VIRGINIA:

IN THE CIRCUIT COURT FOR THE CITY OF RICHMOND

COMMONWEALTH OF VIRGINIA, EX REL. MARK R. HERRING, ATTORNEY GENERAL, **Plaintiff,**	
v.	**Case No.** 19-5566-5
TEVA PHARMACEUTICALS USA, INC.,	
SERVE: Office of the Secretary of the Commonwealth Service of Process Department P.O. Box 2452 Richmond, VA 23218-2452	
	COMPLAINT
AND	
CEPHALON, INC.,	
SERVE: Office of the Secretary of the Commonwealth Service of Process Department P.O. Box 2452 Richmond, VA 23218-2452	
Defendants.	

SUMMARY

Immediate-release fentanyl is the most potent narcotic approved for human use. Since it was first approved by the Federal Drug Administration (FDA) in 1999, its indicated use has consistently been restricted to cancer patients in pain that other narcotics cannot relieve. Yet for the last 20 years, fentanyl manufacturers Cephalon, Inc. and its successor, Teva Pharmaceuticals, USA, Inc., have disregarded these restrictions and deceived health care providers and patients about these drugs' benefits and risks, even as their own knowledge of these drugs' risks grew.

Virginia Consumer Protection Act, Va. Code §§ 59.1-196 through 59.1-207, and has harmed thousands of patients and consumers in Virginia and nationwide. The Commonwealth petitions this Court to enjoin the Defendants' sales and marketing practices and to award restitution, civil penalties, expenses, and attorneys' fees.

PARTIES

1. The Plaintiff is the Commonwealth of Virginia, by, through, and at the relation of Mark R. Herring, Attorney General of Virginia.

2. Defendant Teva Pharmaceuticals USA, Inc. is a Delaware corporation with its principal place of business in North Wales, Pennsylvania. Teva Pharmaceuticals USA, Inc. is a wholly-owned subsidiary of Teva Ltd., a global pharmaceutical company with headquarters in Petah Tikva, Israel and whose shares are traded on the New York Stock Exchange (symbol: TEVA). This Complaint will use "Teva" to refer to Defendant Teva Pharmaceuticals USA, Inc.

3. Defendant Cephalon, Inc. is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. Teva Ltd. acquired Cephalon, Inc. in 2011. Cephalon, Inc. is a wholly-owned subsidiary of Teva Ltd.

JURISDICTION AND VENUE

4. The Circuit Court for the City of Richmond has authority to entertain this action and to grant the relief requested here under Virginia Code §§ 8.01-620, 17.1-513, 59.1-203, 59.1-205, and 59.1-206.

5. This Court has jurisdiction over both named Defendants under Virginia Code § 8.01-328.1(A)(1), (3), and (4) because Defendants have transacted business in the Commonwealth of Virginia; Defendants have caused tortious injury by an act or omission in the Commonwealth; Defendants have caused tortious injury in the Commonwealth by an act or

omission outside the Commonwealth; and Defendants regularly do or solicit business, engage in a persistent course of conduct, and derive substantial revenue from goods used or consumed in the Commonwealth.

6. Venue is permissible in this Court under Virginia Code § 8.01-262(3) and (4) because Defendants regularly conduct substantial business activity within the City of Richmond and the counts alleged here arose, in part, in the City of Richmond.

7. In accordance with Virginia Code § 59.1-203(B), before commencing this action, the Commonwealth gave written notice that these proceedings were contemplated and a reasonable opportunity for Defendants to appear before the Office of the Attorney General to show that no violations of the VIRGINIA CONSUMER PROTECTION ACT had occurred, or, in the alternative, to execute an appropriate Assurance of Voluntary Compliance that is acceptable to Plaintiff. Neither Defendant showed that no violations had occurred and neither Defendant executed an appropriate Assurance of Voluntary Compliance.

FACTS

I. Fentanyl's History.

8. Fentanyl is the most potent narcotic on the market for human use.

9. Fentanyl is now widely legally used and illegally abused.

10. Its history shows how drug manufacturers disregarded fentanyl's terrible risks.

11. This disregard took three forms: failing to study fentanyl's long-term risks, especially its abuse liability (its risk of abuse); downplaying known risks without clinical evidence; and undermining risk mitigation barriers the FDA and other regulatory agencies put up to protect patients.

A. Initial Approval for Inpatient Intravenous Use.

12. Fentanyl was first approved by the FDA in 1968 not as a pain treatment, but as an anesthetic, administered intravenously to produce unconsciousness for surgery.

13. Its initial approval came with no human study of dependence or addiction risks; only animal studies of tolerance and dependence in dogs, monkeys, guinea pigs, and rats.

14. Intravenous fentanyl was restricted to hospital use, administered by medical professionals, not self-administered by patients.

15. Even with a narrow indication and a curtailed setting, intravenous fentanyl saw misuse – medical professionals, aware of its potency, abused it, and clandestine labs created illicit versions, with names like China White.

16. As an anesthetic, fentanyl ultimately proved to be a failure because it was too potent: in patients who had not used opioids before (opioid-naïve), it induced unsafe rates of respiratory depression or hypoventilation (slow breathing).

B. First Oral Formulation Was Oralet, Whose Use Was Also Sharply Restricted.

17. In 1993, the FDA approved a fentanyl lozenge called Oralet.

18. Veterinarians had discovered that sugar cubes of carfentanil, an ultrapotent cousin of fentanyl, rapidly immobilized large wild animals like elk or moose. These carfentanil sugar cubes inspired doctors to create a sweetened fentanyl lollipop lozenge that doctors could give to children or adults for rapid sedation.

19. Oralet's use was sharply restricted. Like intravenous fentanyl, Oralet's indication was as an anesthetic before surgery for children and adults, and it could only be administered by specialty-trained personnel in controlled settings like hospitals; there were essentially no Oralet prescriptions filled in retail pharmacies.

20. Because of these restrictions, Oralet was never a commercial success for Anesta Corporation (Anesta), its sponsor.

21. Anesta was acquired by Cephalon in 2000, which in turn was acquired by Teva Ltd. in 2011.

22. Anesta ceased marketing Oralet altogether in March 2001 when, in the FDA's words, "it became evident that opioid-naïve children who received it could not tolerate the associated adverse events of nausea and vomiting."

C. Duragesic Patch: Fentanyl Is Unleashed into the Real World Without Any Significant Long-Term Testing.

23. It was through a fentanyl patch that fentanyl became broadly used.

24. The patch was a slow-release form of fentanyl created in the 1980s by Alza Corporation ("Alza"), which later merged with Johnson & Johnson in 2001.

25. The patch was approved with minimal human testing of its long-term risks and benefits.

26. Alza submitted a single "long-term" study, which followed only 54 patients for a mere "224 patient months," an average of just over 4 months.

27. None of Alza's studies, including the "long-term" one, tested the patch's "abuse liability."

28. And the "long-term" study significantly differed from how the patch was ultimately used: the study was conducted only on dying ("pre-terminal") cancer patients because the patch was initially proposed to be used only as palliative therapy for terminally-ill cancer patients.

29. Even without studying abuse liability, Alza's sole "long-term" study flashed two warning signs that fentanyl had dangerous flaws as a long-term treatment for pain.

30. First, the fentanyl patch showed potential decreases in efficacy – patients required greater and greater doses of fentanyl over time, a "rate of dose increase of approximately 50% per month of therapy."

31. Second, half of the study patients had serious short-term adverse events, including many deaths, all of which Alza attributed to the patients' underlying metastatic cancer, not the patch.

32. The FDA disagreed, listing patient symptoms like slurred speech, hallucinations, dizziness, falls, disorientation, somnolence, confusion and "spaced out" feelings.

33. This study and others also showed that the fentanyl patch was unsuitable for some forms of acute pain care, such as post-surgical treatment or treating injuries, because it slowed patients' breathing too much.

34. Alza argued that no further testing was needed – there did not need to be a thorough evaluation of the patch in real-world settings – since the patch was initially intended for a limited use in palliative cancer patients.

35. A few FDA reviewers expressed misgivings. They argued there needed to be further real-world testing beyond just cancer patients to ensure that the fentanyl patch would not lead to "extensive improper use and consequent morbidity and mortality."

36. These reviewers' warnings proved prescient. For the next 20 years, fentanyl products would, in fact, be accompanied by "extensive improper use" and the result was "consequent morbidity and mortality" in the form of overdose, addiction, and deaths.

37. There were no further long-term studies of the patch before approval.

38. The FDA ended up approving the fentanyl patch with a far-broader indication than for just cancer pain treatment – it could be used for any form of chronic pain treatment.

39. The result was that fentanyl was unleashed into the broader world without any clinical assessment of its long-term risks and benefits other than Alza's minimal testing on a few terminally-ill cancer patients.

D. Duragesic Was a Marketing Success and Public Health Failure.

40. Marketed aggressively by Janssen Inc. (Janssen), the patch, under the brand name Duragesic, became a blockbuster – it exploded into widespread use for cancer and non-cancer pain treatment. For instance, from 1991 to 1996, fentanyl patch prescriptions skyrocketed from 126,000 to 805,000. Johnson & Johnson made billions.

41. But with the patch's expansion in the 1990s came misuse, abuse, and addiction. Non-industry clinical studies of fentanyl from this period showed why.

42. A study of volunteers without a history of drug dependence given intravenous fentanyl concluded that "many normal individuals may like fentanyl to some extent on initial exposure and that such a response might increase the risk for drug abuse."

43. A study of experienced opioid abusers found they liked intravenous fentanyl too: they rated highly its subjective high and its effect.

44. These clinical experiences were borne out in the real world: Janssen reported adverse drug reactions throughout the 1990s, including overdoses, dependence, addiction, increased tolerance, and withdrawal.

45. Drug abusers were even willing to ingest the patch to get high. And there were horrible reports of children exposed to used fentanyl patches they found in the trash.

