales or that attempt to influence prescribing practices of HCPs, including direct-to-consumer.

2.20 "Promotional Materials" shall mean any item used to Promote Rapamune.

2.21 "Promotional Media" shall mean Promotional Materials in any media format for use in speaker programs.

2.22 "Promotional Speaker" shall mean an HCP speaker engaged by Pfizer to Promote Rapamune.

2.23 "Rapamune" shall mean all Pfizer immunosuppressant Products that contain sirolimus or any other Pfizer Product that is currently approved by the FDA as prophylactic for solid organ rejection after transplant surgery.

2.24 "Reprints Containing Off-Label Information" shall mean articles or reprints from a scientific or medical journal, as defined in 21 C.F.R. 99.3(j), or reference publication, as defined in 21 C.F.R. 99.3(i), describing an Off-Label use of Rapamune.

[5] Pfizer represents that in January 2011, Pfizer withdrew the sales force responsible for marketing Rapamune®.

2.25 "Signatory Attorney General" shall mean the Attorney General of Kansas, or his/her authorized designee, who has agreed to this Judgment.

2.26 "State Consumer Protection Laws" shall mean the consumer protection laws cited in footnote 6 under which the Attorneys General have conducted the investigation.[6]

2.27 "Unsolicited Request" shall mean a request for information regarding Rapamune communicated to an agent of Pfizer that has not been prompted by or on behalf of Pfizer.

2.28 "Wyeth" shall mean Wyeth Pharmaceuticals Inc., a wholly owned subsidiary of Pfizer Inc.

