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IN THE SUPERIOR COURT FOR THE STATE OF ALASKA
THIRD JUDICIAL DISTRICT IN ANCHORAGE

STATE OF ALASKA, Plaintiff, vs. TEVA PHARMACEUTICAL INDUSTRIES, LTD.; TEVA PHARMACEUTICALS USA, INC.; CEPHALON, INC.; ALLERGAN PLC F/K/A ACTAVIS PLC F/K/A ALLERGAN, INC; ALLERGAN FINANCE, LLC, F/K/A/ ACTAVIS, INC., F/K/A WATSON PHARMACEUTICALS, INC.; ALLERGAN SALES, LLC; ALLERGAN USA, INC.; WATSON	)

LABORATORIES, INC.; WARNER CHILCOTT COMPANY, LLC; ACTAVIS PHARMA, INC. F/K/A WATSON PHARMA, INC.; ACTAVIS SOUTH ATLANTIC LLC; ACTAVIS ELIZABETH LLC; ACTAVIS MID ATLANTIC LLC; ACTAVIS TOTOWA LLC; ACTAVIS LLC; ACTAVIS KADIAN LLC; and ACTAVIS LABORATORIES UT, INC., F/K/A WATSON LABORATORIES, INC.-SALT LAKE CITY; ACTAVIS LABORATORIES FL, INC., F/K/A WATSON LABORATORIES, INC.-FLORIDA;

Defendants.

COMPLAINT

I. PRELIMINARY STATEMENT

1. The State of Alaska brings this action in its persistent effort to protect the State and its citizens from the worst human-made epidemic in modern medical history—the over-use, misuse, and abuse of opioids. In the words of Robert Anderson, who oversees death statistics at the Centers for Disease Control ("CDC"), "I don't think we've ever seen anything like this. Certainly not in modern times."

2. The CDC has reported that, in recent years, our nation has seen life expectancy decline. The increasing number of lives lost to overdoses, especially overdoses on opioids, represents the most significant factor in this alarming trend.

3. In Alaska, prescription opioids have created what the CDC called a "public health epidemic"[1] and what the previous President deemed a "public health emergency."[2] In 2011, Alaska saw 66 fatal opioid overdoses; by 2016, that number reached 96, and by 2017, 107—582 deaths over those seven years.

4. The opioid crisis has exacerbated the COVID-19 crisis. Data show people who have been diagnosed with substance abuse disorder are 1.5 times as likely to contract COVID-19, and patients with opioid use disorder are 2.4 time as likely.[3] Because COVID-19 can make it more difficult to breathe, patients on high dose opioids may face greater risks.[4] Lifetime substance abuse disorder results in higher hospitalization and death rates from the virus.[5] Furthermore, the cost of responding to the coronavirus epidemic has placed even greater strain on Alaska health departments, already suffering from having to respond to the opioid epidemic.

5. As explained below, Defendants Teva Pharmaceutical Industries, Ltd., Teva Pharmaceuticals USA, Inc., Cephalon, Inc., ("Teva"); Allergan Finance, LLC f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.; Allergan plc; Allergan Sales, LLC; Allergan USA, Inc. ("Allergan"); Watson Laboratories, Inc.; Warner Chilcott Company, LLC; Actavis Pharma, Inc., f/k/a/ Watson Pharma, Inc.; Actavis South Atlantic LLC; Actavis Elizabeth LLC; Actavis Mid Atlantic LLC; Actavis Totowa LLC; Actavis LLC; Actavis Kadian LLC; Actavis Laboratories UT, Inc. f/k/a Watson Laboratories, Inc.-Salt Lake City; and Actavis Laboratories FL, Inc., f/k/a Watson Laboratories, Inc.-

[1] The CDC, *Prescription Painkiller Overdoses in the US*, November 1, 2011, available at https://www.cdc.gov/vitalsigns/painkilleroverdoses/index.html.
[2] The New York Times, *Trump Declares Opioid Crisis a 'Health Emergency' but Requests No Funds*, October 26, 2017, available at https://www.nytimes.com/2017/10/26/us/politics/trump-opioid-crisis.html.
[3] https://www.drugabuse.gov/about-nida/noras-blog/2020/10/new-evidence-substance-use-disorders-covid-19-susceptibility
[4] http://dhss.alaska.gov/osmap/Pages/covid-19_considerations.aspx
[5] https://www.drugabuse.gov/about-nida/noras-blog/2020/10/new-evidence-substance-use-disorders-covid-19-susceptibility

Florida (the "Former Actavis Entities") played a particularly significant role in this still-unfolding epidemic.

6. Prescription opioids are narcotics. They are derived from and possess properties similar to opium and heroin, and they are regulated as controlled substances. While opioids can dampen the perception of pain, they also can create a euphoric high and are highly addictive. At higher doses, they can slow the user's breathing, causing potentially fatal respiratory depression.

7. Because the medical community recognized these dangers, they originally used opioids cautiously and sparingly, typically only for short-term acute pain or for palliative (end-of-life) care. Consequently, the prescribing of opioids was sharply constrained and, for Teva, unacceptably small. This was especially true for Teva's branded opioids, which were so potent and dangerous that they were only approved for cancer pain in patients who had already become tolerant to opioids.

8. From 2000 to the present, Defendants engaged in a deceptive marketing campaign that minimized the risks of opioids, especially the serious risks of addiction, and sought to convince doctors that there was a significant upside to their use for chronic non-cancer pain by exaggerating their purported benefits. These claims are unsupported by the scientific evidence and were, and remain, too often fatally false. According to the CDC, opioid prescriptions in the U.S., as measured by number of prescriptions and morphine milligram equivalents – a measure of drug strength – per person, tripled from 1999 to 2015. In 2015, on an average day, more than 650,000 opioid prescriptions were dispensed in the U.S.

9. Defendants' fraudulent marketing played a significant role in transforming medical thinking about opioids, persuading doctors that the risk of addiction for legitimate pain patients is modest and manageable and outweighed by the benefits in reduced pain and improved quality of life for their patients. It also increased the comfort level of doctors and patients in converting opioids

prescribed for acute pain—surgery or injuries, for example—to long-term use by patients who experienced or reported ongoing pain. Patients were subject to the same types of marketing messages and trusted that drugs prescribed by their doctors must be safe and useful.

10. Yet roughly one in four patients who receive prescription opioids long-term for chronic pain in primary care settings will become addicted—a condition with which they will struggle their entire lives. Addiction treatment professionals in Alaska have confirmed that opioid addictions in Alaska are steadily increasing.

11. Rather than compassionately helping patients, the explosion in opioid use has come at the expense of chronic pain patients. The CDC director concluded in 2016 that "for the vast majority of [chronic pain] patients, the known, serious, and too-often-fatal risks [of opioids] far outweigh the unproven and transient benefits." As the then-CDC director concluded: "We know of no other medication routinely used for a nonfatal condition that kills patients so frequently."

12. The increased volume of opioid prescribing correlates directly to increased addiction, overdose, and death; black markets for diverted prescription opioids; and an increase in heroin abuse by individuals who can no longer legally acquire—or simply cannot afford—prescription opioids. With the introduction of synthetic fentanyl, which can be added to heroin to increase the high, the transition from prescription pills to heroin has become even more deadly.

13. Compounding the harm they caused, Defendants also failed to control their supply of opioids into the state, in violation of State and federal law. Data available to Teva, Allergan, and the Former Actavis Entities; as well as their own observations from in-person marketing by Teva and Allergan, would have, or should have, put the Defendants on notice of potential diversion.

14. Defendants shipped opioids into Alaska without an adequate system in place to prevent diversion of its opioids and to investigate, report, and refuse to fill orders that they knew or

should have known were suspicious, breaching both their common law duties and their statutory duties under Alaska law. Despite their legal and ethical duty to report "suspicious orders" of their drugs, and, upon information and belief, ample red flags of potential diversion, Defendants have never once reported a suspicious order or prescriber to the DEA or to state law enforcement or the Alaska State Medical Board.[6]

15. While Defendants profited enormously from their deceptive marketing, the State of Alaska and its residents have experienced the consequences in suffering and responding to opioid addiction and overdose, and opioid-related crime and dislocation. While many of those harms cannot be undone or ever adequately compensated, the Attorney General brings this action pursuant to his constitutional, statutory, and common law authority, alleging that Defendants violated, and continues to violate, the Alaska Unfair Trade Practices and Consumer Protection Act ("UTPA"), AS 45.50.471 et seq. The Attorney General also alleges that Defendants' unlawful conduct has created a public nuisance and that they have been unjustly enriched through their actions.

16. For these claims, the Attorney General seeks injunctive relief, abatement of the public health epidemic that Defendants helped create, the maximum civil penalties allowed by law for each violation of law, damages, and equitable relief within this Court's powers to redress and halt Defendants' unlawful practices.

II. PARTIES

17. The State of Alaska brings this action, by and through its Attorney General Treg Taylor, in its sovereign capacity in order to protect the interests of the State and its citizens. The Attorney General brings this action pursuant to his constitutional, statutory, and common law

[6] Alaska is suing the three largest wholesale distributors separately in *State of Alaska v. McKesson Corporation et al.*, No. 3AN-18-10023 CI (Alaska Super. Ct. Oct. 25, 2018).

authority, including the authority granted to him by AS 44.23.020, and the Alaska Unfair Trade Practices and Consumer Protection Act, AS 45.50.471 *et seq*.

18. Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation with its principal place of business in Pennsylvania.

19. Defendant Cephalon, Inc. ("Cephalon") is a Delaware corporation with its principal place of business in Frazer, Pennsylvania.

20. Teva Pharmaceutical Industries, Ltd. ("Teva Ltd.") is global pharmaceutical company with headquarters in Petah Tikva, Israel. Teva Ltd. is a public company traded on the New York Stock Exchange (symbol: TEVA). Teva Ltd. specializes in the manufacture and sale of generic drugs and is the largest generic drug manufacturer in the world.

21. Teva Pharmaceuticals USA, Inc. ("Teva USA"), a subsidiary of Teva Ltd., is a Delaware corporation with its principal place of business in North Wales, Pennsylvania, and the owner of Cephalon. Cephalon became a wholly owned subsidiary of Teva USA when Teva USA acquired it in October 2011.

22. The close connection between Teva Ltd. and its U.S. subsidiaries, as well as the blurred distinction between them, is shown in Teva's websites. For example, on Teva USA's website is a page entitled "Teva Pharmaceutical Industries Limited," on a page labelled "intended for US residents only," which includes the following: "Teva improves health in the US every day, every minute, every second. One in every six prescriptions dispensed in the US is a Teva product. Approximately 22 prescriptions in the US are filled by Teva products every second . . . Teva is the world's largest maker of generic pharmaceutical products."[7] Teva Ltd.'s financial reports list Cephalon's and Teva USA's sales as its own, and its year-end report for 2012 attributed a 22% increase

[7] https ://www.tevausa.com/Company. aspx

in its specialty medicine sales to "the inclusion of a full year of Cephalon's specialty sales . . . ." [8] The United States is the largest of Teva Ltd.'s global markets, and it represents nearly half of its total revenue.[9]

23. Other publicly available information demonstrates Teva Ltd.'s control over Cephalon's operations: For example, immediately after acquiring Cephalon, Teva Ltd. caused Cephalon to increase its product prices up to twenty-five percent.[10] The two companies combined their sales forces[11], product pipelines, and research and development efforts.[12]

24. Teva Ltd. is closely involved in the combined companies' American operations, including in Alaska. Approximately 80% of its revenue derives from the United States. [redacted]

[redacted]

A 2015 audit by Teva Ltd. of Teva USA's handling of controlled substances further demonstrates Teva Ltd's control over its American and Alaskan business units on topics relating to opioid sales and distribution.

25. Teva manufactures, promotes, sells, and distributes branded opioids Actiq, a fentanyl lollipop, and Fentora, a dissolving fentanyl pill, throughout the United States and in Alaska. Actiq and Fentora have been approved by the FDA only for the management of breakthrough cancer pain in patients 16 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain.

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[8] New Yorker; Fact Sheet Teva Pharmaceutical Industries Ltd. Annual Report (Form 20-F) (Feb. 12, 2013) at 62.
[9] *Id*. at 62-64.
[10] Tracy Staton, *Teva jacks up prices on Cephalon legacy brands* (Dec. 7, 2011), http://wwW.fiercepharma.com/story/tevajacks-prices-cephalon-legacy -brands/2011 -12-07.
[11] *NASDAQ OMX 27th Investor Program Conference Call,* Teva Pharm. Indus. Ltd. (Dec. 6, 2011, 5:15 AM), http ://seekingalpha.com/article/315684-teva-pharmaceuticals-management-presents-at-nasdaq-omx-27th-investor-program-transcript?page=4.
[12] *See generally, Teva Pharmaceuticals Industries ' Management Presents at Citi Global Health Care Conference (Transcript)* (Mara 8, 2012), http://seekingalpha.com/article/419471-

26. In 2008, Cephalon pled guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading off-label promotion of Actiq and two other drugs and agreed to pay $425 million.

27. Teva also sells generic opioids throughout the United States and Alaska, including generic opioids previously sold by Allergan plc, whose generics business Teva's parent company acquired in August 2016. Generics sold by Teva include oxymorphone and hydrocodone.

28. Allergan plc (f/k/a Actavis plc, f/k/a Allergan, Inc.) is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland, and its administrative headquarters and all executive officers located in Madison, New Jersey. In October 2012, the Actavis Group was acquired by Watson Pharmaceuticals, Inc., and the combined company changed its name to Actavis, Inc. as of January 2013, and then to Actavis plc in October 2013. In October 2013, Actavis plc (n/k/a Allergan plc) acquired Warner Chilcott plc pursuant to a transaction agreement dated May 19, 2013. Actavis plc (n/k/a Allergan plc) was established to facilitate the business combination between Actavis, Inc. (n/k/a Allergan Finance, LLC) and Warner Chilcott plc. Following the consummation of the October 1, 2013 acquisition, Actavis, Inc. (n/k/a Allergan Finance, LLC Inc.) and Warner Chilcott plc became wholly-owned subsidiaries of Actavis plc (n/k/a Allergan plc). Pursuant to the transaction, each of Actavis, Inc.'s common shares were converted into one Actavis plc share. Further, Actavis plc (n/k/a Allergan plc) was the "successor issuer" to Actavis, Inc. and Warner Chilcott. Actavis plc acquired Allergan, Inc. in March 2015, and the combined company thereafter changed its name to Allergan plc.

29. The transaction that created Actavis plc converted each share of Actavis Inc.'s Class A common shares into one Actavis plc Ordinary Share.[13] Actavis Inc. and Actavis

[13] *See City of Chicago v. Purdue Pharma L.P., et al.* (N.D. Ill. 2015), No. 14-4361, 2015 WL 2208423, at *7.

plc had the same corporate headquarters both before and after the merger; Actavis plc had the same website as Actavis Inc.; and, Actavis plc maintained all of Actavis Inc.'s officers in the same positions.[14] Actavis plc's SEC filings explained that "references throughout to 'we,' 'our,' 'us,' the 'Company' or 'Actavis' refer interchangeably to Watson Pharmaceuticals, Inc., Actavis, Inc., and Actavis plc depending on the date."[15]

30. Defendant Allergan Finance, LLC (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.) is a limited liability company incorporated in Nevada and headquartered in Madison, New Jersey. Allergan Finance, LLC is a wholly-owned subsidiary of Allergan plc.

31. Defendant Allergan Sales, LLC is incorporated in Delaware and headquartered in Irvine, California. Allergan Sales, LLC is the wholly-owned subsidiary of Allergan plc.

32. Defendant Allergan USA, Inc. is incorporated in Delaware and headquartered in Madison, New Jersey. Allergan USA, Inc. is a wholly-owned subsidiary of Allergan plc.

33. Allergan plc; Allergan Finance, LLC; Allergan Sales, LLC; and Allergan USA, Inc. are collectively "Allergan." Allergan manufactures or has manufactured branded and generic opioids.

34. Defendant Watson Laboratories, Inc. is a Nevada corporation with its principal place of business in Corona, California. Watson Laboratories, Inc. was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva. Prior to the sale, Watson Laboratories, Inc. was a direct subsidiary of Actavis, Inc., (n/k/a Allergan Finance, LLC). Watson Laboratories, Inc. was also the manufacturer of various generic opioids.

[14] *See id*.
[15] *See id.*

35. Defendant Warner Chilcott Company, LLC is a limited liability company incorporated in Puerto Rico. Warner Chilcott Company, LLC was a subsidiary of Warner Chilcott plc until Warner Chilcott plc became a wholly owned subsidiary of Allergan plc in 2013. Warner Chilcott Company LLC was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva.