46. The patch's expansion had another consequence. Other drug manufacturers wanted a piece of the profitable fentanyl market, and looked to develop their own forms of fentanyl.

E. The Actiq Fentanyl Lozenge was Initially Deemed Too Risky Even If Limited to Just Palliative Cancer Treatment.

47. After failing with Oralet, Anesta tried to obtain approval for another oral form of fentanyl. In 1998, it applied for FDA approval for Actiq, a rapid-release form of fentanyl.

48. Like Oralet, Actiq was a raspberry-flavored fentanyl lozenge on a stick. But it came in higher doses. And to be more commercially successful, Anesta proposed a broader indication than Oralet: it would not be a pre-surgery sedative; it would be pain treatment for cancer patients.

49. The proposed new indication, however, was still quite restrictive. Anesta proposed that Actiq be limited to treating only cancer patients with metastatic cancers, who were still suffering from "breakthrough pain" despite other opioid treatments.

50. As the FDA put it, Actiq's proposed use was limited to "palliative treatment of breakthrough pain associated with chronic pain of advanced cancer, in patients who already require continuous opioid therapy for pain control and are tolerant to the side effects of opioid agents."

51. The phrases "metastatic cancer," "advanced cancer," and "palliative treatment," speak to the narrow set of patients for which Actiq was being considered: seriously- and terminally-ill cancer patients.

52. And a key part of the proposed indication was that cancer patients be opioid-tolerant. Opioid-naïve patients faced too great a risk of respiratory depression from fast-acting fentanyl products like Actiq.

F. Anesta Submitted Minimal Long-Term Study Data for Actiq, Which Did not Include Studying Abuse Liability.

53. Actiq's approval process played out much like the fentanyl patch's.

54. Anesta sought approval with minimal long-term data on Actiq's risks and benefits. Its long-term evidence consisted of a single still-ongoing study from which it presented only partial data.

55. The long-term study examined only seriously-ill cancer patients. It was open-label; it was not blinded, and not controlled, meaning that it did not compare Actiq to a placebo or alternate pain treatments.

56. The study followed a small sample: at the time of approval, only 10 patients had taken Actiq for eight months or more. The study presented no data on abuse, misuse, or addiction, so it did not evaluate abuse liability.

G. The FDA Initially Declined to Approve Actiq Because of Actiq's Risks of Abuse, Overdose, and Misuse.

57. The FDA initially concluded that Actiq and rapid-release fentanyl were too risky.

58. The FDA thought Actiq's abuse liability was too great. It worried that those with limited exposure to opioids would start abusing Actiq; that those already dependent on opioids would become addicted; and that suffering from addiction would become worse.

59. The FDA concluded that Anesta downplayed Actiq's abuse risk with minimal evidence. Anesta had even cited an infamous 1980 letter in the *New England Journal of Medicine* claiming that addiction was "rare in patients treated with narcotics."

60. Anesta had also claimed that it had not detected abuse in its clinical trials (even though it had not looked for or examined abuse in its trials).

61. Anesta had even speculated that a fentanyl lollipop would be unappealing to

patients suffering from opioid addiction.

62. The FDA also thought Actiq's overdose risks were too great.

63. Actiq presented three distinct overdose risks: to opioid-tolerant patients, to opioid-naïve patients, and to non-patients.

64. Anesta had only studied patients in the first category: patients whose cancer pain persisted in the face of existing opioid treatment, often around-the-clock opioid treatment. Even when prescribed correctly, Actiq still posed an overdose risk to these opioid-tolerant patients.

65. But the FDA was especially worried about overdoses by the wrong patients – the opioid-naïve – or by accidental use, especially by children. Anesta had never studied the risks to these patients.

H. Anesta Obtained FDA Approval for Actiq Only by Presenting a Risk Management Plan under Which It Would Monitor and Limit Off-Label Prescribing.

66. Because of these risks, the FDA initially issued a "non-approval action" for Actiq in November 1997, citing accidental use and the overdose risks to opioid-naïve patients.

67. Anesta tried again. It proposed a restricted approval under 21 C.F.R. § 314.20, which allows the FDA to approve drugs with restrictions on use and marketing "as are needed to assure safe use of the drug product."

68. Restricted approvals are "special safety programs to mitigate serious risks." By granting a restricted approval, the FDA acknowledges that it would not otherwise approve a drug because its risks would outweigh its benefits. The FDA had never granted a restricted approval for an opioid product; Actiq would become the first.

69. Anesta put its proposed restrictions into a "risk management plan." One of the plan's key purposes was to ensure "proper patient selection." Proper patient selection included

ensuring that Actiq was used "solely" to treat breakthrough pain in opioid tolerant cancer patients.

70. Proper patient selection also included preventing Actiq prescriptions for "acute/postoperative pain," for which Actiq was "specifically contraindicated."

71. Actiq's proposed package insert and black box warning reinforced these messages: Actiq should not be used for "acute or postoperative pain" or by the "opioid non-tolerant" because of the risk of "life-threatening hypoventilation."

72. Anesta committed to limit its marketing accordingly.

73. It was supposed to produce educational materials for providers that reinforced the key safety messages, especially proper patient selection messages.

74. It was supposed to work with the FDA to develop and disseminate these educational materials.

75. It was supposed to submit all promotional materials and multimedia programs to the FDA for review.

76. It was supposed to have a salesforce of "Oncology Sales Specialists," who would "play a key role in implementing" the plan.

77. It was supposed to stress to all of its Oncology Sales Specialists the requirements to limit Actiq's promotion to "the approved indication" for cancer use, to "discourage off-label use," and tell them "the serious consequences of violating this policy."

78. Anesta committed to catching and stopping improper use. It agreed to surveil and monitor for improper prescriptions, including routine monitoring of prescription data for each prescriber and pharmacy. It agreed to intervene "when problems are discovered."

79. For example, if individual prescribers were prescribing improperly to non-cancer

or opioid-naïve patients, Anesta agreed to (a) send a warning letter emphasizing Actiq's approved use for cancer pain treatment, and (b) if the problem persisted, visit providers in person to remind them of appropriate prescribing.

80. Anesta also agreed to monitor and take action if certain groups or specialties of physicians were prescribing Actiq off-label, including taking action if "these prescriptions represent potential off-label usage greater than 15% of total quarterly Actiq prescriptions."

81. It even agreed to modify the risk management program as a whole if it was not working.

82. The FDA believed Anesta. Based on Anesta's commitments in the risk management plan, the FDA approved Actiq, "when marketed in accordance with the terms of restricted distribution and use described in the Risk Management Program . . . ."

83. In its approval letter, the FDA stated that the Risk Management Program is an "integral part" and an "essential component" of the approval.

84. It also explicitly warned Anesta not to engage in off-label promotion, not to make any promotional statements or representations that Actiq was safe or effective in treating anyone other than cancer patients with malignancies:

> **In addition, please note that this product has been approved <u>ONLY</u> for the management of breakthrough cancer pain in patients with malignancies who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain.**
>
> **As such, please note that promotional statements or representations by you that this product may indeed be safe and efficacious in the treatment of diseases or patient populations beyond that contained in your approved labeling may be considered a violation of the Act. If you**

(FDA Approval letter for Actiq, November 4, 1999)

85. With these restrictions, the FDA thought it could fence in Actiq, limiting its marketing and use to providers treating metastatic cancer patients. The FDA did so to protect public health.

86. The FDA's public health concerns were based on Actiq's unique risk-benefit calculus.

87. Actiq was limited to patients with metastatic cancers because they have a different assessment of opioids' risks and benefits from other patients.

88. For those patients, the benefits of treating their short-term pain and suffering exceeds the short-term risks of adverse events (side effects) and longer-term risks from opioids – addiction, drug dependency, analgesic tolerance to opioids' pain relieving effects, and hyperalgesia (increased sensitivity to pain).

89. In contrast, Actiq was not approved for treatment of chronic non-cancer pain because these patients are also pursuing different short- and long-term benefits than cancer patients with metastatic cancers.

90. Chronic pain patients need both short-term and longer-term pain relief. They may take pills for a longer period of time than patients with metastatic cancers, in part because they may live longer.

91. This makes non-cancer chronic pain patients more subject to long-term risks like addiction, drug dependency, analgesic tolerance to opioids' pain relieving effects, and hyperalgesia.

92. They are also more likely to see diminishing benefits if opioids prove less and less effective at relieving pain over time.

93. When the FDA approved Actiq, it sent a clear message that Actiq was too risky for non-cancer use: its known risks exceeded its benefits, and Anesta (and other fentanyl manufacturers) had failed to study the long-term risks and benefits for non-cancer patients (and had barely begun to do so for long-term cancer pain treatment).

94. Anesta heard this message. But, as it knew, even if it was subject to these extensive restrictions, physicians were not limited to the approved indication.

95. It was for these off-label uses that Actiq became widely used.

II. Cephalon Made Actiq a Blockbuster by Flaunting the FDA's Restrictions to Sell Actiq to Non-Cancer Patients for Whom It Was Too Risky.

96. In 2001, Anesta was acquired by Cephalon. Cephalon set out to make Actiq a blockbuster.

97. Cephalon succeeded. But it did so by thoroughly subverting its risk management commitments from the start.

98. [redacted]

99. The result was that Cephalon ran a massive uncontrolled experiment to see what happened when non-cancer patients used rapid-release fentanyl.

100. The experiment was conducted on thousands of the very patients it had pledged to protect, patients for whom the FDA had determined that Actiq was too risky. Public health and individual patients suffered the consequences.