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[6] ALABAMA – Alabama Deceptive Trade Practices Act § 8-19-1 *et seq.* (2002); ARIZONA - Consumer Fraud Act, A.R.S. §44-1521 et seq.; ARKANSAS – Arkansas Deceptive Trade Practices Act, Ark. Code Ann. § 4-88-101, et seq.; CALIFORNIA – Bus. & Prof Code §§ 17200 et seq. and 17500 et seq.; COLORADO – Colorado Consumer Protection Act, Colo. Rev. Stat. § 6-1-101 et seq.; DELAWARE – Delaware Consumer Fraud Act, Del. CODE ANN. tit. 6, §§ 2511 to 2527; DISTRICT OF COLUMBIA, District of Columbia Consumer Protection Procedures Act, D.C. Code §§ 28-3901 et seq.; FLORIDA – Florida Deceptive and Unfair Trade Practices Act, Part II, Chapter 501, Florida Statutes, 501.201 et. seq.; GEORGIA - Fair Business Practices Act, O.C.G.A. Sections 10-1-390 et seq.; HAWAII – Uniform Deceptive Trade Practice Act, Haw. Rev. Stat. Chpt. 481A and Haw. Rev. Stat. Chpt. 480; ILLINOIS – Consumer Fraud and Deceptive Business Practices Act, 815 ILCS 505/2 et seq.; INDIANA - Ind. Code §§ 24-5-0.5-0.1 et seq.; IOWA - Iowa Consumer Fraud Act, Iowa Code Section 714.16; KANSAS - Kansas Consumer Protection Act, K.S.A. 50-623 et seq.; KENTUCKY – Kentucky Consumer Protection Act, KRS Ch. 367.110, et seq.; LOUISIANA – Unfair Trade-Practices and Consumer Protection Law, LSA-R.S. 51:1401, et seq.; MAINE – Unfair Trade Practices Act, 5 M.R.S.A. § 207 et seq.; MARYLAND - Maryland Consumer Protection Act, Md. Code Ann., Com. Law §§ 13-101 et seq.; MASSACHUSETTS – Mass. Gen. Laws c. 93A, §§ 2 and 4; MICHIGAN – Michigan Consumer Protection Act, MCL § 445.901 et seq.; MINNESOTA - Minnesota Deceptive Trade Practices Act, Minn. Stat. §§ 325D.43-48; Minnesota False Advertising Act, Minn. Stat. § 325F.67; Minnesota Consumer Fraud Act, Minn. Stat. §§ 325F.68-70; Minnesota Deceptive Trade Practices Against Senior Citizens or Disabled Persons Act, Minn. Stat. § 325F.71.; MISSISSIPPI - Mississippi Consumer Protection Act, Miss. Code Ann.§ 75-24-1, et seq.; MISSOURI – Missouri Merchandising Practices Act, Mo. Rev. Stat. §§ 407.010 et seq.; NEBRASKA – Consumer Protection Act, Neb. Rev. Stat. §§ 59-1601 et seq. and Uniform Deceptive Trade Practices Act, Neb. Rev. Stat. §§ 87-301 et seq.; NEVADA – Deceptive Trade Practices Act, Nevada Revised Statutes 598.0903 et seq.; NEW HAMPSHIRE - New Hampshire Consumer Protection Act, RSA 358-A; NEW JERSEY – New Jersey Consumer Fraud Act, NJSA 56:8-1 et seq.; NEW MEXICO – NMSA 1978, § 57-12-1 et seq.; NEW YORK – General Business Law Art. 22-A, §§ 349-50, and Executive Law § 63(12); NORTH CAROLINA – North Carolina Unfair and Deceptive Trade Practices Act, N.C.G.S. 75-1.1, et seq.; NORTH DAKOTA – Unlawful Sales or Advertising Practices, N.D. Cent. Code § 51-15-02 et seq.; OHIO – Ohio Consumer Sales Practices Act, R.C. 1345.01, et seq.; OKLAHOMA – Oklahoma Consumer Protection Act 15 O.S. §§ 751 et seq.; OREGON – Oregon Unlawful Trade Practices Act, Or. Rev. Stat. § 646.605 et seq.; PENNSYLVANIA – Pennsylvania Unfair Trade Practices and Consumer Protection Law, 73 P.S. 201-1 et seq.; SOUTH DAKOTA – South Dakota Deceptive Trade Practices and Consumer Protection, SDCL ch. 37-24; TENNESSEE – Tennessee Consumer Protection Act, Tenn. Code Ann. 47-18-101 et seq.; TEXAS – Texas Deceptive Trade Practices-Consumer Protection Act, Tex. Bus. And Com. Code 17.41, et seq.; UTAH - Consumer Sales Practices Act, Utah Code Ann. §§ 13-11-1 et seq.; VIRGINIA-Virginia Consumer Protection Act, Va Code Ann. §59.1-196 et seq.; WASHINGTON – Unfair Business Practices/Consumer Protection Act, RCW §§ 19.86 et seq.; WISCONSIN – Wis. Stat. § 100.182 et seq. (Fraudulent Drug Advertising Representations).

2.29 Any reference to a written document shall mean a physical paper copy of the document, an electronic version of the document, or electronic access to such document.

3. COMPLIANCE PROVISIONS

IT IS FURTHER ORDERED, ADJUDGED AND DECREED THAT:

Promotional Activities

3.1 Pfizer shall not make, or cause to be made, any written or oral claim that is false, misleading, or deceptive regarding any Pfizer Product.

3.2 Pfizer shall not make any claim comparing the safety or efficacy of a Pfizer Product to another product when that claim is not supported by substantial evidence as defined by Federal law and regulations.

3.3 Pfizer shall not Promote Rapamune to an HCP who practices in a specialty that is unlikely to prescribe for a use in Rapamune's FDA approved Labeling.

3.4 Pfizer shall not make any written or oral Promotional claim of safety or effectiveness for any Pfizer Product in a manner that violates the FDCA, accompanying regulations, or voluntary agreements with FDA, as interpreted by the FDA in a writing by the Director of the Center for Drug Evaluation at the FDA.