36. Defendant Actavis Pharma, Inc. (f/k/a Watson Pharma, Inc.) is a Delaware corporation with its principal place of business in New Jersey. Actavis Pharma, Inc. was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva.

37. Defendant Actavis South Atlantic LLC is a Delaware limited liability company with its principal place of business in Sunrise, Florida. Actavis South Atlantic LLC was listed as the ANDA[16] holder for oxymorphone and fentanyl transdermal. Actavis South Atlantic LLC was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva.

38. Defendant Actavis Elizabeth LLC is a Delaware limited liability company with its principal place of business in Elizabeth, New Jersey. Actavis Elizabeth LLC was also the holder of ANDAs for the following Schedule II opioid products: oxycodone/acetaminophen; homatropine methylbromide/hydrocodone bitartrate; morphine sulfate capsule; morphine sulfate tablet; oxycodone/hydrochloride tablet; oxycodone/ibuprofen; and oxymorphone tablet. Actavis Elizabeth LLC was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva.

39. Defendant Actavis Mid Atlantic LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Actavis Mid Atlantic LLC has held the

[16] Abbreviated New Drug Application, when approved, giving a generic manufacturer the right to sell a bio-equivalent drug.

ANDA for homatropine methylbromide/hydrocodone bitartrate. Actavis Mid Atlantic LLC was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva.

40. Defendant Actavis Totowa LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Actavis Totowa LLC has held the ANDAs for the following Schedule II opioid products: oxycodone/acetaminophen; homatropine methylbromide; oxycodone/hydrochloride.

41. Defendant Actavis LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Defendants Actavis South Atlantic LLC, Actavis Elizabeth LLC, Actavis Mid Atlantic LLC, and Actavis Totowa LLC were all direct subsidiaries of Actavis LLC, which was an indirect subsidiary of defendant Watson Laboratories, Inc. Watson Laboratories, Inc., in turn, was a direct subsidiary of Actavis, Inc. (n/k/a Allergan Finance, LLC). Actavis LLC was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva.

42. Defendant Actavis Kadian LLC is a Delaware limited liability company with its principal place of business in Morristown, New Jersey. Actavis Kadian LLC was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva.

43. Defendant Actavis Laboratories UT, Inc. (f/k/a Watson Laboratories, Inc.-Salt Lake City) ("Actavis UT") is a Delaware limited liability company with its principal place of business in Salt Lake City, Utah. Actavis Laboratories UT, Inc. was sold to Teva Pharmaceutical Industries Limited as part of Allergan plc's 2016 sale of its generic businesses to Teva. Prior to the sale, Actavis Laboratories UT, Inc. was a direct subsidiary of Actavis, Inc. (n/k/a Allergan Finance, LLC).

44. Defendant Actavis Laboratories FL, Inc. (f/k/a Watson Laboratories, Inc.-Florida) is a Florida limited liability company with its principal place of business in Davie, Florida. Actavis Laboratories FL, Inc. was the ANDA holder of the following Schedule II opioid products: hydrocodone/acetaminophen; hydrocodone/ibuprofen; oxycodone/aspirin; and hydromorphone tablet. Actavis Laboratories FL, Inc. was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva. Prior to the sale, Actavis Laboratories FL, Inc. was a direct subsidiary of Andrx Corporation, which was a direct subsidiary of Actavis, Inc. (n/k/a Allergan Finance, LLC). Andrx Corporation was transferred to Teva as part of the 2016 sale.

45. Watson Laboratories, Inc.; Warner Chilcott Company LLC, Actavis Pharma, Inc. (f/k/a Watson Pharma, Inc.), Actavis South Atlantic LLC, Actavis Elizabeth LLC, Actavis Mid Atlantic LLC, Actavis Totowa LLC, Actavis LLC, Actavis Kadian LLC, Actavis Laboratories UT, Inc. (f/k/a Watson Laboratories, Inc.-Salt Lake City), Actavis Laboratories FL, Inc. (f/k/a Watson Laboratories, Inc.-Florida) are together the "Former Actavis Entities." The Former Actavis Entities, with Cephalon, Teva USA, and Teva Ltd. are "Teva."

46. Teva and Allergan are at times referred to collectively herein as "Defendants."

47. According to chargeback data, the Actavis entities were responsible for [redacted] dosage units of opioids purchased in Alaska from 2004 to 2016, and Teva was responsible for [redacted] dosage units of opioids purchased in Alaska from 2011 to 2018. (A dosage unit is a single pill, capsule, patch, or other form of administering opioids.) Additionally, Teva was responsible for shipping into Alaska 5,749,765 dosage units of opioids between 2006 to 2014, the years for which ARCOS data is available. In the same period, the Actavis entities were responsible for 40,348,090

dosage units of opioids, and the Allergan entities were responsible for 85,500 dosage units of opioids shipped into Alaska.

III. FACTUAL ALLEGATIONS

A. Teva Misrepresented the Risks and Benefits of Opioids

48. Defendant Teva misrepresented the safety and efficacy of its branded opioids, through direct marketing channels and through its support of third party content, including continuing medical education programs. In its direct and indirect marketing, Teva issued misrepresentations minimizing the prevalence of addiction in patients treated with chronic opioid therapy—including risks known to Teva from its own clinical trials—and exaggerating the potential benefits that patients would experience using opioids. Teva further omitted to mention increased risks at higher doses, and falsely taught that unauthorized dose escalations or other aberrant behavior could be signs of "pseudoaddiction." They did so even knowing their primary branded opioids were only permitted by the FDA to be marketed only for the treatment of breakthrough cancer pain in patients receiving and tolerant to around-the-clock long-acting opioids. Because of these limitations on Teva's branded drugs, however, and its substantial generics business, Teva sought to promote the acceptance of opioids as a class to treat chronic non-cancer pain conditions.

49. Teva relied on its sales representatives to convey its marketing messages and materials to prescribers in targeted, in-person settings. According to internal Teva documents, from 2000 until 2017, Fentora sales representatives visited and/or called Alaska healthcare providers [redacted] times.

50. To ensure that sales representatives delivered the desired messages to prescribers, Teva directed and monitored its sales representatives through detailed action plans, training, and review of representatives' "call notes" from each visit. It further ensured marketing consistency nationwide through sales representative training. Thus, upon information and belief, its sales forces

in Alaska carried out national marketing strategies, delivering centrally scripted messages and materials that were consistent across the country.

51. Teva also used "key opinion leaders" ("KOLs")—experts in the field who were especially influential because of their reputations and seeming objectivity—to deliver paid talks and continuing medical education programs ("CMEs") that provided information through third party organizations about treating pain and the risks, benefits, and use of opioids. These KOLs received substantial funding and research grants from Teva, and the CMEs were often sponsored by Teva—giving it considerable influence over the messenger, the message, and the distribution of the program. Upon information and belief, doctors supportive of Teva's messages regarding the use and safety of opioids for chronic pain received these funding and speaking opportunities, which were not only lucrative, but helped doctors build their reputations and bodies of work. For example, one Teva KOL, Dr. Scott Fishman, was a prominent speaker on the under-treatment of pain, and has written a book about responsible opioid prescribing. He claimed he received no royalties, but beginning around 2010, corrected himself and acknowledged that he received fees for teaching medical education courses, some of which were funded by drug companies. Another leading KOL for Teva, Dr. Russell Portenoy, subsequently acknowledged that he gave lectures on opioids that reflected "misinformation" and were "clearly the wrong thing to do."

52. In addition to talks and CMEs, these KOLs served on the boards of patient advocacy groups and professional associations, such as the American Academy of Pain Medicine, that were influential because of their seeming independence. Teva exerted influence and control over such groups by providing funding directly to them. These "front groups" for the opioid industry created

patient education materials and treatment guidelines that supported the use of opioids for chronic pain by overstating their benefits and understating their risks.[17]

53. The FDA does not regulate unbranded advertising or marketing funneled through third-parties. Thus, neither these third-party unbranded materials, nor the marketing messages or scripts relied on by Teva's sales representatives, were reviewed or approved by the FDA. Unbranded marketing materials promote the benefits of opioids as a class, which in turn aid in the sale of generic opioids.

54. Upon information and belief, all of the messages described below were disseminated to Alaska prescribers and patients through sales representative visits, medical education programs, marketing materials, or other sources.

(1) Cephalon Deceptively marketed Actiq for Off-Label Use

55. Both Actiq, sold by Teva starting in 2000, and Fentora, launched in 2007, are extremely powerful fentanyl-based opioids. Actiq delivers fentanyl into the bloodstream via a lollipop lozenge that dissolves slowly in the mouth. As described by one patient, Actiq "tastes like the most delicious candy you ever ate." Fentora is administered by placing the tablet in the mouth until it dissolves. Both are rapid-onset opioids that take effect within 10-15 minutes, but last only a short time. Neither is approved for, nor has either been shown to be safe or effective for, treating chronic pain. The drugs are approved solely for breakthrough cancer pain in patients who are tolerant to opioid therapy.

[17] An investigation and report by the U.S. Senate notes, "many patient advocacy organizations and professional societies focusing on opioids policy have promoted messages and policies favorable to opioid use while receiving millions of dollars in payments from opioid manufacturers. Through criticism of government prescribing guidelines, minimization of opioid addiction risk, and other efforts, ostensibly neutral advocacy organizations have often supported industry interests at the expense of their own constituencies." Staff Report, *Fueling an Epidemic, Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups*, at 3.

56. Actiq was given "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." Restricted approvals are "special safety programs to mitigate serious risks." This meant that the FDA expressly prohibited Teva from marketing Actiq for anything but cancer pain. As set forth in the Novermber 4, 1998 approval letter:

> In addition, please note that this product has been approved **ONLY** 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 have any questions or concerns about this matter, please contact the Center for Drug Evaluation and Research's Division of Drug Marketing, Advertising, and Communications.

57. From the time Cephalon acquired rights to Actiq in 1999 and began marketing it in 2000, it sought to circumvent these requirements by targeting pain specialists, believed to be "more aggressive [prescribers " than oncologists.

58. By 2002, Actiq sales had increased by 92%, which Teva attributed to "a dedicated sales force for ACTIQ" and "ongoing changes to [its] marketing approach including hiring additional sales representatives and targeting our marketing efforts to pain specialists."[18] Actiq became Cephalon's second best-selling drug. By the end of 2006, Actiq's sales had exceeded $500 million. Only 1% of the 187,076 prescriptions for Actiq filled at retail pharmacies during the first six months of 2006 were prescribed by oncologists. One measure suggested that "more than 80 percent of patients

[18] Cephalon, Inc. Annual Report (Form 10-K) at 28 (Mar. 31, 2003), https://www.sec.gov/Archives/edgar/data/873364/000104746903011137/a2105971z10-k.htm.

who use[d] the drug don't have cancer."[19] The *Wall Street Journal* found in 2003 that Actiq was the 15th most costly drug in workers' compensation programs, despite relatively little treatment of cancer through those programs.[20]

59. Cephalon's sales quotas for its general pain sales force would be unattainable if they did not deceptively promote Fentora off-label. [redacted]

60. [redacted] Another prescriber told the Actiq sales representative in 2004 that he thought Actiq was "best used for migraines." These call notes demonstrate Cephalon's knowledge of off-label use, and the inclusion of physical medicine doctors and dedicated pain clinics on its call plan indicate an intent to promote the drug off-label.

61. In 2004, the FDA and Teva held a meeting regarding the FDA's concern over Teva's promotion of Actiq for off-label use. According to the meeting minutes, the FDA's specific concerns included Teva's prescriber targeting criteria and physician screening, as well as sales

[19] *Id*.
[20] "Narcotic Actiq's Use and Abuse Raise Concern." *Wall Street Journal*, May 15, 2004.

representative training practices that "inappropriately broaden the drug's labeled indication, the eliciting of and response to off-label inquiries regarding Actiq . . . and the promotional use of disease awareness materials that discuss conditions for which Actiq is not indicated to treat." Additionally, according to the minutes, the FDA told Teva that "off-label promotion is illegal, and especially with a drug with a risk profile like Actiq, raises significant public health concerns."

62. In 2004, as well, regulators became increasingly alarmed with Actiq abuse and diversion. For instance, the attorney general of Pennsylvania warned of street abuse of Actiq in 2004, citing its strength and "berry flavor."[21]

63. In 2008, the Department of Justice ("DOJ") accused Cephalon of promoting Actiq, along with two non-opioid drugs, for uses the FDA had not approved. Cephalon agreed to settle the charges for $425 million. The DOJ charged that Cephalon promoted Actiq to non-cancer patients for conditions such as "migraines, sickle-cell pain crises, injuries, and in anticipation of changing wound dressings or radiation therapy." The DOJ also accused Cephalon of promoting Actiq for patients who were not opioid-tolerant, "for whom it could have life threatening results." The DOJ outlined Cephalon's sales tactics as follows:

> Cephalon instructed the Actiq sales representatives to focus on physicians other than oncologists, including general practitioners, and to promote the drug for many uses other than breakthrough cancer pain. . . . Cephalon also structured its sales quota and bonuses in such a way that sales representatives could reach their sales goals only if they promoted and sold the drugs for off-label uses. . . . Cephalon employed sales representatives and retained medical professionals to speak to doctors about off-label uses of Actiq. . . . The company funded continuing medical education programs, through millions of dollars in grants, to promote off-label uses of its drugs, in violation of the FDA's requirements.

64. Acting U.S. Attorney Laurie Magid stated that Cephalon had violated the very process meant to protect the public from harm in order to boost its bottom line, and noted, "[p]eople

[21] "Abuse of Narcotic 'Perc-A-Pops' reported, *Associated Press*, April 28, 2014.

have an absolute right to their doctors' best medical judgment. They need to know the recommendations a doctor makes are not influenced by sales tactics designed to convince the doctor that the drug being prescribed is safe for uses beyond what the FDA has approved."

65. Despite the multi-million dollar fine and admonitions from the DOJ and FDA concerning Actiq, Teva conducted a campaign to promote Fentora between 2007 and 2015 for chronic pain and other non-cancer conditions for which it was not approved, appropriate, or safe. As part of this campaign, Teva used CMEs, speaker programs, KOLs, journal supplements, and detailing by its sales representatives to give doctors the false impression that Actiq and Fentora are safe, effective, and appropriate for treating non-cancer pain.

(2) Teva Misrepresented the Safety and Efficacy of Fentora While Promoting It For Off-Label Uses As Well

66. In 2006 Actiq faced impending generic competition. To stave off loss of marketshare, Cephalon introduced Fentora in 2006. Cephalon, and later Teva, thus began a program to migrate patients who were taking Actiq to Fentora, as well as to start new patients on Fentora.

67. Cephalon initially sought FDA approval for Fentora for the same limited indication – cancer pain treatment – for which Actiq had been approved.

68. From the start, Cephalon anticipated that even with this limited indication doctors would still prescribe Fentora off-label – it estimated that even with cancer-pain indication, doctors would still largely prescribe Fentora for off-label uses, mainly for back pain and neuropathic pain. Internal projections in 2004 estimated that less than 10% of providers would prescribe Fentora appropriately for cancer patients.

69. On September 27, 2007, the FDA issued a public health advisory to address numerous reports that patients who did not have cancer or were not opioid tolerant had been prescribed Fentora, and death or life-threatening side effects had resulted. The FDA warned: "Fentora should not

be used to treat any type of short-term pain." Indeed, FDA specifically denied the application, in 2008, to broaden the indication of Fentora to include treatment of non-cancer breakthrough pain and use in patients who were not already opioid-tolerant.

70. Cephalon's marketing plan for Fentora made off-label use a forgone conclusion: the company would simply target the most frequent Actiq prescribers, whom, data showed, were largely prescribing Actiq for inappropriate off-label uses.

71. Cephalon also promoted Fentora for off-label uses by creating template "letters of medical necessity" to obtain insurance reimbursements for off-label conditions, including lower back pain and neuropathic pain.

72. By using the same types of targeting, even with a new compliance system, Teva's marketing strategies ensured that the public health result for Fentora would be the same as for Actiq - massive wrongful prescribing of Fentora to non-cancer patients.

73. Cephalon's own market research studies confirm that its Fentora promotions were not focused on the physicians who treat breakthrough cancer pain. Cephalon commissioned several market research studies to determine whether oncologists provided an "adequate" market potential for Fentora. These studies' central goal was to determine whether oncologists treat breakthrough cancer pain themselves, or whether they refer such patients to general pain specialists. The first study, completed in 2007, reported that 90% of oncologists diagnose and treat breakthrough cancer pain themselves, and do not refer their breakthrough cancer pain patients to pain specialists. The second study, completed in 2009, confirmed the results of the 2007 study, this time reporting that 88% of oncologists diagnose and treat breakthrough cancer pain themselves and rarely, if ever, refer those patients to general pain specialists. (One reason that general pain specialists typically do not treat

oncological pain is that the presence of pain can, in itself, be an indicator of a change in the patient's underlying condition that should be monitored by the treating oncologist.)