[redacted]

101. [redacted]

102. [redacted]

103. [redacted]

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105. [redacted]

106. [redacted]

107. [redacted]

[redacted]

108. [redacted]

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109. [redacted]

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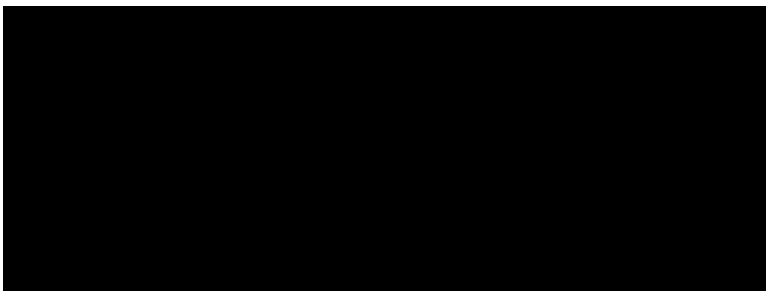
115. [redacted]



116. [redacted]

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121. [redacted]

122. For example, a Virginia Beach rheumatologist [redacted]

123. [redacted] the doctor continued to aggressively prescribe Actiq (and other opioids) to patients suffering from fibromyalgia, chronic pain, and headaches.

124. From December 2003 to August 2008, five of his patients died of narcotics overdoses. Others were hospitalized for drug-related conditions, including two of his Actiq patients, both of whom were sent to psychiatric treatment and drug detoxification in February 2004.

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126. [redacted]

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127. [redacted]

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B. [redacted]

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141. [redacted]

[redacted]

142. Cephalon also targeted patients, especially new patients. It did so by disbursing coupons good for six free Actiq lozenges.

143. [redacted]

144. [redacted]

145. [redacted]

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147. [redacted]

148. [redacted]

149. [redacted]

150. [redacted]

1. [redacted]

151. [redacted]

152. [redacted]

153. [redacted]

154. [redacted]

155. [redacted]

2. Cephalon's Sales and Marketing of Actiq Was a Business Success and a Public Health Problem.

156. Cephalon's marketing efforts paid off. Prescriptions skyrocketed from 10,000 in the first quarter of 2001 to over 90,000 in the last quarter of 2003.

157. By 2004, there had been 700,000 Actiq prescriptions [redacted]

158. Revenue soared too. In Actiq's first full year of use, 2000, Cephalon made $15 million from Actiq sales. By 2002, it had made over $100 million. By 2005, $412 million. By 2006, $600 million a year.

159. [redacted]

160. Actiq contributed to a broader explosion in legal fentanyl use. From 1997 to 2007, fentanyl prescriptions overall increased approximately 500%, from 891,000 prescriptions to 5.5 million, with the majority of prescriptions for the fentanyl patch.

C. [redacted]

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166. [redacted]

[redacted]

167. [redacted]

168. Cephalon, along with other opioid manufacturers, also promoted the unsubstantiated claim that patients who started demonstrating alarming drug-related behaviors were not actually suffering; they were just experiencing "pseudoaddiction."

169. Cephalon claimed that when patients exhibited addiction-like behaviors, they did not need addiction treatment, they needed more pain treatment in the form of greater doses of opioids.

170. So Cephalon trained doctors to increase opioid doses, including Actiq doses, in the face of aberrant drug-related patient behaviors.

171. This had real world consequences. For example, a Henrico, Virginia, physical medicine doctor, who had attended Cephalon presentations and to whom Cephalon had made over 100 sales visits, was disciplined by the Virginia Board of Medicine in April 2016 for overprescribing narcotics, including Actiq, to seven patients from 2007 through 2014, including patients who doctor-shopped to get narcotics from multiple physicians and who repeatedly sought early refills of their narcotics, all red flags of addiction problems. In his defense, the doctor claimed he thought the patients were suffering from "pseudo-addiction."

172. Cephalon also downplayed addiction risk. [redacted]

[redacted]

173. [redacted]

174. Cephalon had limited support for any of these messages, and no support from its clinical trials. As noted above, prior to FDA approval, there had been no clinical study of Actiq's abuse potential.

175. Collectively the aim of these messages was to promote Actiq's use, while misinforming doctors and patients about Actiq's risks and benefits. Variations of these messages would continue for years to come, as discussed below.

III. Cephalon's Off Label Marketing Subverted Actiq's Risk Mitigation Program.

A. Cephalon's Own Auditors Could Not Stop its Off-Label Marketing.

176. As it became clear in the early 2000s that most Actiq prescriptions were written for the wrong patients, Cephalon squelched internal [redacted] efforts to check these practices.

177. Internally, in 2003, a Cephalon auditor concluded that it was not in compliance with its risk management commitments to monitor and prevent off-label prescribing. Instead of changing its practices, it terminated the auditor. [redacted]

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186. [redacted]

187. [redacted]

188. [redacted]

189. [redacted]

190. [redacted]

191. [redacted]

C. [redacted]

192. [redacted]

193. [redacted]

194. [redacted].

195. [redacted]

196. [redacted]

197. [redacted]

198. [redacted]

[redacted]

199. [redacted]

200. [redacted]

201. [redacted]

202. [redacted]

D. The Consequences from Actiq Promotion from 2001 to 2006

203. Cephalon's promotion of Actiq from 2001 to 2006 to patients who did not have metastatic cancers disregarded Actiq's known risks and benefits.

204. Millions of Actiq lozenges went to patients for whom Cephalon and Anesta had not clinically evaluated Actiq's safety, risks, and benefit.

205. More than half a million patients across America and thousands in Virginia bore these risks, taking Actiq for conditions that had not been studied, or for which the long-term risks and benefits were unstudied and unknown.

E. 2008 Actiq Settlements

206. Cephalon was held partially accountable for its off-label promotion of Actiq in September 2008, when Cephalon settled four related lawsuits alleging it engaged in illegal off-label marketing of Actiq (and two other non-opioid products) from 2001 to 2006.

207. Those lawsuits included federal criminal misbranding charges.

208. They also included multistate civil Medicaid fraud claims, including charges brought by the Commonwealth of Virginia. Cephalon agreed to pay $375 million to resolve the state Medicaid fraud claims. Globally, it agreed to undertake measures to prevent further off-label marketing.

209. [redacted]

F. Actiq to Fentora: [redacted]

210. By 2008, Cephalon had largely moved on from Actiq to its new rapid-release fentanyl product, Fentora.

211. It did so in part because Actiq's exclusivity patent expired in 2006, and a number of new immediate-release fentanyl products were due to enter the market, potentially cutting into Actiq's sales.

212. [redacted]

213. [redacted]

214. [redacted]

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[redacted]

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[redacted]

217. [redacted]

[redacted]

IV. Cephalon's Clinical Trials on Fentora

A. Cephalon Ran Two "Long-Term" Clinical Trials on Fentora that Failed to Study Abuse Liability.

218. From 2006 to 2019, Cephalon and Teva would rely upon and cite Fentora clinical trial data to support a variety of claims about Fentora's benefits, efficacy, and risks. As the companies came under more scrutiny and as the opioid crisis worsened, they relied more and more upon these clinical trials as the source for their risk-benefit claims. Understanding how the Fentora clinical trials proceeded provides context for Fentora's approval by the FDA and shows how these trials became a vehicle for deceptive and misleading claims about Fentora's risks and benefits.

219. For Fentora, Cephalon ran two parallel series of clinical trials from 2004 to 2007. One series studied Fentora in cancer patients. The other studied Fentora in opioid-tolerant chronic pain patients who did not have cancer.

220. Each series included a set of short-term, randomized, controlled clinical trials to show that rapid-release Fentora could treat pain.

221. As with the Actiq studies in the 1990s, each series also included a single long-term, non-controlled, open label clinical trial purporting to examine long-term safety and efficacy. But neither of these long-term clinical trials set out to examine risks to patients of abuse, misuse, or addiction, nor did they direct investigators to look for abuse or misuse.

222. The long-term cancer clinical trial ran from April 2004 to November 2006.

223. It tracked opioid-tolerant patients with metastatic cancers for what was supposed to be 12 months and more.

224. Teva later called this the "Weinstein study" after Dr. Sharon Weinstein, the sole non-Cephalon author on a 2009 publication in the journal *Cancer* describing the clinical trial.

225. The long-term non-cancer clinical trial, called "study 3040," overlapped in time, running from March 2005 to May 2007, tracking patients for 18 months.

226. It had more patients than the cancer clinical trial and the patients were not terminally ill – they mainly suffered from chronic back pain.

B. Cephalon's Long-term Clinical Trials Both Showed Patients Misusing and Abusing Fentora.

227. Both of Cephalon's long-term clinical trials allowed patients a surprising amount of discretion in administering Fentora.

228. Patients were given 100 to 150 tablets at once, which was supposed to be a month's supply.

229. Patients took the Fentora at home.

230. Patients could take one tablet for every breakthrough pain episode, no matter how close those episodes were, and if pain relief was inadequate, they could take a second tablet.

231. [redacted]

232. If patients went through their 100 to 150 tablets in less than a month, they could come back early to get more.

233. Given 100 or more pills and few limits, patients began abusing and misusing Fentora.

234. [redacted]

235. [redacted]

236. [redacted]

237. [redacted]

238. Cephalon failed to give direction to its study investigators about how to monitor, treat, or track abuse or misuse.

239. Nor did it give investigators clear instructions about how to handle patients abusing or misusing Fentora, including when to withdraw those patients from the clinical trial or how to classify such patients in trial results.

240. As a result, investigators marked 49 of the 197 cancer patients as withdrawing for reasons listed as "Other." Some of these "Other" patients were misusing or abusing Fentora and other opioids during the clinical trial, including the following:

- [redacted] reported the study drug [Fentora] stolen [redacted]
- [redacted];
- [redacted]
- [redacted]
- [redacted]
- [redacted] was "taking more study drug than study allows," [redacted]
- [redacted]

241. [redacted]

[redacted]

242. In study 3040, the non-cancer clinical trial, which had a greater number of patients, there were also frequent incidents of abuse and misuse: [redacted] Cephalon publicly disclosed similar numbers in a trade publication in January 2011 that it did not broadly disseminate: there it stated that across its non-cancer clinical trials, there were 9 Fentora overdoses, 45 medication theft events, and 79 Fentora overadministration events.