3.5 Pfizer shall not Promote any Pfizer Product for Off-Label uses.

3.6 Pfizer shall not make any claim that contradicts or minimizes a precaution, warning, or adverse reaction that is described in product Labeling for Rapamune.

3.7 In Promotional Materials, Pfizer shall Clearly and Conspicuously disclose all material facts regarding the following: the risks associated with Rapamune as set forth in the products' FDA-approved Labeling; information in any boxed warning; and facts about the

negative consequences and side effects that can result from use of Rapamune. Pfizer shall present information about effectiveness and risk in a balanced manner. Whenever Pfizer knows or has reason to believe the current Labeling does not reflect the efficacy or risks of Rapamune, Pfizer shall promptly notify the Food and Drug Administration.

3.8 Pfizer shall not affirmatively seek the inclusion of Rapamune in hospital protocols or standing orders unless Rapamune has been approved by the FDA for the indication for which it is to be included in the protocol or standing order.

3.9 Pfizer shall require that all Promotional Speakers comply with Pfizer's obligations in paragraphs 3.1 through 3.8, 3.24, and 3.28 of this Judgment, including, but not limited to, ensuring that all Promotional Speakers' Promotional Materials and Promotional Media for Rapamune comply with Pfizer's obligations in this Judgment.

3.10 Pfizer shall notify its sales force promptly of any warning letter received from the FDA which affects the conduct of any sales representative in Promoting the relevant Pfizer Product and shall promptly provide a detailed explanation of the effect of the letter on the Promotion of Pfizer Products.

Financial Incentives to Pfizer Sales, Medical Outcome Specialists, and/or Pfizer Marketing

3.11 Pfizer's financial incentives shall be designed to ensure that Pfizer Sales, Medical Outcome Specialists, and/or Pfizer Marketing are not motivated to engage in improper Promoting, selling, and marketing of Rapamune.

3.12 Pfizer's financial incentives shall not include mechanisms to provide incentive compensation for sales that may be attributable to the Off-Label uses of any Pfizer Product.

3.13 For six years from the Effective Date of this Judgment, Pfizer shall continue to implement measures whereby sales goals, if any, for Rapamune can be met without including Off-Label prescriptions.

Dissemination and Exchange of Medical Information

The following provisions shall be effective for six years from the Effective Date of this Judgment.

3.14 Pfizer shall not knowingly disseminate any Medical Information Response, including one that describes any Off-Label use of Rapamune, that makes any false, misleading, or deceptive representation regarding Rapamune or any false, misleading, or deceptive statement concerning a competing product.

3.15 Pfizer Sales, Pfizer Marketing, and Medical Outcomes Specialists shall not develop the medical content of Medical Information Responses regarding Rapamune. Notwithstanding the foregoing, Medical Outcomes Specialists may assist in the development of pharmacoeconomic content of Medical Information Responses.

3.16 Medical Information Responses to Unsolicited Requests for Off-Label information regarding Rapamune may be disseminated only by Pfizer Medical.

3.17 Pfizer Medical shall have ultimate responsibility for developing and approving all Medical Information Responses regarding Rapamune. Additional approvals may be provided by Pfizer's legal department. Pfizer shall not distribute any such materials unless:

(a) clinically relevant information is included in these materials to provide scientific balance;

(b) data in these materials are presented in an unbiased, non-Promotional manner; and

(c) these materials are clearly distinguishable from sales aids and other Promotional Materials.

Responses to Unsolicited Requests for Off-Label Information

The following provisions shall be effective for six years from the Effective Date of this Judgment.

3.18 If Pfizer elects to respond to an Unsolicited Request for Off-Label information Pfizer Medical shall provide specific, accurate, objective, and scientifically balanced responses. Any such response shall not Promote Rapamune for any Off-Label use(s).