74. Cephalon also continued to use its general pain sales force (which numbered over 110 representatives) to promote Fentora to general pain specialists. Within Alaska, of the 16 prescribers for whom Teva provided meal reimbursement payments from 2010-2015 relating to Fentora, only 5 specialized in oncology.

(3) Cephalon and Teva Misrepresented Data From Fentora Clinical Trials

75. From 2006 to 2019, Teva would rely upon and cite Fentora clinical trial data to support a variety of claims about Fentora's benefits, efficacy, and risks, including in non-cancer pain. 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.

76. 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.

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

78. 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.

79. The long-term cancer clinical trial ran from April 2004 to November 2006. It tracked opioid-tolerant patients with metastatic cancers for what was supposed to be 12 months and more.

80. 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.

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

82. Both of Cephalon's long-term clinical trials allowed patients a surprising amount of discretion in administering Fentora. Patients were given 100 to 150 tablets at once, which was supposed to be a month's supply, which they took home. 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. For most of the time these clinical trials ran, there was no limit on the number of tablets that could be used in a single day.

83. If patients went through their 100 to 150 tablets in less than a month, they could come back early to get more. Given 100 or more pills and few limits, patients began abusing and misusing Fentora. In the cancer clinical trial, patients quickly escalated their doses. For example, more than ten of the 197 long-term patients took more than ten pills per day of the strongest dose of Fentora given, 800 mcg. By way of comparison, Cephalon's product label for Actiq at the time warned patients not to take more than four lozenges per day. Patients on opioids for more than a brief period develop tolerance, requiring even further high doses to achieve pain relief. Higher doses, however, increase risk of addiction and overdose, described below.

84. Cephalon let this continue for more than two years. Then, finally, Cephalon imposed a global cap on all its clinical trials (including both the cancer and non-cancer trials) limiting patients to eight Fentora tablets per day. In reports on the cancer clinical trial, it claimed this amendment was to "provide clarification" to patients, but in other regulatory filings it more candidly admitted "[t]his change was made due to reports that patients were using up to 11 tablets per day for BTP [breakthrough pain]."

85. Cephalon's marketing materials on the cancer trials never disclosed the cap's true purpose.

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

- Patient 06003 reported the study drug [Fentora] stolen from her home and she "took excessive amt of study drug and claimed her daughter stole her medication";
- Patient 11006 took 3 doses of study drug but "forgot to put in diary because she went to Las Vegas" and repeatedly ran out of medication weeks before her scheduled monthly visits and was given more;
- Patient 32005 was "lethargic at visit, admitted to using methadone day before since he had run out of both orovescent [Fentora] and Actiq. Pt left diaries for past month on the train."
- Patient 351004 "wasn't completing diaries correctly and seemed to be overusing study drug," claimed to need more Fentora tablets due to them disappearing down kitchen sink, and claimed other Fentora tablets had been "destroyed";
- Patient 351006 "was going to ER to get additional opiates";

- Patient 41001 was "taking more study drug than study allows," "ran out" of pills and reported them missing, and was given "firm talking-to" by the investigator about adherence to medication schedule;

- Patient 86001 was "[n]ot following directions, not providing diary," "continued to use Actiq despite being counseled not to," and "used study medication does [sic.] (100 tabs) before patients was due for refill."

- There were also at least two patients who were lost to follow up and did not return large numbers of Fentora tablets: Patient 02006 "was sent a certified letter, but no drug has been returned to date" and was marked "lost to follow up," and Patient 26006 who was "non- compliant with appointments to clinic and return of study drug."

- In study 3040, the non-cancer clinical trial, which had a greater number of patients, there were also frequent incidents of abuse and misuse: 11 patients overdosed; one patient's husband overdosed; 35 patients reported their Fentora stolen; dozens dropped out without accounting for the 100-plus Fentora tablets they had been given; and five study centers reported Fentora stolen from supposedly secured lockers. 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 over-administration events.

87. Beyond the misuse and abuse of opioids, the two long-term clinical trials produced data showing that patients who actually completed the trials needed substantially greater daily doses of Fentora over time.

88. [redacted]

89. In a March 2008 FDA filing, and 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.

90. In the 2008 FDA filing, Cephalon disclosed that patients who they tracked over 18 months had a 31% increase in pain episodes per day, from 3.5 to 4.6 episodes/day; took 26% more Fentora tablets per day, from 3.5 to 4.4 tablets/day; and had a 42% increase in their average daily

Fentora dosage, from 2,162 mcg/day to 3,088 mcg/day. 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.

91. As discussed below, in the years to come, Teva rarely disclosed this data, other than to regulators and in the single April 2011 publication, which it did not disseminate broadly.

92. And Teva had similar data from its cancer clinical trials that it appears to have never disclosed.

93. That cancer clinical trial data showed that the few patients who completed 12 months of the long term cancer clinical trial had the same signs of tolerance as their non-cancer counterparts. An analysis of trial data shows what they buried: the long-term cancer patients also increased their daily dosages of Fentora over time, just as the non-cancer patients did.

94. These data suggest that over time patients might be growing tolerant to Fentora and other opioids, and, as a result, Fentora might not be retaining its efficacy. This is consistent with other data on fentanyl.

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

96. 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.

97. Second, they would also claim cancer patients did not misuse or abuse Fentora.

98. 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.

99. These misrepresentations were communicated to persons at third party payors responsible for determining formularies, leading to available coverage for Actiq and Fentora in Alaska.

For example, Cephalon's Fentora Dossier, describes the Weinstein study as establishing "[t]he safety and tolerability of FENTORA" and "study 3040" as establishing that Fentora was "generally well tolerated across dose ranges 100 mcg – 800 mcg." It did not give the reason why patients discontinued or list abuse as an observed risk factor in this communication to potential payors. Without formulary coverage for the branded drugs, or the expanded market due to off-label promotion, there would not have been a market for generic versions of Actiq and Fentora, which were themselves, upon information and belief, oversupplied in Alaska and subject to abuse.

(4) Teva Deceptively Used Third Party Marketing and Continuing Medical Education to Promote Actiq and Fentora

100. Teva and Cephalon also spread misleading messages through its sponsorship of continuing medical education programs. Although ostensibly neutral, Teva used the same vendors and sponsors multiple times, and some faculty members had prior relationships with Teva, including acting as promotional speakers or consultants. These CMEs also encouraged off-label uses of Teva's TIRF opioids. Upon information and belief, these CMEs were available to prescribers in Alaska.

101. In 2007, Cephalon sponsored the publication of an article titled "Impact of Breakthrough Pain on Quality of Life in Patients with Chronic, Noncancer Pain: Patient Perceptions and Effect of Treatment with Oral Transmucosal Fentanyl Citrate," published in the nationally circulated journal *Pain Medicine*, to support its effort to expand the use of its branded fentanyl products. The article's authors (including Dr. Lynn Webster, discussed below) stated that the "OTFC [fentanyl] has been shown to relieve BTP more rapidly than conventional oral, normal-release, or 'short acting' opioids" and that "[t]he purpose of [the] study was to provide a qualitative evaluation of the effect of BTP on the [quality of life] of noncancer pain patients." The number-one-diagnosed cause of chronic pain in the patients studied was back pain (44%), followed by musculoskeletal pain (12%)

and head pain (7%). The article cites Dr. Portenoy and recommends fentanyl for non-cancer BTP patients:

> In summary, BTP appears to be a clinically important condition in patients with chronic noncancer pain and is associated with an adverse impact on QoL. This qualitative study on the negative impact of BTP and the potential benefits of BTP-specific therapy suggests several domains that may be helpful in developing BTP-specific, QoL assessment tools.

102. Cephalon sponsored a CME written by pro-opioid physician Dr. Lynn Webster, who also acted as a consultant to Teva entitled, *Optimizing Opioid Treatment for Breakthrough Pain*, offered by Medscape, LLC from September 28, 2007 through December 15, 2008. The CME taught that non-opioid analgesics and combination opioids containing non-opioids such as aspirin and acetaminophen are less effective at treating breakthrough pain because of dose limitations on the non-opioid component.

103. Another Cephalon-sponsored CME presentation titled *Breakthrough Pain: Treatment Rationale with Opioids* was available on Medscape starting September 16, 2003 and was given by a self-professed pain management doctor who treated "previously operated back, complex pain syndromes, the neuropathies, and interstitial cystitis." He describes the pain process as a non-time-dependent continuum that requires a balanced analgesia approach using "targeted pharmacotherapeutics to affect multiple points in the pain-signaling pathway."[22] The doctor lists fentanyl as one of the most effective opioids available for treating breakthrough pain, describing its use as an expected and normal part of the pain management process. Nowhere in the CME is cancer or cancer-related pain even mentioned, despite FDA restrictions that fentanyl use be limited to cancer-related pain.

[22] Daniel S. Bennett, *Breakthrough Pain: Treatment Rationale With Opioids*, Medscape, http://www.medscape.org/viewarticle/461612 (last visited Oct. 10, 2017).

104. Cephalon paid to have a CME it sponsored, *Opioid-Based Management of Persistent and Breakthrough Pain*, published in a supplement of Pain Medicine News in 2009. The CME instructed doctors that "clinically, broad classification of pain syndromes as either cancer- or noncancer-related has limited utility" and recommended Actiq and Fentora for patients with chronic pain. The CME is still available online.

The level of specificity included in the Teva-sponsored CME uniquely describe Teva's products rendering these CMEs impermissibly promotional, and the fact that speakers such as Webster acted as Teva consultants, and continued to do so after these off-label promotional materials appeared, suggests a concrete purpose to use CME channels to promote its products for off-label uses. By enlisting accrediting agencies in support of their branded promotional efforts, as well, Teva was able to change the medical consensus in favor of a dangerous off-label use of its fentanyl products, one specifically prohibited by the FDA.

(5) Off-Label Marketing And Prescribing Continued Despite FDA Warnings And the TIRF REMS Program

105. On March 26, 2009, the FDA warned Cephalon against its misleading advertising of Fentora ("Warning Letter"). The Warning Letter described a Fentora Internet advertisement as misleading because it purported to broaden "the indication for Fentora by implying that any patient with cancer who requires treatment for breakthrough pain is a candidate for Fentora . . . when this is not the case." It further criticized Cephalon's other direct Fentora advertisements because they did not disclose the risks associated with the drug.

106. In December 2011, however, Teva widely disseminated, including on information and belief, in Alaska, a journal supplement entitled "Special Report: An Integrated Risk Evaluation and Mitigation Strategy for Fentanyl Buccal Tablet (FENTORA) and Oral Transmucosal Fentanyl Citrate (ACTIQ)" in Anesthesiology News, Clinical Oncology News, and Pain Medicine News – three

publications that are sent to thousands of anesthesiologists and other medical professionals. The Special Report openly promotes Fentora for "multiple causes of pain" – and not just cancer pain.

107. On December 28, 2011, the FDA mandated a Risk Evaluation and Mitigation Strategy ("REMS") for the class of products to which Teva's Actiq and Fentora belong, Transmucosal Immediate Release Fentanyl ("TIRF"). The TIRF REMS programs included mandatory patient and prescriber enrollment forms, as well as certification requirements for prescribers. The forms are not totally comprehensive and do not, for instance, disclose that addiction can develop when prescribed as directed, nor do they disclose that risks are greatest at higher doses—and that patients must already be opioid-tolerant and taking high doses of opioids to be prescribed Actiq and Fentora. However, according to a former Fentora and Actiq sales representative, even after the TIRF REMS program was implemented, he continued to market to the same prescribers who prescribed Actiq and Fentora to non-cancer patients, and his promotional messages regarding Actiq and Fentora did not change.

108. Moreover, a review of the TIRF REMS program shows that it did not deter off-label prescribing. Submissions to the FDA in conjunction with the TIRF REMS program show that Teva knew of extensive off-label use. Based on data available in 2008 prior to the implementation of the TIRF REMS, 41% of patients prescribed Fentora had not been opioid tolerant. A study of the TIRF REMS program's effectiveness based on the periodic reports Teva was required to submit found that between 36% and 55% of patients receiving TIRF were non-tolerant. Furthermore, 39% of prescribers surveyed reported prescribing TIRF opioids for chronic, non-cancer pain.[23] The TIRF REMS failed to address off-label prescribing because, upon information and belief, Teva continued to

[23] Rollman JE, Heyward J, Olson L, Lurie P, Sharfstein J, Alexander GC. Assessment of the FDA Risk Evaluation and Mitigation Strategy for Transmucosal Immediate-Release Fentanyl Products. JAMA. 2019;321(7):676–685. doi:10.1001/jama.2019.0235.

engage in off-label marketing and targeting that overrode both the purpose and letter of the REMS program.

109. Teva was also required by the terms of the TIRF REMS to report non-compliant stake-holders to the FDA, but there is no evidence it did.

110. Teva, in fact, used the occasion of the TIRF REMS to further promote its deceptive marketing, publishing an insert in Pharmacy Times titled "An Integrated Risk Evaluation and Mitigation Strategy (REMS) for FENTORA (Fentanyl Buccal Tablet) and ACTIQ (Oral Transmucosal Fentanyl Citrate)." Despite the repeated warnings of the dangers associated with the use of the drugs beyond their limited indication, as detailed above, the first sentence of the insert states: "It is well recognized that the judicious use of opioids can facilitate effective and safe management of chronic pain." Upon information and belief, this publication was available to prescribers in Alaska.

(6) Teva Promoted The Safety And Efficacy of Opioids As a Class

111. In addition to deceptively promoting its more expensive, branded drugs for off-label uses, Teva promoted the use of opioids as a whole for the treatment of chronic non-cancer pain.

112. For example, Teva sponsored and facilitated the development of a guidebook, Opioid Medications and REMS: A Patient's Guide, which included claims that "patients without a history of abuse or a family history of abuse do not commonly become addicted to opioids." Upon information and belief, this publication was available to patients and prescribers in Alaska.

113. In February 2003, a Teva-sponsored CME presentation titled Pharmacologic Management of Breakthrough or Incident Pain, posted on Medscape declared:

> [C]hronic pain is often undertreated, particularly in the noncancer patient population. . . . The continued stigmatization of opioids and their prescription, coupled with often unfounded and self-imposed physician fear of dealing with the highly regulated distribution system for opioid analgesics, remains a barrier to effective pain management and must be addressed. Clinicians intimately involved with the treatment of patients with chronic pain recognize that the majority of suffering patients lack interest in substance abuse. In fact, patient fears of developing

> substance abuse behaviors such as addiction often lead to undertreatment of pain. The concern about patients with chronic pain becoming addicted to opioids during long-term opioid therapy may stem from confusion between physical dependence (tolerance) and psychological dependence (addiction) that manifests as drug abuse.
>
> Upon information and belief this CME was available to Alaska prescribers.

114. Further, in 2007, Cephalon, along with Purdue Pharma, L.P., sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which also falsely reassured patients that opioid agreements between doctors and patients can "ensure that you take the opioid as prescribed."[24] The publication also falsely taught that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining opioids from multiple sources, or theft. Further, it stated that opioids have "no ceiling dose" and therefore are safer than NSAIDs. The publication also falsely attributed 10,000 to 20,000 deaths annually to NSAID overdose, when the figure is closer to 3,200. Upon information and belief, this publication was available to prescribers in Alaska.

115. These claims misleadingly suggest that opioids are safe even at high doses and omit important information regarding the risks of high-dose opioids. When under the continuous influence of opioids over a period of time, patients grow tolerant to their analgesic effects. As tolerance increases, a patient typically requires progressively higher doses in order to obtain the same levels of pain reduction he or she has become accustomed to—up to and including doses that are considered to be "frighteningly high."[25] At higher doses, the effects of withdrawal are more substantial, thus leaving a patient at a much higher risk of addiction. The FDA has acknowledged that available data suggest a relationship between increased doses and the risk of adverse effects.

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[24] By 2011, APF was dependent on Purdue, Teva, and others for funding. Despite its ties to and dependence on Defendants, APF held itself out as an independent organization. In 2012, the U.S. Senate Finance Committee began looking into APF's to ascertain any links between the organization and the manufacturers of prescription opioids. Within days of becoming a target of this investigation, the APF voted to dissolve. APF then closed its doors and declared that the organization had ceased to exist.