C. Cephalon Omitted Cancer Clinical Trial Data Showing Possible Declines in Fentora's Analgesic Efficacy over Time.

243. Beyond the misuse and abuse of opioids, Cephalon's [redacted] clinical trials produced data showing that patients who actually completed the trials needed substantially greater daily doses of Fentora over time.

244. [redacted] in a subsequent April 2011 trade publication, Cephalon discussed and presented data and multiple tables and graphs from its non-cancer studies showing that patients were increasing their average daily dose of Fentora over time.

245. [redacted] In the April 2011 publication, Cephalon disclosed that patients' average daily dose of Fentora increased over 18 months from 2,108 mcg/day to 3131.8 mcg per day.

246. As discussed below, in the years to come, Cephalon rarely disclosed this data,

other than to regulators and in the single April 2011 publication, which it did not disseminate broadly.

247. [redacted]

248. [redacted]

249. [redacted]

[redacted]

251. [redacted]

D. Takeaway from the Clinical Trials

252. For the next decade or more, Cephalon and Teva would misrepresent three key outcomes of these clinical trials.

253. First, they would claim patients showed little sign of developing tolerance to Fentora's pain relieving effects, when, in fact, they concealed known data suggesting the opposite.

254. [redacted]

255. Third, they would claim the clinical trials had examined Fentora's long-term risks and safety, when they had not examined long-term risks of abuse, misuse, or addiction.

V. Cephalon Agrees to a Risk Mitigation Program to Obtain FDA Approval for Fentora and then Begins Subverting Its Risk Mitigation Commitments Again.

A. FDA Approves Fentora for Restricted Use – So Long as Cephalon Complies with a New Risk Mitigation Program.

256. In 2005, Cephalon applied for FDA approval for Fentora.

257. Cephalon did not submit any new abuse liability studies with the Fentora application. Instead, Cephalon relied on the Actiq and Oralet clinical trial data (which did not include abuse liability) and animal studies of injectable fentanyl from the 1960s and 1990s that studied tolerance and dependence in dogs, monkeys, guinea pigs, and rats (all of which grew tolerant to fentanyl's analgesic effects or showed signs of dependence).

258. In reviewing the clinical trial data that Cephalon did submit, even without any abuse liability analysis, the FDA reviewers identified alarming amounts of opioid misuse by clinical trial patients.

259. In May 2006, looking at preliminary clinical trial results, the FDA's Controlled Substance Staff noted 12 patients in study 3040, the longer-term non-cancer clinical trial, exhibiting "abnormal opioid use (misuse, abuse and suspected addiction)."

260. And they noted the same problems with 9 patients in the long-term cancer clinical trial.

261. The reviewers suggested that Cephalon had understated these risks by listing these patients as withdrawing from the clinical trials for reasons such as "Other," or "lack of efficacy."

262. The reviewers also observed that patients withdrawn due to dizziness and drowsiness might have been suffering from excessive opiate effect.

263. The reviewers thought these "aberrant drug use behaviors" were "very unusual" in the controlled setting of a clinical trial – especially since the clinical trials screened out high-risk patients with any history of prior substance abuse – and concluded that these events "illustrate the significant risks of misuse, abuse, and diversion" associated with Fentora.

264. As it had with Actiq, Cephalon pitched the FDA on the idea that it could mitigate Fentora's risks of accidents, overdose, misuse, or abuse through yet another risk management plan.

265. The FDA again trusted Cephalon. Its approval letter stated that Fentora's "significant risks" would be mitigated by Cephalon's "extensive and thorough," "state of the art in its scope and mechanisms," and "carefully crafted" risk management plan.

266. The FDA's optimism was misplaced again.

B. Cephalon's 2008 Risk Mitigation Plan for Fentora Committed It to Intervene Quickly if It Detected Wrongful Fentora Prescriptions for Non-Cancer Treatment or for Opioid-Naïve Patients.

"*it is important to note that, should a concerning signal develop in the post-marketing period, the plan will allow the sponsor and the Agency to act quickly to intervene*" (FDA, 2006)

267. Cephalon's "state of the art" risk management plan for Fentora was to institute nationwide monitoring for off-label or inappropriate prescribing and to "respond with more timely and focused interventions" if this monitoring detected problems.

268. As with Actiq, this plan served an important public health goal: to allow cancer

patients, the "intended patient population" to have the benefits of relief from "suffering unbearable pain due to cancer" while limiting the risks associated with "improper use," which included use of Fentora by non-cancer patients.

269. The plan required Cephalon to monitor and detect inappropriate use, including "prescribing patterns not consistent with labeling."

270. It required Cephalon to maintain "active and passive surveillance methods" to detect off-label use, along with accidental use, abuse, and misuse.

271. If surveillance detected inappropriate prescribing or other "concerning signal[s]" of misuse, Cephalon pledged swift action.

272. The FDA believed Cephalon: as the following passage from its approval letter indicates, the FDA approved Fentora on the premise that Cephalon would "act quickly to intervene, "should a concerning signal develop":

> abuse of the product. Since no plan will be fully successful, it is important to note that, should a concerning signal develop in the post-marketing period, the plan will allow the sponsor and the Agency to act quickly to intervene. Given this RiskMAP and the importance of the addition of FENTORA to the cancer pain armamentarium, I recommend that this drug be approved for the management of breakthrough pain in patients with cancer who are already receiving and who are tolerant to opioid therapy.

(FDA Approval letter for Fentora, September 25, 2006)

273. Unfortunately, there was no explicit mechanism in the risk management plan to sanction or deter Cephalon if it did not "act quickly to intervene" in the face of data showing inappropriate off-label use.

274. The FDA once again relied on Cephalon to do what it was not inclined to do: limit prescriptions for Fentora to opioid tolerant cancer patients, monitor for off-label use and misuse, and "to act quickly to intervene" if off-label prescribing patterns surfaced.

275. It appears that Cephalon read this as a carte blanche to continue its high-pressure

sales to physicians.

C. [redacted]

276. [redacted]

277. [redacted]

278. [redacted]

279. [redacted]

280. [redacted]

281. [redacted]

282. And the Launch Playbook identified a key threat to Fentora as doctors' "[f]ear of abuse, addiction, and diversion . . . ."

283. Cephalon's sales targeting reflected its marketing: it kept essentially the same targeting criteria for sales visits that the FDA had lambasted in 2004 as a public health risk.

284. As Cephalon's marketing director described on a 2007 earnings call, Cephalon's primary target audience for Fentora sales visits were 2,000 "high prescribing opioid physicians" who "were responsible for 80% of ACTIQ prescriptions."

285. He said that from mid-2006 to March 2007, Cephalon's salespeople "had detailed

over two thirds of those 2,000 core prescribers five times or more" to promote Fentora.

286. Its next tier of targets was "high prescribers of opioids but who have not historically prescribed ACTIQ." He never mentioned limiting sales visits to prescribers treating cancer patients. And they did not.

287. [redacted]

288. [redacted]

289. [redacted]

290. [redacted]

291. [redacted] The predictable, predicted, and alarming result was that Fentora continued to be prescribed widely for non-cancer conditions like back pain, headaches,

and migraines – conditions for which it was too risky.

D. [redacted]

292. [redacted] Fentora launched quickly, with prescriptions increasing five-fold from approximately 14,600 in 2006 to nearly 91,000 in 2007.

293. [redacted]

294. [redacted]

295. [redacted]

296. [redacted]

297. [redacted]

298. [redacted]

299. [redacted]

300. [redacted]

[redacted]

301. [redacted]

[redacted]

302. The wrongful off-label prescriptions caused patient harm. As the FDA learned, the majority of reported adverse events involving "improper use and medication errors" with Fentora occurred when "patients were being treated for off-label uses for Fentora, such as back pain, chronic/non-cancer pain, and migraines."

E. September 2007: Deaths and Life-Threatening Side Effects from Off-Label Use of Fentora Lead to a Public Health Advisory.

"These reports of death and life-threatening side effects occurred in patients who: 1) should not have been prescribed Fentora (patients who did not have cancer and /or were not opioid tolerant) . . . ." (FDA, 2008)

303. The FDA quickly realized its prediction that Cephalon's risk mitigation plan for Fentora would actually reduce risk in the real world was not coming true. In September 2007, the agency was forced to issue a Public Health Advisory for Fentora based on post-market reports of "death and life-threatening side effects" in (1) patients who "should not have been prescribed Fentora (patients who did not have cancer and/or were not opioid-tolerant);" (2) patients who were prescribed the wrong Fentora dose; or (3) patients "who took too many Fentora doses."

304. As a result, the FDA required Cephalon to disseminate "dear doctor" or "dear healthcare provider" letters to prescribers, pharmacists, insurers, and professional organizations warning of Fentora's dangers and recommending against off-label prescribing.

305. It also required Cephalon to disseminate a press release that cautioned patients and doctors about Fentora's potentially fatal risks, that stated that using Fentora outside of approved guidelines could result in fatal overdoses.

306. The FDA also directed Cephalon to change its sales practices. They were to tell providers to use Fentora only for cancer pain treatment, to not prescribe it for acute pain, and to not prescribe it to opioid-naïve patients.

[redacted]

VI. Cephalon Applies for Formal Approval to Use Fentora to Treat Chronic Non-Cancer Pain and Reveals Data on Patient Misuse and Abuse in its Chronic Pain Clinical Trials, Startling the FDA.

> *"Based on the information available to date, CSS* [FDA's Controlled Substances Staff] *finds that: ● The risks of unintentional potentially fatal overdose, as well as of misuse or abuse of fentanyl, and of [Fentora] in particular, are extremely high, even when compared to risks posed by other transmucosal fentanyl products."*
> (FDA's April 2008 review of Fentora's abuse and diversion potential)

308. Despite the widespread problems with off-label and improper use of Fentora, in November 2007, Cephalon charged ahead and applied to the FDA to formally extend Fentora's approved uses to include non-cancer pain treatment.