3.19 Any written Pfizer response to an Unsolicited Request for Off-Label information regarding Rapamune shall be a Medical Information Response and shall include:

(a) a copy of the FDA-required Labeling, if any, for the product (e.g., FDA- approved package insert and, if the response is for a consumer, FDA-approved patient labeling);

(b) a prominent statement notifying the recipient that the FDA has not approved or cleared the product as safe and effective for the Off-Label use addressed in the accompanying materials;

(c) a prominent statement disclosing the indication(s) for which FDA has approved or cleared the product;

(d) a prominent statement providing all important safety information including, if applicable, any boxed warning for the product;

(e) non-biased information or data relating to the particular Off-Label use that is the subject of the request, including applicable data that are not supportive or that cast doubt on the safety or efficacy of that use; and

(f) a comprehensive list of references for all of the information disseminated in the response (e.g., a bibliography of publications in peer-reviewed medical journals or in medical or scientific texts; citations for data on file, for summary documents, or for abstracts).

3.20 Pfizer Sales, Pfizer Marketing, and Medical Outcome Specialists may respond orally to an Unsolicited Request for Off-Label information regarding Rapamune only by offering to request on behalf of the HCP that a Medical Information Response be sent to the HCP in follow up or by offering to put the HCP in touch with Pfizer Medical. Notwithstanding the foregoing, Medical Outcomes Specialists may respond to inquiries related to pharmacoeconomics or health outcomes from formulary decision makers or the groups responsible for the management of health benefits within Healthcare Organizations, but not prescribers unless employed or engaged by a Healthcare Organization in a role connected to formulary decisions or the management of health benefits.

3.21 Information distributed by USMI in response to an Unsolicited Request for Off-Label information shall be:

(a) provided only to the individual making the request;

(b) tailored to answer only the specific Off-Label question(s) asked;

(c) scientific in nature; and

(d) unaccompanied by other material or information that is Promotional in nature or tone.

Reprints

3.22 Pfizer shall not disseminate any information describing any Off-Label use of any Pfizer Product if such use has been submitted to the FDA for approval and the FDA has either advised Pfizer that it refuses to approve such application or that FDA-identified deficiencies must be resolved before approval can be granted unless Pfizer has first Clearly and Conspicuously disclosed to the recipient of the information that the FDA has issued such advice. Pfizer may disclose to any recipient of such information whether the information was presented to the FDA prior to the FDA's issuance of such advice regarding the Off-Label use.

3.23 Pfizer shall not disseminate information describing any Off-Label or unapproved use of Rapamune unless such information and materials comply with applicable FDA regulations and the recommended actions in FDA Guidances for Industry.

Reprints Containing Off-Label Information

3.24 Pfizer Medical shall be responsible for the identification, selection, approval and dissemination of Reprints Containing Off-Label Information regarding Rapamune.

3.25 Reprints Containing Off-Label Information regarding Rapamune:

(a) shall be accompanied by the FDA approved Labeling for the product and contain a disclosure in a prominent location, which would include the first page or as a cover page where practicable, indicating that this article discusses Off-Label information; and

(b) shall not be referred to or used in a Promotional manner.

3.26 Reprints Containing Off-Label Information regarding Rapamune may only be disseminated by Pfizer Medical to HCPs. Notwithstanding the foregoing, Medical Outcomes Specialists may disseminate reprints relating to pharmacoeconomics or health outcomes to formulary decision makers or the groups responsible for the management of health benefits within Healthcare Organizations, but not prescribers unless employed or engaged by a Healthcare Organization in a role connected to formulary decisions or the management of health benefits.

3.27 Nothing in this Judgment shall preclude Pfizer from disseminating reprints which have only an incidental reference to Off-Label information. If reprints have an incidental reference to Off-Label information, such reprints shall not be subject to the requirements of Section 3.23 and such incidental reference to Off-Label information shall not be referred to or used in a Promotional manner as prohibited by Section 3.25(b).

3.28 Pfizer shall maintain a disclosure program which allows for the anonymous disclosure of compliance policy violations and contains a no retaliation policy.