[25] Mitchell H. Katz, Long-term Opioid Treatment of Nonmalignant Pain: A Believer Loses His Faith, 170(16) Archives of Internal Med. 1422 (2010).

116. Patients receiving high doses of opioids (*e.g.*, doses greater than 100 mg morphine equivalent dose ("MED") per day) as part of long-term opioid therapy are three to nine times more likely to suffer overdose from opioid-related causes than those on low doses. As compared to available alternative pain remedies, scholars have suggested that tolerance to the respiratory depressive effects of opioids develops at a slower rate than tolerance to analgesic effects. Accordingly, the practice of continuously escalating doses to match pain tolerance can, in fact, lead to overdose even where opioids are taken as recommended. The United States Centers for Disease Control and Prevention also recognizes that higher doses of opioids tend to increase overdose risks relative to any potential patient benefit.[26]

117. Cephalon also sponsored the Federation of State Medical Boards' ("FSMB") *Responsible Opioid Prescribing* (2007), which taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, which are signs of genuine addiction, are all really signs of "pseudoaddiction." Upon information and belief *Treatment Options* was available to Alaska prescribers.

118. Cephalon and Teva's efforts to trivialize the risk of addiction were, and remain, at odds with the scientific evidence. In March 2016, the FDA emphasized the "serious risk[] of . . . addiction" to opioids."[27] That same month, after a "systematic review of the best available evidence" by a panel excluding experts with conflicts of interest, the CDC published the CDC Guideline for prescribing opioids for chronic pain. The CDC Guideline noted that "[o]pioid pain medication use

[26] Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. MMWR Recomm Rep 2016;65(No. RR-1):1–49. DOI: http://dx.doi.org/10.15585/mmwr.rr6501e1

[27] U.S. Food & Drug Admin., *FDA Announces Safety Labeling Changes and Postmarket Study Requirements fo rExtended-release and Long-acting Opioid Analgesics* (Sept. 10, 2013); *see also* U.S. Food & Drug Admin., *FDA Announces Enhanced Warnings for Immediate-release Opioid Pain Medications Related to Risks of Misuse, Abuse, Addiction, Overdose and Death* (Mar. 22, 2016), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm491739.htm.

presents serious risks, including overdose and opioid use disorder" (a diagnostic term for addiction).[28] The CDC also emphasized that "continuing opioid therapy for 3 months substantially increases risk for opioid use disorder."[29]

119. Nowhere in the CDC Guideline is it recommended that opioid doses be increased if a patient is not experiencing pain relief. To the contrary, the CDC Guideline explains that "[p]atients who do not experience clinically meaningful pain relief early in treatment . . . are unlikely to experience pain relief with longer-term use,"[30] and that physicians should "reassess[] pain and function within 1 month" in order to decide whether to "minimize risks of long-term opioid use by discontinuing opioids" because the patient is "not receiving a clear benefit."[31]

120. Cephalon and Teva's misrepresentations concerning opioids as a class benefitted its sales of both branded and generic opioids. [redacted]

B. Allergan Misrepresented The Safety And Efficacy Of Kadian

121. The Actavis entities acquired the rights to Kadian, a branded extended release morphine, from King Pharmaceuticals, Inc., on December 30, 2008 and began marketing Kadian in 2009. Actavis promoted Kadian through a highly deceptive marketing campaign that it carried out principally through its sales force. Based on the highly coordinated and uniform nature of Actavis's marketing, and as confirmed by both prescriber recollection interviews and data, Actavis conveyed these deceptive messages to Alaska prescribers. At the peak of Actavis's promotional efforts in 2011, the company spent $6.7 million on detailing.

[28] CDC Guideline at 2.
[29] *Id.* at 21.
[30] *Id.* at 13.
[31] *Id.* at 25.

122. A sales training from 2010, titled "Kadian Learning System," trained Kadian sales representatives on the marketing messages—including deceptive claims about improved function, the risk of addiction, the false scientific concept of "pseudoaddiction," and opioid withdrawal—that sales representatives were directed and required, in turn, to pass on to prescribers, nationally and in Alaska.

123. Further, the 2010 sales training module highlighted the risks of alternate pain medications without providing a comparable discussion of the risks of opioids, painting the erroneous and misleading impression that opioids are safer. Specifically, the document claimed that "NSAIDs prolong the bleeding time by inhibiting blood platelets, which can contribute to bleeding complications" and "can have toxic effects on the kidney." Accordingly, Actavis coached its sales representatives that "[t]he potential toxicity of NSAIDs limits their dose and, to some extent, the duration of therapy" since "[t]hey should only be taken short term." By contrast, the corresponding section related to opioids neglects to include a *single* side effect or risk associated with the use of opioids, including from long-term use.

124. This sales training module also severely downplayed the main risk associated with Kadian and other opioids—addiction. It represented that "there is no evidence that simply taking opioids for a period of time will cause substance abuse or addiction" and, instead, stated "[i]t appears likely that most substance-abusing patients in pain management practices had an abuse problem before entering the practice." This falsely suggests that few patients will become addicted, that only those with a prior history of abuse are at risk of opioid addiction, and that doctors can screen for those patients and safely prescribe to others. But, to the contrary, as described above in Section V.D.2, opioid addiction will affect a significant population of patients; while patients with a history of abuse may be more prone to addiction, all patients are at risk, and doctors may not be able to identify, or safely prescribe to, patients at greater risk.

125. The sales training also noted that there were various "signs associated with substance abuse," including past history or family history of substance or alcohol abuse, frequent requests to change medication because of side effects or lack of efficacy, and a "social history of dysfunctional or high-risk behaviors including multiple arrests, multiple marriages, abusive relationships, etc." This is misleading, as noted above, because it implies that only patients with these kinds of behaviors and history become addicted to opioids.

126. Further, the sales training neglected to disclose that no risk-screening tools related to opioids have ever been scientifically validated.

127. Upon information and belief, misrepresentations in sales trainings were conveyed to prescribers in Alaska.

128. Actavis distributed two promotional materials, a Co-Pay Assistance Program Brochure and a "PK to PK Comparison Detailer" that claimed that use of Kadian to treat chronic pain would allow patients to return to work, relieve "stress on your body and your mental health," and cause patients to "enjoy their lives." The FDA warned Actavis such claims were misleading, writing: "We are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug has in alleviating pain, taken together with any drug-related side effects patients may experience . . . results in any overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life." Upon information and belief, these statements were disseminated in Alaska.

129. Actavis also commissioned surveys of prescribers to ensure Kadian sales representatives were promoting the false message that long-acting opioids are less addictive because they do not have "peaks" but rather release a steady level of opioids, which ignores that because long-acting opioids typically come in higher doses, they expose patients to higher risks of tolerance and

addiction. That same survey—paid for and reviewed by Actavis—found repeated instances of prescribers being told by sales representatives that Kadian had low potential of abuse or addiction. This survey also found that prescribers were influenced by Actavis's messaging. A number of Kadian prescribers stated that they prescribed Kadian because it was "without the addictive potential" and wouldn't "be posing high risk for addiction." As a result, Actavis's marketing documents celebrated a "perception" among doctors that Kadian had "low abuse potential." This take-away is false and misleading, as Kadian is a Schedule II opioid. Upon information and belief, the marketing of Kadian gave Alaska prescribers the false and misleading impression Kadian had low abuse potential.

130. In addition to the misleading and unsubstantiated claims highlighted in the FDA's warning letter, Actavis also grew Kadian sales by misrepresenting that Kadian patients could exhibit symptoms of "pseudoaddiction" for inadequately treated pain, that Kadian had a low abuse potential, that Kadian had no maximum or ceiling dose, and that Kadian had negligible risk of alcohol-induced premature release of the active ingredient, also known as dose-dumping.

C. Teva and Allergan Marketed Generic Opioids

131. Both Teva and Allergan, through the Former Actavis Entities, had sophisticated and well-developed generic marketing programs. Allergan's top opioid products included generic versions of Opana ER (oxymorphone ER), Kadian and MS Contin (morphine sulfate ER), and generic fentanyl. Teva sold a generic version of OxyContin (oxycodone ER) between 2004 and 2007, and again from 2016 to the present; as well as its own version of oxymorphone ER, a generic version of Actiq, and short-acting immediate release opioids. Teva also sells generic versions of addiction treatment drugs, including buprenorphine, and naloxone, an opioid overdose treatment drug.

132. Allergan used its branded sales force to promote generic opioids as well. Not long after Allergan received FDA's warning letter, it sought FDA approval for generic Kadian, which was granted in late 2011. The marketing launch for generic Kadian included direct mail and email

campaigns as well as detailing through the Kadian branded sales team. One of the primary messages of the campaign was Kadian's claimed long history of safe and effective use. The generic Kadian training for the sales team encouraged sales representatives to emphasize "[n]ow you can prescribe the same KADIAN with it's [sic] long history of safety and efficacy at a generic price." Allergan made these claims to prescribers even though it knew there was a "complete lack of clinical data for Kadian."

133. Further, despite the FDA warning, Allergan continued to use misleading and unsubstantiated superiority claims to market Kadian. A September 2012 sales training, for example, highlighted the message that Kadian patients "[e]xperience sustained morphine release with less fluctuations vs. morphine sulfate," "[r]eport improved management of pain vs. morphine sulfate," and "[r]equire less rescue medication vs. morphine sulfate."

134. The ultimate goal of Allergan's sales team was to drive the growth of the generic business by growing the overall market for Kadian. To facilitate this growth, the sales team was encouraged to sell "prescribers on the features and benefits of [Kadian] just like you've always done."

135. Further, in December 2010, Allergan received approval for generic Opana (Oxymorphone) and launched an aggressive marketing campaign in July 2011. The marketing promotional plan noted that "[b]ecause Endo discontinued the 7.5 and 15mg strengths in March 2011, Allergan will be implementing a more aggressive promotional campaign for this launch." The launch plan included a two wave direct-mail campaign to the top 10,000 prescribers, using the Kadian sales team to deliver sellsheets to pain doctors [redacted]. Allergan's goal was to "target physicians to continue to write and increase their scripts" of oxymorphone. To this end, Allergan

created a contest and bonus plan for the representatives who sold the most oxymorphone ER, and launched a massive direct mail campaign to oxymorphone ER prescribers.

136. In March 2012, Actavis celebrated the success of its launch campaign. Actavis noted that the prescriptions increased to 50% of the amount prior to Endo's discontinuation of its branded Opana. Actavis attributed the increase in its generic prescriptions to "[c]ontinued promotion by Actavis (direct mail / email programs); and the help of the KADIAN sales team."

137. Teva also promoted its generic drugs by advertising price and availability to pharmacies and distributors, including promoting itself as having access to relevant manufacturing quota, after itself lobbying for expanded individual manufacturing quotas.

D. Defendants Breached Duties to Maintain Effective Controls Against Diversion and to Report Suspicious Prescribers.

(1) Defendants Have A Legal Duty to Maintain Effective Controls Against Diversion

138. Defendants had statutory duties under Alaska's Controlled Substance Act ("ACSA") and implementing regulations, which incorporate the requirements of the federal Controlled Substances Act, ("CSA"), 21 U.S.C. § 811 - 830. AS §17.30.020(a) (incorporating obligations under the CSA). Under both federal and Alaska law, Defendants must register annually with the DEA to manufacture schedule II controlled substances, like prescription opioids. See 21 U.S.C. § 823(a)(1). Any registration must be consistent with the public interest based on a consideration of, among other factors, "maintenance of effective controls against diversion." Id. In addition, Alaska law, through its incorporation of federal law, requires Defendants to "design and operate a system to disclose to the registrant suspicious orders of controlled substances." 21 C.F.R. § 1301.74(b). Registrants are not entitled to be passive (but profitable) observers, but rather "shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant." Id.

139. Defendants also assumed a duty, when speaking publicly about opioids and their efforts and commitment to prevent diversion of prescription opioids, to speak accurately and truthfully. Defendants made statements to the media, regulators, and the public at large claiming to take all reasonable precautions to prevent drug diversion. For example, Allergan publicly touted its purportedly state-of-the-art Suspicious Order Monitoring ("SOM") systems and processes, and professed its commitment to legal compliance and combatting diversion as evidence of its corporate responsibility.[32]

140. It is well-settled that effective controls against the diversion of controlled substances require manufacturers to detect, report, and halt suspicious orders. For example, the CSA, 21 U.S.C. § 801 et seq. and its implementing regulations, impose a duty on registrants (entities, like Defendants, licensed to manufacture controlled substances) to monitor, detect, report, investigate, and refuse to ship suspicious orders. Specifically, the CSA requires registrants of Schedule II substances like opioids to: (a) limit sales within a quota set by the DEA for the overall production of Schedule II substances; (b) register to distribute opioids; (c) maintain effective controls against diversion of the controlled substances that they distribute; and (d) design and operate a system to identify suspicious orders of controlled substances, halt such unlawful sales, and report them to the DEA. See 21 U.S.C. § 823; 21 C.F.R. § 1301.74.33

141. The CSA and its implementing regulations, and the ASCA created a "closed system" of distribution; every entity that handles controlled substances is required to meet specific

[32] https://www.allergan.com/-/media/allergan/documents/us/Investors/Report-to-the-Stockholders-of-Allergan-Form-the-Board-of-Directors-Board-Report.pdf

[33] *See also* Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Off. of Diversion Control, Drug Enf't Admin., U.S. Dep't of Justice, to Cardinal Health (Sept. 27, 2006), filed in *Cardinal Health, Inc. Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-51 (hereinafter, "2006 Rannazzisi Letter"); Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Off. of Diversion Control, Drug Enf't Admin., U.S. Dep't of Justice, to Cardinal Health (Dec. 27, 2007), filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-8 (hereinafter, "2007 Rannazzisi Letter").

record-keeping and distribution standards. As the Congressional Record reflects, "Such a closed system should significantly reduce the widespread diversion of these drugs out of legitimate channels into the illicit market, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control." 970 U.S.C.C.A.N. 4566. In enacting the CSA, "Congress was particularly concerned with the diversion of drugs from legitimate channels. It was aware that registrants, who have the greatest access to controlled substances and therefore the greatest opportunity for diversion, were responsible for a large part of the illegal drug traffic." United States v. Moore, 423 U.S. 122, 135 (1975).

142. The CSA requires manufacturers of Schedule II substances including opioids to: (a) register; (b) maintain effective controls against diversion of the controlled substances that they manufacture or distribute; and (c) design and operate a system to identify suspicious orders of controlled substances, halt such unlawful sales, and report them to the DEA.

143. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. 21 C.F.R. § 1301.74(b). These criteria are not exclusive; any one of them can trigger the duty to report and stop shipment, and other factors not listed in the regulations also may point to suspicious orders. A volume of orders of a controlled substance disproportionate to the population or historic use in an area, for example, may provide reason for suspicion. In addition, orders skewed toward high-dose pills or drugs valued for abuse should alert manufacturers to potential diversion.

144. A manufacturer can only fill, and avoid reporting, suspicious orders of opioids after a diligent investigation has allayed the reason for its suspicion. Of course, due diligence efforts must be thorough: "the investigation must dispel all red flags indicative that a customer is engaged in diversion to render the order non-suspicious and exempt it from the requirement that the distributor

'inform' the [DEA] about the order. Put another way, if, even after investigating the order, there is any remaining basis to suspect that a customer is engaged in diversion, the order must be deemed suspicious and the Agency must be informed."[34] This due diligence requirement extends, in the case of manufacturers, to an obligation to "know your customers' customer." It is not enough to ship opioids to wholesalers and distributors and trust them to do the right thing.

145. The DEA has testified in *In Re: National Opiate Litigation*, MDL 2804 ("MDL") that:

a. DEA registrants are required to block all suspicious orders of prescription opioids.

b. Shipping a suspicious order is a per se violation of federal law.

c. If a wholesale distributor blocks a suspicious order, they should terminate all future sales to that same customer until they can rule out that diversion is occurring.

d. After the fact reporting of suspicious orders has never been in compliance with federal law.

21. In sum, the law imposes on Defendants a duty to help prevent diversion, due to the position of special trust and responsibility afforded by their license to manufacture and profit from prescription opioids.[35] Defendants may not ignore red flags of illegal conduct and must use the information available to them to identify and report potential diversion. That would include

[34] *Masters Pharmaceuticals, Inc.*, Decision and Order, 80 Fed. Reg. 55418-01 at *55477 (DEA Sept. 15, 2015).