309. This time, finally, the FDA demanded data on abuse and misuse of Fentora in clinical trials. After almost a decade and approximately a million prescriptions, this would be the first risk assessment of Actiq or Fentora's abuse liability. What Cephalon showed them was startling.

310. In November 2007, Cephalon submitted to the FDA an assessment of Fentora's risks of abuse and diversion, looking for what Cephalon called "aberrant drug-use behaviors." In January 2011, Cephalon published an article disclosing this same data on "aberrant drug-use behaviors." The abuse risk assessment and the article examined data from Cephalon's non-cancer clinical trials (and no data from its cancer clinical trials), including two short-term clinical trials ("generally less than a month"), one 12-week clinical trial study, and the 18-month long-term clinical trial, whose data was interim at this point.

311. The aberrant drug use behavior analysis was "retrospective." As discussed above, Cephalon had failed to set up these clinical trials to monitor for misuse, abuse, or aberrant drug behavior; so this analysis was conducted more than a year after they concluded, and Cephalon had to retroactively review the data to look for signs of aberrant drug-use behaviors. As outside consultant Dr. Steven Passik later put it, "you did the trials and we post hoc tried to make sense of the [data]."

312. The risk assessment for the FDA included 941 patients from these four clinical trials who took at least one Fentora dose. The later published article included 1,160 patients from five clinical trials who took at least one Fentora dose.

313. For both the 2007 assessment and the 2011 article, Cephalon identified categories of aberrant drug behaviors and then searched their clinical safety dataset for patients exhibiting these behaviors, ultimately identifying 15 categories of aberrant behaviors and choosing three categories as "high risk."

314. Cephalon's risk analysis reached two main conclusions. First, it concluded that 17% of the patients who took at least one dose of Fentora in these four non-cancer clinical trials "exhibited at least one aberrant behavior." Second, in the FDA assessment it concluded that only

3% of patients exhibited "high-risk" behavior. In the later published article, it concluded that "[a]buse-related events occurred at a rate of 2% in this analysis."

315. The FDA's Controlled Substances Staff concluded that this level of aberrant drug behavior was unacceptable, Cephalon's analysis was flawed, and Cephalon's conclusions incorrect. It summarized these concerns in its conclusion: "Based on the information available to date, CSS [FDA's Controlled Substances Staff] finds that: ● The risks of unintentional potentially fatal overdose, as well as of misuse or abuse of fentanyl, and of [Fentora] in particular, are extremely high, even when compared to risks posed by other transmucosal fentanyl products."

316. There were six different reasons that Cephalon's analysis of aberrant behavior rates actually understated the true rate of aberrant behavior.

317. First, it is unusual to have aberrant drug use behavior at all in the controlled setting of a clinical trial, where investigators generally monitor patients more closely than in a general outpatient setting. As the FDA said, "[d]etection of aberrant drug use behavior in the controlled setting of a clinical trial is very unusual and raises concern for the safe use of this drug in the general outpatient setting." That fact alone showed that Fentora had "significant risks of overdose, misuse, abuse, and diversion."

318. Second, as the article observed, there was a significant level of aberrant drug use behavior even though these studies excluded patients likely to abuse opioids, as Cephalon had screened out patients with a prior history of drug or alcohol abuse; as the article put it, "this population was highly select."

319. Third, Cephalon undercounted aberrant behaviors for two main reasons. First, Cephalon never trained its investigators to look for, capture, and code patients' aberrant

behavior, "information essential to providing accurate information." Second, when the FDA reviewed the patient data, it found 41 more patients exhibiting aberrant drug use behavior that Cephalon had not counted.

320. [redacted]

321. [redacted]

322. [redacted]

323. [redacted]

324. The FDA disagreed. It thought patients like these should be counted as exhibiting aberrant behavior.

325. Fourth, the FDA was alarmed that massive amounts of Fentora had been stolen from five of the clinical trial study sites. Together, the FDA calculated that over 8,000 Fentora tablets were stolen from these five sites, in addition to the 35 reported thefts from patients.

326. Fifth, the FDA disbelieved Cephalon's claim that only 3% of patients exhibited "high risk" behavior, especially since Cephalon could not adequately explain its definition of "high risk." As a result, it thought Cephalon's conclusions of the "potential health risks" of

Fentora were "not consistent" with the FDA's assessment and "underestimate this risk."

327. [redacted]

328. [redacted]

329. [redacted]

330. Sixth and finally, Cephalon was padding its numbers to conceal the long-term risk – that long-term Fentora patients were more likely to exhibit aberrant drug use behavior than

short-term patients.

331. By combining short-term and long-term study data, Cephalon conflated hundreds of patients who took Fentora for a week or less (or even just one dose) with patients who took Fentora for a year or more.

332. This diluted the data; almost all of the cases of aberrant drug behavior were in Cephalon's long-term trials. Or, as the European Union later put it, had they only analyzed long-term data the "true incidence" of abuse would have been higher.

333. [redacted]

334. [redacted]

335. Cephalon's statistical shuffling played with lives. After the risk assessment, Cephalon knew that if you gave Fentora and other opioids to patients with no prior history of substance abuse, and they took these drugs for a year, even in a closely monitored clinical setting, [redacted] would exhibit aberrant drug related behavior – they might start misusing, abusing, and overusing opioids, they might start making up stories about lost or stolen opioids to obtain more, or they might start doctor shopping for more. [redacted]

336. In short, [redacted] Cephalon had its own data, however imperfect, showing

Fentora had alarming abuse risks, [redacted]

[redacted]

VII. May 2008: FDA Rejects Cephalon's Application to Expand Fentora to Chronic Pain Patients Because it Was Too Dangerous, Too Addictive, and Cephalon Had Not Adhered to Its Risk Management Commitments.

"Cephalon has not proactively considered or instituted interventions and/or adjustments to address the RiskMAP goal failures, in particular RiskMAP Goal # 1 (Fentora should be used only by opioid tolerant patients with cancer)." (FDA, 2008)

337. [redacted] in April and May 2008, the FDA also reviewed the performance of Cephalon's risk management program for Fentora. Just as with Actiq, the FDA concluded the program had failed, causing public harm, and that Cephalon had allowed this to happen, despite its commitments.

338. The FDA connected ongoing improper off-label prescribing of Fentora to public health harms. Off-label prescribing, including prescriptions for migraine headaches and back pain, was involved in most reported serious adverse events, most cases of medication errors, overdoses, suicides, drug misuse, and accidental exposures.

339. Intentional overdoses and drug diversion were also increasing, despite the risk mitigation program.

340. And the FDA found its 2007 public health advisory and Cephalon's "Dear Doctor" letter did not have any appreciable impact on these practices and results.

341. Overall, the FDA concluded that Cephalon had committed to a risk management plan whose "Goal #1" was "that Fentora should only be used by opioid tolerant patients with cancer," and Cephalon had regularly collected and reported data showing this goal was failing – as the FDA put it, the data was "trending opposite" of what it should have been.

342. While Cephalon claimed to be complying with the risk management plan, in fact,

Cephalon never intervened or even considered intervening to prevent off-label prescribing of Fentora, even in the face of widespread off-label use and the serious consequences that resulted, though it had committed to do so.

343. Instead, as illustrated in the following passage, Cephalon went so far as to argue that because off-label use was so prevalent, this off-label use should be formally condoned by the FDA:

> Based on our review of the postmarketing experience with Fentora, we do not believe the RiskMAP has been effective in minimizing the risks it was developed and implemented to minimize. Fentora RiskMAP Reports and our own drug utilization data reviews demonstrate data that is trending opposite of what would be expected with effective risk minimization strategies. Off-label use rather than indicated use dominates for the product; use in opioid intolerant patients has been steadily increasing; and signals of product misuse, abuse, and diversion are appearing. In addition, medication errors related to dosing and administration dominate the adverse event reports for Fentora.
>
> Cephalon has not proactively considered or instituted interventions and/or adjustments to address the RiskMAP goal failures, in particular RiskMAP Goal # 1 (Fentora should be used only by opioid tolerant patients with cancer). Instead, Cephalon uses the large extent of product off-label use (a goal failure under the RiskMAP), to justify the proposed expanded indication for Fentora. Expanding the Fentora indication as proposed will most likely amplify and exacerbate the adverse event trends and use patterns (including use in opioid non–tolerant individuals) we have already observed.

(April 8, 2008, FDA's Office of Surveillance and Epidemiology's review of "Fentora Risk Minimization Action Plan (RiskMAP) and Postmarketing Experience")

344. In May 2008, the relevant FDA committees voted 17-3 against an expanded indication for Fentora. The committees said, "we have already seen more reports of serious and life-threatening adverse events in both properly-prescribed and mis-prescribed patients then we have ever seen for Actiq over similar periods of time."

345. In September 2008, the FDA formally denied Cephalon's application, stating, "you have not adequately addressed the public health concern of increased abuse, misuse, overdose and addiction that is to be expected with more widespread availability of this product in the community. Your proposed plan to mitigate these risks has not been adequately tested to

assure that it will, indeed, achieve this outcome for your currently approved indication, let alone the proposed expanded indication."

VIII. 2009 American Pain Society Guidelines Put Cephalon on Notice that Opioids' Benefits are Unproven and Risk Mitigation Measures Do Not Work.

346. In January 2009, two leading industry-friendly professional organizations, the American Pain Society and American Academy of Pain Medicine undermined Cephalon's already shaky claims regarding Fentora's and Actiq's benefits and risks. The pain organizations tried but largely failed to create evidence-based recommendations about how to use opioids to treat chronic non-cancer pain. They aimed to answer 37 remarkably basic questions about opioid use, such as: what are opioids' benefits for chronic non-cancer? What are their harms? Can we screen patients to determine which patients will benefit or be harmed by opioid therapy? Are non-opioid therapies better than opioids? Can monitoring, urine drug screening, or opioid agreements reduce or mitigate opioids' abuse risks?