Clinical Research

3.29 Pfizer shall report clinical research regarding Rapamune in an accurate, objective and balanced manner, and as required by applicable law. For all Pfizer-sponsored clinical trials and to the extent permitted by the National Library of Medicine, Pfizer shall register clinical trials and submit clinical trial results to the federal clinical trial registry and results data bank regarding Rapamune on the publicly accessible NIH website (www.clinicaltrials.gov) as required by the FDA Amendments Act of 2007, Public Law No. 110-85, 121 Stat 823, and any accompanying regulations that may be promulgated pursuant to that Act.

3.30 When presenting information about a clinical study regarding Rapamune in any Promotional materials, Pfizer shall not do any of the following:

(a) present information or conclusions from a study that is inadequate in design, scope, or conduct to furnish significant support for such information or conclusions;

(b) use the concept of statistical significance to support a claim that has not been demonstrated to have clinical significance or validity or fails to reveal the range of variations around the cited average results;

(c) 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 the study, the design or protocol of which is not amenable to formal statistical evaluations;

(d) present the information in a way that implies that the study represents larger or more general experience with the drug than it actually does;

(e) use statistics on numbers of patients, or counts of 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. If any results derived from pooling data are presented, Pfizer shall disclose the method of pooling;

(f) use tables or graphs to distort or misrepresent the relationships, trends, differences, or changes among the variables or products studied; or

(g) use reports or statements represented to be statistical analyses, interpretations, or evaluations that are inconsistent with or violate the established principles of statistical theory, methodology, applied practice and inference, or that are derived from clinical studies the design, data, or conduct of which substantially invalidate the application of statistical analyses, interpretation, or evaluation.

3.31 Pfizer shall not seek to influence the prescribing of Rapamune in hospitals or transplant centers in any manner (including through funding clinical trials) that does not comply with the Federal anti-kickback statute (codified at 42 U.S.C. § 1320a-7b).

4. PAYMENT

4.1 No later than 30 days after the Effective Date of this Judgment, Pfizer shall pay a total amount of Thirty-Five Million Dollars ($35,000,000.00) to be divided and paid by Pfizer directly to each Signatory Attorney General of the Multistate Working Group in an amount to be designated by and in the sole discretion of the Multistate Executive Committee. Said payment shall be used by the States as attorneys' fees and other costs of investigation and litigation, or to be placed in, or applied to, the consumer protection enforcement fund, including future consumer protection enforcement, consumer education, litigation or local consumer aid fund or revolving fund, used to defray the costs of the inquiry leading hereto, or for any lawful purpose, at the sole discretion of each Signatory Attorney General. The Parties acknowledge that the payment described herein is not a fine, penalty, or payment in lieu thereof.

5. RELEASE

5.1 By its execution of this Judgment, the State of Kansas releases Pfizer and all of its past and present, subsidiaries and divisions, predecessors, successors, and assigns (collectively,

the "Released Parties") from the following: all civil claims, causes of action, damages, restitution, fines, costs, and penalties that the Kansas Attorney General has asserted or could have asserted against the Released Parties under the above-cited consumer protection statutes resulting from the Covered Conduct up to and including the Effective Date.

5.2 Notwithstanding any term of this Judgment, specifically reserved and excluded from the release in Paragraph 5.1 as to any entity or person, including Released Parties, are any and all of the following:

(a) any criminal liability that any person and/or entity, including Released Parties, has or may have to the State of Kansas.

(b) any civil or administrative liability that any person and/or entity, including Released Parties, has or may have to the State of Kansas not expressly covered by the release in Paragraph 5.1 above, including, but not limited to, any and all of the following claims:

(i) state or federal antitrust violations;

(ii) claims involving "best price," "average wholesale price," "wholesale acquisition cost," or any reporting practices;

(iii) Medicaid claims, including, but not limited to, federal Medicaid drug rebate statute violations, Medicaid fraud or abuse, and/or kickback violations related to any State's Medicaid program;

(iv) state false claims violations; and

(v) actions of state program payors of the State of Kansas arising from the purchase of a Pfizer Product.