[35] The existence of this duty at all relevant times is confirmed by the MDL's grant of partial summary judgment to the "Track One" bellwether plaintiffs. There, the MDL Court held, that defendants, had, and have, an obligation under the federal Controlled Substances Act ("CSA") to identify and report suspicious orders, and not to ship suspicious orders unless due diligence reasonably dispels the suspicion. Grounding its holding in uniform precedent, as well as the plain language of the statute and its implementing regulations, the Court described itself as "hard-pressed to think of a more basic requirement than not to ship a dubious order bearing indicia that the drugs could be diverted to illegal channels." *See In re: National Prescription Opiate Litig.*, Case No. 1:17-MD-2804 Doc. 2483 (N.D. Ohio Aug. 19, 2019). That was the only summary judgment motion granted by the MDL Court, which declined both defendants' and plaintiffs' motions for summary judgment on issues of fact related to their compliance (among others filed by defendants).

reviewing their own data, relying on their observations of prescribers, pharmacies, and customers, and following up on reports or concerns of potential diversion.

22. As laid out below, Defendants systemically failed to comply with the law. Their shipments of orders destined for unlawful channels, and their failure to report and halt potential diversion, perpetuated the opioid epidemic in Alaska and imposed, and continue to impose, substantial costs upon the State. Defendants have a duty, and are expected, to be vigilant in deciding whether a prospective customer can be trusted to deliver opioids only for lawful purposes. Defendants breached these duties by failing to: (a) maintain effective controls to prevent diversion; (b) report suspicious orders; and (c) halt shipments of opioids in quantities they knew or should have known could not be justified and were indicative of an oversupply of opioids.

(2) Defendants Were Aware of Their Obligations.

23. The DEA sent a letter to Defendants on December 27, 2007, reminding them that as registered manufacturers of controlled substances, they must each abide by statutory and regulatory duties to "maintain effective controls against diversion" and "design and operate a system to disclose to the registrant suspicious orders of controlled substances." The DEA's December 27, 2007 letter reiterated the obligation to detect, report, and not fill suspicious orders and provided detailed guidance on what constitutes a suspicious order and how to report (e.g., by specifically identifying an order as suspicious, not merely transmitting data to the DEA). The letter referenced the Revocation of Registration issued in *Southwood Pharmaceuticals, Inc.*, 72 Fed. Reg. 36,487-01 (July 3, 2007), which discusses the obligation to report suspicious orders and to have "some criteria to use when determining whether an order is suspicious."

24. In addition, the letter made clear that "rely[ing] on rigid formulas to define whether an order is suspicious may be failing to detect suspicious orders." The letter noted:

For example, a system that identifies orders as suspicious only if the total amount of a controlled substance ordered during one month exceeds the amount ordered the previous month by a certain percentage or more is insufficient. This system fails to identify orders placed by a pharmacy if the pharmacy placed unusually large orders from the beginning of its relationship with the distributors. Also, this system would not identify orders as suspicious if the order were solely for one highly abused controlled substance if the orders never grew substantially. Nevertheless, ordering one highly abused controlled substance and little or nothing else deviated from the normal pattern of what pharmacies generally order.

25. Defendants were aware of their obligations to maintain effective controls to prevent diversion and to identify, report, and reject, suspicious orders.

(3) Defendants Kept Careful Track of Prescribing Data and Knew About Suspicious Orders and Prescribers, But Used the Information for Marketing Instead of Legal Compliance.

26. Defendants funneled far more opioids into communities across the United States, including Alaska, than could have been expected to serve legitimate medical use, and ignored red flags of suspicious orders.

27. Defendants were in possession of information that they could have used to identify potentially suspicious orders of opioids. Specifically, at all relevant times, Defendants were in possession of national, regional, state, and local prescriber- and patient-level data and information that allowed them to track prescribing patterns over time.

28. This information includes the following facts:

a. Manufacturers have access to detailed data on the sale and distribution of opioids, which can be broken down by zip code, prescriber, and pharmacy and includes the volume of opioids and dose;

b. Defendants make use of that data to target their marketing and, for that purpose, regularly monitor the activity of doctors and pharmacies;

c. Defendants regularly visit pharmacies and doctors to promote their products, which allows them to observe red flags of diversion; and

d. Defendants purchased chargeback data (in return for discounts) that allowed them to monitor the combined flow of opioids into a pharmacy or geographic area.

29. Manufacturers' access to data that showed where their opioids were going permitted—and obligated—them to identify and prevent diversion. The DEA has confirmed that manufacturers have an obligation to use available chargeback and prescribing data for suspicious order monitoring and as part of effective controls to prevent diversion. Upon information and belief, Defendants possessed chargeback data and could have used it to enable their compliance departments to see that many pharmacies and pain clinics were purchasing opioids from multiple distributors, a red flag for diversion since it may indicate an intent to avoid detection or limits placed by individual distributors.

30. In addition to chargeback data, Defendants, upon information and belief, also had detailed information from data vendors or other sources. Pharmaceutical companies are the primary customers for the prescribing data sold by these vendors. And, as a routine practice, "[p]harmaceutical companies monitor the return on investment of detailing - and all promotional efforts - by prescription tracking."

31. The data vendors manufacturers obtain this information from include but are not limited to: IMS Health, QuintileslMS, IQVIA, Pharmaceutical Data Services, Source Healthcare Analytics, NDS Health Information Services, Verispan, Quintiles, SDI Health, ArcLight, Scriptline, Wolters Kluwer, and/or PRA Health Science, and all of their predecessors or successors in interest (the "Data Vendors"). One product sold by IQVIA (formerly IMS) called "Xponent," provided Defendants with information on every opioid prescription filled, tracking the doctor who wrote the prescription and the drug prescribed. Defendants purchased this information from IQVIA in order to assess their own sales efforts. They could track precisely which doctors were prescribing their drugs and tailor their marketing efforts accordingly. IQVIA data was the lynchpin of the Defendants' marketing efforts and, in particular, of the compensation scheme for their sales

representatives. Without the detail in the IQVIA data, the Defendants would not have been able to tell which sales representatives were most effective at their jobs, because they would not have known which doctors were writing the prescriptions reflected in their sales.

32. The data provided by these vendors allowed Defendants to track prescribing trends, and assess their competition in the market. Defendants could, and did, use the data to view, analyze, compute, and track their competitors' sales, and to compare and analyze market share information. IQVIA/IMS Health, provided Defendants with reports detailing prescriber behavior and the number of prescriptions written between competing products.[36]

33. This data also could have been used by Defendants to track and identify instances of overprescribing, to identify pill mills, and to identify suspicious orders. In fact, one of the Data Vendors' experts testified that the Data Vendors' information could be used to track, identify, report and halt suspicious orders of controlled substances.[37] However, Defendants used this valuable information for marketing and sales purposes only and did not incorporate it into their suspicious order monitoring programs.

34. Defendants also have specialized and detailed knowledge of potential suspicious prescribing and sale of opioids through their regular visits to doctors' offices and pharmacies. Their extensive boots-on-the-ground presence through their sales forces allows Defendants to observe signs of suspicious prescribing and dispensing, such as lines of seemingly healthy patients, out-of-state license plates, and cash transactions, to name just a few.

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[36] Paul Kallukaran & Jerry Kagan, *Data Mining at IMS HEALTH: How We Turned a Mountain of Data into a Few Information-Rich Molehills,* (accessed on February 15, 2018), http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.198.349&rep=repl&type=pdf, Figure 2 at p.3.

[37] *See Sorrell v. IMS Health,* expert Eugene "Mick" Kolassa testified, on behalf of the Data Vendor, that "a firm that sells narcotic analgesics was able to use prescriber-identifiable information to identify physicians that seemed to be prescribing an inordinately high number of prescriptions for their product." *Id.; see also* Joint Appendix in *Sorrell v. IMS Health,* No. 10-779, 2011 WL 687134, at *204 (Feb. 22, 2011).

35. Instead of encouraging them to report potential diversion, however, Defendants' sales incentives rewarded sales representatives who had pill mills within their territories, enticing those representatives to look the other way even when their in-person visits to such clinics should have raised red flags. Defendants' obligation to report suspicious prescribing ran head on into their marketing strategy. Defendants routinely identified doctors who were their most prolific prescribers, not to report them, but to market to them. It would make little sense to focus on marketing to doctors who may be engaged in improper prescribing only to report them to law enforcement, just as it made little sense to Defendants to report those doctors who drove their sales. As one former Teva sales representative has explained: "In general, sales representatives did not want to report suspicious prescribers because they were the money-makers. We did not want to shoot the golden goose."

(4) Defendants Failed to Monitor the Wholesalers They Used to Supply their Opioids.

36. Defendants ignored not only their own systemic failures and the suspicious orders into Alaska that they were legally obligated to report and halt, but they were relying on large distributors which had systemic failings of their own, and lacked the systems to properly guard against diversion.

37. Defendants had a duty to know their direct customers, including the distributors that bought and shipped their drugs to Alaska and across the country. This included an obligation to assess their distributors to ensure they were compliant with applicable law. Any reasonable diligence would have revealed not only glaring, facial deficiencies in distributors' compliance systems, but DEA enforcement actions against these distributors for their noncompliance with the CSA.

38. In May 2014, the United States Department of Justice, reported that the DEA had issued final decisions in 178 registrant actions between 2008 and 2012. These included a number of actions against large wholesalers such as AmerisourceBergen Drug Corporation, Cardinal Health Inc., and McKesson Corporation, which the Government sued on June 6, 2018 and which Defendants relied on as their distributors. The federal actions revealed systemic failures by distributors that would have impacted Defendants' sales of opioids into Alaska.

39. For example, pursuant to an Administrative Memorandum of Agreement entered into between McKesson and the DEA in January 2017, McKesson admitted that, at various times during the period from January 1, 2009 through the effective date of the Agreement (January 17, 2017) it "did not identify or report to [the] DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters."[38] McKesson admitted that, during this time period, it "failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain of its customers in violation of the CSA and the CSA's implementing regulations, 21 C.F.R. Part 1300 *et seq.*," at multiple McKesson distribution centers. Additional examples include:

- On May 2, 2008, McKesson Corporation entered into an Administrative Memorandum of Agreement after the DEA alleged that McKesson failed to maintain effective controls and failed to report suspicious orders or thefts. To resolve these allegations, McKesson paid a $13.25 million civil penalty. The MOU provided that McKesson would "maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 C.F.R. § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program."

[38] Settlement Agreement and Release between the U.S. and McKesson Corp., at 5 (Jan. 17, 2017) [hereinafter "2017 Settlement Agreement and Release"] ("McKesson acknowledges that, at various times during the Covered Time Period [2009-2017], it did not identify or report to DEA certain orders placed by certain pharmacies, which should have been detected by McKesson as suspicious, in a manner fully consistent with the requirements set forth in the 2008 MOA."), available at https://www.justice.gov/opa/press-release/file/928471/download.

- On April 24, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the AmerisourceBergen Orlando, Florida distribution center alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement that resulted in the suspension of its DEA registration.

- Reflecting systemic failures across Cardinal's distribution system, on September 30, 2008, Cardinal Health entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement with the DEA related to its Auburn, Lakeland, Florida, Swedesboro, New Jersey, and Stafford, Texas distribution centers. The DEA alleged that Cardinal failed to maintain effective controls, and Cardinal paid $34 million to resolve these charges.

- On February 2, 2012, the DEA issued an Order to Show Cause and Immediate Suspension Order against Cardinal Health's Lakeland, Florida, facility for failure to maintain effective controls against diversion of oxycodone; and

- On December 23, 2016, Cardinal Health agreed to pay a $44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland facility.

40. Chain pharmacies which bought and dispensed prescription opioids from Defendants have likewise faced enforcement actions. For example, in September 2012, the DEA issued an immediate suspension order ("ISO") regarding one of Walgreens'[39] three Schedule II distribution centers, finding Walgreens' distribution practices constituted an "imminent danger to the public health and safety" and were "inconsistent with the public interest." The ISO included, among other information, a statement of facts explaining that Walgreens had not "recognized and adequately reformed the systemic shortcomings discussed" in the ISO. CVS faced similar enforcement actions, as well; the company has paid fines totaling over $40 million as the result of a series of investigations by the DEA and the United States Department of Justice ("DOJ").

[39] The Government sued Walgreens on December 19, 2019.

(5) Defendants Worked In Concert to Limit Enforcement.

41. Defendants worked together to achieve their common purpose through trade or other organizations, such as the Healthcare Distribution Alliance ("HDA"). Through these organizations, Defendants lobbied for higher quotas and to weaken DEA enforcement. Although the HDA membership directory is private, the HDA website confirms that Allergan and Teva were members of the HDA.[40]

42. While Defendants have consistently blamed the DEA for their failure to follow the law and their oversupply of opioids, Defendants worked together in and through the HDA to limit the authority of law enforcement to rein in illicit or inappropriate distribution. For example, Defendants, acting through the HDA, lobbied for and drafted portions of the Ensuring Patient Access and Effective Drug Enforcement Act of 2016, which raised the standard for the DEA to suspend a registrant.

43. Defendants also worked to ensure that quotas for opioids allowed by the DEA remained artificially high.

(6) Specific Defendants' Failures to Prevent Diversion

Allergan

44. Allergan's SOM system included separate systems operated by two of the Former Actavis Entities, Watson Pharmaceuticals, Inc. ("Watson") and Actavis, Inc. ("Actavis"). Neither of the two prior companies, nor the merged group, maintained effective controls against diversion.

45. Before the year-end 2012 merger between Watson and Actavis, Actavis produced twelve different generic opioids, including some of the most abused and diverted opioids such as generic OxyContin (Oxycodone I hydrochloride tablet), generic Opana ER (Oxymorphone tablet)

[40] Manufacturer Membership , Healthcare Distribution Alliance https://www.hda.org/about/membership/manufacturer. (last accessed Nov. 26, 2019).

and a generic version of Janssen's Duragesic. Meanwhile, from November 2000 through October 2012, the company maintained the same rudimentary threshold-based SOM system. Under that system, a Customer Service group printed a report "several times a day" showing any controlled substance order that was "25% over the customer's rolling average" of orders placed over the prior six months. Then, "Customer Service [would] review[] (eyeball[]) the suspicious order report throughout the day (when a new report is created)" and "any order that look[ed] unusual [was] investigated and any unusual items [we]re cleared before the order [wa]s released."

46. This 2000-2012 system only flagged orders unusual in size; it did not flag orders unusual in frequency or pattern in real time, as the law required. It did not utilize any downstream customer information available to Actavis, did not differentiate among National Drug Codes ("NDC"s) for drugs with a higher risk of diversion, nor did it automatically stop orders from shipping. And, although Actavis mailed reports to the DEA of orders that were identified in the system from 2009-2012, the lack of any analysis of such data, and the fact that Actavis shipped the orders notwithstanding its suspicion, made the reports meaningless.

47. Further, although Actavis's marketing group designed a separate program starting in January 2011, that program tracked only "oxycodone IR suspicious orders." The marketing program compared monthly order rates and noted "any individual customer locations that have ordered 50% or greater than their established six month order average." However, it was not designed to track DEA regulations, and appears to have been abandoned after only three months of trials.

48. Internal documents reflect that in September 2012, Actavis was implementing a statistics-based, more modern SOM system designed by outside consultants from the

Buzzeo/Cegedim group to detect "orders of interest" in "[d]irect Customer sales." On October 1, 2012, that system began working alongside Actavis's prior system.

49. Watson's pre-merger SOM system, like the early pre-merger Actavis system, dated to the early 2000's. This system, however, was even more rudimentary. According to a 2001 memo, Watson's inventory system automatically compiled a "12-month average" of customers' various orders, and reported potentially suspicious orders to Customer Service personnel (also known as the "Call Center" group). A May 2004 Operational Procedure added a "SOMS multiplier table" to the system, which increased the level at which the inventory system would alert a potentially suspicious order. The multiplier placed a different value for various "classes of trade." Orders from wholesalers, distributors and chain pharmacies were regularly allowed at triple the historical average, or more.

50. The program was also understaffed. Between 2009 and 2012, the Watson Call Center/Customer Relations Operation added no new staff to handle the SOMs "validations," even though the number of validations increased substantially. Between 2009 and 2010 alone, the number of "SOMs validations" handled by each "administrator" jumped from 62 "SOMs validations" per month to an average of 180. In 2011, the number reached 280.

51. The Watson system was flawed, as well, in that it affirmatively allowed customers to get around violations by canceling the order or cutting its quantity. Shipping less of an order does not make it less suspicious; it means only that fewer suspicious drugs are shipped. Through 2012, Watson's consistent policy was not to report the order to DEA, but to simply cut or cancel the order instead. Beginning in 2012, Watson added to its requirements, but merely that "[i]f the customer decides to cancel or reduce the quantity, they will need to provide a reason for the reduction or cancellation." Before the merger with Watson, Actavis's internal documents reflect

an understanding that "cutting" an order to a volume that places it beneath the threshold is unacceptable. According to its then-CEO, however, Actavis allowed customers to resubmit unjustifiable suspicious orders in smaller amounts so as to fall below their arithmetic suspicious order monitoring threshold, thereby avoiding reporting.