347. Shockingly, the pain organizations found almost no good answers to their questions. They began with a simple premise: clinical decisions should be driven by the evidence – well-conducted randomized clinical trials, controlled observational studies, evaluations of diagnostic tests. But, for opioid therapy, they could find no credible evidence on "virtually every research question" they thought important.

348. The pain organizations published three papers, an evidence review, a research gap assessment, and new guidelines. The papers had a litany of remarkable conclusions:

- Opioid use was "controversial" because opioids had not been shown to be effective in the long-term.
- Many patients were prescribed opioids "indefinitely," yet most trials and studies were designed primarily to study short-term efficacy and not long-term harms.
- "Evidence on opioids specifically for low back pain, fibromyalgia, and daily headache is very limited or did not show a clear benefit."

- Clinicians cannot predict the patients for whom opioids' benefits exceeded the risks; ("[t]here is insufficient evidence . . . to reliably identify factors that predict benefits or adverse effects . . . or the balance of benefits achievable with tolerable adverse effects".)
- No randomized trials compared opioids to nonopioid therapies and no studies evaluated ways to identify patients more likely to benefit from nonopioid versus opioid therapy.
- The use of opioids for chronic pain was steadily increasing, despite the lack of evidence.
- Physicians were not making evidence-informed clinical decisions when prescribing opioids.

349. To cap it off, the pain organizations also looked specifically at evidence about Fentora and Actiq and other short-acting opioids. They found this evidence lacking too – looking at two Cephalon-sponsored publications, they found that these trials were too short in duration and only compared Fentora and Actiq to a placebo, rather than to other opioids or to non-opioid therapies.

350. Following this evidence review, the pain organizations produced practice guidelines for opioid therapy. Troublingly, the guidelines essentially condoned continued opioid prescribing, despite the lack of evidence. For instance, the guidelines strongly recommend that physicians try chronic opioid therapy for chronic pain sufferers for whom the therapeutic benefits outweigh the harms, even though this was supported by "low-quality evidence," and even though the evidence showed there was no established way to determine patients for whom opioids' benefits outweigh the harms.

351. Regarding the use of Fentora and Actiq and rapid-onset opioids to treat breakthrough pain, the guidelines gave a "weak recommendation" and noted the "low-quality evidence," specifically citing:

- Insufficient evidence regarding optimal treatment strategy for breakthrough pain.
- Limited evidence that rapid onset opioids can treat breakthrough pain.
- More studies needed to evaluate long-term benefits and harms.

- More studies needed to compare short to long-acting opioids.
- Access to a short-acting drug may increase the risk of aberrant-drug behavior in high risk patients.
- Clinicians should carefully weigh potential benefits and risks and consider other therapy options, including both opioids, non-opioids, and non-drug treatments.

352. [redacted]

353. [redacted]

354. [redacted]

355. [redacted]

IX. Cephalon's Knowledge as of 2009.

356. By January 2009, Cephalon had knowledge or notice of the following:

- Cephalon had consistently been told by the FDA, including in 1999, 2004, and 2008, that its off-label promotional activities of Actiq and then Fentora were impermissible or illegal, violated its risk management obligations, could or did result in patient harm and deaths, and were a "serious public health concern."
- Actiq and Fentora were widely prescribed improperly for back pain, acute pain, migraines and headaches, and arthritis, in part because of Cephalon's past promotion of Actiq for these uses.
- Cephalon's long-term Fentora studies produced evidence suggesting that Fentora's efficacy declined over time [redacted] with patients having significant increases in their pain episodes per day, resulting in them taking significantly more Fentora tablets per day and, as a result, significantly greater daily doses.
- Cephalon's long-term Fentora studies produced evidence that significant numbers of patients with no prior history of substance abuse would start engaging in aberrant drug-related behaviors including misusing opioids, overusing opioids, or lying about their opioid use in order to acquire more.
- Cephalon had no evidence to show that screening measures could predict which patients would start engaging in these aberrant drug-related behaviors.
- Cephalon had not established that taking Actiq or Fentora improved patient outcomes, including patient quality of life, patient functioning, activities of daily living, or mental health.
- Cephalon had not compared Actiq or Fentora to any alternate non-opioid therapies for pain for any extended period of time.

357. Taken together, Cephalon knew that patients taking Actiq or Fentora for months or longer exposed themselves to extremely high risks and diminishing pain relief, and knew that its studies had never established that taking Actiq or Fentora improved patient outcomes, such as their quality or life, activities of daily, functioning, or mental health.

358. Going forward, Cephalon needed to fight against this tide, and it did so by touting its long-term studies that had gone so poorly, claiming that these studies showed that Fentora worked.

X. The Weinstein Publication and Other Publications: Laundering Shoddy Data on Efficacy, Safety, and Abuse Liability.

"FBT [Fentora] was generally well tolerated and had a favorable safety profile. Unexpected AEs [adverse events] did not occur, thus confirming and extending the findings of previous short term studies. Response to FBT [Fentora] was maintained over the period ≥12 months."

359. Cephalon published and broadly disseminated several whitewashed versions of what happened in its long-term cancer and non-cancer studies.

360. [redacted] was its publication of an article on its long-term cancer study in June 2009 in the prestigious journal *Cancer*. [redacted] Its publication was written by Cephalon staff, but an outside academic, Cephalon advisory board member and "key opinion leader" Sharon Weinstein, was listed as the lead author. [redacted]

361. In the *Cancer* article, Cephalon warped the study data to fit two key conclusions. First, it wanted to show that over the long-term, the cancer patients in the study did not develop incremental tolerance to Fentora. Second, it wanted to show that Fentora was safe.

362. The *Cancer* article's conclusions were as follows:

> To our knowledge, the current study is the first to follow a large patient population with chronic cancer pain for > 12 months in the evaluation of FBT [Fentora] for the management of BTP [breakthrough pain]. FBT was generally well tolerated and had a favorable safety profile. Unexpected AEs [adverse events] did not occur, thus confirming and extending the findings of previous short term studies. Response to FBT was maintained over the period ≥12 months.

363. These conclusions were also framed similarly in the article's synopsis.

364. Regarding the development of incremental tolerance, Cephalon claimed that Fentora treatment "demonstrated control" of breakthrough pain for more than 12 months, meaning that patients did not become tolerant over time, "suggesting there was no decline in

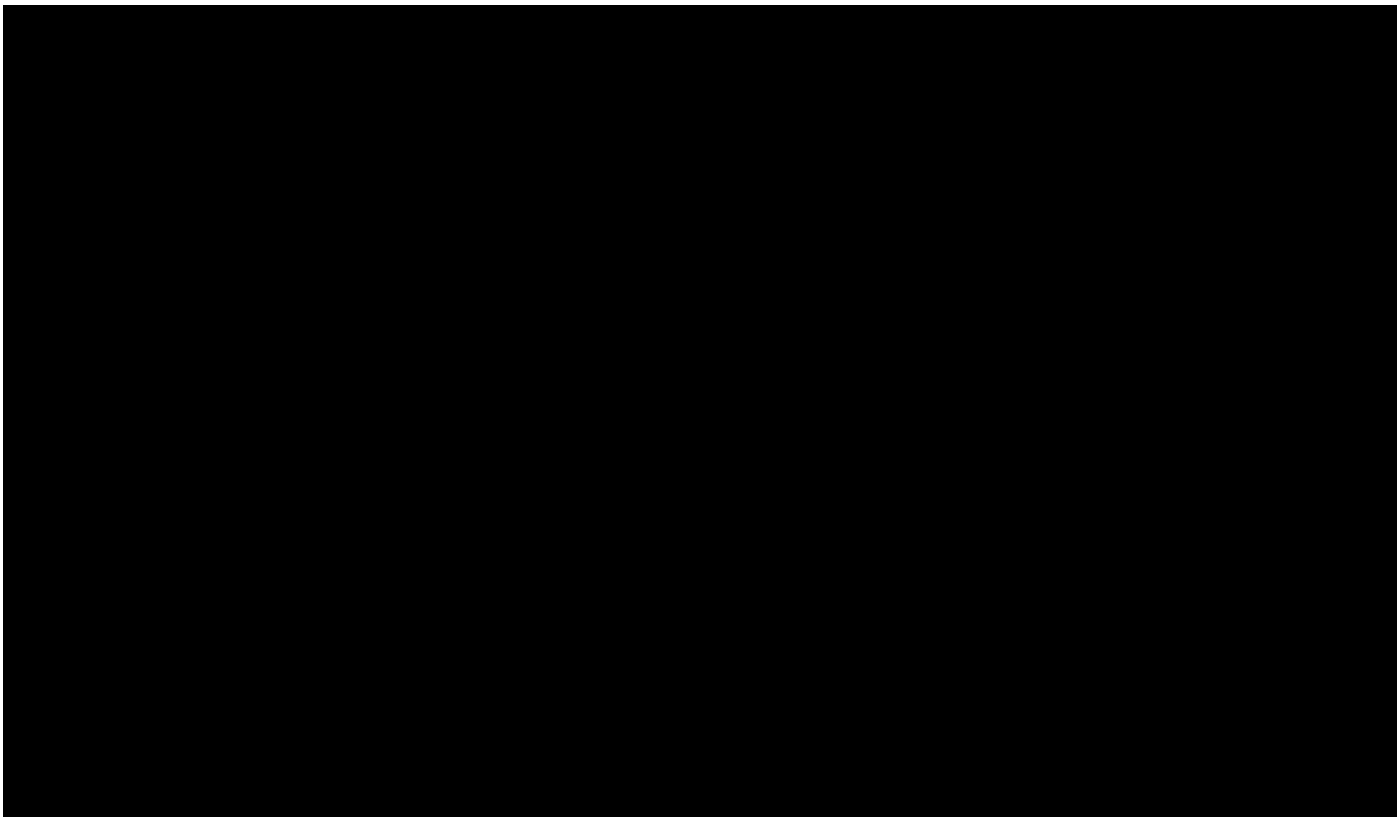
analgesic efficacy over time in most patients." Cephalon claimed this showed the "[r]esponse to FBT [Fentora] was maintained over the period ≥12 months." This conclusion would become a central part of Cephalon and Teva's marketing over the next decade.