(c) any liability under the State of Kansas's above-cited consumer protection laws which any person and/or entity, including Released Parties, has or may have to individual consumers.

5.3 Nothing contained in this Judgment shall relieve Pfizer of the obligations it maintains under any other Judgment or agreement relating to any Pfizer Product.

6. DISPUTE RESOLUTION

6.1 For the purposes of resolving disputes with respect to compliance with this Judgment, should any of the Signatory Attorneys General have a reasonable basis to believe that Pfizer has engaged in a practice that violates a provision of this Judgment subsequent to the Effective Date of this Judgment, then such Attorney General shall notify Pfizer in writing of the specific objection, identify with particularity the provision of this Judgment that the practice appears to violate, and give Pfizer thirty (30) days to respond to the notification; provided, however, that a Signatory Attorney General may take any action if the Signatory Attorney General concludes that, because of the specific practice, a threat to the health or safety of the public requires immediate action. Upon receipt of written notice, Pfizer shall provide a good-faith written response to the Attorney General notification, containing either a statement explaining why Pfizer believes it is in compliance with the Judgment, or a detailed explanation of how the alleged violation occurred and a statement explaining how Pfizer intends to remedy the alleged breach. Nothing in this section shall be interpreted to limit the state's Civil Investigative Demand ("CID") or investigative subpoena authority, to the extent such authority exists under applicable law, and Pfizer reserves all of its rights in responding to a CID or investigative subpoena issued pursuant to such authority.

6.2 Upon giving Pfizer thirty (30) days to respond to the notification described above, the Signatory Attorney General shall also be permitted reasonable access to inspect and copy relevant, non-privileged, non-work product records and documents in the possession, custody, or control of Pfizer that relate to Pfizer's compliance with each provision of this Judgment pursuant to that State's CID or investigative subpoena authority. If the Signatory Attorney General makes or requests copies of any documents during the course of that inspection, the Signatory Attorney General will provide a list of those documents to Pfizer.

6.3 The State may assert any claim that Pfizer has violated this Judgment in a separate civil action to enforce compliance with this Judgment, or may seek any other relief afforded by law, but only after providing Pfizer an opportunity to respond to the notification described in paragraph 6.1 above; provided, however, that a Signatory Attorney General may take any action if the Signatory Attorney General concludes that, because of the specific practice, a threat to the health or safety of the public requires immediate action.

7. GENERAL PROVISIONS

7.1 Pfizer shall not cause or encourage third parties, nor knowingly permit third parties acting on its behalf, to engage in practices from which Pfizer is prohibited by this Judgment.

7.2 The acceptance of this Judgment by the Kansas Attorney General shall not be deemed approval by the Kansas Attorney General of any of Pfizer's advertising or business practices. Further, neither Pfizer nor anyone acting on its behalf shall state or imply, or cause to be stated or implied, that the Kansas Attorney General or any other governmental unit of the

State of Kansas has approved, sanctioned or authorized any practice, act, advertisement, or conduct of Pfizer.

7.3 Any failure by any party to this Judgment to insist upon the strict performance by any other party of any of the provisions of this Judgment shall not be deemed a waiver of any of the provisions of this Judgment, and such party, notwithstanding such failure, shall have the right thereafter to insist upon the specific performance of any and all of the provisions of this Judgment.

7.4 This Judgment represents the full and complete terms of the settlement entered into by the Parties hereto. In any action undertaken by the Parties, no prior versions of this Judgment and no prior versions of any of its terms that were not entered by the Court in this Judgment, may be introduced for any purpose whatsoever.

7.5 This Court retains jurisdiction of this Judgment and the Parties hereto for the purpose of enforcing and modifying this Judgment and for the purpose of granting such additional relief as may be necessary and appropriate.