52. After the merger, the combined company reverted to the existing Watson SOM system, and cutting or cancelling suspicious orders without reporting them was not generally prohibited. Watson also allowed orders to be shipped based on an e-mail justification from an employee (including salespeople with a financial incentive to complete the sale).

53. As described above, like the pre-merger Actavis system, the automated portion of Watson's system only looked for orders of unusual size and not for frequency and/or pattern. The rigid formula used did not satisfy DEA requirements to detect and investigate suspicious orders. The automated portion of the system did not utilize any downstream customer information and did not differentiate among NDCs for drugs with a higher risk of diversion. The SOM program was not an effective control against diversion.

54. On September 28, 2011, Watson received an audit report from the outside consulting firm, Buzzeo/Cegedim, regarding its SOM program. The problems were evident from the very first page: "Watson's current approach is based upon thresholds that are somewhat arbitrary and not in conformance to the specific requirements of the regulations." In its findings, Buzzeo/Cegedim noted that Watson's SOM program was based on the "class of trade" grouping and the application of a "multiplier," as discussed above. The report found that an individual order that was deemed in excess of the multiplier by the class of trade would then be "pended" for investigation by Watson staff, and that approximately 10% of "pended" orders were considered "orders of interest" and sent to security/regulatory for further review. Buzzeo/Cegedim found that,

nationwide, Watson reported only *one order* to the DEA. In its recommendations, Buzzeo/Cegedim stated that due to the SOM system's inconsistences with the "specific requirements noted in the regulations and with written guidance provided by the DEA to all registrants," Watson should "revisit its entire approach to SOM to fully address the specific regulatory requirements and other guidance documents provided by the DEA, to include evaluating all orders on the basis of size, frequency, and order pattern deviation.

55. The audit also found that certain accounts, such as McKesson and AmerisourceBergen, had "managed inventories" which are pre-set inventory levels. Watson staff could approve orders by these accounts when inventory was low. Buzzeo/Cegedim described this system as "self-gaming," and pointed out that reduced inventory is an indicator of increased product movement," and "not a justification for increased order size." Buzzeo/Cegedim recommended that Watson reform its SOM program to identify "unexplained changes in order behavior."

56. Finally, Buzzeo/Cegedim discussed Watson's report identified as "EDI 867" which showed who their customers were selling to. Buzzeo/Cegedim recommended that this report be incorporated into the SOM program to "[redacted]."

57. Watson did not implement the changes Buzzeo/Cegedim recommended to bring its SOM system into compliance with DEA regulations. Its flawed system remained in place and was carried forward into the merged company.

58. In 2015, Allergan, announced it was selling the Former Actavis Entities to Teva. It ceased operating even the deficient Watson SOMS program at that time. After the sale of the

Former Actavis Entities, Allergan outsourced its manufacturing, transport and delivery systems, and is no longer a DEA registrant with regard to its branded opioids, Kadian and Norco. It appears Allergan takes the view that it is a "virtual manufacturer" and need not have a suspicious order monitoring system at all. DEA regulations recognize no category of "virtual" manufacturers, and Allergan cannot delegate its duties to prevent diversion. However, responsibility for the SOMS program remained with Allergan Finance, LLC, which was not included in the sale to Teva.

59. Even before 2015, internal documents show that both Watson and Actavis employees recognized that the suspicious order monitoring systems described above were not an effective control against diversion.

60. In February 2009, the Senior Manager of Actavis's Customer Service Department, Nancy Baran told her boss that the existing Actavis process was inadequate to "prevent shipping excess product" because it was not cumulative and because there were too many orders over the 25% threshold. Baran would later testify in federal multidistrict litigation arising out of the opioid epidemic (the "MDL") that she remembered only one order between 2008 and 2017 that was ever deemed to be suspicious and reported to the DEA. All other orders flagged by the system were shipped.

61. In a 2011 Project status review, Baran would also make clear that "'Cutting' orders to a volume that puts the order under a threshold is not acceptable." The same presentation explains that the "DEA has stated on this topic, 'That is like saying a little bit of diversion is okay'").

62. On September 12, 2012, at the same time Actavis was preparing to implement the recommended Buzzeo/Cegedim SOM system, Actavis had an approximately three-hour meeting with DEA personnel at the DEA's Arlington, Virginia office to discuss opioid diversion. At the meeting Barbara J. Boockholdt, Chief of the DEA's Regulatory Section, told Actavis that its

products were being distributed in Florida in quantities and under circumstances highly suggestive of diversion. Leonard Levin, Staff Coordinator of the DEA Regulatory Section told Baran that Actavis should have a member of its compliance team visit certain pharmacies in south Florida, "get to know their customers, visit distribution sites, visit customers of those distributors, check on customers' suspicious order monitoring systems, review due diligence files, and obtain printouts of pharmacies or practitioners who are receiving Actavis products," among other steps. Upon information and belief based on industry practices, however, Actavis already had detailed information about its customers, prescribing doctors, and pharmacies. It simply used this information to advance their sales, rather than prevent diversion.

63. Actavis's Ethics & Compliance Officer, Michael R. Clarke, testified in the MDL that "the tone and the tenor of the meeting" was such that it seemed the DEA was viewing and speaking with the Actavis representatives "as street dealers" rather than "as professionals." "[T]hey described it," Clarke said, "without using these specific words, but in a way that we would just manufacture, put the product out on the street, and not have a care as to where it went" and "described finding or seeing or obtaining product, you know, opioid products that seemed to be diverted relatively easily."

64. In late October 2012, Actavis had a follow-up meeting with two field representatives from the DEA's Newark, New Jersey office where, according to Clarke, DEA requested a reduction of approximately 30%-40% in Actavis's manufacturing quota for oxycodone. According to Clarke, Actavis's then CEO, Doug Boothe, rejected the DEA's request.

65. Further, like Nancy Baran at Actavis, Thomas Napoli at Watson made clear – internally— that the system did not comply with the DEA laws and regulations. In November 2008 Napoli wrote a memo stating that:

> It is highly recommended that industry utilize a 'total SOM model.' This model favors a more statistically-based model that dynamically evaluates a variety of order characteristics to determine whether an order should be pending. Characteristics include order size, ordering frequency, ordering patterns and percentage of CS ordered.

His memo continued "[t]his approach is viewed to be more effective and defensible than the traditional approach of just setting a threshold." A 2012 PowerPoint from Napoli's files also describes the feedback from Buzzeo/ Cegedim as critical.

66. Other internal Allergan emails show that, according to the employees responsible, the suspicious order monitoring system "d[id] a lousy job." One explains that, "for example," "if a customer's monthly usage is 3000 units – they can order 2999 units every day of the month and it would not be caught." The same internal e-mail, from February 2009, states that orders in excess of the threshold "come in all day long" and "[i]t would be crippling". . . "[i]f Allergan stopped to question and put on hold every one of these orders." In another internal document, Allergan similarly acknowledged its program as "not consistent with specific requirements within the regulations and guidance."

67. As explained above, Allergan was, and should have been, well aware of its obligations. This is particularly true given that its branded opioid Norco was so widely diverted that it had the street name "Watson" – the name of the Allergan predecessor that brought the drug to market – and that the DEA blamed it for a "diversion wave." Further, the association between Allergan's predecessors and diversion was not limited to Watson. Actavis, too, was "frequently associated in social media, online message boards, and markets with inappropriate use and questionable distribution" of oxycodone; and its name was adopted by "performers such as 'DJ Actavis,' and songs such as 'Cream Soda and Actavis's."

68. Tellingly, however, former CEO Boothe testified in the MDL that he believed Actavis's responsibility was only to make certain that orders were received from licensed

pharmacies and were within numerical thresholds, and that Actavis had no responsibility (or accountability) for preventing diversion:

> Again, I don't think we had responsibility for, accountability for preventing diversion. We had responsibility and accountability for making certain that the orders that we received were valid from licensed pharmacies and were within our suspicious order monitoring thresholds as it was described earlier then with the Buzzeo model or the more statistical model. So we -- that was our responsibility. Once it goes outside of our chain of custody, we have no capability or responsibility or accountability to -- or at least my understanding, I'm not a lawyer, as it relates to diversion. So, once we ship a valid order to a wholesaler or ship a valid order to a distributor or another smaller wholesaler, our chain of custody is finished at that point.

69. Despite these failures, Allergan's Board publicly claimed in 2019 that it "employed a number of controls," including holding and flagging suspicious orders, monitoring large shipments, and evaluation of customer data.[41]

Teva

146. Teva's internal documents show that, as of September, 2012, Teva had no written suspicious order monitoring system in place, and, until that time, had never had one. In 2012, Teva hired Ronald Buzzeo and Cegedim to perform a review of Teva's process for identifying and halting suspicious orders. The review resulted in a starkly critical September 2012 report which noted the absence of written procedures, Teva's failure to report a single suspicious order, ever, and the "rudimentary" nature of Teva's program, such as it was. In that regard, the audit also revealed that Teva's customer due diligence process was limited to checking customers' registration and DEA credit-worthiness. And, the audit explained, Teva's order monitoring system was "not sufficiently sensitive to customer ordering practices to result in any meaningful analysis of customer order practices."

[41] https://www.allergan.com/-/media/allergan/documents/us/Investors/Report-to-the-Stockholders-of-Allergan-Form-the-Board-of-Directors-Board-Report.pdf

147. Teva ultimately decided not to hire Buzzeo to implement a compliance program, a decision that appears to have been based on its assessment of the costs involved.

148. Ultimately, in January 2014, Teva hired Joe Tomkiewicz from AmerisourceBergen to design and operate the suspicious order monitoring program for this multi-national corporation.

149. Tomkiewicz later coined the program he designed "DefOps," short for "Defensible Operations," a name he admitted in an MDL deposition was chosen because it "sounded good" and was intended to keep Teva out of trouble with the DEA. In August 2014, nearly two years after the Buzzeo report stated Teva needed to have written procedures in place, the written Standard Operating Procedures ("SOPS") for Teva's system finally were approved.

150. The system developed was fundamentally flawed. Most glaringly, the SOPS maintained the key investigatory role in the hands of Teva's sales department. The sales department would then direct customer service to contact the customer for initial investigation and to gather information, and to send a sales representative to the customer if the response was not satisfactory.

151. Teva recognized the conflicts of interest inherent in this system. Notably, Tomkiewicz developed a 2017 PowerPoint on Teva's suspicious monitoring system which references the sales department under the slide titled "Managing Conflicts."

152. Teva's SOM program also suffered from other glaring deficiencies. Teva Ltd. audited Teva's DEA compliance department in 2015 and prepared a report critical of the department and the SOM program. The report stated that Teva Ltd. investigated 10,000 line orders per month of Schedule II products, 95% of which were automatically released. It found that the company's DEA Department was in "non-compliance with DEA requirements" and was at "High Risk" of DEA regulatory action, and that the SOM program was at "Moderate Risk" for such action. For the SOMs program, the report focused primarily on the fact that suspicious orders were cleared through the

decisions of a single person (Tomkiewicz), which exposed the system to the risk of mistaken releases. It also recognized that the program must clear 5,000 pending potentially suspicious line orders per month under pressure from the sales department to clear those orders quickly so as not to delay their customers' opioid orders. That number likely more than doubled after the 2016 acquisition of generic business from Allergan.[42]

153. Internally, Teva also acknowledged that it was not scrutinizing the distributors it used (or chain pharmacies for that matter) as closely as it would other customers.

154. The inadequacy of Teva's system is confirmed by the fact that even after it implemented a written SOM policy, it reported and stopped very few suspicious orders. Teva reported its first ever suspicious order to the DEA on February 13, 2013. In total, from 2013 through 2016, nationally, Teva reported only 6 suspicious orders out of 600,000 total line orders (and not all were opioid products). None were in Alaska.

155. Teva also conducted in-person sales visits to Alaska prescribers who were subsequently involved in disciplinary proceedings but did not report any concerns. [redacted] Dr. Davidhizar continued to engage in suspicious behavior, resulting in a five year consent agreement in 2009 with the Alaska State Medical Board over concerns with overprescribing and failure to monitor, and a 2019 surrender of DEA license.

[42] This was not the only critical safety-related audit of Cephalon. Notably, Teva Ltd. through its Global Drug Safety and Pharmacovigilance Department also conducted an internal audit of Teva USA's pharmacovigilance system. The audit states "the safety system in Teva U.S. has multiple gaps and the reporting of safety matters to the FDA ... cannot be assured." It further stated "The safety system in Teva U.S. is largely out of control and the reporting of safety matters to FDA (and by extension other regulatory agencies and business partners) cannot be assured."

IV. DEFENDANTS' MISCONDUCT FUELED THE OPIOID EPIDEMIC AND SIGNIFICANTLY HARMED ALASKA AND ITS RESIDENTS.

156. Upon information and belief, the vast market for opioids was created and sustained, in significant part, by Defendants' deceptive marketing in establishing and maintaining opioids as a first-line treatment for chronic pain. Defendants' deceptive marketing caused patients to believe they would not become addicted, addicted patients to seek out more drugs, and health care providers to make and refill opioid prescriptions that maintain dependence and addiction. In addition, Defendants fueled the opioid epidemic in Alaska by failing to put in place appropriate procedures to prevent diversion and to detect and report suspicious orders, instead continuing to fill orders that it knew or should have known were suspicious, which supplied far more opioids than were justified.

157. Defendants' marketing has been effective. The effects of sales calls on prescribers' behavior is well-documented in the literature, including a 2017 study that found that physicians ordered fewer promoted brand-name medications and prescribed more cost-effective generic versions if they worked in hospitals that instituted rules about when and how pharmaceutical sales representatives were allowed to detail prescribers. The changes in prescribing behavior appeared strongest at hospitals that implemented the strictest detailing policies and included enforcement measures. Another study involved the research of four different practices which included visits by sales representatives, medical journal advertisements, direct-to-consumer advertising, and pricing, and found that sales representatives have the strongest effect on driving drug utilization. An additional study found that doctor meetings with sales representatives are related to changes in doctor prescribing practices and requests by physicians to add the drugs to hospitals' formularies. Defendants necessarily expected a return on its investment in opioid marketing, and carefully calibrated their promotion efforts to serve that end.

158. Teva devoted substantial resources to its marketing efforts. As described above, its sales representatives visited prescribers in Alaska, and it made substantial contributions to third-party front groups and funded speakers' programs. In addition, upon information and belief, it devoted substantial resources to making the launch of its branded drugs a success.

159. Teva also internally tracked its sales representatives to ensure that their messages were being absorbed by prescribers and to monitor or evaluate Teva's "return on investment" ("ROI"). An internal Teva document, for example, described a "hefty ROI" among rh[e]umatologists and emergency medicine doctors and lowest rate of return among oncologists)." According to an internal document, Teva tracked the impact of its sales representatives' key messages about Fentora. For example, from this tracking, Teva learned that Fentora sales representatives were more likely to be rated highly by doctors they visited if they reviewed a prescription savings program with the doctor. Additionally, some of the "success drivers" of the sales representatives' marketing of Fentora included messaging regarding the fast onset of its analgesic effect, improved patient physical and cognitive function with use, and its convenience and ease of use. Thus, Teva was aware of the strengths of its in-person marketing.

160. Representing the NIH's National Institute of Drug Abuse in hearings before the Senate Caucus on International Narcotics Control in May 2014, Dr. Nora Volkow explained that "aggressive marketing by pharmaceutical companies" is "likely to have contributed to the severity of the current prescription drug abuse problem."

161. In August 2016, U.S. Surgeon General Vivek Murthy published an open letter to be sent to physicians nationwide, enlisting their help in combating this "urgent health crisis" and

linking that crisis to deceptive marketing.[43] He wrote that the push to aggressively treat pain, and the "devastating" results that followed, had "coincided with heavy marketing to doctors . . . . [m]any of [whom] were even taught—incorrectly—that opioids are not addictive when prescribed for legitimate pain."[44]

162. Scientific evidence demonstrates a strong correlation between opioid prescriptions and opioid abuse. For example, a 2007 study found "a very strong correlation between therapeutic exposure to opioid analgesics, as measured by prescriptions filled, and their abuse."[45] In a 2016 report, the CDC explained that "[o]pioid pain reliever prescribing has quadrupled since 1999 and has increased in parallel with [opioid] overdoses." Prescription opioids and heroin account for the majority of overdoses. For these reasons, the CDC concluded that efforts to improve the safer prescribing of opioids must be intensified "to reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity." A Staff Report by the U.S. Senate Homeland Security & Governmental Affairs Committee Staff Report noted the link between drug maker payments to prescribers and physician prescribing practices. It found that "a clear link exists between even minimal manufacturer payments and physician prescribing practices."[46] The Report quotes findings that "doctors who received industry payments were two to three times as likely to prescribe brand-name drugs at exceptionally high rates as others in their specialty."