365. But that conclusion was false and misleading. [redacted]

366. Instead, Cephalon twisted the data. What Cephalon said is that "The majority of patients had a final dose that was the same as their initial successful dose, suggesting there was no decline in analgesic efficacy," and "[t]he majority of patients did not have dose changes over time; the final dose of FBT [Fentora] at the last study visit was the same as the initial successful dose for 136 of 197 (69%) patients . . . ."

367. What Cephalon was claiming was that Fentora's efficacy was sustained because 69% of its patients kept taking the same strength tablet – their "dose" was not changed by study investigators from the day they started the study to the end.

368. [redacted]



369. [redacted]

370. [redacted]

371. [redacted] and its website.

372. [redacted]

373. [redacted]

374. [redacted]

375. This 69% figure and the claim that the study assessed incremental tolerance relied

on several misrepresentations.

376. First, it relied on implying or expressly representing, [redacted] that the patients they were counting, 197 patients, took Fentora for 12 months or more.

377. That was false: 197 patients did not take Fentora for 12 months or more. Only 34 patients did. In fact, more patients died during the study, 60 patients, than completed it. The median patient lasted only 122 days, or four months. Fifty-three percent of patients received the study drug for less than six months – or, put another way, by six months more than half the patients had withdrawn.

378. Cephalon therefore used the data from patients who left the study due to illness, death, non-compliance, or choice – including patients who died in the first week – to claim falsely that the "majority" or "69%" of patients, showed no increase in tolerance to Fentora over 12 months.

379. Second, Cephalon measured incremental tolerance solely by measuring whether investigators ever changed the dose strength of each patient's tablets.

380. That is misleading: by solely touting dose strength, they did not account for daily dosage, or the total number of Fentora tablets patients were taking per day. It was as if you asked someone how much coffee they drank, and they said "8 ounces," without telling you they were drinking five, ten, or even twenty 8-ounce cups of coffee each day.

381. [redacted]

382. [redacted]

[redacted]

[redacted]

A. Defendants Knew the Data They Omitted from Cancer Publication and the Weinstein Study Undermined its Long-term Efficacy Claims.

383. In contrast to the *Cancer* publication, the Defendants' regulatory filings, as well as publications in smaller trade journals, [redacted] show [redacted] data on daily pain episodes, tablets taken, and daily dose – undermined its long-term efficacy claims.

384. First, the Defendants generally knew that studying long-term efficacy and tolerance should include tracking how patients' pain episodes per day change over time. [redacted] Cephalon also discussed the change in the average daily dose of Fentora in an April 2011 trade publication on long-term dosing and tolerability of Fentora.

385. [redacted]

386. Second, Defendants knew they had this data. They selectively disclosed some of it, and buried the rest. [redacted] they disclosed to the European Union around 2012 a 48.6% increase

in patients' average daily Fentora dosage from 2,108 mcg/day to 3,132 mcg/day. [redacted]

387. Third, Defendants knew this actual data undermined Fentora's claims to long-term efficacy. [redacted]

388. The European Union, in particular, was alarmed by Defendants' efficacy data. In May 2013, it concluded the 48.6% increase in average daily dosage implied "that over time the effect of EFFENTORA [Fentora] declined dramatically." [redacted]

B. [redacted]

389. [redacted]

390. [redacted]

[redacted]

391. [redacted]

[redacted]

392. [redacted]

[redacted]

393. [redacted]

394. [redacted]

395. [redacted]

[redacted]

396. The Defendants preferred to claim, falsely, in the *Cancer* publication and subsequent marketing materials, that Fentora "demonstrated control" of pain over time and that patients did not have "incremental tolerance" or any diminution in efficacy.

397. These misrepresentations go to the heart of the opioid crisis: even for palliative care, but especially for long-term cancer and chronic pain sufferers, Fentora increased the risk of addiction while bringing fleeting and diminishing relief, and Defendants both knew this.

C. The Weinstein Cancer Publication Knowingly Omitted Data on Risks of Addiction, Misuse, and Aberrant Drug-Use Behavior.

398. Beyond efficacy, the *Cancer* publication had another key misrepresentation about safety: it claimed that Fentora was "well tolerated" and had a "favorable safety profile."

399. This claim was a misrepresentation for three reasons.

400. First, it was misleading to claim that the study showed Fentora was safe and well-

tolerated without disclosing that the study was not intended to monitor (and did not monitor) patients for abuse liability.

401. Second, even without that monitoring, the publication never discussed how study patients were actually abusing and misusing opioids. Cephalon claimed the study's objective was to study long-term safety.

402. The *Cancer* publication made it appear as if Cephalon was discussing all aspects of Fentora's safety. For instance, it disclosed 35 types adverse events, from nausea to pharyngolaryngeal pain (sore throats). But it failed to include any discussion of study patients' abuse, overuse, misuse, or aberrant drug-related behavior in this list of events.

403. Cephalon knew better. It knew a safety study should discuss abuse liability. [redacted]

This advice embodies common sense: especially in the long-term, patients and doctors worry about opioid addiction and aberrant drug-use along with traditional side effects like sore throats.

404. The omission was significant, because, as detailed above, Cephalon knew that, even using its underestimates, 17% of patients in other studies taking Fentora for the long-term, for four months or more, had exhibited aberrant drug-use behaviors that were a sign of or precursor to addiction, [redacted]

405. Cephalon's omission was willful. [redacted]

406. [redacted]

[redacted]

407. [redacted]

408. [redacted]

409. The final misrepresentation of the *Cancer* publication was to downplay adverse events. Cephalon had a too-convenient explanation for every serious adverse event.

410. As noted above, 60 of the 197 patients studied died before the study was completed. Ten more withdrew due to serious adverse events. [redacted] Cephalon's study investigators examined each of the 60 deaths and 10 serious adverse events and concluded that all of them were unrelated to Fentora, they were all due to cancer progression.

411. Even without a comparison group, Cephalon concluded that "the rate of attrition is typically unavoidable in a population with progressive disease, such as the one in this study."

412. So Cephalon claimed that the study had "no unexpected" adverse events. [redacted]

XI. [redacted]

413. [redacted]

414. [redacted]

415. [redacted]

416. [redacted]

417. [redacted]

418. [redacted]

419. [redacted]

[redacted]

420. [redacted]

421. [redacted]

422. [redacted]

423. [redacted]

424. [redacted]

425. In September 2009, the Virginia Board of Medicine disciplined the doctor for prescribing Actiq, stating that she had inappropriately prescribed Actiq for non-cancer pain for two patients, and excessively prescribed Actiq for another four patients. [redacted], was, in fact, "negligent conduct . . . that causes or is likely to cause injury to a patient or patients," "conducting [her] practice in such a manner as to be a danger to the health and welfare of [her] patients or to the public" and "performing any act likely to deceive, defraud, or harm the public."

426. The doctor's license was reprimanded. [redacted]

XII. 2012 to Present: Another Risk Mitigation Program Fails to Detect and Prevent Dangerous Fentora Prescribing – Yet Teva Touted it as a Success.

427. Finally, Teva has continued to thwart its risk management obligations from 2012 to the present.

428. From 2012 to the present, Teva has been subject to a revised risk management plan, with the same goal as past plans: to ensure that immediate-release fentanyl products were only prescribed appropriately to opioid-tolerant cancer patients. The last iteration was called the TIRF REMS program (Transmucosal Immediate Release Fentanyl Risk Evaluation and Mitigation Strategies), which has been in place from 2012 to the present.

429. TIRF REMS is an industry-run registration system. Teva and other immediate-release fentanyl manufacturers can provide their fentanyl products only to registered distributors, pharmacies, and prescribers. To be registered, all participants had to take mandatory education and had to agree to distribute, prescribe, and dispense the immediate-release fentanyl products according to the label, that is to opioid-tolerant cancer patients. Prescribers, dispensers, and even patients have to certify that they understood the appropriate indication and use.

430. Teva and other manufacturers have presented TIRF REMS as a success. In regular annual assessments, they cite rising numbers of enrolled patients (rising from 10,000 in 2012 to over 40,000 in 2015) and rising number of prescribers and pharmacists, with few problems.

431. They state they found few prescribers or pharmacists to be non-compliant – and they have never disenrolled a single doctor or pharmacist from the system for inappropriate prescribing or dispensing. So they have concluded, every year, that there were no reports of inappropriate prescribing: "no reports of TIRF [immediate release fentanyl] medicines being prescribed to an opioid non-tolerant individual."

432. But in December 2014, prompted by a scathing report from the Inspector General of the Department of Health and Human Services, the FDA asked manufacturers to compare prescription data to insurance claims to check if patients receiving immediate-release fentanyl products were the right patients, if they were actually opioid-tolerant.

433. [redacted]

434. But what the fentanyl manufacturers as a whole reported to the FDA was frightening: of 25,322 patients receiving immediate-release fentanyl products from October 2014

to 2015, 49% (12,916) of patients were opioid-naïve, meaning they were at significant risk of overdose and respiratory failure if they took fentanyl.

435. [redacted]

436. Taken together, Teva (and other manufacturers) claimed that they had never detected any improper prescribing and never disenrolled any prescribers, when data showed that inappropriate and dangerous Fentora (and other fentanyl) prescriptions were widespread.