7.6 This Judgment may be executed in counterparts, and a facsimile or .pdf signature shall be deemed to be, and shall have the same force and effect as, an original signature.

7.7 All Notices under this Judgment shall be provided to the following via email and Overnight Mail:

For Pfizer Inc:
Joshua S. Levy
ROPES & GRAY LLP
Prudential Tower, 800 Boylston Street
Boston, MA 02199-3600
joshua.levy@ropesgray.com

Margaret M. Madden
Vice President and Assistant General Counsel
Pfizer Inc
235 East 42nd Street
New York, NY 10017
margaret.m.madden@Pfizer.com

For Office of the Kansas Attorney General:
Office of the Kansas Attorney General
Consumer Protection/Antitrust Division
c/o Meghan E. Stoppel
120 SW 10th Ave., 2nd Floor
Topeka, Kansas 66612-1597
meghan.stoppel@ag.ks.gov

7.8 To the extent that any provision of this Judgment obligates Pfizer to change any policy(ies) or procedure(s) and to the extent not already accomplished, Pfizer shall implement the policy(ies) or procedure(s) as soon as reasonably practicable, but no later than 120 days after the Effective Date of this Judgment.

IT IS THEREFORE ORDERED, ADJUDGED AND DECREED that the stipulations and agreements of the Parties contained herein are adopted and approved as the findings of fact and conclusions of law of the Court and any monies owed hereunder by Defendant immediately become a Judgment upon filing.

IT IS FURTHER ORDERED, ADJUDGED AND DECREED that pursuant to the Kansas Consumer Protection Act and the provisions of K.S.A. 50-632(b), the Court hereby approves the terms of this Judgment and adopts the same as the Order of the Court.

IT IS SO ORDERED.

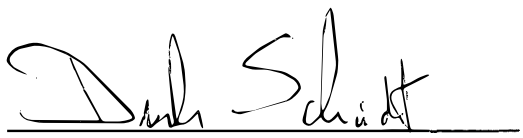
DISTRICT COURT JUDGE

SEAL of the DISTRICT COURT SHAWNEE CO. KANSAS

STATE OF KANSAS, COUNTY OF SHAWNEE, S.S.
JANUARY 29, 1861 hereby certify the above and foregoing to be true and correct copy, the original of which is filed and entered of record in the court.
Dated August 6, 2014
CLERK of the DISTRICT COURT
By Ashley Michaelis DEPUTY

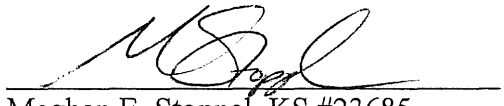
JOINTLY APPROVED AND
SUBMITTED FOR ENTRY:

FOR PLAINTIFF, STATE OF KANSAS



Date: 8/6/2014

Derek Schmidt, KS #17781
Attorney General
Office of the Kansas Attorney General
120 SW 10th Ave., 2nd Floor
Topeka, Kansas 66612-1597
Phone: (785) 296-2215



Date: 8/6/14

Meghan E. Stoppel, KS #23685
Assistant Attorney General
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120 SW 10th Ave., 2nd Floor
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Phone: (785) 296-3751
Fax: (785) 291-3699

FOR PFIZER INC

By: _____ Date: 7/31/14

Margaret M. Madden
Vice President and Assistant General Counsel
Pfizer Inc

FOR WYETH PHARMACEUTICALS INC.

By: _____ Date: 7/31/14

Margaret M. Madden
Vice President and Assistant General Counsel
Pfizer Inc

FOR PFIZER INC & WYETH PHARMACEUTICALS INC.

By:_____ Date: 8-1-14

Joshua S. Levy
Ropes & Gray LLP
Prudential Tower, 800 Boylston Street
Boston, MA 02199

LOCAL COUNSEL FOR PFIZER INC & WYETH PHARMACEUTICALS INC.

By: Taylor Fields Date: 8/1/14

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