163. The U.S. Senate's report, *Fueling an Epidemic: Exposing the Financial Ties*

[43] CDC, *Examining the Growing Problems of Prescription Drug and Heroin Abuse* (Apr. 29, 2014), http://www.cdc.gov/washington/testimony/2014/t20140429.htm; Vivek H. Murthy, *Letter from the Surgeon General*, August 2016, available at http://turnthetiderx.org.
[44] *Id.*
[45] Theodore J Cicero *et al.*, *Relationship Between Therapeutic Use and Abuse* of *Opioid Analgesics in Rural, Suburban, and Urban Locations* in the United States, 16.8 Pharmacoepidemiology and Drug Safety, 827-40 (2007).
[46] U.S. Senate Homeland Security & Governmental Affairs Committee, Ranking Members' Office, February 12, 2018 https://www.hsdl.org/?abstract&did=808171 ("*Fueling an Epidemic*").

Between Opioid Manufacturers and Third Party Advocacy Groups,[47] which arose out of a 2017 Senate investigation, has also found that front groups "amplified or issued messages that reinforce industry efforts to promote opioid prescription and use, including guidelines and policies minimizing the risk of addiction and promoting opioids for chronic pain."[48] In addition, according to the report, "Patient advocacy organizations and professional societies like the Front Groups play a significant role in shaping health policy debates, setting national guidelines for patient treatment, raising disease awareness, and educating the public."[49] "Even small organizations—with 'their large numbers and credibility with policymakers and the public'—have 'extensive influence in specific disease areas.' Larger organizations with extensive funding and outreach capabilities 'likely have a substantial effect on policies relevant to their industry sponsors.'"[50]

164. The FDA also has made clear that "most opioid drugs have 'high potential for abuse,'" and "the serious risks of misuse, abuse, neonatal opioid withdrawal syndrome (NOWS), addiction, overdose, and death [are] associated with the use of ER/LA opioids overall, and during pregnancy." (Emphasis added.) According to the FDA, because of the "known serious risks" associated with extended-release opioid use, including "risks of addiction, abuse, and misuse, even at recommended doses, and because of the greater risks of overdose and death," opioids should be used only "in patients for whom alternative treatment options" like non-opioid drugs have failed. (Emphasis added.)

[47] *Fueling an Epidemic* at 1.
[48] *Id*. at 12-15.
[49] *Id*. at 2.
[50] *Id*.

165. An estimated 60% of the opioids that are abused come, directly or indirectly, through physicians' prescriptions. A study of 254 accidental opioid overdose deaths in Utah found that 92% of the decedents had been receiving prescriptions from health care providers for chronic pain.

166. Upon information and belief, the escalating number of opioid prescriptions written by doctors who were deceived by Defendants' deceptive marketing scheme, along with Defendants' failure to put in place appropriate procedures to ensure suspicious orders would be reported and their continuing to fill orders which supplied far more opioids than were justified, caused a correspondingly dramatic increase in opioid addiction, overdose, and death throughout Alaska.

167. Defendants' failure to monitor suspicious orders and maintain effective controls to prevent diversion contributed to the spread of illicit opioids in Alaska, causing the State to incur costs to address opioid diversion, misuse, addiction, and overdose, among other consequences.

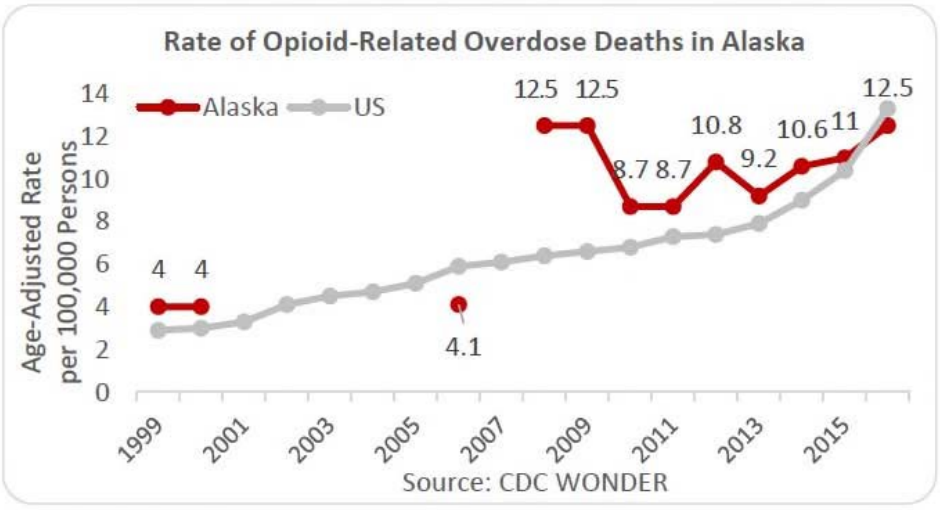
168. Research from the American Action Forum shows that as authorities went after pill mills and rogue doctors – later than had Defendants complied with their obligations – sales of heroin and powerful synthetic opioids such as fentanyl filled the void. Because heroin is cheaper than prescription painkillers, many prescription opioid addicts migrate to heroin. An individual who abuses opioid pain medication is 40 times more likely to develop a heroin addiction. Nationally, eighty percent of heroin users previously used prescription opioids; providers from addiction treatment programs across the state likewise report that more than half and up to 90% of their heroin-addicted patients were first exposed to opioids through a doctor's prescription. In Alaska, many of the patients in treatment programs seeking help with heroin addictions started with prescription opioids, but turned to heroin when pills were no longer available to them or too expensive. According to one Alaska emergency department doctor, every one of her patients who abused heroin began with prescription

opioids – theirs or someone else's. From 2009 to 2015, the number of heroin-associated deaths in Alaska more than quadrupled.

169. Beyond overdoses, Alaska hospitals have struggled to deal with other effects of the opioid epidemic. Dealing with these impacts has become a new normal for doctors and administrators, who report dealing with patients who threaten violence or suicide if they are not given prescription opioids. One doctor described opioids as a daily part of practice from patients seeking refills, to patients with complications from injecting opioids, to patients in active withdrawal from opioids. Depending on the day, 15 to 30 of the patients in one emergency department will be there on issues related to opioids, and one doctor described it as surprising to see patients not affected by opioids.

170. Addiction has consumed the lives of countless Alaskans exposed to opioids prescribed by doctors either directly, from their own prescriptions, or indirectly, from prescription drugs obtained by others and found in family medicine cabinets. It is difficult to describe the lifelong struggle individuals addicted to opioids will face. The desire to get drugs becomes so consuming that addicts can no longer work or care for their children, and will resort to desperate means to persuade doctors to provide their next prescription.

171. Alaska exceeds the national rate of opioid-related overdose deaths in 2018, and has been above the national rate for the preceding ten years. There were 68 opioid-related overdose deaths in Alaska in 2018, a rate of 8.8 deaths per 100,000 persons. From 2006 through 2016, the number of opioid-related deaths in Alaska tripled, though incomplete reporting likely understates the number of lives lost.



172. A recent, even more sinister problem stemming from the prescription opioid epidemic involves illicit fentanyl that, in synthetic form, has made its way into Alaska communities. As a result of the rise in illicit sources of opioids, Alaska has been designated as a High Intensity Drug Trafficking Area.[51]

173. Overdose deaths are only one consequence of the proliferation of opioid use. Opioid addiction and misuse also result in an increase in emergency room visits, emergency responses, and emergency medical technicians' administration of naloxone—the antidote to opioid overdose. Between 2016 and 2017, hospital visits in Alaska due to opioid overdoses cost more than $23 million. There were 375 opioid overdose emergency department visits between July 1, 2017 and June 30, 2018. In a similar one-year period, from June 1, 2017 and May 31, 2018, Emergency Medical Services and law enforcement administered 550 doses of Narcan and Project Hope, a state-wide program to get Narcan into the hands of heroin users, distributed 7,082 kits in Alaska. Between 2012 and 2017, Naloxone administrations by EMS more than doubled, from 8.0 per 1,000 EMS calls in 2012 to 17.7 per 1,000 EMS calls in 2017.

[51] https://alaskamentalhealthtrust.org/wp-content/uploads/2019/07/Addressing-Alaska-Opioid-Epidemic_Comprehensive-Presentation_V1.pdf

174. The COVID-19 crisis has exacerbated opioid addiction and abuse, with the highest recorded number of overdose deaths in a 12-month period recorded between May 2019 and May 2020. According to Michael Carson of the Mat-Su Opioid Task Force, Coronavirus has moved opioid addiction to the forefront of the community's health problems.[52]

175. As communities have worked to save lives, the opioid epidemic has continued to outpace their efforts. According to the National Survey on Drug Use and Health, an estimated 60,128 Alaskan adults, 11.5% of the state's population, need substance use disorder treatment. In 2016, Alaska-funded programs provided substance use disorder treatment to 7,808 people. Yet 88.2% of people in Alaska suffering from drug dependence or abuse go untreated. During calendar year 2017, Alaska awarded $57.8 million in substance use disorder grants to local jurisdictions, and $55.7 million in 2018.[53] In that same time period, Alaska's Medicaid program spent $21 million on reimbursing opioid-related diagnoses, and an additional $3 million on substance use disorder treatment drugs. Spending on substance abuse treatment drugs rose to nearly $5 million in 2018.[54]

176. Diseases connected to injecting drugs, particularly hepatitis C, are another side effect of opioid and heroin addiction. According to Dr. Jay Butler, formerly Alaska's Chief Medical Officer and Division of Public Health Director, "[w]e talk mostly about opioid overdose deaths, but there's a lot more that happens related to opioid use than just deaths … The most concerning trend that we see is an increasing number of diagnoses [of hepatitis C in people] age 18 to 29."[55] While there are new direct-acting antiviral drugs to treat hepatitis C, the cost of treatment, approximately

[52] https://www.adn.com/alaska-news/2020/12/23/overdose-deaths-in-alaska-have-been-on-the-rise-since-the-pandemic-began-report-says/
[53] https://alaskamentalhealthtrust.org/wp-content/uploads/2019/07/Addressing-Alaska-Opioid-Epidemic_Comprehensive-Presentation_V1.pdf
[54] https://alaskamentalhealthtrust.org/wp-content/uploads/2019/07/Addressing-Alaska-Opioid-Epidemic_Comprehensive-Presentation_V1.pdf
[55] Zachariah Hughes, KTOO Public Media, *Wave of addiction costs is hitting Alaska's health care system*, June 29, 2017, https://www.ktoo.org/2017/06/29/wave-addiction-costs-hitting-alaskas-healthcare-system/.

$85,000 to $94,500 for two common medications, puts an enormous burden on the State's Medicaid program. In 2015, Alaska's Medicaid program spent $5.9 million on hepatitis C treatments, according to Erin Narus, the lead pharmacist for the state's Medicaid program. The next year, that more than doubled to $13.6 million. The McDowell Group, a research and consulting firm in Alaska, calculated that treating just the estimated 1,009 people in Alaska infected with hepatitis C from injecting drugs in 2015 would cost $90 million.

177. Perhaps the most profound effect of the opioid crisis has been on children and teenagers. Across the country there is a significant increase in children being abused, neglected, and eventually separated from their parents due to opioid addiction. Alaska is no exception. From 2012 to 2016, the number of children in foster care in Alaska increased from 1,860 to 2,802, more than 50%—five times the national rate. In 48% of Alaska's foster care placements, parental substance use was a factor. Grandparents have also been caring for children impacted by the opioid epidemic.

178. According to the CDC, from 2009 to 2015, while alcohol and marijuana use among Alaska youths declined, prescription drug use remained stable. A survey of high school students ages 14 to 18 taken by the Alaska Youth Risk Behavior Surveillance determined that prescription drugs are the most frequently used drug category after alcohol and marijuana. More youth reported current prescription drug use than reported using cocaine, heroin, or methamphetamine. According to data from the National Survey on Drug Use and Health, one-third of all new prescription drug users in the past year were youth between the ages of 12 and 17.

179. Even infants have not been immune to the impact of opioid abuse. There has been a dramatic rise in the number of infants who are born addicted to opioids due to prenatal exposure and who suffer from neonatal abstinence syndrome ("NAS," also known as neonatal opioid withdrawal syndrome, or "NOWS"). These infants painfully withdraw from the drug once they are born, cry

nonstop from the pain and stress of withdrawal, experience convulsions or tremors, have difficulty sleeping and feeding, and suffer from diarrhea, vomiting, and low weight gain, among other serious symptoms. The long-term developmental effects are still unknown, though research in other states has indicated that these children are likely to suffer from continued, serious neurologic and cognitive impacts, including hyperactivity, attention deficit disorder, lack of impulse control, and a higher risk of future addiction. When untreated, NAS can be life-threatening.

180. A State of Alaska Epidemiology study of births between 2004 through 2015, found that there was a 566% increase in babies diagnosed with NAS during that time period, from 15 in 2004 to 100 in 2015—541 infants in total over the twelve-year period. According to an Alaskan maternal and child health epidemiologist and study author Abigail Newby-Kew, the study only looks at Medicaid-eligible births because that is the most complete, long-term data set available, therefore these numbers do not represent the entire population. Moreover, because of difficulties in identifying symptoms, or delays in manifesting them, additional babies may not have been included in the statistics.

181. From 2014 to 2015, 97 babies admitted to Providence Alaska Medical Center's Neonatal Intensive Care Unit ("NICU") had NAS. Dr. Mary-Alice Johnson, the NICU medical director at Providence, stated: "Everybody is concerned about the fact that we're seeing more moms exposed and therefore more babies suffering from neonatal abstinence syndrome."[56]

182. The full cost of this human tragedy cannot be calculated or adequately compensated. But the financial costs that are already known are staggering. The McDowell Group, a research and consulting firm in Alaska, estimated that the economic cost of substance abuse and

[56] Hope Miller, Anchorage Daily News, *How hospitals are treating babies caught in the crosshairs of Alaska's opioid crisis*, May 8, 2016, https://www.adn.com/alaska-news/article/how-hospitals-are-treating-babies-caught-crosshairs-alaska-s-opioid-epidemic/2016/05/09/.

addiction in Alaska amounted to $1.22 billion in 2015 alone. This estimate includes costs related to loss of productivity, traffic collisions, criminal justice and protective services, healthcare, public assistance and social services.

E. Defendants Fraudulently Concealed Their Misconduct

183. Defendants also fraudulently concealed their misconduct. First, and most prominently, Defendants disguised their own roles in the deceptive marketing of chronic opioid therapy by funding and working through patient advocacy and professional front organizations and KOLs. Defendants purposefully hid behind these individuals and organizations to avoid regulatory scrutiny and to prevent doctors and the public from discounting their messages.

184. While Defendants were listed as sponsors of many of the publications described in this Complaint, they never disclosed their role in shaping, editing, and exerting final approval over their content. Defendants exerted their considerable influence on these promotional and "educational" materials.

185. In addition to hiding their own role in generating the deceptive content, Defendants manipulated their promotional materials and the scientific literature to make it appear that they were accurate, truthful, and supported by substantial scientific evidence. Defendants distorted the meaning or import of studies they cited and offered them as evidence for propositions the studies did not support, including most notably downplaying the adverse effects from Actiq and Fentora. The true lack of support for Defendants' deceptive messages was not apparent to the medical professionals who relied upon them in making treatment decisions, nor could they have been detected by the Alaska.

186. Defendants further concealed their contributions to opioid diversion. Defendants publicly portray themselves as maintaining sophisticated technology as part of a concerted effort to thwart diversion and present themselves as committed to fighting the opioid epidemic. However, their public pronouncements are at odds with their concealed misconduct. On February 26, 2018, Judge

Dan A. Polster, who presides over the Multidistrict Opioid Litigation, ordered that the Drug Enforcement Administration release ARCOS data reflecting the market share of various manufacturers in the states and Alaska.

187. To the extent that information about Defendants' violations of the federal CSA and its implementing regulations was disclosed through settlement agreements, that information concerned facilities outside Alaska, but such enforcement actions are relevant to Defendants' conduct throughout the country and in Alaska. Further, as described in this Complaint, such settlement agreements have typically been followed by or coupled with promises to improve compliance.

188. Defendants were deliberate in taking steps to conceal their active role in the oversupply of opioids and their failure to prevent the entry of prescription drugs into illicit markets, which fueled the opioid epidemic.