437. This suggested a fundamental failure in the TIRF program: Teva and other manufacturers claimed that they had never detected any improper prescribing and never disenrolled any prescribers, when, in fact, half the patients were receiving inappropriate and dangerous Fentora (and other fentanyl) prescriptions.

438. On November 10, 2016, the FDA finally wrote Teva and other manufacturers to tell them the program had failed to achieve its first and overarching objective, prescribing immediate release fentanyl only to appropriate patients.

XIII. Conclusion

439. Fentanyl drug overdoses have skyrocketed since 2013. From 2013 to 2016, fentanyl overdose deaths doubled each year, rising to 18,335 deaths in 2016. Prescription fentanyl significantly contributes to this increasing death rate. Through the actions of the Defendants and other manufacturers, fentanyl, which was intended to be used only for the most untreatable pain, has now become entrenched in both the legal and illegal market: it is widely prescribed, used, and abused, with Virginians and other Americans bearing the consequences.

CAUSES OF ACTION

COUNT I

Virginia Consumer Protection Act - Misrepresentations Regarding Opioid Products' Benefits and Efficacy

440. Plaintiff adopts by reference paragraphs 1 through 439.

441. Virginia Code § 59.1-197 provides that the Virginia Consumer Protection Act is to be applied as remedial legislation to promote fair and ethical standards of dealings between suppliers and the consuming public.

442. Virginia Code § 59.1-198 defines "consumer transaction" to mean "[t]he advertisement, sale, lease, license or offering for sale, lease or license, of goods or services to be used primarily for personal, family or household purposes."

443. Virginia Code § 59.1-198 defines "supplier" to mean "a seller who advertises, solicits or engages in consumer transactions."

444. In part, Virginia Code § 59.1-200 provides:

> A. The following fraudulent acts or practices committed by a supplier in connection with a consumer transaction are hereby declared unlawful:
>
> . . .
>
> 5. Misrepresenting that goods or services have certain quantities, characteristics, ingredients, uses, or benefits;
>
> . . .
>
> 14. Using any other deception, fraud, false pretense, false promise, or misrepresentation in connection with a consumer transaction.

445. Defendants have engaged in "consumer transactions" by advertising, offering for sale, and selling opioid products, which are used primarily for personal, family, or household purposes.

446. Defendants are suppliers because they advertised, solicited the sale of, and engaged in the sale of opioid products in Virginia.

447. From 2001 to the present, Defendants violated Virginia Code § 59.1-200(A)(5) and (A)(14) by misrepresenting the benefits and efficacy of their opioid products, Actiq and Fentora.

448. Defendants misrepresented Actiq's and Fentora's benefits and efficacy in three ways.

449. First, as alleged in paragraphs 218 to 255, 356 to 412, and 420 to 426, since 2006, Defendants have misrepresented Fentora clinical trial data to claim that cancer and non-cancer patients showed little sign of developing tolerance to Fentora's pain-relieving (analgesic effects), including misrepresenting that Fentora "demonstrated control" of pain over time and that patients did not develop "incremental tolerance," that there was "no decline in analgesic efficacy over time in most patients," that "Response to FBT [Fentora] was maintained over the period ≥12 months," and that patient "dosing was unchanged in 69% of patients after 12 months," when, in fact, Defendants knew that patient data from [redacted] long-term clinical trials suggested the opposite: that over time long-term patients had increases in their pain episodes, increases in Fentora tablets taken, and increases in average daily dosages of Fentora and other opioids taken, suggesting that Fentora does not demonstrate control of pain over time, that patients taking Fentora were developing incremental tolerance, and that Fentora's analgesic efficacy did decline over time.

450. [redacted]

[redacted]

451. [redacted]

[redacted]

452. Third, as alleged in paragraphs 8 to 439, since 2001, Defendants have misrepresented that the benefits of Actiq and Fentora exceeded their risks for non-cancer patients, including patients suffering from lower back pain, arthritis, fibromyalgia, headaches or migraines, or other chronic non-cancer pain conditions, when, in fact, Defendants knew, and the FDA repeatedly and consistently told Defendants, that use of Actiq and Fentora for non-cancer indications was inappropriate, improper, wrongful, led to significant public health problems, and created high or extremely high risks of abuse for patients when used for chronic non-cancer pain treatments.

453. Defendants have willfully engaged in these acts and practices in violation of the Virginia Consumer Protection Act.

454. Individual consumers have suffered losses as a result of these Virginia Consumer Protection Act violations.

COUNT II

Virginia Consumer Protection Act - Misrepresentations Regarding Opioid Products' Risks

455. Plaintiff adopts by reference paragraphs 1 through 454.

456. From 2001 to the present, Defendants violated Virginia Code § 59.1-200(A)(5) and (A)(14) by misrepresenting the risks of their opioid products, Actiq and Fentora.

457. Defendants misrepresented Actiq's and Fentora's risks in four ways.

458. First, as alleged in paragraphs 8 to 439, since 2001, Defendants have misrepresented Actiq's and Fentora's safety and risks to cancer patients, including claiming that Actiq and Fentora had a "favorable safety profile," were generally "well tolerated," and that Defendants had studied long-term safety and risks, when, in fact, Defendants had not tested, monitored, or tracked abuse liability in clinical study patients, including testing for or monitoring the development of aberrant drug-related behaviors, including drug abuse, misuse, or diversion.

459. [redacted]

460. Third, as alleged in paragraphs 308 to 345, [redacted] Defendants have known that their own retrospective abuse risk assessment using their long-term and short-term clinical trial data from non-cancer studies showed that Fentora had significant abuse risks when used in the long-term: at minimum, 17% of patients exposed for a median of four months, even in a closely monitored clinical setting, exhibited aberrant drug-related behaviors, including misusing and abusing opioids, [redacted]

461. Further, as alleged in paragraphs 308 to 345, since at least April 2008, Defendants knew that the FDA thought its abuse risk assessment data showed that Fentora's risks of overdose, misuse, or abuse, "are extremely high, even when compared to risks posed by other

transmucosal fentanyl products."

462. Therefore, as alleged in paragraphs 335 to 345, 364 to 418, 426 to 432, and 449 to 450, Defendants have misrepresented Fentora's abuse liability by knowingly failing to disclose the abuse risk assessment data when discussing Fentora's long-term safety in marketing materials targeted at both health providers and patients, [redacted] the Weinstein *Cancer* publication [redacted] and their website. Instead, Defendants disclosed safety data about side effects, including minor side effects like mouth swelling or sore throats, rather than the abuse risk data, [redacted]

463. Fourth, Defendants have misrepresented clinical indicia of aberrant drug-related behavior and of potential abuse, misuse, and addiction, including promoting concepts such as pseudoaddiction or pseudotolerance to justify further prescribing of opioids to patients in distress.

464. Defendants have willfully engaged in these acts and practices in violation of the Virginia Consumer Protection Act.

465. Individual consumers have suffered losses as a result of these Virginia Consumer Protection Act violations.

COUNT III

Virginia Consumer Protection Act - Misrepresentations Regarding Risk Mitigation Programs

466. Plaintiff adopts by reference paragraphs 1 through 465.

467. Since 2001, Defendants have violated Virginia Code § 59.1-200(A)(5) and (A)(14) by misrepresenting the risk mitigation measures they took or purported to take to prevent, deter, and reduce wrongful off-label use of Fentora and Actiq.

468. As alleged in paragraphs 47 to 95, 151 to 160, 176 to 191, 203 to 217, 256 to 302, 303 to 307, 337 to 345, 356, and 427 to 439, since 2001, Defendants have pledged as a condition of approval for both Actiq and Fentora to monitor for wrongful off-label prescribing, including prescribing for non-cancer conditions or prescribing to opioid-naïve patients, and to intervene if off-label prescribing was occurring.

469. [redacted]

470. [redacted]

471. [redacted]

472. [redacted]

473. As alleged in paragraphs 96 to 160, 176 to 202, 210 to 217, 256 to 302, 337 to 345, and 427 to 439, Defendants failed to intervene to prevent off-label prescribing, including from 2000 to the present, failing to cease detailing individual off-label providers or groups of providers, and from 2012 to the present failing to disenroll off-label prescribers or dispensers from participation in the TIRF REMS program.

474. [redacted]

475. [redacted]

476. Defendants have willfully engaged in these acts and practices in violation of the Virginia Consumer Protection Act.

477. Individual consumers have suffered losses as a result of these Virginia Consumer

Protection Act violations.

PRAYER FOR RELIEF

WHEREFORE, the Plaintiff, the Commonwealth of Virginia, prays that this Court:

A. Preliminarily and permanently enjoin Defendants and their officers, employees, agents, successors, and assigns from violating the Virginia Consumer Protection Act pursuant to Virginia Code § 59.1-203;

B. Grant judgment against Defendants and award to the Commonwealth all sums necessary to restore to any consumers the money or property acquired from them by Defendants in connection with violations of the Virginia Consumer Protection Act pursuant to Virginia Code § 59.1-205;

C. Enter any additional orders or decrees as may be necessary to restore to any consumers the money or property acquired from them by Defendants in connection with violations of the Virginia Consumer Protection Act pursuant to Virginia Code § 59.1-205;

D. Grant judgment against Defendants and award to the Commonwealth civil penalties of up to $2,500.00 per violation for each willful violation of the Virginia Consumer Protection Act pursuant to Virginia Code § 59.1-206(A), the exact number of violations to be proven at trial;

E. Grant judgment against Defendants and award to the Commonwealth its costs, reasonable expenses incurred in investigating and preparing the case up to $1,000.00 per violation of the Virginia Consumer Protection Act, and attorneys' fees pursuant to Virginia Code § 59.1-206(C); and

F. Grant such other and further relief as the Court deems equitable and proper.

COMMONWEALTH OF VIRGINIA,
***EX REL.* MARK R. HERRING,**
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