189. As set forth in this Complaint, Defendants concealed the existence of the Government's claims by hiding their lack of cooperation with law enforcement and affirmatively seeking to convince the public that they were complying with their legal duties to report suspicious orders and maintain effective controls against diversion.

190. The State of Alaska did not discover the nature, scope, and magnitude of Defendants' misconduct and its full impact on Alaska until recently, and Alaska could not have acquired such knowledge earlier through the exercise of reasonable diligence.

V. CAUSES OF ACTION

FIRST CLAIM FOR RELIEF
(Violations of the Unfair Trade Practices and Consumer Protection Act)

191. Defendants engaged in trade or commerce in the State of Alaska.

192. The Alaska Unfair Trade Practices and Consumer Protection Act (the "UTPA") states that "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of trade or commerce are declared to be unlawful." AS 45.50.471(a).[57] The Alaska Supreme Court has determined if actions are unfair or deceptive by inquiring:

> (1) Whether the practice, without necessarily having been previously considered unlawful, offends public policy as it has been established by statutes, the common law, or otherwise—whether, in other words, it is within at least the penumbra of some common-law, statutory or other established concept of unfairness; (2) whether it is immoral, unethical, oppressive, or unscrupulous; (3) whether it causes substantial injury to consumers (or competitors or other businessmen).[58]

193. Further, the UTPA lists fifty-seven different trade practices or acts that are expressly considered "unfair" or "deceptive" in violation of the Act, but does not limit violations of the Act to these enumerated practices. AS 45.50.471(b). At all times relevant to this Complaint, Defendants, directly, through the control of third parties, and/or by aiding and abetting third parties, violated the UTPA by making or causing to be made and by disseminating unfair, false, deceptive, and misleading statements and statements that were false and misleading by virtue of material omissions, to Alaska prescribers and consumers to promote the sale and use of opioids to treat chronic pain.

194. Teva and Allergan violated the UTPA, as codified in AS 45.50.471, *et seq.*, by:

a. Representing that prescription opioids have sponsorship, approval, characteristics, ingredients, uses, benefits, or qualities that they do not have, in violation of AS 45.50.471(b)(4);

b. Disparaging the goods, services, or business of another by false or misleading representation of fact, in violation of AS 45.50.471(7);

c. Engaging in other conduct creating a likelihood of confusion or of misunderstanding and which deceived or damaged a buyer or a competitor

[57] In light of the exemption set forth in A.S. § 45.50.481(a)(1) and the statute's subsequent amendment in 2012, Plaintiff only asserts claims under the UTPA for Defendants' post-August 15, 2012 conduct.
[58] *State v. O'Niell Investigations, Inc.*, 609 P.2d 520, 528 (Alaska 1980).

in connection with the sale or advertisement of goods or services, in violation of AS 45.50.471(b)(11).

d. Using or employing deception, fraud, false pretense, false promise, misrepresentation, or knowingly concealing, suppressing, or omitting a material fact with the intent that others rely upon the concealment, suppression, or omission in connection with the sale or advertisement of goods or services, in violation of AS 45.50.471(b)(12).

195. Teva's violations include, but are not limited to, deceptively and misleadingly:

a. Claiming that the risks of long-term opioid use, especially the risk of addiction were overblown;

b. Omitting that opioids are highly addictive and may result in overdose or death;

c. Claiming that signs of addiction were "pseudoaddiction" reflecting undertreated pain and should be responded to with more opioids;

d. Claiming that the risk of addiction to opioids could be managed and avoided through risk screening tools and other strategies;

e. Claiming that opioid doses can be increased, without disclosing the greater risks of addiction, other injury, or death at higher doses;

f. Claiming that opioids are an appropriate treatment for chronic pain and failing to disclose the lack of long-term evidence for their use;

g. Claiming chronic opioid therapy would improve patients' function and quality of life;

h. Marketing Actiq and Fentora for unapproved indications for which they were unsafe, including chronic non-cancer pain and in patients who were not tolerant to opioids;

i. Omitting other material facts that they had a duty to disclose by virtue of other representations to Alaska consumers, including other adverse effects from opioid use;

j. Failing to create and maintain and use a compliance program that effectively detects and prevents suspicious orders of controlled substances;

k. Failing to report suspicious orders of controlled substances;

l. Filling suspicious or invalid orders for prescription opioids;

m. Permitting orders to be filled where red flag warnings indicated potential diversion; and

n. Failing to exercise due diligence to ensure that customers could be trusted with opioids.

196. Allergan's violations include, but are not limited to, deceptively and misleadingly:

a. Claiming that the risks of long-term opioid use, especially the risk of addiction were overblown;

b. Omitting that opioids are highly addictive and may result in overdose or death;

c. Claiming that signs of addiction were "pseudoaddiction" reflecting undertreated pain and should be responded to with more opioids;

d. Claiming that the risk of addiction to opioids could be managed and avoided through risk screening tools and other strategies;

e. Claiming that opioid doses can be increased, without disclosing the greater risks of addiction, other injury, or death at higher doses;

f. Claiming that opioids are an appropriate treatment for chronic pain and failing to disclose the lack of long-term evidence for their use;

g. Claiming chronic opioid therapy would improve patients' function and quality of life;

h. Omitting other material facts that it had a duty to disclose by virtue of other representations to Alaska consumers, including other adverse effects from opioid use;

i. Failing to create and maintain and use a compliance program that effectively detects and prevents suspicious orders of controlled substances;

j. Failing to report suspicious orders of controlled substances;

k. Filling suspicious or invalid orders for prescription opioids;

l. Permitting orders to be filled where red flag warnings indicated potential diversion; and

m. Failing to exercise due diligence to ensure that customers could be trusted with opioids.

197. Defendants' acts and practices described in this Complaint had the capacity and tendency to deceive and were capable of being interpreted in a misleading way.

198. Defendants' acts and practices were also unfair under AS 45.50.471(a). These unfair and deceptive acts or practices include, but are not limited to, (a) deceptively promoting its highly addictive opioids, as described above, knowing that, once started, many patients would be unable to stop taking them; and (b) failing to maintain effective controls against opioid diversion by oversupplying opioids into Alaska while failing to create, maintain, and use an adequate compliance program, failing to investigate, report, and halt suspicious orders, filling suspicious orders, and failing to exercise due diligence to ensure the customers to whom it sold and marketed could be trusted with prescription opioids.

199. In addition, Defendants' acts or practices were immoral, unethical, oppressive, or unscrupulous, caused substantial injury to consumers and businesses, and violated public policy, including:

a. The policy of "Harm reduction, Overdose prevention, and Education" being implemented by the Department of Health and Human Services;

b. The policy, reflected in the recommended Interagency Guideline on Prescribing Opioids for Pain, which suggests a focus on "preventing the inappropriate transition from acute and subacute opioid use to chronic opioid use and to avoid [chronic opioid analgesic therapy] COAT altogether when other alternatives for treating pain may be equally effective and safer in the long-term;"

c. The policy, reflected in the Alaska Opioid Policy Task Force Final Recommendations (2017) of increasing public awareness and understanding of appropriate opioid use and opioid abuse and addiction;

d. The policy, reflected in the recommended Interagency Guideline on Prescribing Opioids for Pain, that continuing to prescribe opioids for chronic pain in the absence of clinically meaningful improvement in function, or after development of a severe adverse outcome, such as an overdose event, is not appropriate care;

e. The policy, reflected in the recommended Interagency Guideline on Prescribing Opioids for Pain, of prescribing the lowest possible effective dose;

f. The policy, reflected in the recommended Interagency Guideline on Prescribing Opioids for Pain, of ensuring informed consent regarding the risks and benefits of treating chronic pain with opioids;

g. The policies of preventing abuse and diversion of opioids and of education and awareness concerning risks, reflected in SB 174, which requires all prescribers to register with and use the State's prescription drug monitoring program and requires education on pain management and opioid use and addiction, and HB 159, which limited initial prescriptions of opioids and prescriptions for more than a 7-day supply;

h. The policy, reflected in the recommended Interagency Guideline on Prescribing Opioids for Pain, of reducing the risk to the community from diversion of opioids, which has been shown to correlate with the amount of opioids prescribed; and

i. The policy, reflected in ACSA and incorporated federal law, which requires the monitoring and reporting of suspicious orders of controlled substances and aims to reduce diversion.

200. As a direct result of the foregoing deceptive acts and practices, Defendants obtained income, profits, and other benefits that they would not otherwise have obtained.

201. Defendants' acts and practices as alleged herein substantially impacted the community of patients, health care providers, law enforcement, and other State government functions, and caused significant actual harm.

202. Defendants' conduct has caused substantial injury to the State—in lives lost to drug overdoses, addictions endured, emergency room visits, the creation of an illicit drug market and all its concomitant crime and costs, and broken lives, families, and homes.

203. Defendants' acts and practices as alleged herein were motivated by a desire to retain and increase its market share and profits.

204. Defendants' use of acts or practices in violation of the UTPA warrant the maximum amount of civil penalties under AS 45.50.551.

205. As a result of Defendants' conduct as alleged herein, Alaska consumers, including the State and its agencies, suffered and continue to suffer injury.

206. In addition to penalties and restitution, Defendants are liable for attorneys' fees and costs, including costs of investigation, under AS 45.50.537(d).

SECOND CLAIM FOR RELIEF
(Public Nuisance)

207. A public nuisance is an unreasonable interference with a right common to the general public, such as a condition dangerous to health, offensive to community moral standards, or unlawfully obstructing the public in the free use of public property.

208. Defendants' conduct, as described in the Complaint, involves a significant interference with the public health, the public safety, the public peace, the public comfort or the public convenience, and unreasonably interferes with a public right by creating a public health epidemic in Alaska.

209. As the Restatement (Second) of Torts § 821B(2) (1979) explains, [c]ircumstances that may sustain a holding that an interference with a public right is unreasonable include" conduct that "involves a significant interference with the public health, the public safety, the public peace, the public comfort or the public convenience," that "is proscribed by a statute, ordinance or administrative regulation," or that "is of a continuing nature or has produced a permanent or long-lasting effect, and, as the actor knows or has reason to know, has a significant effect upon the public right." Defendants' conduct has created an ongoing, significant, unlawful, and unreasonable interference with rights common to the general public, including the public health, welfare, safety, peace, comfort, and convenience of the State and its residents.

210. Defendants created or assisted in the creation of a condition that is injurious to public health, public safety, public peace, public comfort and public convenience, and offends the moral standards of communities throughout the State and significantly harmed a considerable number of the State's residents.

211. Here, Defendants' conduct is prescribed by statutes and regulations, including the Alaska UTPA, AS § 45.50.471, and the ACSA, AS §17.30 *et seq.*, and the federal CSA and regulations incorporated therein.

212. Defendants violated the standard of conduct set forth in the Alaska CSA by failing to design and operate a system that would disclose the existence of suspicious orders of controlled substances and/or by failing to report and reject suspicious orders of opioids, and violated the Alaska UTPA, AS 45.50.471 through their unfair and deceptive practices described in this Complaint.

213. Defendants knew and should have known that their promotion of opioids was false and misleading and that their deceptive marketing schemes and other unlawful, unfair, and fraudulent actions would create or assist in the creation of a public nuisance.

214. Defendants knew and should have known that their failure to comply with their statutory and common law duties to maintain effective controls against diversion, including by monitoring, reporting, and exercising due diligence not to fill suspicious orders, would create or assist in the creation or maintenance of a public nuisance.

215. Defendants' conduct is of a continuing nature and has produced a permanent or long-lasting effect on the public right that Defendants knew, or had reason to know, would occur.

216. Defendants' conduct created or increased an unreasonable risk of harm.

217. Defendants' conduct is unreasonable, intentional, reckless, and/or negligent, and unlawful.

218. The public nuisance is substantial and unreasonable. Defendants' actions caused and continue to cause the public health epidemic and state of emergency described in the Complaint.

219. It was reasonably foreseeable that Defendants' actions and omissions would result in the public nuisance and harm to the State described herein.

220. Defendants' actions were, at the very least, a substantial factor in opioids becoming widely available and widely used, in deceiving prescribers and patients about the risks and benefits of opioids for the treatment of chronic pain, and in the public health crisis that followed and has reached a state of emergency. Defendants controlled these actions and, therefore, willingly participated to a substantial extent in creating and maintaining the public nuisance. Without Defendants' actions, opioid use, misuse, abuse, and addiction would not have become so widespread, and the opioid epidemic that now exists and the injury to the State would have been averted or much less severe.

221. The public nuisance—i.e., the oversupply of opioids and the opioid epidemic—created, perpetuated, and maintained by Defendants can be abated and further recurrence of such harm and inconvenience can be abated.

222. The State has been, and continues to be, injured by Defendants' actions in creating a public nuisance.

THIRD CLAIM FOR RELIEF
(Strict Products Liability – Design Defect and Failure to Warn)

223. Defendants' opioids failed to perform as safely as an ordinary consumer or an ordinary prescriber would expect when used in an intended or reasonably foreseeable manner because:

a. Defendants' opioids carried far greater risk and actual rate of addiction than the public was lead to believe, and,

b. Defendants' opioids failed to provide functional improvement for chronic pain patients and caused side effects, including addiction, that diminished their function and quality of life.

224. Under the circumstances, which include Defendants' unfair and deceptive marketing, Defendants failed to provide adequate warning that clearly indicated the scope of the risk or danger posed by its branded opioids, reasonably communicated the extent or seriousness of harm that could result from this risk or danger, and was conveyed in a manner that would alert a reasonably prudent person.

225. Defendants actually knew of the defective nature of their opioids, but continued to market and sell branded and generic opioids without proper warning, and with misrepresentations and omissions that contradicted and undermined its drug labels, in order to increase its sales and profits, in conscious disregard for the foreseeable harm caused by these drugs.

226. As a proximate cause and legal result of Defendants' failure to perform as reasonably expected and Defendants' failure to appropriately warn of known and reasonably knowable dangers associated with the use of its opioids, the State has suffered and will continue to suffer damages as outlined in this Complaint.

FOURTH CLAIM FOR RELIEF
(Unjust Enrichment)

227. Defendants have unjustly retained a benefit to the State's detriment, and Defendants' retention of that benefit violates the fundamental principles of justice, equity, and good conscience.

228. The State has suffered, and continues to cope with, a crisis of opioid addiction, overdose, injury, and death that Defendants helped create.

229. Further, as an expected and intended result of its conscious wrongdoing as set forth in this Complaint, Defendants profited and benefited from the increase in the distribution and purchase of opioids within the state, including from opioids foreseeably and deliberately diverted within Alaska. The State has expended substantial amounts of money in an effort to remedy or mitigate the societal harms caused by Defendants' conduct. These expenditures include the provision of healthcare services and treatment services to people who use opioids. These expenditures have helped sustain Defendants' businesses.

230. Unjust enrichment arises not only where an expenditure by one party adds to the property of another, but also where the expenditure saves the other from expense or loss.

231. Defendants have reaped revenues and profits from the State's payments for opioid prescriptions and sale of addiction treatment drugs, enriching themselves at the State's expense. This enrichment was without justification, and the State lacks an adequate remedy provided by law.

232. In addition, the State has conferred a benefit upon Defendants by paying for Defendants' externalities: the cost of the harms caused by Defendants' improper marketing and distribution practices. This enrichment was without justification, and the State lacks an adequate remedy provided by law.

233. Accordingly, under principles of equity, Defendants should be disgorged of money retained by reason of its deceptive and illegal acts that in equity and good conscience belong to the State and its citizens.

PRAYER FOR RELIEF

WHEREFORE, the State prays for judgment against Defendants as permitted by Alaska law, as follows:

a. For a declaration that each Defendant has violated the UTPA;

b. For an injunction pursuant to AS 45.50.501 enjoining Defendants from engaging in any acts that violate the UTPA, including, but not limited to, the unfair and deceptive acts and practices, and unfair methods of competition alleged in this Complaint;

c. For restoration of money Defendants obtained from consumers under AS 45.50.501(b);

d. For civil penalties in the amount of $25,000 for each and every violation of the UTPA under AS 45.50.551;

e. For an injunction permanently enjoining Defendants from engaging in the acts and practices that caused the public nuisance;

f. For an order directing Defendants to abate and pay damages for the public nuisance;

g. For restitution or disgorgement of Defendants' unjust enrichment, benefits, and ill-gotten gains, plus interest, acquired as a result of the unlawful or wrongful conduct alleged herein pursuant to common law;

h. For punitive damages;

i. For costs, interest, and attorney's fees; and

j. For all other relief deemed just by the Court.

Dated: March 31, 2021.

Respectfully submitted,

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